An Organizational Ethics Framework to Balance Individual Privacy and Population Interests Regarding Genetic Technologies

Christine Trani

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AN ORGANIZATIONAL ETHICS FRAMEWORK TO BALANCE INDIVIDUAL PRIVACY AND POPULATION INTERESTS REGARDING GENETIC TECHNOLOGIES

A Dissertation
Submitted to the McAnulty College and Graduate School of Liberal Arts

Duquesne University

In partial fulfillment of the requirements for the degree of Doctor of Philosophy

By
Christine C. Trani

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AN ORGANIZATIONAL ETHICS FRAMEWORK TO BALANCE INDIVIDUAL PRIVACY
AND POPULATION INTERESTS REGARDING GENETIC TECHNOLOGIES

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ABSTRACT

AN ORGANIZATIONAL ETHICS FRAMEWORK TO BALANCE INDIVIDUAL PRIVACY AND POPULATION INTERESTS REGARDING GENETIC TECHNOLOGIES

By

Christine C. Trani

December 2017

Dissertation supervised by Dr. Gerard Magill

The American culture holds the right to privacy as one of the most esteemed rights for individuals. As such, the culture adamantly defends the right to privacy to ensure individuals have the opportunity to live freely. In the American healthcare system, the right to privacy is critical for individual autonomy. However, genetic science has pushed this boundary as it emphasizes the interdependency between individual and population health. Genetic technologies for healthcare have been increasing at an exponential rate since the early 2000s. Their implantation into clinical care has been a slower process due to ethical dilemmas. Specifically, ethical dilemmas revolve around the use of individual genetic information for population benefit and future research. Ethical discourse on these dilemmas is typically from either the individual or population health perspective. This dissertation presents a healthcare organization’s perspective of ethical dilemmas when integrating genetic technologies into the organization. Specifically, this dissertation develops an organizational ethics framework to address the tensions between
individuals and populations when implementing genetic technologies. The framework integrates three recurring and related ethical concepts in discussions about genetics: consent, conflict, compromise. The proposed framework is intended for organizational use to balance individual privacy and population benefits in both clinical care and research settings.
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Chapter 1 Introduction

Emerging genetic technologies create ethical tensions between individual privacy and population interests as they strive to provide quality healthcare. These tensions need to be resolved at the organizational level insofar as healthcare organizations are morally responsible for their research initiatives and clinical practices and because genetic technologies are emerging at an increasing pace laying the foundation for future initiatives. Since healthcare organizations will have significant responsibility for the implementation of genetic technologies, an ethical framework to resolve these tensions could be valuable.

The dissertation presents an organizational ethics framework for genetic technologies that integrates three recurring and related ethical concepts in discussions about genetics: consent, conflict, compromise. The proposed framework seeks to balance individual privacy and populations. The purpose is to balance consent in both clinical and research settings with professional conflicts that require organizational compromises to foster trust in healthcare as it implements genetic technologies for individuals and populations. First, the framework engages the interaction between individual and organizational consent that characterizes moral agency. Second, the framework considers the conflicts that impact professionalism in a pluralistic society. And third, the framework explains the significance of compromise to maintain trust in healthcare.

Chapter one will provide the basic background of healthcare ethics dilemmas between individuals and populations. Chapter two will present the structure and role of healthcare organizations as moral agents who are capable of addressing such complex ethical issues. Chapter three will explain the organizational ethics framework that integrates the three recurring
and related concepts of consent, conflict, and compromise. Chapter four and five will apply the consent, conflict, and compromise framework to therapeutic interventions and research development respectively. Chapter four specifically focuses on the changing landscape of individual consent considering genetic technologies. Chapter five addresses individual compromises necessary for genetic research purposes designed to address population health issues.

Issues surrounding genetic technologies are increasingly prominent in bioethics. These emerging genetic technologies raise many ethical dilemmas for individuals and populations. More specifically, genetic technologies create ethical tensions between individual privacy and population interests as they strive to provide quality healthcare. An organizational level resolution is required for these tensions in part because they are novel dilemmas which require cautious groundwork for future initiatives and in part because healthcare organizations have significant responsibility for implementing genetic technologies which require the highest ethical standards. Hence, these organizations need an ethical framework to address and hopefully resolve these tensions as they seek to provide quality healthcare in the genetics arena.

Organizational ethics highlights the notion that organizations are capable of acting as moral agents.¹ Healthcare organizations can help to resolve the ethical dilemmas between individuals and populations across society. Resolutions can occur by healthcare organizations adopting an organizational ethics framework that integrates business, professional, and personal relationships.² This framework can enable healthcare organizations to develop goals, cultures, and markets that constructively influences clinical care.³ Like individual moral agents, the decisions of healthcare organizations represent their organizational moral stance. A healthcare organizational ethics framework can provide the ability to maintain individual patient wellbeing,
to foster population interests, and to contribute to the organization’s business success. However, the specifics of a practical organizational ethics framework have been ambiguous in the literature on healthcare organizations. This dissertation addresses the urgent need to provide a plausible ethical framework for healthcare organizations, especially one that is relevant for genetic technology.

Genetic technologies magnify the tension between individual rights and population health. While offering a new approach to healthcare and medicine for individuals, the development of these technologies requires a society-wide effort. Research initiatives develop genetic technologies for personalized medicine via analysis from families or groups of people in diverse communities. However, group analysis, as a requirement, can compromise individual privacy. The right to privacy is essential for bioethics as it is an essential element in the traditional informed consent process. The risks of genetic technologies are distinctive since, unlike other areas of medicine, there is not always a direct benefit to individuals participating in genetic research and development. Hence, there is a delicate ethical balance that needs to be maintained between social responsibility and individual personal rights.

Increasingly, healthcare organizations will integrate genetic technologies into their standard of care. Thus, healthcare organizations are responsible for identifying and maintaining an appropriate ethical balance between individual and population health interests. A need for balance is especially apparent when faced with developing and implementing new genetic technologies into clinical care. There has been little research on organizational ethics to address the dilemma of providing cutting-edge care while respecting both individual and population rights. Thus, the proposed framework addresses both organizational ethics as well as clinical and research ethics. This dissertation discusses the need for organizational ethics to address the needs
of both individuals and populations regarding genetic technologies, as described in the thesis statement. The following sections summarize the chapters in the dissertation.

Chapter 1. Introduction.

This dissertation provides an organizational ethics framework to balance individual privacy and population interests regarding genetic technologies. Introducing and using genetic technologies develops tensions between individual privacy and population interests to organizational concerns as they strive to provide quality, ethical healthcare. These tensions require organizational level attention insofar as healthcare organizations are morally responsible for their clinical practice and research initiatives and because genetic technologies are in the infant stages which influence the direction for future initiatives.

The concern is described in terms of balancing consent (of patients or research participants) with potential conflicts that require compromises to maintain trust in healthcare organizations regarding the use of genetic technologies. Hence, the concern and its resolution revolve around the integration of these three concepts: consent, conflict, and compromise.

The basis of the dissertation’s thesis is the tension between the individual and population in light of genetic technologies. This tension can only be resolved at the organizational level for it is too complicated to expect individuals to resolve on their own. However, because of the high hopes for medicine in genetic technologies, organizations need to reevaluate current ethical frameworks to resolve the tensions and provide quality healthcare. Hence, this dissertation seeks to develop an organizational ethics framework for genetic technologies.

Examples in therapy and research demonstrate the organizational concern. When applying genetic technology to therapy, the patient is required to consent to situations in which
the treatment has genetic variability. As a result, this can raise conflicts that require compromises to be made in the context of being attentive to population health. In the context of genetic research, the subject may have to provide consent that can be open-ended regarding the use of data in circumstances where there may be conflict regarding commercialization. This tension raises questions about potential compromises related to the design of biobanks to enhance population health.

These issues suggest that healthcare organizations need an ethical framework to balance individual and population interests in the context of genetic technologies for both therapy and research purposes.

Chapter two and three analyze this tension and present the ethical framework to ease it. Chapter two discusses individual privacy and population interests from a social justice framework to clarify the tension healthcare organizations must resolve when introducing genetic technologies. Chapter three then presents an organizational ethics framework to ease this tension. The organizational ethics seeks to integrate three recurring and related concepts that arise when discussing genetics technologies: consent, conflicts, and compromise. First, the framework explains the interaction between individual and organizational consent that characterizes moral agency. Second, it considers the conflicts that impact professionalism in a pluralistic society. And finally, the framework explains the significance of compromise to maintain trust in healthcare.

Chapter four and five apply the organizational ethics framework to resolve tensions between individual and population interests in the context of genetic therapies and research. Chapter four applies the framework of consent, conflicts, and compromise to current and
potential genetic technology based therapeutic interventions. Patient consent exemplifies the complex relation between probability, risk, and uncertainty. These factors introduce conflict regarding genetic variability and susceptibility, requiring compromise regarding the limits and quality of care from the perspective of population health interests. Chapter five explores research protocols with genetic technologies using the ethical framework to integrate consent, conflict, and compromise. A research participant’s consent has to consider open access to the research data when there may be conflict regarding commercialization and patents, requiring compromise related to the design of biobanks from the perspective of population health interests. The above chapter summaries are now explained in more detail.

Chapter 2. Tension between Individuals and Populations in Genetics

Chapter two discusses individual privacy and population interests within a social justice perspective to clarify the tension that healthcare organizations must resolve when introducing genetic technologies. This will be supported by first presenting the current justification of the right to privacy and its significance for the ethics of the informed consent process. Following, there will be an analysis of the conflict that the right to privacy and informed consent in genetics pose for population health interests. The conflict will be considered by discussing human rights and social justice.

a. Rights to Privacy and Informed Consent

This section will present the current standards of an individual’s right to privacy and the ethics of the medical requirement for informed consent. Considering these standards, there will be an analysis of the complications which arise when these standards are applied to the area of genetics. Informed consent is primary ethical requirements practiced in the United States and arguably the most emphasized in order to protect the individual from unwanted harms. An
individual’s right to privacy is compromised by genetic technologies insofar as authentic informed consent for genetics has effects on more than the consenting individual. As a result, disclosure and respect for privacy can present a conflict of interest.\textsuperscript{8} For this reason, informed consent for genetics can create a dilemma between individual wellbeing and the right to privacy.\textsuperscript{9}

An understanding of informed consent is significant because it is based on the justification that individuals are autonomous and self-determined beings and therefore have the right to make their own decisions.\textsuperscript{10} Consistent characteristics of authentic consent require the individual to be informed and competent for consent to be voluntary, and require the process to be free from interference. Individual privacy is a necessary component to the informed consent process as it allows the individual to be free from external pressures to make their decision. For these reasons, the issues which arise between genetics and rights to privacy need to be addressed by organizations so that the appropriate method to obtain informed consent for genetics may be determined.\textsuperscript{11}

Informed consent ethical standards support the idea that individuals have the right to make their own decisions. In the context of genetics, there is difficulty obtaining individual informed consent and protecting this right. This is due in part by the limited availability of information about burdens, risks, and benefits. This is especially problematic insofar as genetics can have many interactions with other variables to which the individual exposed.\textsuperscript{12} It is imperative to protect the individual from being coerced into procedures which are inconsistent with autonomy. All individuals should be allowed the opportunity to avoid undesired harms, to promote their wellbeing, and to avoid paternalism.\textsuperscript{13} These standards are to be applied consistently across both therapeutic interventions and research procedures. Based on this
understanding, the individual’s decision making process becomes complicated due to genetics’ variability and interactions with other biological phenomena.\(^14\)

The ethical standards for informed consent will be further developed by considering the need to communicate genetic results to other individuals than merely to the consenting individual. Since more accurate information about genetic technology risk and benefit is dependent on another individual’s genetic information, the right to privacy can generate a conflict of interest regarding disclosure. Privacy issues in informed consent are present in both therapeutic interventions and genetic research studies.\(^15\) These studies can use stored genetic material for an unpredictable amount of future uses. When an individual’s genetic material is stored, there is an indefinite number of times the data can be utilized and thus an indefinite number of incidences that privacy can become a concern for which organizations are morally responsible. Furthermore, these conclusions from genetic data can affect more than the individual, extending to family members.\(^16\)

These issues raise the question of the obligation upon institutions to protect the individual’s privacy while providing safe and effective care plans. Informed consent is essential to protect individuals from what used to be called “eugenics” or limiting the reproductive rights of those deemed unfit for a society.\(^17\) The right to privacy entails a duty to protect the right, or at least not to infringe upon it. It is the organization’s responsibility for ensuring that the right to privacy is protected.\(^18\) While all procedures require consent from an individual, genetics raises the question of informed consent’s appropriate role in medicine. Genetic interventions highlight the right to privacy in informed consent insofar as research requires a collective effort associated with population concerns.\(^19\)
b. Population Health Interests

This section will present an alternative view of genetics from a population health perspective and the conflicts which arise in relation to genetic information. Population interests in genetics can conflict with ethical standards and the right to privacy. Informed consent is dependent upon unpredictable variables and creates risks for population health. This constitutes an ethical dilemma around consent. In the grand scale of genetics, individuals are perceived as more a part of a community than a particular agent. The right to health and genetic technology interventions constitutes a population endeavor. Thus, a framework for genetic policy typically develops degrees of communitarian philosophy insofar as the individual sacrifices an aspect of rights for the greater good of the community. In this framework, there are circumstances which justify the individual’s right being compromised for the community.

A population health approach is significant because genetic data is most accurate with large sample sizes yet these samples can have identifying characteristics which ultimately compromise an individual’s privacy. In other words, genetic intervention and research are more precise and directly correlated to a number of people participating. As a result, population interests are prioritized over the individual’s. Recent attempts to do collective population based genetics research has been prevented in the United States by federal and state laws such as HIPAA. Privacy concerns are most evident in cases involving discrimination as an adverse side effect of population genetics. However, some researchers suggest that a global collaboration will eventually be necessary to reach the full potential for population genetics research. Therefore, compliance with ethics will be required to reach the full potential of population genetics.
The communal perspective will be presented first by addressing the goals of population health interests. In the context of genetics, population health interests are complicated because “health” is ambiguously defined. Therefore, it is challenging to justify a standard or goal to be achieved which might additionally contribute to the compromised rights of an individual.

Ambiguity in health contributes to conflicts between population interests and the individual as the larger interests might not be with individual interests. Genetics further provokes the question of whether to prioritize the rights of the individual or the population. This circumstance is one which needs to be addressed from an organizational ethics level.

An example of this would be genetic screening which has proven to be highly beneficial to determine clinical risk factors to increase the effectiveness of medical intervention yet can compromise a non-consenting individual who shares similar DNA sequences.

This section considers the intimate, dependent relationship between individual and population to achieve health. Similar to other areas of medicine, genetic precision is best achieved with a large sample size. However, unlike other areas of medicine, individuals are less likely to receive direct benefits from the research and the conclusions can be identified which compromise the individual’s right to privacy. It would be unethical to argue an individual’s worth in society is only as great as their contribution to the population’s health. However, a public health ethics perspective would argue that the individual is best served when they belong to a healthy community and therefore, it would be in the best interest of the individual to contribute to the community. Thus, the tension lies in the voluntary aspect of participating in public health initiatives. For this reason, organizations need to determine an appropriate ethical balance between the individual’s contribution to health and the limits of population interests.
Population health interests are a driving force behind genetic technologies and require collective participation from a majority of the individuals in the community to be effective and accurate. Because of the ambiguity of “health” there is debate about the boundaries between individual and population rights. For this reason, population genetics exemplifies the tensions between individual privacy and population health efforts. Due to this apparent tension, the United States has developed some efforts to protect the individual possibly because this is the current framework and social construct in the country. The population health perspective needs to be assessed in order to appropriately develop the ethical framework for genetic technologies in both research and clinical situations.

\[ \textit{c. Human Rights and Social Justice} \]

The previous two sections identify larger issues of rights and social justice. Within this context, the third section explores ethically justifiable areas in which an individual’s right to privacy might take second place to population health. While there might be a right to health, the question to address regards the extent this right requires contribution from other individuals in the society.

In order to develop the framework, this section will begin by explaining some foundations of human rights including the characteristic of solidarity which will most contribute to the genetics discussion. A historical analysis of human rights argues that rights are developed from an awareness of the other and their vulnerabilities. By becoming aware of another’s vulnerabilities, individuals developed stronger relationships among each other. Healthcare organizations are responsible for protecting and promoting individual human rights. Furthermore, healthcare organizations are partially responsible for maintaining the individual’s wellbeing and health. In turn, this affects the individual’s ability to live out their rights and social
justice responsibilities in the collective community. One of the greatest issues currently being faced by healthcare organizations is reasonable access to healthcare resources.\textsuperscript{35}

The concept of solidarity as a human right is most strongly exemplified in UNESCO’s Universal Declaration on Bioethics and Human Rights. Human rights are grounded in the understanding that there is solidarity among individuals. More specifically, individuals are more inclined to act with solidarity through vulnerabilities.\textsuperscript{36} Given this interaction, it is evident that human beings are social beings or at least, relational beings insofar as human beings depend on one another for their safety and security. History has many examples when individuals come together in solidarity to defeat or protect each other from a common vulnerability. Here the collective defense is the common good which becomes a foundation for the community’s understanding of human rights.\textsuperscript{37}

An example of active participation in human rights would be treating all individuals equally including their right to just healthcare access. Currently, research and clinical medical practices are performed under two distinct frameworks; research uses public health ethics while clinical practice emphasizes individual rights.\textsuperscript{38} Healthcare access to genetic technologies creates a new and distinct level of vulnerabilities for humans in genetics. Awareness of genetic vulnerabilities creates a greater awareness of the unity between individuals and their codependency on another. As a result, there is a greater understanding of the collective perspective which contributes to an individual’s health.\textsuperscript{39}

Because an individual’s ability to participate in human rights is related to their health, then just access to healthcare is a human rights and social justice issue. The United States is currently attempting to reorganize the healthcare system to allow greater access. There is rarely a consensus on how to achieve just access although it is believed to be attained throughout more
effective resource allocation. Genetics will pose greater questions as to the access of technologies and healthcare especially in regards to privacy and confidentiality issues. A reasonable human rights framework to navigate genetics will require an exchange between individuals and the community to protect each individual.

This section develops an understanding of human rights from an individual perspective. Human beings are relational beings which require collective participation to ensure safety and survival. It is through collective awareness of the vulnerabilities that solidarity is evident as a characteristic of human rights. Access to healthcare becomes an essential component both for individual flourishing and for thriving communities. However, while research is typically performed with consideration for public health, clinical medicine generally deals with the individual patient. Implementation of genetics in clinical practices requires organizations to acknowledge that at least this component of medicine will require collective participation for success.

**Chapter 3. Organizational Ethics Framework for Genetic Technologies**

Chapter three explains the moral agency of health care organizations. Organizations work intimately in cooperation with individuals and populations to promote human rights and social justice through healthcare access. This chapter introduces the organizational ethics framework that integrates consent, conflicts, and compromises. This ethical framework is designed to foster trust regarding genetic technologies and will be adopted throughout the remainder of the dissertation.

**a. Individual and Organizational Moral Agency**

Ethical issues of consent are a primary concern for organizational ethics practices in Western medicine but often inappropriately attributed to only individual agents. For this reason,
they are a necessary component to successful development of an organizational ethics framework for genetic technologies. Individuals are moral agents if they are capable of performing actions of moral value. Organizations like individuals can have moral agency. Moral agents, as individual persons or as organizations, exist within a structure of relationships. As moral agents, they are capable of determining goals and fulfilling actions with moral value. It is with a common understanding of the ends, or mission, that an organization determines its moral agency and identity within the served community. However, it is important that the organization defines its mission and goals in a manner that is specific to the served population. This determination will help better identify and track the effects caused by organizations. Due to their presence as moral agents, organizations have significant influence when determining the value of a new technology or treatment.

As agents, individuals and organizations are interactive and dependent upon one another. A healthcare organization’s moral agency is dependent upon the ability to balance individual, society, as well as its own needs to foster trust. Such dependency thereby highlights the importance of trust as a relational component of consent. Currently, trust in American healthcare organizations is low for a variety of reasons. However, trust in healthcare organizations is inevitable to fulfill the ethical requirements of consent and to obtain care. This trust component will have an even more significant role in the context of genetic technologies especially considering genetic variability in the clinical environment.

Healthcare organizations are sometimes compared to an ecology system with levels of codependency creating a system of checks and balances. Each individual contributes in a variety of ways with a hospital or healthcare system. Each healthcare system has its own values or standards as they foster their relationship with the patient. For example, Catholic healthcare
organizations strictly prohibit research on and the use of embryonic stem cells for therapeutic purposes because it disregards human life.\textsuperscript{50} Similar to an ecosystem, the organization is comprised of other moral agents who also need to consider their own moral agency both as individual agents and agents of the organization. Individuals within this system take a particular position and must consider how that perspective contributes to their understanding of the organization’s moral agency. Healthcare organizations are unique as they must ensure that decisions by individuals promote the reputation and identity of the organization as a moral agent.\textsuperscript{51}

These characteristics of organizational moral agency indicate that organizations must honor ethical principles which guide all their actions in addition to business’ success. This analysis assists in highlighting the complexity of organizational ethics.\textsuperscript{52} Yet, survival of the organization depends upon the efficiency of interactions with other agents. Hence it is necessary to consider the consent of all moral agents. Healthcare organizations must operate as businesses, professional societies, and clinical resources. Rather than all three fields separately, this approach to organizational ethics emphasizes the importance of being patient centered. However, in the genetics environment, there is a natural shift from being patient centered to being community or population centered with accompanying implications for the meaning of consent.\textsuperscript{53}

Organizational moral agency influences the implementation of genetic technologies in both research and clinical settings. Hence, organizational moral agency contributes to the development of frameworks by which genetic technologies may be justified. As moral agents, healthcare organizations must respect the role of consent from both individual and population perspectives.\textsuperscript{54} In summary, organizational moral agency is analogous to individual moral agency. In a similar manner, the moral agency of healthcare organizations must engage the
conflicts that inevitably arise in the context of genetic technologies, as discussed in the next section.

b. Professionalism in a Pluralistic Society

A healthcare organization and its professionals must be held to the ethical standards of the society which it serves. Typically, an organization is defined by four characteristics: division of labor, focus on mission, reporting, accomplishment of goals through rules and procedure.\(^{55}\)

Healthcare organizations serve pluralistic populations and are more often a part of national healthcare systems. Policies and procedures must meet professional and ethical standards established at an organizational level. Additionally, the policies and procedures must be attentive to community needs.\(^{56}\)

The organization is held accountable in a pluralistic society which inevitably complicates the identification of appropriate standards to evaluate the organization. In order to appropriately evaluate an organization, an understanding of relative factors is necessary: hospital history, patient population, available resources.\(^{57}\)

Thus, there are a series of influences that contribute to standards. These interconnected standards are all more important in the context of genetics, especially from the perspective of conflict of interests.

Evaluating policies in the United States is particularly challenging as the nation has established on its pluralistic perspectives inclusive of all individuals and values.\(^{58}\)

This openness contributes to the conflicts between organization and society. Generally speaking, organizational frameworks should support the organization’s mission because this is what makes the organization a moral agent.\(^{59}\)

At the same time, these frameworks are often perceived as limitations on health care practices. A common example is in religiously affiliated hospitals where an ethical framework is developed to protect life and therefore limits clinical practices of abortion. The limitation can be disputed in terms of medical necessity or the standard of care.
from outside the organization. Nonetheless, the ethical stance establishes an internal point of reference for professionalism within the organization. However, this contrast between internal and external standards creates conflicts when treatment requires removing a fetus which is believed to be non-viable. In this example, the determination of medical necessity changes appropriately for each individual’s circumstances and population needs while maintaining professionalism within the established framework.60

The organization’s professionalism is reflected by its clinicians. Therefore, the organization’s ethical framework should consider professional’s moral agency within the organization again to avoid internal conflict. This framework would be one which does not intrude on the sacred patient-physician relationship allowing the two parties to determine the appropriate manner of care. Policy specifically addressing physician practices should lead back to patient care. That being said, the patient and physician maintain the right to determine appropriate medical treatments or plans, albeit, consistent with the organization’s ethical perspective.61 The physician, as a representative of the organization, is responsible for balancing patient’s needs while considering larger implications for the organization and society. In policy implementation, conflicts of interest are more observable where intersections between patient’s right and public wellbeing cause an organization to prioritize clinical, professional, and business aspects. Certainly, these circumstances make it difficult to establish appropriate standards to maintain professionalism in a pluralistic society.62

Additionally, professionalism in a pluralistic society creates difficulties because of the variables which contribute to the framework, standards, and overall outcomes.63 The evaluation should aim to achieve high patient quality care as well as to ensure the system is working efficiently to maximize this care and minimize any harmful side effects. Because organizational
moral agency should reflect the moral stance of the organizations, there can be conflict in terms of compliance with established regulations and ethics. Organizational policy does not equate to ethics and because of pluralistic societies, the policy is not necessarily universal from a compliance perspective. Standards outside the organization must be upheld regarding urban regulations, state and federal laws. At the same time, religiously affiliated hospitals should consider their tradition as they pursue regulatory compliance. This conflict reveals the complicated layers of professionalism related to the organizational moral agency.

Professionalism in a pluralistic society should consider all moral agents’ participation in healthcare from the perspective of the organization. This should occur to establish an appropriate framework capable of evaluation and change. The organization’s moral agency establishes a benchmark for acceptable procedures and treatment options that impact patient care. A reliable organizational ethics framework must honor the patient-physician relationship in relation to empirical evidence, and the organization’s mission. Hence, an organization’s professionalism is crucial for resolving organizational ethics conflicts that arise. In addition to addressing concerns with regard to consent and conflict, it is crucial that an organizational ethics framework is capable of establishing compromises to be flexible while practical.

c. Trust and Organizational Theory

This third section will discuss the significance of trust in organizational theories. The section will first address the issue of maintaining trust in an uncertain environment and then develop an understanding of the necessity for cooperation despite these uncertainties.

Organizational theories acknowledge the complex relationships which form an organization and maintain its survival. In order to obtain benefits from genetic technologies, there must be an inherent trust between individuals, population and healthcare organizations. By
necessity, patients have to trust healthcare organizations and the healthcare professionals. The concept of trust generally consists of a nonverbal contract between parties who agree to perform a set of actions. For healthcare organizations in particular, there is a high dependency on trust because best services are often provided to the patient with limited knowledge. In this circumstances then, trust is self-reinforcing.

While trust is being continuously built, it can be destroyed in an instant especially in difficult ethical terrains such as genetics. Of particular interest to organizational theory are undisclosed conflicts of interests which can lead to destruction of trust. A contributing factor to trust is accountability in the organization. If the organization is accountable for their actions, then it would follow that the organization is trustworthy. Organizations must openly acknowledge their ethically questionable decisions and must not cover up or deny their actions. Should there be a conflict of interest between the policy and implementation, the ethical recommendation would be to disclose the conflict to relevant individuals. Individuals, as moral agents, maintain the right to disclosure about conflicts of interest to ensure the ability to continue to make ethical decisions. However, there might be some instances when disclosing information could be more harmful than beneficial.

Ultimately, trust in healthcare organizations is a necessity in order to receive appropriate medical attention. Consider purchasing insurance in the United States as an example of trust with healthcare organizations. Individuals buy their plans without complete knowledge of exactly what treatments will be covered under specific circumstances. Ideally, individuals will have access to preventative services to limit the amount of encounters with more serious and intense healthcare interventions. When individuals can consistently access health care services, trust increases. When there is uncertainty about which treatments might be covered, the individual is
less likely to visit the doctor even in emergency situations. When individuals do not feel they can trust healthcare in general, it compromises the entire system. In order for a population to be healthy, the individuals which compromise the population must maintain healthy lifestyles fostered by trust in the organizations that serve them.

Increased use of technologies has been blamed for part of the trust decline in healthcare. This is because greater use contributes to higher cost and therefore limits healthcare access to those who can afford it. Additionally, the uncertainty and experimental interventions which can contribute to medical errors are also believed to contribute to decreasing trust in healthcare systems despite the fact that accurate reporting is difficult to obtain. The uncertainty of efficacy and safety plays a significant role in the ability to promote trust in healthcare organizations. To establish cooperation between the individual and the healthcare organization there needs to be a compromise between the unknown risks and any attempt at interventions. Acknowledgment of the cooperation between the individual and the organization could prove to be beneficial for genetic research and interventions.

In summary, trust is a necessary component for healthcare organizations and therefore must be a significant factor for developing an organizational ethics framework involving genetics. A consistent breaking point for trust is uncertain environments where organizations attempt to hide or cover up complicated ethical decisions. Acknowledgment of uncertainty will potentially contribute to the process of building trust. With acknowledgment as a starting point, individuals and organizations will have a better foundation for cooperation that requires compromise. Hence, compromise is a crucial component of the organizational ethics framework that is summarized below.
d. Organization Ethics Framework

Having discussed the ethical issues around consent, conflict, and compromise in relation to genetic technologies, then a successful organizational ethics framework should integrate these concepts. The purpose of this organizational ethics framework is to create a balance between individual risk and population benefit. From an organizational perspective, the cornerstone of the framework will be the organization’s moral agency which respects concerns of professionals, individuals, and the population. The organizational ethics framework focuses on consent to address genetics technologies as providing as safe, effective healthcare.

Further, the organizational ethics framework is designed to engage the conflicts in professionalism in a pluralistic society that arise due to genetic interventions. These conflicts include maintaining a respectful patient-provider relationship and safety for population health. Living in a pluralistic society like the United States requires an organizational ethics framework a framework that balances individual moral agency while successfully meeting the larger preventative population needs.

Also, the organizational ethics framework needs to foster compromise to establish trust in the uncertain environment of genetic technologies. The capacity for compromise provides the crucial foundation to foster trust in organizational development and uses of genetic technologies. In the subsequent chapters, this organizational ethics framework is applied and developed to illustrate its flexibility and practicality for genetic technologies with regard to both therapy and research.

Chapter 4. Therapeutic Interventions with Genetic Technologies

Having established an organizational ethics framework to address genetic technologies, the framework will now be applied to therapeutic contexts when genetics are intended to prevent
or relieve the burden of genetic diseases. This section will explain how the integration consent, conflict, and compromise are crucial for therapeutic interventions. The current understanding of consent is difficult to apply to genetic therapies because of gene interactions and genetic unpredictability. Second, there is potential for conflicts because of genetic susceptibility and variability which can lessen the success of a therapy. Third, compromise is necessary to establish a balance between limits and quality in care regarding genetic interventions.

\textbf{a. Probability, Risk, Uncertainty}

The normative standard for informed consent aims to protect the individual’s right to autonomy and avoid exploitation. However, these standards have proven to be inadequate in addressing gene therapy.\textsuperscript{80} Genetic technologies have made significant strides in treatments for monogenetic diseases or disorders. Most of these strides were made for rare diseases while polygenetic issues such as cancers and heart disease have remained stationary.\textsuperscript{81} When consenting to genetic treatment options, there are a variety of unknown factors such as probability, risk, and uncertainty. As a result of these factors, consent is inherently compromised in the clinical setting. It would be unreasonable to cease all efforts towards improving treatment. Therefore, it is necessary to assess the significance of these factors to determine which are ethically justified to accept and which urgently need to be addressed before consenting to treatment.

The current practice of consent in medicine today revolves around the concept of individual autonomy. An individual has the right to offer voluntary consent with adequate information to assess a decision in light of their moral values. Ethically and legally, it is required to obtain consent to protect individual autonomy. The idea is argued to originate from around the time of eugenics. Thus, consent is significant to distinguish therapeutic genetics from eugenics.\textsuperscript{82}
This is a crucial distinction which should be carried over to the next generation of the genetics era. When considering genetics and consent, there are three participants who are affected by the procedure: the individual, the family, and the population. Consent needs to consider the probably, risk and uncertainty of each group in order to protect any interpretation of autonomy. While the argument is around treatments, it is not always in genetics that the risk is consented to by the individual who will sustain the burden from the potential intervention.83

Individual forms of consent fail to acknowledge the usefulness of dependency and disclosure of genetic information for the sake of limiting undesired risk and uncertainty in consent. The individual model does not necessarily equate to ethical practice in the genetic era. By retaining the individual model, there is a limitation to the prevention of unknown risk and uncertainty for therapies. Individual consent to genetic therapies creates a tension between benefit and success of treatment and the individual’s privacy.84 If the framework were to continue with the individual autonomy model, then it would be assumed that until these genetic therapies progress with precision, the individual would be consenting to uncertainty. Consenting to uncertainty is an ethical paradox insofar as the individual has not been able to fulfill the criteria of consent that is, to weigh the risks and benefits in light of the individual’s moral values.85

Organizations are in a good position to influence therapeutic interventions that eradicate diseases. Therapeutic genetic interventions are an attempt to alter or prevent a genetic expression. There is a sensitive line which distinguishes eradicating diseases for health benefits and selectively determining undesirable traits which could benefit the population.86 This line particularly difficult to determine in discussions about genome preventative sequences and thus, develops into a right to healthcare access. There could come a point when individuals have
changed so much about their genome, it has crossed the line into enhancement. Enhancements are arguably no longer therapeutic intervention because of its extreme circumstance.\textsuperscript{87} Thus, there would need to be a predetermined method such as a menu approach or all-or-nothing approach developed with population data to assist the individual in appropriate consent processes.\textsuperscript{88} In situations when many agents predetermine the population's health status, it appears that there can be another form of consent than traditional consent.\textsuperscript{89}

When ethically assessed, traditional consent forms which require a standard of information for rational decision-making can fail to respect autonomy. Due to probability, risk, and uncertainty, genetic therapies create a tension between traditional informed consent required for ethical medical practice and the patient’s ability for authentic informed consent.\textsuperscript{90} This becomes an organizational problem when the problem is consistent across clinical care. However, the proposed solutions are limited in their capacity to respect individual autonomy insofar as they tend to create blanket concepts of “disease” or “health.” As a result, the apparent solutions contribute to the inability to inform patients for their decision-making process.\textsuperscript{91} Not surprisingly, just as genetic technologies raise new questions around patient and population consent, they also highlight new types of conflicts that need to be engaged in healthcare.

\textit{b. Genetic Variability & Susceptibility}

Therapeutic intervention begs the question to what the individual is giving consent. Provided that probability, risk, and uncertainty limit individual consent, so too is the organization’s ability to offer quality, safe care.\textsuperscript{92} For this reason, the organization needs to address the conflict between patient safety and quality care. This section will address the organizational ethics dilemma of proving beneficial care with genetics therapies when the therapy’s success is dependent upon unknown variability and an individual’s susceptibility.
Expanding upon that argument, the tension between the population’s health and patient’s risk will be addressed as an organizational responsibility again, to promote beneficial care.

It is the combination of genes which makes an individual susceptible to drug reactions, the effectiveness of treatment, and disease severity. Susceptibility is a sliding scale where conditions can vary from minimally to severely serious most commonly in the context of an individual and not the population. From an organizational standpoint, knowing a patient’s genetic susceptibility can influence their treatment options and drug choices.\textsuperscript{93} Simply because individuals might have a gene or combination of genes which could make them more susceptible to a certain condition, this does not suggest they are is unhealthy and/or require genetic therapeutic intervention.\textsuperscript{94} For this reason, there is not an ethical obligation to provide preventive therapies. The ability to know and expand ideas of personalized medicine creates ethical dilemmas which at the current point in medicine create a conflict between patient safety and quality care.\textsuperscript{95}

Predictive genetic testing reads DNA sequences to determine which genes are present in a genome. Multiple factors can affect the expression of the present gene so testing does not necessarily provide conclusive evidence due to genetic variability and susceptibility.\textsuperscript{96} Followed by accurate gene therapy, potentially susceptible genes can be altered, eliminated, or corrected to “cure” the patient of the disease. Some might argue that once gene therapy becomes a reliable option, it would be unethical to withhold such treatments which could potentially benefit the patient.\textsuperscript{97} Unlike other forms of treatment or therapy which have known or predictable side effects, genetic therapy is complicated because of co-dynamic factors such as the genome, environment, and lifestyle choices.\textsuperscript{98}
It would be impossible to predict all factors which will influence the success or failure of a specific treatment, monogenetic interventions being an exception. Furthermore, gene alterations can unknowingly be heritable affecting the population and future generations. Some changes cannot be known until an F3 generation, or grandchildren, are born, studied, and even contract specific conditions. Even at this point in development, it is difficult to precisely determine the exact cause of specific traits or susceptibility to diseases. However, the process of gene alteration and heritability highlights the influence of genetics on more than the patient in a clinic presenting the ethical conflict between who should bear the burden of disease, patients or population.99

Issues of providing treatments with high quality and patient safety are not new for healthcare organizations. These are organizational and system issues and therefore not necessarily a specific concern for genetic therapeutic intervention.100 What is specific to genetic therapeutic intervention is the hope to create personalized medicine regarding which both quality and safety are dependent more upon communal data than individuals.101 In addition to the above ethical issues of consent and conflict, genetic technology also raises the crucial need for compromise between patient and population perspectives on health, as discussed in the next section.

c. Limits & Quality of Care

In order to progress and develop reasonable standards for the concerns mentioned, it is necessary to improve while simultaneously acknowledging the current known limits. This approach is already being practiced at the most basic level when considering definitions of “nature” or “life.” These theoretical terms have a symbiotic relationship with culture and science throughout time as each is able to contribute to the other.102 Similarly, it could follow that patient
safety and genetic therapy is a symbiotic relationship at the most practical level. Genetic interventions can be better understood with regard to population and patient safety when there are more therapies. The compromise in genetic therapies will be between limits of patient safety and quality in standards of care.

The goal of genetic therapies is to reproduce a natural process for human benefit similar to other types of preventive measures. Perhaps, the treatment might not cure the disease, but it might delay or ease the burden of the disease for an individual and thus, provide greater quality of life. The gene therapy goal is lofty and severely limited at the current stage because of unknown genetic variability.\textsuperscript{103} An organization should acknowledge the goal of patient safety by creating a protocol to catch and limit unacceptable standards in quality of care. This protocol would be one which discloses any adverse side effects to the patient and supports the patient in the burden. The support mirrors the break from individual consent creating a balance for the risk.\textsuperscript{104} The compromise between patient safety and genetic variability affects both the current patient and potentially future generations.

A major concern and current limit for therapeutic genetics and quality care is the possibility of harming germ lines. Up until recently, it was the standard of care that genetic therapies would be non-germ line intervention. Currently, there is a limited ability to prevent and track the effects of genetic changes on future generations. However, it could be argued that humans have been intentionally and unintentionally altering their germ lines for generations with the belief that humans are progressing.\textsuperscript{105} That being said, gene therapy is currently being used specifically for germ line therapy in fetal diagnosis of mitochondrial disease where the mitochondrial genes in a mother’s egg are replaced as a cure for the baby.\textsuperscript{106} From an organizational standpoint, there is debate about what is a reasonable amount of control on the
germ-line effects. There is an ethical boundary which should be crossed with caution for healthcare organizations to protect their patient population. The ethical limit of care is one which organizations need to revisit as the science and precision of therapies progress. Other boundaries to consider to develop the limit of care are legal and professional boundaries. By establishing these limits, the organization furthers defining its moral agency.\textsuperscript{107}

Having argued that there is a boundary, organizations are ethically required to establish their limits specific to genetics in order to increase quality of care. Without such limits, the organization risks ethical problems regarding patient safety. Defining a standard of care can be ambiguous for genetics purposes because of variability and therefore, require extensive compromise between patient safety and quality of care.\textsuperscript{108} From the current situation, the standard of care might only be reactive action since the probability of risk is still highly unknown and unpredictable. The hope would be to obtain standard of care similar to surgery and other specialties.\textsuperscript{109} The ethical standard of care for genetics is two-fold; it is one which should be revisited as the science and precision of therapies progresses additionally, it is one which considers the standard of care from legal and professional perspectives to protect the organization’s moral agency.

A compromise between limits and quality of care will be significant to the progression of genetic medicine as it will ultimately affect patient trust in an organization’s ability to provide quality therapeutic care. For this reason, it will be vital for the organization to develop a safe ethical environment in which providers will be supported to disclose necessary information and therefore maintain the patient trust.\textsuperscript{110} A safe ethical environment for genetic therapeutic intervention will be one which makes safety a priority, values its employees, and puts significant emphasis on full disclosure.\textsuperscript{111} These standards will contribute to the organization maintaining its
identity as a moral agent and be a representation of the organization’s value on quality patient care and safety despite the variability and unknown risks in genetic therapies which, as argued, create ethical issues of consent and conflict between individual patient risk and population health benefits.112

Chapter 5. Protocols Concerned with Genetic Technologies

The final section will discuss genetic research protocols that raise organizational ethics questions. The section will implement the organizational ethics framework adopted throughout the essay. First, there will be an analysis of research consent as a closed process between the researcher and participant to protect the research subject’s right to privacy. The second issue will address patents and the commercialization of genetic therapeudic research evidence and conclusions; these can lead to conflicts with regard to scientific integrity and the community’s trust. The final section will discuss organizational concerns that arise with regard to genetic biobanks insofar as they can cause a compromise of data that requires anonymization to protect confidentiality.

a. Individual Privacy & Open Consent

Thus far, a discrepancy between individual privacy and communal benefit in genetic research has been highlighted. In genetic research, there is an inherent, albeit unintended, risk of compromising privacy in the informed consent process. After an individual provides consent and a researcher obtains genetic samples, the individual’s privacy and the privacy of those who share the individual’s genetic information can be at risk.113 In genetics research, there is too much emphasis on the traditional form of informed consent to maintain privacy. A more nuanced approach to consent is required.114
The most traditional approach to informed consent in genetics research is blanket or broad consent. When offering broad consent, the participant allows the researcher to use the acquired genetic information for all future purposes without having to return for additional consent. The broad approach is similar to giving consent in the clinical realm. The researcher provides the participant with the study’s significance, risks and benefits, and data analysis procedures. From this, the participant can review the purpose of the research with regard to their moral values to elicit consent. This broad approach frees the researcher from having to return to the research participant for consent to subsequent use of the acquired information. A major difficulty of this broad approach to consent is the exclusion of the participant from continued research on the individual’s genetic data. After giving consent, the individual’s continuing role in the research of the acquired genetic information is not required. As a result, this process of broad consent can be construed as conflicting with the patient’s privacy, thereby potentially compromising the public’s trust in genetic research. If the participant gives broad consent, then the genetic material could be used in subsequent research that may not be entirely consistent with the individual’s values that guided the original consent. Broad consent may further scientific research and knowledge and perhaps promote public health for populations. However, broad consent raises the ethical concern of protecting the patient’s privacy in the subsequent research.

There needs to be an informed consent process that is more relevant to the nature of genetic research insofar as samples are used long after the initial agreement. Open consent is an example of a different approach. Here, there is a dynamic relationship between the participant and research, with varying types of interaction that can foster effective consent for continued genetics research. In open consent, the participant may disclose or restrict the relevant genetic
information: disclosing to public or scientific databases; or restricting strictly to the study. This type of consent would offer a more interactive perspective for consent to genetic research. Open consent is a participant centric approach to genetic research. The model is intended to create collaboration between the participant and the researcher allowing the participant to reevaluate and potentially adjust the level of participation in the research. From this perspective, the researcher and participant collaborate to enhance the genetic research in an ongoing manner.

This type of informed consent requires both the researcher and the participant to seek out each other for continuous updates about the research process and incidental findings that could negatively impact the privacy identified in the original consent. Because some diseases occur in populations with low literacy rates and communication access, efforts must be made to engage effectively with the individuals involved. This more dynamic method of informed consent enhances the participant’s continuing influence in research while protecting privacy. The major distinction between the two models lies in the emphasis of privacy. In broad consent, there is concern about protecting the participant’s privacy in subsequent research that was not identified in the original consent. In open consent, there is more participant participation in the ongoing research that better protects the subject’s privacy as the genetics research continues.

Open consent facilitates a reevaluation of the original agreement in order to enhance the impact of the emerging research. Open consent can honor the general standards of traditional informed consent by fostering an interactive relation between researcher and subject in an ongoing manner that enables each to engage emerging information. Moreover, this ongoing and interactive approach to consent enables organizations to engage genetics research more effectively in a manner that fosters trust in the community. From these related perspectives of
the researcher and the subject as well as the organizations and the community, informed consent and subject privacy can be consistent with the changing needs and burdens of fast developing genetics research.\textsuperscript{124} However, even when consent can be achieved in a manner that protects the privacy of the human subject in ongoing genetics research, there are conflicts that can arise, especially with regard to patents and the commercialization of genetics research. These are discussed in the next section.

\textbf{b. Commercialization & Patents}

From an organizational perspective, patents and the commercialization of genetics research can introduce conflict that impacts social justice and as a result the trust of the public. In most other areas of research, it is a researcher’s and organization’s right to patent and sell their “product.” Patents are granted by federal government organizations to protect the intellectual property rights of an invention or discovery for a temporary amount of time.\textsuperscript{125} Recent statistics from Europe suggest that there are patents filed or pending for about 20\% of the human genome.\textsuperscript{126} From the beginning of the race to sequence the human genome there has been a conflict between that which could and could not be patented by both private and public organizations.\textsuperscript{127}

The history of patents shows a continuum of patents from plants and animals to bacteria. Typically, there is a distinction between what is found in nature that is not patentable versus what results from human manipulation and can provide significant utility.\textsuperscript{128} The principle of utility is one justification for the act of patenting genes whereby the researchers have property rights over the utility developed from the gene. The principle of utility is arguably a motivation to undertake and patent genetic research.\textsuperscript{129} In order to patent an invention, the research must
show a contribution to the utility of genetic research. Arguments supporting patents suggest that law should encourage advances in knowledge based upon temporary legal protection.  

Patenting a gene protects the patented information from being used, thereby controlling the use of the information. This creates a social justice issue in the cases when genetic information is restricted yet necessary for beneficial research purposes. It would be ethically unjustified to patent gene therapy to prevent it from being used and to profit from a less effective method. It appears counterintuitive to patent materials which are of common heritage within species. Some argue that it is morally acceptable to patent a gene for economic protection rather than merely as a piece of nature or creation. Generally, the ethical debate on gene patents focuses on the intention of the organization or researcher and the effects this will have on the general population, highlighting concerns of proportionality to address issues of social justice.  

In contrast to the debate over gene patents, commercialization of genes suggests a growing trend in the commodification whereby genes are a source of wealth. The trend has developed in a similar manner to the debate on body tissues. Joint ventures between universities and public industry are typically tied to the commercialization of their products. Some argue that humans are never in full possession of their body and therefore do not have the right to commercialize their bodies. In particular, if commercialization disproportionally negatively affects patient populations, then it would be a problem from the perspective of social justice, thereby contributing to mistrust of healthcare organizations among the general public. In other words, commercialization of genetic data could limit access to knowledge and potentially life changing diagnosis. As a result, commercialization could trump ongoing research, thereby compromising the public’s trust in institutions.
The trend to commercialize genetic data tends to encounter significant cultural resistance and has been compared to the buying and selling of athletes or purchasing surrogate mothers. The comparison is an example of a continuum of mistrust over the commodification of bodies that risks the genetic exploitation of individuals. Moreover, commercialization of genetic materials appears as a misuse of human life as it is inherently communal material as a species. From this perspective, there is something unsettling about an organization selling materials which are, at the biological level, already shared. Genetic research requires collaboration between private, public, individuals, and families. From this perspective, DNA is more than a combination of nucleotides; it provides the instructions to develop proteins which are shared among humans. For this reason, it is ethically counterintuitive to patent and sell something that seems as universal for humanity as a species.

Issues of patents and commercialization to promote research will create significant conflict with the public’s trust, highlighting organizational and social justice issues such as property rights and access to healthcare. The sequencing of the human genome could have gone on for years or decades longer without openly shared information between researchers. Since that project ended, organizations tend to be divided on the ability to patent gene sequences and developments from genes. This reflects the tension between those who wish to make their research publicly available and others who seek to sell their information. If patents for genes and genetic research were to continue to develop, then it is predicted that a patent process similar to the Plant Patent Act of 1930 would be most suitable which does not have the same moral weight that traditional patents carry but maintain the same legal obligations. It is still unclear what will be the effects of patents on scientific creativity and progress. Nonetheless, there is a robust effort to have genes and gene sequences patented. A similar dilemma in organizational
ethics from the perspective of conflict caused by patents and commercialization is the topic of biobank research that highlights how compromise can be an effective ethics strategy to resolve tensions.

c. Biobank Research

This final section will address ethical issues in genetic biobanks by suggesting anonymization and confidentiality as a compromise between individuals and researchers. These issues are not new to ethics. Yet, genetic biobanks offer new risks and dilemmas to old questions. Biobank research is efficient insofar as it allows researchers to increase use and minimize requests for future research participants. Once the samples are obtained, typically, genetic material is no longer physically stored. Rather, it is stored electronically in biorepositories. Using electronic sources, researchers are more capable of sharing data. This method is a more effective method for research because it gives the researcher the desired sample size. Some critics of informed consent for genetic biobanking argue that a significant risk is unwarranted information dispersal. Longitudinal studies promote new risks for the privacy of the original consenting individual. However, sharing conclusions or genetic data can be most beneficial for public health and ongoing scientific research. For this reason, there needs to be a balance between protecting a participant’s anonymity and the need to foster confidential efficient research studies.

Insofar as genetic biobanks electronically store information it can be argued that information can never truly be anonymized. Furthermore, unauthorized use of genetic information from these biobanks can lead to stigmatization, discrimination, and familial distress. In theory, the researcher could store the participant’s genetic information without the participant ever knowing about it. This has been observed in cases of banking body tissues. Since this would
distribute the participant’s information without consent, this would violate the donor’s privacy.\textsuperscript{147} Perhaps for the sake of developing genetic biobanks while trying to protect the privacy of the donating individual, too much is being asked of the traditional informed consent standard. Some suggest that privacy is no longer a realistic option for this type of research. Rather, it might be more reasonable to maintain confidentiality of the information.\textsuperscript{148}

The reliability of informed consent seems to diminish as science progresses. In general, for even those who give informed consent, it can be contested whether donors truly understand what their consent entails scientifically.\textsuperscript{149} Nonetheless, there is understandable hesitation to move away from informed consent if the consented information can identify the individual. Biobank researchers have adapted the terms “non-identifiable” and “anonymous” to avoid informed consent setbacks. For genetics research, it is difficult to predict any potential longitudinal studies and what the results of those studies might develop from genetic biobank information. For this reason, it might be more reasonable to consider a shift from privacy to confidentiality.\textsuperscript{150}

In the event that it is not possible or not ideal to anonymize genetic data, confidentiality must be protected for the participant's sake. Some research might require continuous contact to follow prognosis or environmental factors.\textsuperscript{151} It is a justified concern of participants that their information might be used against them by other institutions, such as causing discrimination by insurance or employment or identity theft. Concern for confidentiality will determine the development of the biobank infrastructure.\textsuperscript{152} Thus, biobanks are not a haphazard collection of information for any user. Non-confidential, identifiable information about individual health and family would directly affect their willingness and trust in biobanks.\textsuperscript{153} Lack of trust in these biobanks will contribute to incomplete or insufficient biobanks, thereby compromising research.
goals. The public’s trust is pivotal for scientific research. This is especially true for research which is so dependent upon public participation.\textsuperscript{154}

If donors consent to genetic material being stored, they accept significant risks in genetic biobanks, such as a breach of security in the system. The compromise for genetic research is that donors are required to trust the researchers to protect their genetic information.\textsuperscript{155} Currently, there are no strict regulations or suggestions on genetic biobank research. Rather, the standards are more a patchwork of regulations for the researchers. For this reason, as genetic biobank research becomes more attractive to researchers, it will be necessary for organizations to develop an ethical argument to achieve a compromise between genetics research and individual rights, perhaps focusing on the distinction between privacy and confidentiality.\textsuperscript{156}

\textbf{Chapter 6. Conclusion}

Conflicts of genetic technologies are explained from an organizational ethics perspective. The analysis presented highlights the tension between individual privacy and population health benefits. This tension can only be addressed at the organizational level due to its complexity. The organizational ethics framework developed creates a justified balance between individual risk and population benefit environments with regards to genetic technologies. This framework consists of three parts: consent, conflict, and compromise. In regards to genetic therapeutic interventions, the framework assesses the significance of probability, risk, and uncertainty to individual autonomy (consent). Furthermore, it discusses the significance of genetic susceptibility and variability on the organization’s quality of care (conflict). The framework is a compromise between individual consent and population benefit which defines appropriate limits of care (compromise). As a result, the framework protects the individual’s and organization’s moral agency. In genetics research, the framework addresses issues of individual privacy
(consent) and patents and commercialization (conflict). These issues are property rights issues between the individual and organizations. Biobank protocols balance the individual privacy and research rights in genetic research at an organizational level (compromise). These compromises define the organizational ethics framework which address the relevant issues of genetic technologies. Ultimately, the organizational ethics framework aims to enhance public trust in healthcare institutions to ease the integration of genetic technologies while maintaining high quality care.

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50 Ethical and Religious Directives for Catholic Health Care Services, 5th ed. (United States Catholic Conference of Bishops, 2009), 27.
75 Stephen Holland, Public Health Ethics (United Kingdom: John Wiley & Sons, 2007), 47-51.
102 Joachim Boldt, "Creating Life: Synthetic Biology and Ethics.," in Synthetic Biology and Morality: Artificial Life


Chapter 2 Tension Between Individuals and Populations in Genetics

Genetic technologies present a unique dilemma between individuals and populations insofar as the successful of implementation for either is dependent upon the other. This issue is particularly challenging in the United States where a culture of privacy and individualism has prospered for centuries. For this reason, scientific progression in the field of genetics is not only dependent on the resources but requires an in depth analysis of the human rights issues. Chapter two discusses individual privacy and population interests within a social justice perspective to clarify the tension that healthcare organizations must resolve when introducing genetic technologies.

This will be supported by first presenting the current justification of the right to privacy and its significance for the ethics of the informed consent process. The traditional understanding of informed consent as practiced in the United States is in conflict with the methods used to advance genetics in clinical care and research. As currently understood, privacy is an essential element of informed consent. Yet, due to the nature of genetic information, implementation can affect more than the consenting individual thereby creating a conflict of interest.

Following the individual analysis, there will be an analysis of genetic initiatives for population health efforts. Population health efforts are aimed at providing for the collective population to promote a well society through the collective whole. A right to health essentially requires a population effort insofar as individual health is influenced by the society. Therefore, in order to pursue these efforts, an individual level of participation is required.

Finally, the conflict will be considered by discussing the principle of solidarity and cooperation to balance individual human rights and population health. Solidarity and cooperation
are used to identify the common end between the individual and population while maintaining a practical application. This will be highlighted through examples of just healthcare access from the perspective of an institutional, cultural, and individual level.

**a. Individual Privacy**

The United States culture is heavily influenced by protecting the right to privacy. The strong influence is due in part by both recent events as well as being integrated in the foundation of the nation’s history. Individuals consider privacy to be a mechanism for the protection of their rights to live as they choose. The significance of individual privacy carries over into healthcare practices which makes privacy an essential element to the informed consent process.

**I. Rights to Privacy and Informed Consent**

The right to privacy and informed consent have developed from a lack of protection for individual decision making. This section will present the current standards of an individual’s right to privacy and the ethics of the medical requirement for informed consent. Following, there will be an analysis of the complexity of applying these standards to genetics.

1. **Historical Understanding of Privacy and Informed Consent**

Informed consent is a primary ethical requirement for clinical and research ethics practiced in the United States. Arguably, it is the most emphasized in order to protect the individual from unwanted harms. An individual’s right to privacy is compromised by genetic technologies insofar as authentic informed consent for genetics has effects on more than the consenting individual. As a result, disclosure and respect for privacy can present a conflict of interest. Therefore, there appears to be an inherent dilemma between an individual’s wellbeing and the right to privacy.
It is essential to understand the history and current application of informed consent in the United States because it is a society in which individual autonomy and privacy are highly emphasized throughout the culture. Globally, legal history of normative informed consent standards begins after the Holocaust. During this time, prisoners were subjected to experiments without first obtaining consent. Following World War II, researchers who conducted experiments on individuals were found to be guilty of battery by international courts. As a result, the purpose of informed consent became to protect the individual from abuse including eugenics. In order to legally fulfill the requirements of informed consent, four major characteristics must be met: the individual must be competent, allowed privacy, provide autonomous, and voluntary consent.

The concept of voluntary consent dates back to what is believed to be the beginning of medical ethics in Ancient Greece. Individuals maintain the right to protect their bodies from unwarranted interactions with other individuals. This idea is supported by individual autonomy which suggests people have the right to govern their body. A history of legal cases in the United States supports the individual’s rights to self-determination and the voluntary nature of medical decision making. The combination of the United States courts’ determinations suggests that informed consent is based on the patient’s right, not the physician’s duty. Informed consent is voluntary when the individual is competent to making autonomous decisions. Current standards understand an individual to be deemed competent because he is cognitive and maintains decision making capacities. In order to make such autonomous decisions, the individual must be free from external stresses and have sufficient time to reflect on their decision. In other words, the individual maintains the right to privacy.
A significant implication of autonomy for genetic application is an individual’s right to privacy protection. From a philosophical perspective, privacy and confidentiality are important to determine relationship boundaries. For instance, when one person discloses private information to another person, this establishes a level of trust in the relationship. Or, on the other hand, if information is not disclosed, then this establishes boundaries for the relationship from the negative action. These boundaries are essential for practicing medical ethics especially in situations sensitive in nature such as genetic information. In informed consent, the right to privacy entails a duty to protect the right, or at least, not infringe upon it. Since informed consent were historically developed to prevent coercion and/or abuse, current standards continue to carry put a heavy emphasis on these issues. Therefore, the providers and researchers (going forward to be referred to as providers) alike have a duty to obtain authentic informed consent.

With wider availability of genetic information, individuals are more sensitive to what information is disclosed and therefore, are seeking more control over their information as a way of distinguishing their relationships. Even in communitarian societies where individuals share majority of information, there is still an established boundary between the individual and community insofar as, the individual is part of the community. In order for the individual to be a part of something, they have to allow their information to be shared. Further, the communitarian society might not share information with other societies as a means to determine the dependency between the two communities.

2. An Application of Privacy and Informed Consent in Healthcare Ethics

Individual privacy and confidentiality contribute to the component of respect for autonomy. The standards of autonomy, privacy, competence, and voluntariness are generally accepted in medical ethics practice throughout the United States. However, ideal standards of
consent regulations vary depending on the discipline in which consent is being practiced. For instance, within the medical field there are attempts to distinguish between clinical and research informed consent standards.\textsuperscript{14} In both instances, there is a responsibility to obtain consent. Clinically, it is the physician’s responsibility to provide sufficient information for the patient to make a reasonable decision regarding their health. In other words, the reasonable personal standard is applied to create the relevant information required to fulfill the consent requirements.

In the clinic, patients typically arrive to an underlying condition and seek relief. Therefore, the patient is intending to receive direct benefit from risky procedures. The mindset of receiving direct benefit from a clinical procedure can change the amount of information an individual requires to offer authentic informed consent. Take for example an individual who is desperate to relieve their suffering, they might be more willing to take greater risks to achieve less benefits.\textsuperscript{15}

From a research perspective, the reasonable volunteer standard is used to manage informed consent invites the individual to participate in research which could produce knowledge.\textsuperscript{16} This standard is distinct from the clinical standard as it assumes that the individual is in control of their wellbeing as opposed to physicians offering opinion for clinical wellbeing. Unlike a clinical patient, a research subject might require additional information about risks to make their decision because they are a volunteer in the research.\textsuperscript{17} From these common characteristics, the researchers and participants both maintain responsibilities in order to promote ethical research through the informed consent process.\textsuperscript{18}

To adequately approach the informed consent process, the researchers are required to disclose necessary information and obtain the informed consent. According to U.S. federal regulations, necessary information includes the type of research, the purpose of the research, risks and benefits for the participants, alternatives, expected standards of confidentiality, and
compensation or treatment for injury during the research.\textsuperscript{19} However, it will be argued that when informed consent is applied to genetics, it is difficult to maintain confidentiality and privacy for a variety of reasons. Perhaps, the researcher has determined the population and therefore, the population’s demographics.\textsuperscript{20} He is better able to determine the risks and benefits the population might face during the research process. The researcher would be unreasonable to expect written informed consent from and illiterate population. Therefore, in determining the population’s demographics, the researcher is more capable of producing an informed consent form specific to the population. Therefore, the researcher has a better opportunity to obtain true informed consent.\textsuperscript{21}

For an individual to consent to research, the researcher is to provide enough information to aid the individual’s decision making process without impeding the individual’s private action. Otherwise, if the individual’s actions are impeded by another individual, then the former has not had complete sovereignty over his decision making capabilities. Therefore, the former individual’s respect for autonomy has been violated. The exception to this would be when an individual’s actions are harmful to another.\textsuperscript{22}

Some critics of informed consent in research argue the subject-oriented informed consent is the best type of consent. Subject-oriented informed consent reminds researchers the purpose of research. Furthermore, it gives the participants a sense of authority. Some studies suggest when a participant is given ample information and input on procedures, they are more likely to give informed consent and participate in research. This could imply informed consent enhances some research projects.\textsuperscript{23} Of course, even this type of informed consent is not perfect. Biotechnologies create tension between informed consent and individual autonomy. Some genetics research requires no more than a minimally invasive swab for cells from which genes can be extracted.
and a medical history. If the individual believes research done on his cells is no less invasive than research done on his heart, then he should make the researcher aware of such a belief. The researcher has an obligation to respect autonomy. He can only succeed if individuals make known their beliefs. Although this could result in less research participants, it would increase the integrity of the research.\textsuperscript{24}

The process of obtaining informed consent in clinical care and research are from the individualistic perspective. For this reason, critics of informed consent standards argue the standards are strictly Western orientated. The Nuremberg Codes were developed to protect the individual’s humanity and promote the researcher’s humaneness. In other words, the code promoted individual autonomy.\textsuperscript{25} However, not all cultures practice individual autonomy which is why obtaining informed consent for genetic technologies can be particularly difficult. The procedural standards of self-determination, right to be informed, and confidentiality have all been associated with individual autonomy. So then, it would seem the western ideology of informed consent would be either improper or even disadvantageous to apply to non-western or minority cultures in the United States.\textsuperscript{26}

3. Autonomy and Multicultural Societies

Genetic technologies offer an opportunity a new avenue to approach the healthcare disparity among minority populations who are significantly affected by diseases such as cardiovascular disease and diabetes. While this type of disparity is not in and of itself a result of lacking healthcare quality, failing to appropriately use the information is an ethical dilemma. There is an association between ethnicity and genetic traits which are a predisposition to diseases which can leave minority individuals at risk for adverse reactions such as unjust discrimination by insurers or employers.\textsuperscript{27} This is especially true if minority populations are unable to obtain
therapy for their preconditions. Furthermore, it would be ethically problematic to suggest healthcare disparities are due to these genetic differences. Thus, healthcare providers should be aware of these associations to properly treat patients while sensitive to the biases which might result from the information.28

In 2011, estimates suggest there were about 48.6 million uninsured individuals. Among these 48.6 individuals there is a larger representation of minority populations than whites. The Institute of Medicine defines a disparity as one which is a result of racial or ethnic differences and not clinical needs or preferences. Disparities contribute to the overall low health status of these individuals which can be caused by the healthcare system, environmental, genetic, and social factors. There is a direct correlation with minority populations in low income situations with lower health care quality. Health disparities create a circular limitation resulting in an ethical dilemma. When individuals cannot get healthcare because of low income, they cannot maintain employment contributing to their low income and ultimately, their low health status.29 For these reasons, a major concern for genetic implementation ethical standards and regulations is to avoid exploitation of vulnerable populations. Minority cultures are in a vulnerable position for care and research compared to the majority as they are often misunderstood and underrepresented. Ethically speaking, it would be unjust to place an unequal burden of genetic consent and implementation on minority population simply because they are underrepresented. In order to avoid exploitation then, it is most essential for providers to obtain informed consent from these individuals. This can be difficult though as often, non-Western cultures have a different interpretation of privacy than that with which informed consent was developed.30

Non-Western cultures rely heavily on communal participation of individual lifestyles including decision making processes. Without cultural competence, this method of decision
making process can conflict with other more common methods in western societies. Some families prefer to make their children the surrogate decision makers especially in end of life decisions. Meanwhile, in western cultures, the default decision maker is the parent until competency is called into question or the parent chooses to give up their right to decision making.\textsuperscript{31} Cultural understanding can relieve any potential ethical issues which might surround privacy and decision making processes of individuals from non-Western cultures. Attempts to understand individual understanding of privacy are important for western cultures but significantly important for non-Western individuals in order to ensure authentic informed consent is being provided.\textsuperscript{32} In cultures which place an emphasis on the community over the individual, it may be unacceptable and in some cases unethical to approach the individuals for informed consent. But, the United States does not approve of obtaining informed consent from anyone other than the individual himself.\textsuperscript{33} As this contradiction begins to develop, some critics argue ethical standards are not blanket statements. Furthermore, the standards cannot be globally applied.\textsuperscript{34}

Western perspectives without cultural competence could skew interpretations of privacy as constraint or disrespect for the individual. As a result, there could be a greater injustice due to the misunderstanding about alternative culture’s understanding of privacy.\textsuperscript{35} This misunderstanding is addressed by attempting to bridge language gaps as a method to connect interpretations of privacy and thereby, respect culture. Creating a bridge for language is limited insofar as, both individuals in the conversation often lack cultural competence of the other. Without one individual able to provide cultural competence, communication cannot be completed limiting respect for privacy.\textsuperscript{36} Varying interpretations of the individual’s rights make it difficult for the providers to determine the most appropriate approach to obtaining informed
consent. So for the provider, the next question to be addressed is how to maintain ethical standards across all cultures regarding genetic technologies. There are two proposed solutions to this problem. First, provider could impose their institution’s or personal ethical standards on the consenting individual. This could be beneficial if the individual lacks a sufficient understanding of their own culture. However, this method also risks paternalism.\(^3\) The second proposed solution is the concept of double standards. Ultimately, this method develops an acceptance of ethical principles which are universal (i.e. privacy). However, the application of the principles is dependent upon the individual case.\(^3\) With each individual case of obtaining informed consent for genetic application, individual relationships can create conflicts between the privacy and disclosure.

**II. Disclosure and Privacy: A Conflict of Interest**

The importance of informed consent has been established by the desire to prevent abuse to individuals via maintaining privacy. However, as mention, the standards for informed consent are imperfect especially when it comes to its application to genetics. Some general obstacles for achieving informed consent are most noticeable if not magnified in genetics research. The following section will discuss issues of disclosure and privacy when obtaining informed consent in genetics.

1. **Identifying Conflicts of Interests**

Conflicts of interests (COIs) are frequent occurrences in healthcare and healthcare research specifically. Unfortunately, COIs are not always clearly identified as the term is frequently and inconsistently used.\(^3\) When identifying a COI, it is important to consider primary and secondary interests as well as the underlying conflict itself. A primary interest in healthcare
would be one which promotes patient safety and quality medicine. Typically, these are the objective ends of a treatment plan or research project. Secondary interests are sometimes identified as financial gain, personal or professional advancement, or even personal favors.\textsuperscript{40} While these secondary interests can be honorable (i.e. professional or personal advancement), they create a conflict when they influence the primary interest. The fact that there can be degrees of secondary influence on primary interests makes identifying COIs difficult.

The varying degrees of influence allows COIs to be assessed on a sliding severity scale. Essentially, assessment of a COI is two-fold as it is based on the possibility of a decision being made based on the secondary interest and the gravity of the harm as a result of the influence. There are two factors which create an effective assessment of the degree of influence. First, the seriousness of an individual’s relationship with the secondary interest affects their likelihood of influencing the primary interest. This might be the case with individuals who believe they have had frequent dissatisfactory experiences with healthcare facilities. Second, the value of the primary interest is essential to quantify harm done as a result of secondary influence.\textsuperscript{41} This assessment is complicated when considering relationships such as family members, other patients, colleagues, and even institutions.\textsuperscript{42} As currently regulated and pursued in both clinical care and research, genetic technologies appear to affect all of these relationships. For these reasons, COIs are not only difficult to identify, but also incredibly complex when it comes to assessing the overall value of the COI.

COIs are further complicated when trying to obtain authentic, informed consent in genetic implementation. Providers can trace diseases, viruses, and human ancestry through human DNA. Genetic markers are alleles on the chromosome which enable researchers to track specific traits or diseases. Practical application of this method can predict familial or public
health threats. These predictions can lead to breakthroughs in genomic medicine and therapy. One example of these breakthroughs which is already being practiced is gene therapy. Generally speaking, gene therapy is the transfer of genes for therapeutic benefit. These methods could have innumerable therapeutic and public health benefits insofar as gene therapy is developed around the unique makeup of an individual or disease.

While genetics offers great promise for personalized therapies, it can also create a COI surrounding the traditional understanding of informed consent. As mentioned, a key aspect of informed consent is respect for autonomy which requires the individual to be free from external pressure to give voluntary consent. There are a variety of motivations for an individual to consent, or not, to genetic testing and these reasons are grounded in the individualistic model of traditional consent. However, individuals can experience difficulty giving authentic, informed consent if the individual has a limited understanding of their genetics and might require further information from their family members. For this reason, privacy in genetics has been argued to be incompatible with genetics as a social endeavor. Since individuals chose between privacy and disclosure of result and these two appear to be mutually exclusive concepts.

The ethical standards for informed consent suggest a need to communicate genetic results to other individuals (i.e. blood relatives or spouses) than merely to the consenting individual. Before arguing whether there is a duty to disclose information, it is essential to identify motivations behind the disclosure which create the COI. Genetics has altered the perspective of the modern family in a way which extends familial ties. Traditionally, familial ties were associated with heritage or culture. However, genetics offers a new approach to defining the family by using DNA. Because such detailed information is available, it appears now that passing genetic mutations which lead to diseases or conditions is considered selfish of parents.
and family members.\textsuperscript{48} The argument follows such that if individuals have a right to respect for autonomy and a parent knowingly or intentionally unknowingly passes along a harmful genetic mutation, then the parent is irresponsible and selfish. From this understanding, it appears that the family member who chooses to get genetic testing takes on the responsibility to disclose relevant information to their family members.

Consistently found in genetic counseling that individuals are often reluctant to disclose genetic information to their relatives for this can alter family history or stigmatize individuals. In fact, there seems to be a correlation between disclosure and major life events such a marriage or graduation.\textsuperscript{49} The concern to disclose such information to relatives is sometimes motivated by concern to relay information about health-related benefits. In some cases, the standard to disclose information requires that the benefits be immediately actionable. For diseases which are not actionable such as Huntington’s, it is more difficult to argue that individuals have a right to know and/or duty to disclose such information to their relatives since, there is no therapeutic intervention.\textsuperscript{50} For this reason, the same argument can be reversed to suggest that individuals should not tell their relatives genetic information if there are not immediate interventions.\textsuperscript{51}

Disclosure to affected individuals is significant since another’s genetic information helps achieve more accurate genetic information regarding risks and benefits. Disclosure to a spouse is arguably equally as significant as it can influence family planning. As a result, disclosure of these results is contradictory to the privacy standard of informed consent. These issues are present in both genetic therapy and research studies.\textsuperscript{52} When considering genetic therapy, an individual might benefit most by knowing their familial history. Take for example a history of breast cancer. Annually up to 18,000 cases of breast cancer could be due to genetic conditions.\textsuperscript{53} From a privacy perspective, it appears to be acceptable to tell a provider that a family member
had breast cancer. However, it appears to be another issue to request or obtain the genetic information from a family member to make a more informed decision for the patient. Relaying of this information affects not only the provider patient relationship but also the patient’s relationship with their family members.\textsuperscript{54}

2. Privacy Concerns for the Secondary Subjects

The discussion of COIs so far has revolved around therapeutic genetic testing and whether the individual patient has a responsibility to their family member. There is a significant amount of research data which suggests that relatives feel they are entitled to such information. One reason consent can be so difficult to obtain from the participant is that even the researcher can be unclear of his post-research intentions. Further complicating matters, genetic material is inert and therefore, if properly stored, can be preserved for hundreds of thousands of years.\textsuperscript{55}

From a research studies perspective, the genetic information can be stored for an infinite amount of time and be used for an unpredictable amount of future uses. The open accessibility of genetics makes it ideal for public uses. Genetic material then is a researcher’s best material because even after the research has concluded, the researcher can go back and reinitiate work on a sample. Perhaps a new test or theory has been introduced which the researcher could find beneficial. However, these new tests do not necessarily coincide with the participant’s intentions. This issue raises more questions the statute of limitations on informed consent.\textsuperscript{56}

However, in 2008, aggregate genetic information made available by researchers on the internet had to be removed when it was observed that individuals could be identified by the available data.\textsuperscript{57} These issues of identification and risks of privacy will most likely become more frequent with increased use of genetics in research.\textsuperscript{58} Thus, there is a need to determine at what point the risk of breach of confidentiality has been exceeded. Further, these examples identify the
need to determine how to either protect privacy or clarify appropriate instances of disclosure while protecting the individual who’s information is disclosed.\textsuperscript{59} For this reason, the providers have the obligation to offer necessary information for the individual yet, all necessary information in genetics might impede on another individual’s privacy. At the same time, the individual’s limitation does not directly require the researcher to teach a participant every aspect of the research.\textsuperscript{60}

Ultimately, genetics affects the privacy of two groups of individuals: those who’s privacy is respected and those who’s privacy is prioritized second to disclosure. However, ethical and legal standards only require obtaining informed consent from one group of individuals (those who consent to genetic testing).\textsuperscript{61} The standard begs the question as to whether individuals have an obligation to their family members or future children which results in a duty to know their genetic makeup.\textsuperscript{62} In these circumstances, the individual would have to know their genetic makeup in order to assist their family member. In other words, it is not an ethically equivalent dilemma to complete genetic testing without personally obtaining the results. Perhaps the only way to ideally justify this problem is to argue that disclosure of genetic information requires respect for autonomy of the individual who’s information is disclosed. Of course, this argument is easily reciprocated to state that if an individual does more harm to their autonomy than good to another’s well-being, then there would not be a duty to know the genetic information.\textsuperscript{63}

The second group of individuals whose autonomy is affected by genetics research is known as the “secondary subjects.” These individuals are relatives or in the same demographic as the individuals who offered consent. Factoring in the rights of secondary subjects is critical for individuals who are part of minority populations since it might reveal unique genetic characteristics which might not otherwise be identified. By relation, secondary subjects might
benefit from disclosure of results. Secondary subjects do not directly give consent to offer their genetic material. However, information from this group of individuals becomes known by through the consenting individual’s information. When provider has sequenced the consenting individual’s genetics, these conclusions reveal information about the individual’s family or community.  

The threat to secondary subjects’ privacy raises additional questions about genetics implementation. First, it infringes upon privacy rights of individuals. As mentioned, these individuals have not given informed consent to study their genetic material. But, because of their relationship to an individual who has given consent, secondary subjects’ information can become public information. Private information can include family medical history offered by the participant to the researcher. Second, the secondary individual is not in a position to receive benefits from the results. Therefore, the individual is placed at a risk for breach of confidentiality without the prospect for benefits. The risk to breach of confidentiality is a threat to individual autonomy because the individual’s rights to offer information were not respected. Even when there is promise for anonymization, scientific advancements enable information to be traced back to the individual.

However, if it were possible for the secondary subject’s information to remain private, this would pose a problem for the providers. Germline theories and pedigrees require large sample sizes for accurate and precise conclusions. Therefore, to reconcile the issue between the individual and genetic information, some providers adopt a more communitarianism perspective of genetic research. Communitarianism argues the dependence of the individual on the society determine the obligation of the citizens to participate in maintaining the common good. For this reason, some researchers suggest individuals even have an obligation to participate in genetic
research because of the benefits the research promises. From an American perspective, there is a cultural hesitation to the communitarianism approach for a few reasons. First, individuals personally pay for health insurance. Therefore, some individuals might be hesitant to disclose information for fear of discrimination and raises to their health insurance. Additionally, there is significant mistrust and fear of over surveillance.

Studies suggest that research participants would want their genetic information shared with at least one relative after the participant’s death. From a research perspective, relatives can gain access to the participant’s genetic information through a variety of avenues. The Health Insurance Portability and Accountability Act (HIPAA) permits the sharing of information for the purposes of treatment. Generally, critics of HIPAA argue this outlet it too broad. Additionally, HIPAA does not address what is meant by treatment, how immediately actionable a treatment must be, and how long after the research the relative may request such information. Further, it appears inconsistent with privacy to allow a relative’s provider information about the participant’s genetic information even if for therapeutic purposes. From a researcher’s perspective, they do not hold the same responsibility to the relative as they do the participant. Thus, it would appear in this case that the researcher would have to respect the individual’s choices outlined in the informed consent document.

Informed consent regulations protect individuals from undue burdens of therapy and research. However, genetic implementation affects more than the consenting individual’s rights. Rather, conclusive genetic endeavors can develop information about a whole community or population and thereby create a conflict between privacy and disclosure. Furthermore, genetic research can even require participation from a whole population or demographic sample in order to obtain the most accurate results. As a result of the community based approach, there has been
a transition from emphasis on the individual to population benefits with regards to genetics. For this reason, genetic implementation has caused bioethicists to reevaluate the efficacy of informed consent in these settings.\textsuperscript{73}

Issues surrounding consent for the purposes of genetic technologies raise the question of the obligation upon institutions to protect the individual’s privacy while providing safe and effective plans in both research and clinical care. Informed consent is essential to protect individuals especially since genetic technology is associated with a history of “eugenics” or limiting the reproductive rights of those deemed unfit for society.\textsuperscript{74} The right to privacy entails a duty to protect the right, or at least not to infringe upon it. It is the organization’s responsibility to ensure protection to the right to privacy.\textsuperscript{75} While all procedures require consent from an individual, genetics raises the question of informed consent’s appropriate role in medicine. Genetic interventions highlight the right to privacy in informed consent insofar as both clinical care and research interventions require a collective effort associated with population concerns.\textsuperscript{76} Issues of population benefits from genetic implementation will be further developed in the following section.

\textit{b. Population Health Interests}

While much of the genetic debate focuses on individuals, genetic implementation presents at an individual level and can have large scale implication for population wide health. Further, implementation at an individual is often developed using population wide data and information. Population health interests is an alternative perspective which must be carefully considered with the progression of genetics. Specifically, genetics will highlight the interdependence of individuals and the population to promote health on multiple levels.
I. Right to Health: A Population Effort

An understanding of the right to health can have drastically different applications depending on the culture’s prioritization of the ethical principles and the adopted healthcare model. In the United States, the culture focuses on individual health care and is hesitant to shift towards a population effort to manage health. The following sections will highlight the current state of health care in the United States, its strengths and limitations, and the possibilities of population efforts to obtain health.

1. Healthcare Access in the United States

Various healthcare models throughout the global community highlight the nation’s stance on the right to health and right to healthcare. In countries such as Germany and England, there are variations of the universal payer model. In these models, the government helps subsidized and distribute access to healthcare resources. The United States is the only country to use the private payer model. Unlike the England and Germany, it lacks universal healthcare coverage for its citizens. In the single payer model, commercial insurers sell healthcare coverage to individuals or employers and as a result, reimburse medical expenses. Individual and group risks standardize healthcare insurance reimbursement rates, not the government. Thus, the more risk factors an individual has either as an individual or within a specific cohort such as age or sex. This type of market increases competition, a fundamental principle in US markets, among healthcare providers and attempts to keep government authority removed from the healthcare market. Increased competition allows for greater opportunity of individual choice for healthcare providers and ultimately treatment options. Funding for healthcare services comes from the private sector which includes pharmaceutical companies, medical technologies, academics, and
more. However, due to the competition and private funding, it is argued that patients are most often negatively affected as they experienced high premiums and medical bills.\textsuperscript{80}

Rather than the government, employers are responsible for providing health insurance to their employees. Further, the state governments do not regulate the employer provided plans. For-profit, private insurers can vary their premiums offered by an employer based on pooled data of the employees. So high-risk jobs could mean high premium insurance.\textsuperscript{81} If an employee cannot obtain healthcare from his employer or as an individual purchase, the federal government offers and regulates Medicaid services. This insurance is often targeted to populations deemed the deserving poor. Although it is often not the case, Medicaid is only intended to be a temporary solution. However, the federal government’s regulation in Medicaid is limited to institutional and practitioner fees, thereby allowing states to regulate medications, medical facilities, and hospital fees.\textsuperscript{82}

In 2011, the United States spent approximately $2.7 trillion on healthcare. The United States is reported to have some of the worst health standards of developed nations in proportion to spending the highest percentage of GDP (17.9\% in 2011) on healthcare. Government spending now covers about 90\% of hospital costs, 80\% of physician costs highlighting the significance of healthcare spending in the United States political forum.\textsuperscript{83} It is estimated that about 80\% of healthcare spending is on people younger than 65 years who suffer from chronic diseases or experience trauma such as motor vehicle accidents. Government initiatives and reports have a primary focus on individual health status such as obesity, smoking, mental illness, and violence, which contribute to overall population health. A secondary focus is environmental exposure factors which contribute to individual health. A tertiary focus affecting population health is of societal factors such as food security, housing, employment.\textsuperscript{84} It is worthy to note that the
statistics, policies, and influence factors vary by state. The state themselves are sometimes successful examples of working healthcare systems about public health issues such as obesity, smoking, and violence.85 The states’ ability to distinguish their selves from the national healthcare disparities highlights the complex and multilevel healthcare system in the United States.

Part of the complexity is in the perception of healthcare itself. American healthcare system revolves around the idea of a medical market. Generally, the medical market can be understood as the relationship between insurance, medical technologies such as pharmacies, organizations, and providers. Due to the market perception, history in the American medical market shows a trend of attempts to decrease conflicts of interests, control costs, provide medical care and limit government interferences.86 Physician incentives are often a result of the interconnectedness but unregulated relationships between them and the market for healthcare products.87 This relationship can influence hospitals and providers compete for patients incentivizing providers to act or behave in certain manners ultimately affecting patient care. In other words, it was through provider referrals and prescriptions that insurance and hospitals attempted to regulate costs. These incentives to make certain referrals resulted in conflicts of interests for providers. Sometimes, these conflicts of interests result in over or misuse of treatment options, which can result in misidentified healthcare trends.88

While the United States healthcare delivery landscape varies so differently from other developed nations, the Institute of Medicine report on mortality suggests the differences are due in part only minimally by finances. Rather, the United States public health status is more an issue of cultural norms and health behaviors.89 Therefore, the United States has a larger issue than simply healthcare delivery to promote public health. Additionally, it should be concerned about
the population’s healthy behaviors as an interdependent system for the wellbeing of the nation.\textsuperscript{90} For about the last half a century, there is evidence of decreased dependency on acute care facilities and an increase in urgent care or retail clinics. This suggests that the healthcare landscape throughout the United States has become more fragmented.\textsuperscript{91} The shift from large institutions to clinics transfers power from government and provider to patient which is essentially the opposite of the other countries in this essay. However, since the change has occurred so recently, there is not enough research to highlight how this has affected quality.\textsuperscript{92}

Unlike the other nations described, the United States has not come to a consensus on the right to healthcare. On the national level, the United States seems hesitant to develop national policies to regulate public health efforts similar to those seen in Germany and the UK. The hesitation is motivated by fear of restricting respect for autonomy which is so deeply rooted in the culture.\textsuperscript{93} The positive side of this is it limits government authority in the healthcare market. The negative side is that healthcare is considered a consumer driven market. These aspects of the medical market are justified in the principle of autonomy described in the next section.

2. Understanding Respect for Autonomy in American Culture

The individual payer model is based on the principle of autonomy as it relies on individual choice to contribute to and participate in the healthcare system. In order to act autonomously, there must be intention, understanding, and voluntariness. The conditions suggest that an autonomous individual is one who can govern their self and make their own decisions.\textsuperscript{94} If an individual does not desire, then he is not necessarily required to respond to government or other institutions. The individual’s choice is the basis of the traditional American culture. An important characteristic of respect for autonomy as defined by UNESCO is that autonomy can be found in communities or among relationships.\textsuperscript{95} While the American culture emphasizes
individual autonomy, it is not to suggest that the UK’s or Germany’s citizens do not have respect for autonomy in their health systems because they exhibit limited individual freedoms. However, when applied to healthcare initiatives and public health specifically, the principle of respect for autonomy is often found to conflict with justice and solidarity.  

While there are three standard conditions for autonomy, individuals might have varying interpretations of health and healthcare. From the autonomous perspective, health cannot be determined by government standards and therefore, individuals should be free to choose the status which they claim to be healthy or unhealthy. These are the positive obligations of respect for autonomy. This aspect is distinct from the application of previous principles for the determination comes from the individual who will have a significant contribution to the development of US public health. At the same time, while individuals might not rely on their government or institutions, the principle of autonomy can be interpreted with regard to different cultural contexts. It has been observed that in order to respect autonomy in some cultures, individuals choose not to make decisions but defer to relatives or the higher authorities in the community. In Western medical ethics, autonomy is highly influential and especially capitalist nations such as the United States as it proposes an obligation to obtain permission from the individual himself.

Although respect for autonomy is mainly focused on individuals, some interpretations of the principle acknowledge that one individual’s autonomy cannot impede or harm another individual’s. Thus, there is an inherent social responsibility similar to the other principles described which is associated with autonomy. However, in the literature, this aspect of autonomy is often referred to as the negative obligation of autonomy insofar as there is an obligation not to do harm to another’s autonomy. The negative right is greatly influenced and determined by the
individual’s intention. If there is intent to do harm, then the individual’s rights to choose are justifiably restricted. This negative freedom will have great implications for respect for autonomy in the community. Respecting privacy is essential for the negative obligations since a voluntary decision should be one that is free from outside influences.

When considered in relation to public health, autonomous societies such as the United States do not depend on the government to provide healthcare or public health measures as much as the other countries described. The lack of dependency is accurate for both providers and patients in the medical market. Rather, individuals are left to develop their own health which in turn, contributes to overall public health. Therefore, unlike other countries, public health in the United States is a composition of individual health choices. Of course, the government can intervene when public wellbeing is severely threatened as this would qualify as a negative obligation. In these cases, health care institutions might limit individual freedoms to protect the greater community and have the support of federal agencies. Government intervention was observed in the 2014 Ebola outbreak cases. Even then, citizens of the United States questioned the legality and ethics of quarantining individuals. By questioning the decision to quarantine individuals, it is as if to say that the government and institutions need to have a substantial amount of evidence to restrict individual freedoms and therefore, respect for autonomy.

These restrictions on individual autonomy are at odds with the principles of justice and solidarity. Unlike the other two, the application of the principle autonomy is based on individual merits. Even in clinical decision making, an individual’s autonomy is respected if so much information can be retained and understood. Therefore, to restrict rights for public health ends seems counter intuitive to autonomy for it is not based on merit but rather communal statistical evidence. An ethical justification to limit autonomy in favor of justice require the following
conditions: effectiveness, proportionality, necessity, least infringement, and public justification. One cannot deny the relationship between community wellbeing and its benefits to the principle of respect for autonomy. Evidence suggests that individuals in healthy communities tend to live healthy lifestyles and are more capable of expressing their autonomy. The important factor though in a community such as this is the freedom to behave in a healthy manner rather than being coerced or manipulated.

It is through the principle of respect for autonomy that an individual has the right to self-reflection, deliberation, and action. This process is the ideal for decision making. If the process is believed to be too far from this ideal, decision making is called into question. There appear to be inherent conflicts when it comes to applying autonomy to public health efforts as the efforts tend to limit individual freedoms. When applied to public health efforts, it is not always the case that individual perceptions are taken into consideration for decision making. For this reason, public health efforts in the United States will require a cultural change if they are to successfully and effectively address and of the issues deemed public health. The following section will highlight the current public health status in the United States, the strengths of the system, and the undeniable weaknesses which tend to overshadow these strengths.

3. Identifying the Need for Cultural Shifts to achieve Population Health

As stated, the United States spends more of their GDP on healthcare than any other developed nation. However, the population’s health status does not reflect GDP spending as the nation frequently ranks low on health status comparison. Therefore, it must be asked why the individual payer model based on the principle of autonomy is used if it is not cost effective or medically efficient. There is little doubt that in the United States, public health status is influenced by social determinants and inequality. The United States’ policies to provide public
assistance are often a last resort option for families. This perspective suggests that the government does not support prevention social determinants of health inequality.\textsuperscript{110}

Patient Protection and Affordable Care Act (ACA) in effect as of 2014 highlights a significant federally regulated attempt to create a turning point in the US healthcare system by encouraging a universal healthcare system. This shift is a moderate one which allows more government and legislative control in health insurance for all income levels. As a result of this control, it is intended that individuals will be more capable of receiving preventable care and thereby increasing overall public health.\textsuperscript{111} It is essential that the approximately 40 million uninsured people in the United States obtain health insurance for public health benefit. The ACA alters public health efforts in many ways. Under the new legislation, health care organizations are held to different reporting standards previously in place. The new standards emphasize community needs assessments allowing for a more prepared facility targeting the 60 million individuals who are believed to be medically underserved.\textsuperscript{112}

Medically underserved evidence is apparent in the severe healthcare disparities throughout the US. Healthcare disparities vary between socioeconomic statuses but remain consistent within the socioeconomic class.\textsuperscript{113} The prevalence of diseases or conditions also varies among socioeconomic status. Yet, two people in poor health in different socioeconomic classes will have similar mortality rates. For example, heart disease and cancer are more prevalent in affluent neighborhoods among people in poor health.\textsuperscript{114} This information suggests that it is not necessarily the situation anymore that there is a clear divide between rural and urban or wealthy and disparity struck neighborhoods. Thus, in order to promote population health in the United States, an alternative approach in addition to policy needs to be taken.
While some critics question the government’s constitutional legitimacy to regulate health insurance, if properly implemented, the ACA could provide relief for all income levels regardless of their participation in the act. To provide health care to those who were previously unable to attain it would alleviate burdens of poor population health on the whole population.\textsuperscript{115} The drastic stress in the healthcare system has recently tested the traditional American principles of privacy and individualism. The fundamental principles support the private healthcare model such that if the individual paid for the services, he could receive these regardless of the impact this would have on other individuals either with similar conditions or among the same cohort. However, it was cultural and ethical understanding that an individual would need to pay for his healthcare as he was the one to use it. Thus, those who do not work, suffer the most as they could not afford healthcare services or received government regulated healthcare limiting their options and placing a higher burden on those who paid for healthcare. Thus, there was a one way relationship which is counter to the autonomous model.\textsuperscript{116}

The ACA attempts to address another issue of public health disparities in the US which is unhealthy behavior. Some of the health behaviors present in neighborhoods or groups tie the community together while the behavior is detrimental to their health. Consider the example of chewing tobacco among rural communities. These cultural factors even vary throughout regions of the United States.\textsuperscript{117} An incentive based model is suggested to be more beneficial toward achieving higher levels of health than more traditional approaches were focus strictly on health care access. Depending on how the interpretation of principle of respect for autonomy, one can argue behavioral modifications as either ethical or unethical. It is ethical to intend to achieve greater population health. It is arguably unethical on the principle of autonomy to manipulate an individual into certain actions.
With the perception of public health, this created a circular dilemma where without health and individual could not work. Without work, an individual could not afford healthcare to be healthy. As interpreted by the US, the autonomous model does not support the public health model. Rather, the model is developed in a framework which prioritizes negative obligations more so, than positive. Even now with the ACA in place, evidence is surfacing which suggests that although healthcare coverage has expanded, healthcare access is still highly limited. Either doctors are not accepting the coverage or individuals remain unable to reach the appropriate healthcare facilities.\textsuperscript{118} The former problem is one still rooted in the individualistic autonomy principles. For the latter problem, if individuals do gain access to healthcare services, these tend to be in a more limited or narrow market both in the sense of providers and care options. Lack of access can result in cultural conflicts if not enough options are available to consider cultural sensitivity in a country as diverse as the US.\textsuperscript{119}

The ACA is evidence of attempts to introduce universal healthcare reform in the US. This reform has undertaken some assumptions though. First, it assumes that the single payer model is in fact, less effective than other models. Second, it assumes that there will be a cultural shift in the healthcare market welcoming the universal coverage. Thus far, neither assumption has been significantly supported. These changes are only effective if the American culture eases the stronghold on autonomy and the medical market perspective. It is evident that this reform is similar to other systems such as the Beveridge and Bismarck. These systems are more supported by cultural beliefs than the ACA is in the United States.\textsuperscript{120} Considering the development of these models aims to provide for the entire population, policy makers must have population wide data available. The following section will address population data access for the purposes of genetic intervention.
II. Population Data for Genetic Intervention

The pursuit of genetic technologies further emphasizes the significance of population data to understand and manage health. Currently, there are nationwide efforts to synthesize genetic data to develop the most efficient use of the data. These “big data” efforts are intended to develop clinical care yet, they require a compromise with individual confidentiality.

1. The Relationship between Population Data and Race

Increasing data availability creates a strong push to collect population data to develop therapeutic output. Population genetic information for therapeutic intervention can not only be collected but also predicted with enough information. Theories of genetic inheritance are essential to understanding the significance of genetic inheritance. Perhaps the most basic principle of genetic inheritance is the Hardy-Weinberg principle. This is a basic equation which provides an estimate with how variation of Mendelian traits (dominant or recessive) in a population is maintained or changed based on selection, mutation, migration, and genetic drift. If none of the factors change (there is no migration in or out of the population, no mutation, selection is random, and genetic drift is constant) than the population’s genetic profile will stay much the same throughout generations. Of course, population genetics is not an isolated event and not all traits that are inherited are Mendelian traits. Changes in the Hardy-Weinberg equation result in single nucleotide polymorphisms (SNPs) which can identify differences between indigenous populations and group the populations based on geolocation. Geneticists estimate that in the 3.2 billion nucleotides that make up the human genome, there are approximately 11 million SNPs. Individuals whose genomic sequence consist of a series of SNPs tends to be similar to that of their whole population. Further, for individuals of the same population, the location at which their genome differs tends to differ consistently throughout the population. In
other words, the location of the variation tends to be similar but perhaps not the variation itself.\textsuperscript{123}

In a pluralistic country such as the United States, population specific genetics can be identified in different races although not express themselves. For this reason, studies of genetic clustering are highly important to correlate genetic similarities among different races. Genetic clustering is an analysis which infers the significance of similarities between individuals. Some critics of racial analysis argue that in pluralistic societies, the variation has blurred so much that the analysis is insignificant.\textsuperscript{124} In a study of genetic clustering and the correlation between self-identified ethnic background, results suggested that there were degrees genetic clustering between the studied racial groups (whites, Hispanics, East Asians, and African Americans). This suggests that there are similarities between the racial groups even despite geographical distances between the populations. Because of genetic clustering, it is important to consider racial and ethnic backgrounds for population genetic analysis. Genetic expression is multifactorial and there is a difference of environmental exposure between races. Therefore, it would ultimately be inaccurate and result in misrepresentation if genetic data did not factor race into the results.\textsuperscript{125}

An approach to implementing genetic technologies for population health is to analyze genetic patterns based on racial or ethnic backgrounds. Single base pair polymorphisms are often associated with genetic conditions common among certain populations (i.e. sickle cell anemia in Black Americans). Mutations that have a frequency of less than 2 percent are almost always considered race specific. This is partially because the populations rarely repopulate outside their ethnic background.\textsuperscript{126} Therefore, new genetic variations, which could be both harmful or helpful, are not introduced to the racial or ethnic group.
Interestingly, while race is useful for genetic analysis, the decline of scientific racism has overlapped with the rise of genetics. This correlation is significant considering that the biological distinction between races was used to wage the second world war and the fact that American culture still relies heavily on racial distinctions. Genetic science was critical in identifying differences between races as well as causation.\textsuperscript{127} In Franz Boas study of US immigrants in the early 20\textsuperscript{th} century, Boas determined that skull size, a trait often associated with intelligence, was susceptible to environmental factors. Studies such as Boas which shifted away from anatomical features to identify human worth promoted studies of ethnology. Moving forward in science, studies began to support the similarities between races were due to ancestral overlaps and the differences were multifactorial such as geographic isolation.\textsuperscript{128}

The controversial history of genetics and race or ethnic backgrounds creates an additional social and political dilemma for pursuing genetic technologies from the population health approach. However, to not pursue population genetics in spite of the history would be equally as ignorant and detrimental to the development. Studies suggest that minorities are highly underrepresented in genetic studies. Specifically, one study suggests that African Americans represent only 2.3\% of the population genetic registries on Autism.\textsuperscript{129} As a result, genetic patterns might not be properly identified and targeted interventions might miss the population that would benefit most.

2. \textit{Clinical Implications of Population Genetic Data}

Genetic screening for rare, genetic diseases that have a clinical intervention is an immediate action of genetic application for population health and requires racial and ethnic information. Generally speaking, genetic screening identifies risk probabilities which can be more useful at the population level than the individual level. The individual level requires
genetic screening in combination with family history to manage more accurately prevention and clinical intervention. Accurate genetic screening requires consideration of the individual’s racial and in some cases, even ethnic background. Studies support a difference in racial determinates of diabetes complications. These complications are due in part by socioeconomic status, education, and even healthcare access. In a pluralistic society such as the United States where individuals identify by their racial or ethnic background, this information can be highly significant as the individual is more likely to exhibit the cultural traditions in relation to their geographic location. Therefore, to effectively determine treatment efficacy, it is important to be aware of the individual’s self-identified culture (i.e. their population).

It would be unfair to considered genetic interventions the first effort that requires massive amounts of data for success. For years, and increasingly more recently, healthcare organizations have been using ‘big data’ from the electronic health record (EHR) to develop diagnosis, treatments, and maximize results. “Big data” is defined in a report to Congress as “large volumes of high velocity, complex, and variable data…” Essentially, big data is the collection of individual data for undefined future uses. The healthcare industry can use this data to identify patterns for quality improvement purposes throughout their organization or to target more effectively diagnosis and treatment options for patients. Under the “big data” framework, genetics are categorized as biometric data similar to that of fingerprints, retinal scans, and medical images. Healthcare organizations argue that the combination of big data such as EHR information, medical images, and genetics can help develop new drugs and therapies. Genetic information is particularly interesting to organizations since the collective data can be used to research population level diseases such as cancers and cardiovascular disease.
An example of big data collection is the NIH’s database of Genotypes and Phenotypes (dbGaP). The dbGaP is a repository or registry that maintains individual level genomic sequences for research studies. The NIH then controls and oversees the use of data from dbGaP using the Genome-Wide Association Studies (GWAS) policy. If the NIH funds genetic research, then the data needs to be shared with the NIH to go into the dbGaP. Other investigators can then request data from dbGaP by submitting a research proposal. These efforts are intended to increase individual protection by allowing one site to manage the overall data. Further, this big data approach is intended to maximize data usage by promoting collaboration among researchers. Similar to other big data managers, the NIH is challenged by a need for alternative data management and the protection of privacy for individuals. While aggregate data might be available in the database, there have been various successful attempts to identify individuals from genetic information. Thus, for these big data endeavors, there are issues of trustworthiness throughout the population.

There are two approaches to genetic intervention in population health, a top-down or bottom-up approach. The bottom-up approach is used to identified the genetic pathway which results in the phenotype expression. The top-down approach is essentially a data-mining process requiring ample amounts of genetic information to produce reliable results. This approach builds on existing population health knowledge to identify causation. While single polymorphisms are predictable, more common genetic disorders such as asthma, cancer, or cardiovascular disease are more complicated because they are multi-factorial.

Big data collection is an ongoing project with endless possibilities for healthcare. A population effort is required to fulfill any possible potential benefits from this collection. The NIH has made significant strides to create collaboration across organizations with regard to
genetic data. The current development of population health and the United States’ recent shift in policy supports the fact that individual participation is required to promote population benefits. However, big data collection comes at the price of the individual’s confidentiality. The following section will discuss the conflict between individuals and populations as a rights and social justice issue.

c. Rights and Social Justice

The two sides of the genetic argument are presented from an individual or population perspective. This is generally how the argument is divided throughout the literature. For these reasons, the genetic argument develops into one of human rights and social justice. The ability for individuals to express these rights is often affected by external factors such as stable societies, biological factors, and even access to health. These contributing factors, promote the awareness of the multidimensional individual and therefore, allow for more opportunity of commonality between individuals, i.e. the population. The principle of solidarity is essential to the progression of research and clinical genetics.

I. Solidarity through Vulnerability

Human vulnerabilities have been used to both manipulate and motivate societies toward action. Individual awareness of common vulnerabilities can lead to solidarity for actions toward a common end. Genetic technologies can be used to aid in identifying common differences among individuals and be a contributing factor to promote solidarity.

1. Identifying Human Rights through Common Vulnerabilities

Human rights are consistent and cannot be altered. These rights influence an individual’s own actions, the actions of others, and the perception of humans’ relationship to the
The developed progression of science has widened the scope for individuals with human rights. These rights are essential as they protect and promote an individual’s autonomy.\footnote{139} The principle of autonomy comes both rights and obligations. The individual has a right to act in accordance with his understanding of environment. At the same time, this individual has an obligation to refrain from impeding another individual’s right to autonomy. Therefore, with more knowledge about the environment, it could be argued that a person is more capable of fulfilling his rights and promoting his individual autonomy. Rights are part of a symbiotic relationship between the individual, other individuals, and his society.\footnote{140}

Autonomous decision making consists of two parts; to act or not to act.\footnote{141} These components of human rights suggest two variations of rights. There are both positive and negative rights human nature possess. Positive rights free an individual from obstruction to do an action. An example would be an individual who has the right to ride his bike. There are no laws against riding bikes. However, there are laws which regulate how the individual can ride his bike. The person must wear a helmet and follow traffic laws. These laws might restrict him from riding in certain such as sidewalks and grocery stores. Thus, the individual is not free from negative freedoms. There are laws and regulations which put restrictions on the individual’s total freedom.\footnote{142} On the other hand, a negative right is a right in which an individual is has the freedom not to act. For instance, individuals maintain the right to be free from crime. This perspective promotes the bioethical principle of nonmaleficence. While the individual is free from crime, this does not suggest there is a necessity to actively do good. Therefore, negative rights are inactions. The right does not require action to obtain or fulfill the right but the individual can possess the right by an inaction.\footnote{143}
Arguably, these rights are fostered within the individual. However, protection and promotion of the rights can be affected by external factors. For instance, compare a first and third world nation. Although the rights do not change, there is a different standard of protection and promotion due in part by resource availability. What might be understood as sufficient protection in a third world country might be understood as minimal to very limited protection in a first world. The more options available, the more flexibility and strength that can promote human rights potential. Although the rights do not change between the first and second world, the ability for an individual to prosper does change.\textsuperscript{144}

The available resources required range from housing to more complex research sciences. It is through disciplines such as science that the individual is more capable of expressing creativity and curiosity. By doing so, the individual can come to understand more about their environment and nature. Human beings are a part of nature in so far as they have come into being by the same laws as the rest of the universe. The more an individual is capable of understanding his environment, the more capable the individual is to express his human rights. So, while human rights influence the individual, the individual can influence human rights by progressing knowledge.\textsuperscript{145} Consider the example of genetic information to promote health. As mentioned, human beings share 99.9\% of their DNA. While this fact reduces human beings to their amino acid components, it promotes the idea that all human beings are comprised of the same physical components.\textsuperscript{146} The slight variation in genetic makeup creates the large differences observed in the human population. While this notion will play out for human identity, it is also important for human rights. The differences make each human unique. At the same time, the fundamental components of human beings are vastly similar. This establishes both human rights and the various interpretations of human rights.\textsuperscript{147}
The interpretations of human rights are constantly changing with new knowledge. The ever growing understanding of human rights then leads humans to the right to continue to adapt their understanding. These rights are promoted by the individual’s desire for creativity and curiosity in the environment. The perception of environment might change depending on geographical location or culture, but natural human rights remain contingent upon human nature. Therefore, so long as an individual is a human being, then by nature, he maintains human rights.\(^{148}\)

From this understanding, human rights are intrinsic to human beings. The rights promote an individual’s autonomous decision making capacity. The capability of authentic autonomy is contingent upon an individual’s ability to understand the environment. For this reason, it is important to promote the institutions such as the sciences which provide individuals with a better understanding of environments. So while human rights provide an opportunity, there is also an obligation to not prevent another’s right. Although individuals might have different conclusions from their perceptions, this does not change the fact that human rights are constant. Instead, adapting interpretations allow for more opportunities to develop human rights.\(^{149}\) Human rights are protected and promoted by the individual’s society. A society might be defined by a number of characteristics one being an established understanding of similar beliefs. Citizens and the society have a dependency on one another insofar as society provides a community for the citizen. Historically, the citizen was a subject of the society who was to uphold the society’s foundational beliefs. Therefore, a citizen who committed a crime committed the crime against the whole society, not just the victims of the offence. So government’s philosophy was superimposed on the subject and therefore, disabling the individual from establishing himself independently.\(^{150}\) For societies which were established from a religious foundation, an individual
who acted against the law acted against society and against religious beliefs. The society then received retribution from the individual by inflicting public pain. Ultimately, pain was an immediate punishment for the individual as well as the government’s effort to prevent further acts against the society.\textsuperscript{151} The government exploited individual to become a warning for potential future criminals. Through the exploitation of vulnerability to punish the ‘subjects,’ the understanding of individuals developed into multidimensional beings capable of relating to one another regardless of contextual boundaries. While many individuals might not have similar urges of a criminal, basic foundations enable people to relate to feelings of pain and suffering.\textsuperscript{152}

Exploitation of vulnerability presents two significant developments. First, public reprimand suggests the individual is entitled to a private life which can be humiliated. In order to be capable of humiliating a person, there first has to be a personal boundary which separates certain actions of the individual from the rest of society. Furthermore, without the society, the individual would not need a private life. Therefore, it is only within the confines of a structured society that an individual can exercise their privacy.\textsuperscript{153} Second, the individual is no longer a subject of the society but a citizen with rights. So, rather than a subject serving the society, the citizen is codependent upon the society. This perspective suggests the society is not structured to control the individual. The citizen is not an unrestrained object bound by society’s laws and norms. When the society develops norms in accordance with the codependent relationship, both the individual and community prosper.\textsuperscript{154}

As mentioned, punishments were used to conform individuals to the society. In order for punishments to be truly effective for intimidation and society, the subject had to identify with other individuals. Therefore, self-awareness was a necessary component to the society’s structure. Privacy for experiences became important, empathy and relating to another’s
experience also developed. When an individual was capable of establishing and identifying their own vulnerability in private, they were more capable of identifying with the other’s vulnerability. This helped trickle awareness of privacy and self-reflection down through society’s classes. The multidimensional individual developed more opportunities for members of different social classes to relate to one another. Through common characteristics, new connections and relationships were capable of being developed without having material similarities.

2. Importance of Adaptability in Human Rights

The perception of vulnerability has changed and in some circumstances expanded over time. As argued, to identify vulnerable positions, individuals are typically attempting to relate to one another. Common characteristics to relate to one another can be categorized into two broad characteristics: biological and external. However, regardless of either of these categories, human rights prove to be adaptable and greater than identifiable boundaries. Consider three examples of biological factors which contribute or inhibit identification of human rights: age, gender, and race.

Ageism can affect the ability of an individual to express his human rights. At varying cohorts, an individual’s rights are perceived to different degrees. Consider the extreme ends of the age spectrum: infant and elder individuals. Elderly populations tend to become a burden on societies. Infants and children, on the other hand, can be coerced and manipulated for experimentation and organ trafficking. These populations often require greater investment to protect human dignity yet, they tend to offer less immediate benefits. For despite societies, it might be that if the individual is incapable of work, then there is no benefit in providing investments and resources. However, this would digress back to the understanding of individuals in society previously described.
In addition to age, individuals find identification and self-awareness in gender roles conformed to society’s needs. Women are not a minority group. However, they are often suppressed because of the social standards. Not until the early 20th century did women in Western societies begin to have a political voice. Around this time, society found women could perform similar tasks that men usually do since the men were fighting the World Wars. So again, generally speaking, societies are willing to expand human rights in the event that the expansion will be beneficial to the greater whole.

Finally, consider race as another factor which influences the vulnerability of human rights. While humans are all considered to be of the same species, it was and sometimes still is perceived that there are various dominant characteristics of human genetics. Those who are more intelligent or successful, for example white men in Western societies, were once perceived to have better genetics. With this logic, there was justification to suppress individuals of lesser intelligence because of race or use the people as a means to an end.

Defining human rights by biology suggests there is an ideal which humans are progressing toward. However, there is yet to be a defined ideal environment for human survival and progression. In addition to biological factors are external or contextual factors. These too can affect the vulnerability of human rights. Contextual factors include social class, politics, and education contribute to a cultures’ beliefs and development of human rights. In addition to the biological factors which might define human rights are also the societal factors; religion and social class. Within this context, there were still individuals whose human rights were restricted because of biological factors. There was hesitation to extend political rights to groups other than white men. Once one group received rights, all other groups would demand rights and protection as well.
Religion is an example of an external factor that distinguishes individuals. Religious practicing contributes to lifestyle choices such as foods to eat or practices to refrain from. These practices might make a human vulnerable in a society which does not welcome the religion. Furthermore, individuals of a religious community can live within a society which might be founded on different beliefs. This would cause the community to be in a vulnerable position. The Jewish community is an example of vulnerability due to religion. In American history, Jews were not initially granted religious freedoms. It was not until 1791 that all Jewish citizens, regardless of ancestry, were legally given religious freedoms. However, this is not to say their rights originated at this time or that going forward were protected by the government.

With an understanding of commonality among each other, human rights are in a position to identify with the awareness of the other’s vulnerability. The impact the public humiliation on the individual’s rights became the focus. Knowledge of self and the other, the society transitioned to promote an individual who is capable of growing within a structured framework. Furthermore, only by basing this framework around the individual’s rights and humanness, can the organization implement an appropriate structure. As genetic science highlights, human vulnerability is due to a multitude of factors including individual and societal circumstances. In other words, humans are a product of both their environment and their genetics. Importantly, it is with this complexity that individuals have both more vulnerability and more in relation to one another. Therefore, when individuals are more capable of relating, there is greater awareness of the inherent nature of human rights for all individuals.

The above mentioned factors suggest the human race is progressing toward an ideal species as if one characteristic is better than another and therefore, the vulnerable should be exploited to achieve this change. The shortcoming to this theory is that there has to be a
universally assumed ideal environment for the development of the human species. As genetic research progresses, the ideal human species becomes more and more elusive. There is limited, if any, evidence which suggests some characteristics are greater or more beneficial than others. Rather, this allows for the opportunity to argue in favor of universal human vulnerability and again, supports the multidimensional individual. Ultimately, the differences between individuals support that humans right are universally applicable. Human rights progression was a transition from exploiting vulnerabilities as a method to fit the individual into the confines of society to society being structured for the citizen’s innate right to be relieved from vulnerability. Contextual factors and exploitation of vulnerability limit the ability of individuals to express human rights. The external factors a human is living in can influence their capacity to exercise rights and further develop the dependency of society on exercising rights.

3. Solidarity and Common Heritage

Regardless of age, race, or gender, all humans experience vulnerabilities throughout their life. The development of exploitation of vulnerabilities helps support UNESCO’s principle of solidarity and cooperation to promote human rights put forth in the Universal Declaration on Bioethics and Human Rights. Typically, solidarity is a prerequisite for cooperation. Solidarity and cooperation are possible through an individual’s identification with another individual. Consider again the examples of the use of self-identification to develop early societies so too does solidarity thrive with self-identification with another individual. On a global level, solidarity and cooperation are promoted by the freedom expressed within and by states. Thus, the higher good of the principle of solidarity then is accessible freedom through global solidarity and cooperation identified by the individual. Consider the most primary component of solidarity being the individual. A collection of individuals constitutes a community, so on and so forth to
the larger community. The purest freedoms possible for an individual depend on the cooperation of neighboring individuals to respect the rights to maintain these freedoms. This is so because the individual does not live in isolation but is inevitably the bearer of effects from other individual’s choices. Thus the principle of solidarity contributes to the practical application of freedom of which is found within the community of individuals.\textsuperscript{170}

Solidarity is only possible through the variation of cultures and the freedom to cooperate to obtain a common end. Theoretically speaking then, solidarity should fill the voids of unjustified law, i.e. exploitation of vulnerabilities. Using the principle of solidarity, individuals should seek the higher good regardless of backgrounds or other differences.\textsuperscript{171} This aim will inevitably become essential for the development of genetic technologies. At the same time, solidarity does not require equality. It is important to note that the component of equality was eliminated in the drafts of UNESCO’s Principles of Human Rights. While solidarity is focused towards to a common end, it does not require all participants to come from an equal platform. This requirement would be an unrealistic expectation. Further, this has larger implications when considering appropriate healthcare needs for a group. The means to achieve the common ends need only be consistent with attainability relative to the state.\textsuperscript{172}

Ideally, solidarity and cooperation require both social and diverse individuals or groups to maintain common vision on a greater good. Therefore, participants of solidarity are required to be social and maintain social responsibilities. There are multiple levels of social responsibility for participation: the individual society, an organization, and a collective society. As mentioned, multiple societies are necessary for the principle of solidarity. That being said, no society or culture universally takes precedence over another.\textsuperscript{173} The applicable notion of solidarity makes it important when defining property rights over entities which are believed to be part of the
common heritage of mankind. Originally introduced, the notion was understood as common physical property such as the sea and space. As nation-states expanded their sovereignty, property rights over territories such as oceans and air came into question. It would later be determined that these areas could not be claimed. Additionally, these areas should be maintained for the benefit of all including future generations.\textsuperscript{174} Considering recent technological advancements, there is now consideration for unobservable entities such as DNA and chemical mechanisms of ancient traditions. In this respect, common heritage of mankind has expanded and become more abstract. This will come to be significant when determining justified benefit sharing in a later section. Regardless of the substance of common heritage, the established criteria remain the constants.\textsuperscript{175}

Similar to identification of human rights through vulnerabilities, the common heritage of mankind developed from the lack of protection over all of humanity.\textsuperscript{176} Generally speaking, the notion has developed into the following characteristics. Common heritage is considered to be an entity which was valuable and possibly beneficial to all human beings. The entities must not be a property of the state or territory. Any resources removed from the area must be used for the benefit of all mankind. Restrictions include that the area of common heritage is free from conflict or any resources used in conflict such as military equipment. Finally, any research performed using the common heritage must be freely accessible.\textsuperscript{177} These characteristics of common heritage are highly significant for genetic technologies since property value of genes is debatable. The community has the responsibility to do no harm to the determined common heritage. Additionally, the community has a responsibility to protect and use the common heritage in a manner which promotes benefit and wellbeing for other users. Thus, as mentioned in the criteria, anyone who benefits from the common heritage is responsible for sharing the
benefits or at least, make the benefits available to others. Here the common ends between humans justified by the protecting and use of common heritage that is promoted by solidarity.178

Furthermore, there is a conflict over the amount of independence given if for individuals and organizations who are responsible for the protection of the common heritage. Delegations for declaring common heritage are typically initiated by the state in which the entity exists or a majority population which wishes to preserve their heritage. For this reason, there are underrepresented areas of the world.179 For instance, imagine an attempt to preserve an environmental landmark in Africa. First, it would be important to determine how to share this culture with the rest of mankind, and thus providing support for the significance of the culture. Then, there would need to be a delegation as to who should provide and how to protect. While common heritage is higher than legal authority, a legal authority at some basic level is necessary for any protective service.180 This scenario can and will be similarly applied arguments about patenting and commercialization of genes and genetic technologies.

Common heritage is universal for all humans past, present, and future. The continuity of the entity is essential to the genetics argument for two reasons. First, genes are common throughout all living things and humans share most of their genetic makeup. Second, current developments can influence perceptions of the past and have unpredictable consequences for the future. Considering these points, it is evident that the advancement of genetic knowledge and technology will undoubtedly influence all humans. The principle of solidarity and cooperation create a lens to assess issues between individuals and populations from a human rights perspective. Furthermore, the principle is a piece of the organizational framework required to relieve this tension. In the following section, the principle of solidarity will be applied to the issue of just healthcare access.
II. Just Healthcare Access

The principle of solidarity begs the question of the roles and responsibilities to provide just healthcare access. Solidarity and identification with other individuals through vulnerabilities is essential to defining the justification for healthcare access. There are three examples of current or progressing healthcare access which present the issue on three platforms: institutional, cultural, and future generations.

1. “The Brain Drain” and Access to Healthcare Workers

The first example of issues of healthcare access on an institutional the brain drain. The brain drain addresses the movement of skilled professionals from an area of underdevelopment to an area of higher development with more resources. For argument’s sake, the “brain drain” will refer to the particular movement health care workers. Healthcare access is one of the fundamental steps towards stable socioeconomic conditions because it helps maintain a healthy workforce. The shortage of healthcare workers risks unsustainable healthcare systems which, impede the ability to achieve public health goals and such as genetic interventions. Without these skilled workers, the community, even with global resources, is unable to administer health care such as vaccines, routine evaluations, and essential treatments. Further, research efforts are significantly decreased without sufficient professionals and funding. Thus, without the healthcare workers, there is a weaker general workforce and a weaker society.\textsuperscript{181} The issue was steadily growing with approximately 188 million migrants in 2010. This has more than double from 74 million in 1960. This rate is slightly faster than the world population growth.\textsuperscript{182}

Typically, the underdeveloped area, source community (SC) is left with insufficient healthcare workers in proportion to the population and their needs. Meanwhile, the high developed area, destination community (DC) fills employment gaps in their health systems. Most
often, this movement is from the southern to the northern hemisphere. However, the trend is also observed within countries especially countries which are as large as the United States. The majority of the ethical dilemmas which will be discussed occur because of this particular movement. The major participants in the brain drain are the SC, DC, and the workers themselves. Consider the individuals have the right to emigrate in a vulnerable situation as their society’s unstable infrastructure. This is justified by human rights and therefore, individual cannot be held entirely accountable for seeking strong employment opportunities. However, the SC and DC can be made liable to the extent that the society should be responsible for providing, or progressing towards are sustainable infrastructure. The DC is additionally responsible for being socially aware of the SC’s conditions and promoting the goals of that particular society to become more sustainable.

Consider the comparison of the brain drain presence in both the United States and the African Continent. In both instances, the brain drain creates a human rights issue since health care access is limited. The United States is considered to have a lack of healthcare workers in proportion to the given population. However, the US has more health workers in proportion to the global burden of disease whereas Africa has a lower percentage of health workers in proportion to their global burden. The proportion of the global burden of disease can lead to awareness of the presence of brain drain and is a qualitative measurement of identifying an imbalance of global health accessibility. Another approach to identifying the brain drain, and the most widely used method, is identifying impacts by net financial changes of the countries. Theoretically, the SC’s net financial change might show growth from remittance. Often, this is the “pull factor” leading workers to migrate to DC. Meanwhile, the limited availability of resources is a “push factor.” Financial evidence defining the brain drain provides a motivation
Financial incentives are often the cause of provider migration from rural to urban areas. The net loss fails to identify periods of influx caused by the brain drain which can also drastically affect a community’s stability.\textsuperscript{187}

Healthcare worker shifts create a disparity of healthcare access in resource poor areas. As a result, these regions are less likely to have healthy populations capable of prospering throughout their community. At the same time, healthcare workers have the right to pursue professional advancement. Further, the organization’s role in mitigating the drastic differences between areas is debatable.\textsuperscript{188} What is evident is that the principle of solidarity and cooperation is essential to relieving the healthcare access disparity between communities insofar as, the common end is to create healthy societies and to promote professional development. Since genetic technologies are cutting edge, it would seem that these are only available in resource rich nations.\textsuperscript{189} Access to such technologies will create another driving force behind the brain drain. The following section will present an example of cutting edge reproductive genetic technology and the arguments surrounding the availability of the technologies.

2. Ethics of Genetic Testing and Avoiding Eugenics from Reproductive Technologies

The second example of the application of the principle of solidarity is reproductive genetic testing. Genetic testing can offer an opportunity for doctors and families to prevent genetic diseases and disorders. Some disorders, if caught early in the pregnancy, can be avoided from being expressed or appropriate medical intervention can alter the severity of expression. Advances in vitro fertilization significantly increased the use of genetic screening in embryos as parents can screen the embryos before they are implanted. This ultimately leads to parents being able to choose which embryo they would like to be implanted. Genetic testing as a reproductive technology is an example of individual rights and vulnerabilities at its earliest and most life
altering stages. The issue surrounding reproductive technologies is not whether it should be available but rather the boundaries of availability to ensure appropriate protection for both the individual and population.

The Catholic Church’s stance on reproductive technologies will be used throughout this example since the Church has taken positions on these technologies. The Catholic Church argues in favor of therapeutic genetic testing yet warns against the potential for complications from an ethical and legal perspective. As the technology continues to progress and unveil more about biology, there is potential for continuous changes in debates. For the most part, understanding genetics for therapy is not evil but rather, a progression in science.

The Church is in favor of prenatal genetic screening (PGS) under certain conditions as it can lead to preventing severe disorders or diseases. The intention must be to prevent harm and seek good. Only therapeutic purposes should be taken to limit or prevent the disorder or disease. There are limited regulations on the boundaries of therapeutic purposes. For instance, if there is the potential to switch the gene for Huntington’s disease, then this would be therapeutic as it would prevent the disease. No action which could intentionally and directly prematurely end the pregnancy should be taken. At the same time, even if the family does have the resources, it might be in the best interest of the community for the child to not be born with severe deformities. This understanding supports the notion of solidarity since the individual and the society’s needs are considered in the justification.

While prenatal genetic testing is permissible, the Church still condemns preimplantation genetics diagnosis (PGD) even for therapeutic purposes. The most famous example of PGD would be savior children. In this instance, embryos are tested to be appropriate matches for their siblings who are sick. The child’s body is then used as a resource bank which is harvested from
when something is needed for the other sibling. The concept refers back to the idea that children are a right or owned by their parents. However, this is not the case and therefore, PGD is not a permissible option for the Church. Further, this scenario is similar to individual’s belonging to society or having a purpose which was designated by another individual.

Genetic testing on embryonic stem cells is arguably permissible for the Catholic Church. If the cells are procured from embryonic cells of an IVF treatment, then it is morally permissible to remove life-sustaining treatments, the freezer. Furthermore, similar to organ donations, cells can be extracted from the stem cells and germinated for research. While Roman Catholicism does believe in ensoulment at fertilization, research is justified using the proportionalist method. Proportionalism justifies moral actions value based upon the moral value of the means, ends, and the actor’s intentions. An action’s good consequence is required to be at least equally as important as the evil of the action for the action to be considered right. Additionally, the proportionalist takes into account the doer’s intentions of an action to determine the moral value of an action.

A most recent development of stem cell use is the potential to grow tissues and organs for donations. Techniques allow for the cells to develop into the desired organ and, as a result, be transplanted to a needing patient. Both no harm and PDE can justify these methods of genetic research as the method respects and maintains human dignity while limiting harms of the individual himself and the community. Growing organs for transplants would restrict the perspectives of the body or individuals as an ends to be achieved as in IVF treatments. Therefore, this approach would address the issue of savior children for families. Future arguments would have to reconsider the effects this method would have on the determination of brain dead patients.
The Church warns against the potential of eugenics from genetic research and testing. There is an undetermined boundary which can be crossed by science and family members. Families might find various characteristics defects and continuously choose not to bear that child. As a result, there is a new method of evolution capable of taking place. Searching for a specific desired characteristic might lead to limited variation in the society which is necessary for the survival of the human race. Genetic reproductive technologies present the opposite side of the argument for just healthcare access, namely that just access does not equate to unlimited access. Instead, healthcare access, as justified by the Church, should be considered in light of the consequences for all individuals. Genetic reproductive technologies can influence the perception of creating human life which ultimately will alter an understanding of solidarity among family members and the community. By using the Catholic Church’s stance, it is evident that there are justified boundaries which can promote solidarity throughout the community by ensuring that healthcare access is appropriately managed.

3. Unsustainable Living Conditions and Concern for Future Generations

The third and final issue of healthcare access that is essential to understanding the scope of the problem is a concern for future generations. Protection for future generations is an immediate concern requiring an organizational response. Health and healthcare access are threatened by unsustainable living conditions, environmental factors, and lifestyle choices. The quality of these factors on the current population have downstream effects on future generation’s health and living conditions. Additionally, these factors contribute to the organization’s awareness of their population and should be promoted as this is a concern which impacts the future of humans. It is the organization’s responsibility to address and resolve these issues to provide healthcare access and protect human rights.
Both the brain drain and complexity of reproductive technologies address inaccessible healthcare interventions. Current analysis of the brain drain by finances, health care systems, and social structure support the brain drain is a non-sustainable system limiting the survivability of individuals. Unstable healthcare systems have long term implications for both the immediate community and future generations. Reproductive technologies create an additional factor that influences genetic inheritance and therefore, genetic diversity among communities. One the one hand, reproductive genetic technologies can be understood as a preventative measure. On the other hand, these same technologies can be understood as restrictive to the randomness of genetics which creates genetic diversity. Genetic diversity is pivotal to survivability as it influences disease susceptibility. That being the case, when assessing appropriate methods to address the issue, concern for future generations must be considered.

Arguably, arguments for solidarity gain the most strength when applied to future generations as article 13 maintains precise focus to fulfill the protection of future generations. Health access and sustainable societies for future generations should be a universal concern for healthcare organizations. However, the effects of genetics on these generations is unknown. Unknown risks make it difficult to weight the potential benefits of genetic research and intervention for the current population. Solidarity is applicable in the instances where states do not find themselves responsible or are unable to promote rights of future generations or educations. This is yet another reason why organizations need to move with caution into the field of genetics.

If future generations are not considered, then human rights are also threatened by the unsustainable living conditions, environmental factors, and conflict. There is an obligation to ensure future generations have the opportunity to live with reasonable resources to promote their
expression of human rights. More sustainable living with available healthcare access is associated with higher life expectancy for the individual person.\textsuperscript{203} For, even though these generations are not known by the current generation, there can be a strong assumption that the individuals will maintain the same human rights as humans today.\textsuperscript{204} Considering the issue involves the well being of all future generations, then this furthers the justification that the genetic implementation is a matter that needs to be resolved at the organizational level. Furthermore, the organizations have a responsibility to develop sustainable conditions.\textsuperscript{205}

The principle of solidarity and cooperation is most exemplified in the examples presented. Immediate action is required to protect future individuals despite the benefits being delayed. Human rights are universal regardless of context which includes time. To leave a society in an unsustainable condition for future generations would be an injustice against their human rights.\textsuperscript{206} Therefore, protection for future generations is necessary regardless of context and therefore necessitates solidarity and cooperation to produce effective results.

Considering the genetics can have long term germline effects, concern for future generations is a necessity to develop an organization ethics framework. It would be unethical if the pursuit of genetic technologies disregarded germline effects since these individuals did not consent to the intervention.

d. Conclusion

Presented three examples of current concern for healthcare access. These cases present an institutional level concern, concern for current cultural understanding, and finally, concern for future generations. While the brain drain example highlights dependency across communities to make healthcare access available, the latter two examples are presented with an air of caution to protect human rights for both the individual and population. All three of these concerns are
essential to the development of an organizational ethics framework for genetic technologies. Such a framework will need to incorporate the population and individual rights. Just access to healthcare is a human rights and social justice issue since healthcare access contributes to the success of society.

As argued, population health is a combination of individual collaboration. Specifically, for genetic purposes, institutions pursue big data collection in hopes to maximize benefits for the community. The current American culture is not conducive to individual collection for the population benefit because of the emphasis on privacy. Further, collective participation and disclosure of information create a conflict with the understanding of privacy in the informed consent process for individuals.

Big data initiatives and even other population health approaches create a conflict with individual rights. The population health endeavors create tension with individual rights insofar as, authentic, informed consent for genetics requires disclosure from non-consenting individuals. Currently, in the United States, individual rights and privacy are among a top priority in healthcare. Privacy is essential to informed consent since it is understood to be the individual’s primary protection from undesired burdens. The following section will present the organizational ethics framework as a possible method for relief for the tension between individuals and the populations.


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Chapter 3 Organizational Ethics Framework for Genetic Technologies

Much of the bioethics discussion thus far identifies the issues between individuals and populations regarding genetic technologies. Typically, a resolution suggested requires compromise on either part. However, the literature thus far lacks an agent to implement such a compromise. A potential agent to carry out compromises are the healthcare organizations themselves. Healthcare organizations are in a unique position insofar as they are capable of justifying and regulating potential compromises. In order to ensure this is appropriately managed, an organizational ethics framework is required. Chapter 3 will present the unique position of healthcare organizations as moral agents and suggest an organizational ethics framework as a potential resolution to the tension between individual privacy and population health.

This will be argued by first identifying moral agency of organizations. Moral agents are ones who are capable of making morally valuable decisions and therefore, are also held responsible for these decisions. As a moral agent, the healthcare organization is responsible for the type and quality of care provided to its patient populations this includes the availability of technologies such as genetic technologies.

Further, healthcare organizations are placed in a complex situation as they are more often national corporations serving a pluralistic society. Thus, organizations need to ensure they are making morally good decisions while capable of integrating multicultural patient populations. The ability to do this will promote the organization’s success

The third section will discuss the impact of ethical uncertainty and its impact on trust in the healthcare organization. The significance of the principle of double effect will be crucial to
providing a justification for ethical decision making in ethically uncertain situations. Further, this section argues that cooperation between the organization and its internal and external relationships will be required to promote trust throughout the organization. Specifically for high risk interventions such as genetic therapies, cooperation is required for the organization to identify ethically complex situations.

The fourth and final section will develop the organizational ethics framework. Such a framework will integrate the issues of consent, conflict, and compromise discussed throughout the first chapter. These elements will be used to understand the relationship between individuals, families, and society; to focus the specifics of burdens and benefits available; to suggest the necessity of transparency in compromise. The framework will be one which is applicable to both clinical and research genetic issues as approached from an organizational ethics perspective.

**a. Individual and Organizational Moral Agency**

There is a natural distinction between human beings and non-human animals. While both can have moral status, human beings have moral status and are capable of moral agency. Most individuals are rational beings capable of governing themselves. Further, they are responsible for the moral decisions they make to reach an end. For the purposes of organizational ethics, these characteristics can also be attributed to organizations themselves. Organizations are capable of moral agency as their ends are to provide healthcare and are capable of making moral decisions in complex moral situations. This section will discuss the concept of moral agency as applicable to individuals and healthcare organizations. First, the different philosophical characteristics of moral agency will be discussed each possessing limitations for their application to bioethics. Following, there will be an assessment of the professional’s role in a healthcare organization as
both an independent moral agent and a moral agent working within the organization. Then, there
the concept of moral agency will be applied to healthcare organizations as an individual. Insofar
as healthcare organizations are moral agents, it will be argued that they are responsible for
maintaining a reasonable ethical climate.

I. Moral Agency in Healthcare Organizations

The philosophical understanding of the characteristics of moral agency is vague and
disjointed. However, the concept of moral agency is critical to bioethical debates to determine
when an individual is capable and responsible for making their own moral decisions. Although
the arguments of moral agency are discrepant and sometimes disagree, these understandings can
be used to accomplish two ends. First, they can be used to determine the professional’s role as a
moral agent within healthcare. Additionally, the understandings can identify solutions to ethical
dilemmas that are unique to healthcare situations. This section will present and analysis of moral
agency. Following, there will be an analysis of moral agency with regards to healthcare
professionals. Finally, considering the high stress environment of healthcare professionals, there
will be a discussion of moral dilemmas as they are both unique and frequent to healthcare.

1. Identifying Moral Agency

Moral agency is essential to understanding rational decision making. It suggests that
individuals are more than instinctively reactive. Rather, individuals can methodically reason to
make morally valuable decisions.\(^1\) Moral agency pushes the discussion of moral status a step
further to identify the actor as one who is capable of governing one’s self and making morally
valuable decisions. To have moral agency is to suggest that the individual is capable of having
motivations which guide their moral decision making. The individual must act for the sake of
moral goodness in order to be morally good. Talents and power such as those found in an organization can be harmful if put towards a wrong purpose. If efforts are purposely applied to immoral efforts, then it follows that the moral agents are responsible for their actions and can be held accountable for them. By this understanding, moral agency is a condition of moral status but perhaps not a necessity to identify moral status. To suggest that moral agency is required to have moral status would devalue the most vulnerable populations, elderly, children, etc.

Consider the following example useful to identify moral agents. One can imagine that if we purposely and negligently acted upon our neighbor’s property (i.e. their house) and their pet, our actions would have impacted the moral status of our neighbor and their dog. The house however, does not have moral status. Therefore, the direct action on our neighbor’s house is a direct offense against our neighbor but not the house. The action against the neighbor’s dog is an offense against the neighbor and the dog. This distinction suggests that we have duties to the neighbor and the dog but do not have duties with regard to the house. As exemplified by the example, it follows that moral agency and moral status are distinct.

By being a moral agent, it logically follows that individuals have moral status. To have moral status is to have interests that morally matter for its own sake. In other words, if an entity has moral status, it can be wronged. There are numerous theories to define the moral status as distinct from primitive animals and humans. Theories suggest that humans have moral status distinct from animals because they are classified as Homo Sapiens, based on their cognitive function, sentience, relationships, or moral agency. One reason moral agency is difficult to identify because of various stages of life and circumstances. At each stage and with different capabilities, individuals have varied moral status and therefore their moral agency is questioned. Thus, there must be degrees of moral status. For instance, our offense to the dog does not seem
to equate to the offense against the human being since, the human being maintains a higher moral value. The distinction is not only among species but within human lifetime itself.\(^4\)

It does not logically follow that having moral status directly related to moral agency. Bioethical debates such in vitro fertilization and stem cell research revolve around the moral status of the cells and potential moral agent. Cultures disagree on the moral status of these entities. Consider that when research is conducted on a pregnant woman, both the mother’s and fetus’s status are considered when making an appropriate risk determination. However, if the mother’s life is in jeopardy, it would be ethically justifiable to risk the fetus’s life to save the mother’s without any direct benefit to the fetus.\(^5\) This justification is supported by the fact that there is reason to aid those with full moral status. Cognitively unimpaired human adults have full moral status and therefore, the highest degree of moral status.\(^6\) While infants and the severely impaired have moral status distinct from embryos and stem cells, their status is the most vulnerable.

Logically, since the above-mentioned theories are insufficient in and of themselves to identify moral status, the selective combination of aspects from these theories can create a more cohesive understanding of individual moral status. However, the fact that moral agents have moral status suggests there is a social concept to being a moral agent. The combination of moral status theories can contribute to more comprehensive understanding of moral agency for organizations. Organizations are not humans or species of Homo Sapiens. The physical entity itself is not cognitive or have sentience. Yet, as a functioning organization, they are capable of morally valuable decisions and self-governing. Thus, they have moral agency. Further, organizations are responsible for their decisions. Thus, a third party can hold the organization responsible suggests that the organization resides in a structure of relationships. A society, or
institution, guides moral agents and their decision making. Societies and organizations are unique as their moral agency is not an end since their purpose is to serve the population.

2. Moral Agent’s Role in a Healthcare Organization

As a moral agent, individual has a duty to promote moral goodness. Individuals who strive to promote health and healthcare via the art of medicine are professionals who form healthcare organizations. It is evident that healthcare organizations are a system of moral agents all of whom are required to act professionally in morally complex situations. As individual moral agents function in their moral framework, healthcare professionals are obligated to perform their jobs in the moral framework of the healthcare organization while maintaining personal own moral standards. A healthcare professional’s moral agency is unique insofar as they have a positive duty to respond to patient need and promote health. On the contrary, if a car salesman spends his work day performing personal tasks, customers might not be able to purchase a car that day. However, if a physician spends their day doing the same, patients’ treatment plans and lives could be gravely affected.7 In fact, physicians have a responsibility to place the patient’s good over their own. For these reasons, healthcare professional moral agency is unique because there is a positive duty to act.

Professionals are not only employees of an organization; they are also actors who represent their own moral agency and the served community. Because of their dual representation, healthcare professionals are a crucial piece of the picture in the decision making process for organizational decisions. As members of the decision making group, professionals have a responsibility to represent the served community at the executive level when there might not be adequate representation. The professional representation in healthcare organizations is unique since properly functioning organizations require multidisciplinary professionals. For
instance, a healthcare organization comprised of entirely cardiac surgeons could not adequately serve a community. However, that is not to say all healthcare organizations need to have the same representation of professionals. As another example, a pediatric hospital does not require a geriatrics specialist.  

While not all professionals will be equally represented, certainly it can be determined that the medicine practiced by professionals concerns the acts, processes, and ends that are characteristic of medicine as a science. A healthcare provider’s professionalism is a moral duty to provide technical abilities and informed evidence to treat their patients. The provider must use technical abilities and informed evidence to assess the patient’s condition, possible generic solutions, and the appropriate method of action for the particular patient. Moral complexities lie at the intersection between possible solutions and appropriate methods for the particular patient. In other words, while medicine is rooted in scientific evidence, there are a limited number of formal rules to the provider-patient relationship. Each relationship changes with the circumstances and by the circumstances the professional bases their treatment options. Therefore, the provider’s moral agency is essential to ensuring quality and safe care.

It is evident then that healthcare professionals are a community of providers who are required to work in conjunction to provide quality of care. Thus, the healthcare environment is one of a moral community for the providers. Since provider are not barred from their personal values, a desirable community is one which fosters communication both among the professionals and their patients. In the organization, the provider’s moral community is based on scientific evidence, economic impact, and procedures. When communication is inhibited, the community is fractured. Such a fracture is highlighted by the correlation between medical errors and system
errors as opposed to individual provider malpractice. When providers’ moral conscience remains unheard in a healthcare organization, incidences of medical error continue to proliferate.\textsuperscript{11}

A healthcare provider’s discretion at the intersection of generic and personal medicine is both guided and protected by professional organizations. Professional organizations such as the American Medical Association are developed as a means to identify and protect professional codes of ethics.\textsuperscript{12} Such organizations are distinct from healthcare organizations as they are developed nationally without a commercial association. While professional organizations develop codes which are intended to be reasonable professional standards, the organizations also protect professionals from undue burdens of their fields. Professionals can apply the organization’s established values to ethical dilemmas as a means to find a justified solution.\textsuperscript{13} While healthcare professionals have the ability to interpret the regulations, this is not to suggest that professionals use their personal opinion. Rather, their professional judgment, backed by scientific evidence is required to navigate difficult terrains.\textsuperscript{14}

Healthcare professionals are both independent moral agents and agents representing the organization. They contribute to ethical decision making in clinical care, overall decisions for the organization, and are representatives of their patient population. Considering the complex connection between their professional and personal lives, it is not uncommon that healthcare professionals experience moral distress in times of clinical decision making conflict. Due to the fact that professionals are both independent moral agents and moral agents within the healthcare organization, it is inevitable that providers experience moral distress throughout their jobs.

3. Issues of Moral Distress and Dilemmas in Health Care Organizations

Despite the increasing demands of healthcare professionals, organizations tend to lack general policies or guidelines to provide ethical support for these demands. Issues of moral
distress are frequent throughout healthcare organizations and have been a growing concern for decades. Nurses, pharmacists, social workers, physicians, and other healthcare providers report problems of moral distress. Moral distress is generally defined as an ethical dilemma in which the individual believes to know the right action but is unable to act in such a manner. Common examples in healthcare are when aggressive treatments are being pursued by patients for whom there might not be a reasonable outcome. These types of situations are common for patients who are at the end of life. Chemotherapy treatments are pursued despite a poor prognosis. Dialysis is started for patients with chronic end-stage renal failure. These types of examples are commonly reported in moral distress research.

Moral distress is a result of a moral dilemma. These dilemmas are when there are at least two options which moral values apply, and each is equally as unsatisfactory as the other. Thus, moral distress is not only a result of institutional barriers. Rather, dilemmas can develop from the essence of conflicting values. Regardless of the barriers, a professional must make a decision about the course of action to take to get out of the moral dilemma. From this understanding, moral distress and moral dilemmas occur surrounding the same event. However, a moral dilemma does not necessitate moral distress. In these situations, the team of professionals may support different perspectives of the moral dilemmas. Thus, moral distress is a multifactorial consisting of the institutional barriers, team dynamics, as well as the professional’s conflicting values.

Research suggests that moral distress varies depending on the professional role, experience, and setting. Among those with the highest reported rates of moral distress are nurses and professionals in the ICU setting. Causes of distress include watching patients suffer, diminished care due to lack of team communication, and working with incompetent providers.
Further, moral distress is reportedly higher for providers who are not in a decision making position. Individuals who are both in the ICU and lack a decision making position often report a lack of respect for life as a cause of their moral distress. While some providers state that they consider leaving after repeat exposure to moral distress, others state that they become desensitized to moral distress.

Distress can express itself in healthcare facilities as emotional stress, lower quality of care, and decreased job satisfaction. Studies suggest that professionals are less likely to disclose moral distress for reasons such as harming their image and perceptions of quality of care as their output rather than patient outcomes. Nurses are among those who report high levels of moral distress. Nurses tend to make relationships with their patient and the family members. This relationship leads to what is perceived as an increase in quality of care. However, in times of moral distress providers can distance themselves from the situation by only performing the action of the task but not connecting with the patient. As a result, there is a decrease in quality of care and patient satisfaction.

Moral distress management is related to ethical climate since management is related to support of the professionals experiencing distress. A more positive ethical climate results in professionals being more capable of managing moral distress as well as managing complex ethical situations in the future. Positive ethical climates are ones which consist of professional opportunities to be involved in ethical deliberation. These opportunities prove to be essential for allowing professionals to make their managers aware of moral concerns or the professional’s personal values. However, studies suggest that professionals are unable to integrate their professional and ethical values due to organizational constraints. In the United States, negative
ethical climates are a contributing factor to nurses leaving their position or the nursing profession.\textsuperscript{26}

Moral distress does not cease to exist when the situation is resolved or treatment is discontinued. The crescendo effect describes the influence of moral residue as a result of moral distress on future dilemmas. Moral residue is the remaining emotions or experiences which create a new platform for managing moral distress. Often, such a platform is less suitable than the previous resulting in a decreased ability of a provider, team, or unit to approach situations of moral distress.\textsuperscript{27} Efforts to relieve moral distress focus on particular ethical dilemmas such as in end of life care or pain management. However, relief efforts lack focus on day to day functions of the professional as well as acknowledgment of the organizational policy to mitigate moral distress. The amount of time and effort required to address these problems could be a barrier to an organizational level approach. Ultimately, an organizational approach to relieve moral distress will require multidisciplinary input.\textsuperscript{28}

As a multifactorial problem, moral distress caused by moral dilemmas are the result of not only institutional barriers but also ethical climates and professional perception in their position. Considering that moral distress can cause professionals to leave their current position, this is an organizational ethics issue. Organizations need to draw attention to the promoted ethical climates, their recruitment, and retention strategies. Some organizations such as the American Association of Critical Care Nurses developed a position statement on moral distress. Such a statement has recommendations for both the nurse and organization to handling moral distress.\textsuperscript{29} Resolving these issues will require modifications to relationships between nurses, physicians, managers, and the hospital organization. These issues will be further discussed in the following section.
II. Organizations as Moral Agents

The concept of moral agency expanded to organizations when public interest began to focus on methods to address ethical dilemmas. Similar to individual moral agents, organizations interact with other agents in society on a business, professional, and, for the purposes of healthcare organizations, a clinical level. Thus, these organizations influence the function of society but also the function of the society’s citizens. Similar to the individuals, organizations are moral agents responsible for their actions and duties to other agents. In order to be successful, the organization depends on a trusting relationship with those whom it interacts. By being identified as a moral agent, a healthcare organization’s the trust is challenged in the organization’s function. Thus, it is essential to have an understanding of the healthcare organization’s role as a moral agent in order to make progress towards offering ethically complex technologies like genetic technologies.

1. Moral Agency: Seeing an Organization as an Individual

Moral agency is not limited to individual agents but also includes organizations. Both agents are capable of determining goals and fulfilling actions with moral value. Furthermore, these agents are interactive and dependent upon one another. Dependency highlights the inevitability of trust to be a moral agent.\textsuperscript{30} However, organizations cannot be an end in and of themselves because they would not exist if there was no population to serve. Organizations are unique since they are a means to an end for other moral agents. In other words, organizations are responsible for promoting the common good.\textsuperscript{31} Thus organizations must function as to promote general well being while not exploiting another moral agent for their own ends. A healthcare organization’s moral agency is dependent upon the ability to balance individual and society needs and thus, establishing trust.\textsuperscript{32}
As mentioned, a moral agent is one who is capable of performing morally valuable actions. As the action influences other agents, moral agents can be found but are not limited to an identifiable structure of relationships. An individual is a moral agent in an organization. An organization is a part of a greater system both of which maintains moral agency. All three components of the structure are capable of identifying an end be it moral or immoral. Regardless, the agent must work to achieve the end through a series of actions, again moral or immoral. As a side effect, the agent affects other agents’ ability to act throughout the larger system.33

While there is a broad framework for the interaction between moral agents, it is not necessary that an agent maintains one identity within the structure. Rather, individuals have a purpose of their own. An individual can maintain their moral agency within a family as well as within a political organization.34 So while an individual might be defined by the participation within a specific system, the system is also defined by the individual’s participation. Immoral individual agents will create immoral systems. Furthermore, an individual who is actively a part of an organization is responsible, to some extent, for organization’s actions and survivability for the individual (such as a professional) is the actor of the organization’s moral agency. The system is also responsible for ensuring the organization’s moral value.35

For the structure of moral agency described to be functional, moral agents must inevitably trust one another. In order to promote trust throughout an organization, there must be a level of compliance to regulations or policies. Simply stated, trust is a phenomenon which is often associated with a succession of actions as perceived by the agent affected. Interestingly, trust does not require the affected agent to observe or know action’s truth. Similarly, honesty is not a trust requirement. Trust might wax and wane between agents, and it can even be a one-sided participation event. The act itself is also slightly irrational without evidence or sometimes
consistency.\textsuperscript{36} In order to promote trust and thereby, compliance, organizations must give individuals reasons to comply with policies. If the organization intends to achieve X end to promote the common good, then it must provide an opportunity for professionals to achieve their own moral agency via achieving X end.\textsuperscript{37}

Currently, trust in American organizations is low, and there are a variety of theories as to why this might be the case. The trends in trust are undeniable.\textsuperscript{38, 39} Trust value is measured by surveying population be it an active participant in the organization or not. Trends in American history provide evidence that the population is most trusting of their government when the population is most vulnerable.\textsuperscript{40} However, quickly after the assumed vulnerability, trust again plummets. Presumably, this would be because of harsh criticisms against any action taken.\textsuperscript{41} Previous examples of organizations who lacked trust from the public prospered for a length of time but paid the ultimate price when legal actions were taken. The jury of peers lacked trust in the ability of the organization to rectify any type of wronged situation. Trust is important to establish and maintain to promote action as a moral agent. While an individual might not trust the organization within their society, it would be considered irrational to not seek treatment at the hospital if there was an emergency. However, simply because the healthcare organization is a highly valuable and specialized organization, does not give it the right to disregard trust issues.\textsuperscript{42}

A healthcare organization is a moral agent as the organization sets goals, is capable of acting as a single entity, participate in trusting relationships, and finally, held accountable similar to individual moral agency. Additionally, an organization’s actions have moral worth which affects other moral agents and therefore, are capable of obtaining trust from those with whom it interacts.\textsuperscript{43} A well-established organization would be one which has morally worthy interest and achieves these ends by minimizing harmful or unintended side effects.\textsuperscript{44} In other words, it
maximizes its influence for the common good. However, considering the organization’s position within the broad structure of moral agent dependency, organizations must consider how their actions are affecting both the greater system as well as the individuals who make up the organization.\textsuperscript{45}

Within the organization, there are the business professionals, healthcare professionals, and clinicians all who have various ends to achieve to maintain the organization’s mission. The business perspective of healthcare organizations is most prominent in the United States where healthcare is privatized. Healthcare organization are similar to other businesses in that they are competing against changing markets to provide the best services. Clinics are considered successful when health services are provided. Professionals are respected when actions are consistent with professional standards and achieve patient satisfaction.\textsuperscript{46} The ends to be achieved are a balance between individual health and organization’s sustainability for the whole society.\textsuperscript{47} The depth of an organization’s vision might vary depending upon its size or financial capabilities.\textsuperscript{48} Thus, a healthcare organization in the United States cannot be directly morally responsible for an AIDS epidemic in South Africa. However, the organization does have a responsibility to not contribute to the epidemic. At some point, a healthcare organization will be forced to prioritize between individuals, organization, and society. When either the individual or society feels a situation has not been handled appropriately, trust is weakened between the organization and the other agent. This has been observed in public health outbreaks as well as when an individual might feel they were mistreated in the hospital.\textsuperscript{49} At the boundary of healthcare organization’s responsibilities is an ethical gray area. This area will be further discussed in the next section.
2. Ethics of Healthcare Organizations as Moral Agents

Healthcare organization as a moral agent is distinct from other organizations as health is a right. The organization is morally obligated to function in a manner which all levels of the organization are capable of morally performing their actions to achieve the organization’s goal. Various organizational methods affect care practices and organization’s interaction with society. Organizational ethics literature ranges on topics from mission statements, to pharmaceutical relationships and conflicts of interests, to end of life care, managing patient records, and provider experiences. As mentioned, a healthcare organization is not an isolated entity. Rather, the survival of the organization depends upon the efficiency of interactions with other agents and therefore, requires trust. This is found to be true even within the healthcare organization. Furthermore, this is most specifically true for healthcare organizations as businesses, professional societies, and a clinical resource.

Perhaps the most interesting and controversial component of the healthcare organization is the business perspective as this is a capitalist component of services. Healthcare organizations in the United States must find the balance between not only the service to both individuals and patients, and also the business ends, i.e. profit. Without the business component to an organization, the organization could not survive in the United States. However, this is not to suggest business and health care are incapable of living harmoniously under one system.50

Healthcare professionals are, in a sense, the middle ground between business and clinical fields. From a professional’s perspective, not only does the individual have an obligation to the organization but also the service provided. Physicians are held to a medical oath independent of the healthcare organization. From the beginning of their career, there are two moral systems each physician is to abide by. From there, the physician must navigate the healthcare system to
establish their professional moral agency with the organizational ethics of the particular system.51

Professional standards are exemplified in the quality of care provided in the clinic. Furthermore, this is where a large portion of moral weight is given and which most often affects trust. At the clinical level in the healthcare organization, policy and regulation are established to be patient centered. These three broad positions highlight organization’s internal ethical complexity. Both the business and professional portions of healthcare organizations are focused on satisfying the clinical component to the agency. Clinical ethics is the direct application of organizational ethics at the patient level.52

Rather than all three fields working seemingly separately, an approach to healthcare organizational ethics is to emphasize patient centered as the highest levels. If an organization’s mission is to provide health services then, the patient is the focus for both the business and professional perspectives. It was not until the late 20th century that health practices changed to actively involve patients in their health care. Even at that point, there were groups which claimed to represent patients but had low satisfaction responses. Participation was, broadly speaking, an individual is offered money from their employer and the individual can go choose which health plan would best suit their needs.53

There is a belief that with more patient involvement, better and cheaper healthcare can be provided. Considering moral agency described earlier, this idea is a reasonable one. Unfortunately, it has been shown to fail more times than succeed. There are few examples of patient actually managing a healthcare organization, sitting on boards to represent patient population, needs, and complaints. But patient activity does not necessarily mean patients understand complexity within the system.54 Most recently in the United States, patients can go
online to track their health, make appointments, and choose health insurance plans. Thus, the patient is becoming a greater participant in organizational moral agency. Again, there is hope to better regulate organization’s described fields by improving patient communication and limiting unnecessary visits. Better care provided assumes more trust in the system. This is a benefit to most aspects of the organization as it allows the patient to choose where and how money is being spent. Thus, the patient provides participation in the healthcare organization from a distance.

The patient’s participation in newer healthcare organization models can be interpreted as trust for organization and providers. As mentioned earlier, the organization’s moral agency affects both the individual and society’s moral agency. The organization establishes an ethical climate for those with whom it interacts. An ethical climate is essentially the perception of an agent’s influence on the surrounding environment. For healthcare organizations, this can be confusing in the United States as the organization is not only for the well-being of the individual but is also a business. In some respects, an organization is required to emphasize their participation to establish a trusting relationship.

Ethical climates are established in an organization’s recommendations, policies, and actions. While a hospital might seek to maintain patient health, it would be unjust to limit availability to only a specific population. Healthcare organizational policy must reflect the openness and concern for total population in order to establish this type of ethical climate throughout the organization and society. However, even if the organization is not intentionally limiting availability, the organization bears responsibility to the access and therefore, tends to lose trust in the ethical climate. An organization’s intention to maintain a reasonable ethical climate is stated in an organization’s mission: to balance between the individual and society while surviving as a healthcare organization. Ethical climate established by the organization is
dynamic and relative to the surrounding community’s needs. Again, the business aspect identifies and provides for needs of the individuals in attempts to build a relationship. A healthcare organization has a greater part in a society’s trust in organizations as even society’s survivability is dependent upon healthy and moral, individuals.59

3. Mission Statements and Healthcare Policy

Medical policy and regulation are perceived in literature as limitations on healthcare practices. Religiously affiliated hospitals are most observable examples of this practice. Two-part mission statement conflicts with itself. Individuals are not given unlimited access to healthcare resources as to ensure the well-being of the whole community. The limitation is often determined by the line of medical necessity. If functioning properly, the determination of medical necessity changes appropriately for everyone’s particular circumstances and population needs while maintaining organizational ethics.60

Policy should promote ethical standards for all healthcare employees. This goes beyond the immediate care to patient’s financial burdens after care has been received. Even policy which addresses professionals should lead back to patient care. That being said, the patient and provider maintain the right to determine appropriate medical treatments or plans, the healthcare organization has a larger responsibility to the community. This makes the provider responsible to balance between patient’s needs while considering larger implications to the organization and society.61

A healthcare organization can determine appropriate policy by balancing empirical evidence, the provider, and the mission. Assuming the policy has been appropriately established according to both the society’s needs and organization’s moral agency, then this should be reflected in the organization’s internal ethical climate.62 The ethical climate is established by
policy implemented at all levels of a healthcare organization. From the most basic custodian to the largest CEO, all individuals should feel they are participants in the organization’s moral agency despite differences in the methods to achieve it. However, implementing policy might vary among the individuals if their professions give unequal weight to similar ends.\textsuperscript{63}

In implementation of policy, conflicts of interest are more observable. Tense intersections between patient’s right and public wellbeing are conflicts of interest which cause an organization to prioritize clinical, professional, and business aspects. Meanwhile, even a provider might find himself in a conflict of interest if the professional oath is inconsistent with organizational policy. The organization might be incapable of maintaining moral agency in these cases. Or, at least, the healthcare organization’s moral agency is compromised in these circumstances for not all ends can be ideally achieved.\textsuperscript{64}

As argued, the essence of a healthcare organization’s moral agency is to provide quality care for the patient. Should there be a conflict of interest between organizational policy and implementation at any level, the ethical recommendation would be to disclose the conflict to relevant individuals. Individuals, as moral agents, maintain the right to disclosure of conflicts of interest to ensure the ability to continue to make ethical decisions. However, as mentioned, honesty is not necessary to maintain trust. So there might be some instances when disclosing information could be more harmful than beneficial.\textsuperscript{65} Thus, methods to achieve moral agency depend on the relevant population. In order to appropriately evaluate a healthcare organization, an understanding of relative factors is necessary: hospital history, patient population, available resources.\textsuperscript{66}

Once an organization has established identity as a moral agent and implemented policy to uphold these goals, then, the organization is subject to review by other agents.\textsuperscript{67} The goal of an
evaluation would be to ensure patients are getting accessible, quality care. A secondary goal would be to ensure the organization system is working efficiently to maximize this care and minimize any harmful side effects of their actions. Within the system of evaluation, there is a tension between compliance of established regulations and ethics. The rules do not equate to ethics. Furthermore, rules are not one size fits all in a healthcare organization. Some regulations might restrict organizational moral agency in an unethical manner.68

In the United States, evaluating policy and ethical healthcare organizations holds inherent problems as the pluralistic society seeks to achieve a variety of ends for different relationships.69 There are immediate urban regulations, state and federal laws. Additionally, religiously affiliated hospitals have to be true to tradition. There are also non-governmental regulations which are required of the healthcare professionals such as the American Medical Association and Joint Commission for Accreditation of Health Care Organizations.70 The evaluation process highlight layers of agency and identity within a healthcare organization. The evaluation process highlight layers of agency and identity within a healthcare organization. All layers contribute to the same goal established by the healthcare organization.71

Healthcare organization’s in the United States are in a position to succeed as a business as well as health provider. These ends contribute to the complications to ethically evaluate organizational morality. Evaluation is necessary to help the organization maintain trust both internally and externally among their professionals, patients, and larger community. The healthcare organization’s survivability depends on these relationships to maintain moral agency. Ultimately, the balance of these relationships is necessary for an organization, acting as a moral agent, to maintain trust and successful function.
b. Professional Ethics in a Pluralistic Society

Part of what is unique about organizations as moral agents is that the organization is an ecosystem for other moral agents to conduct work. Specifically, healthcare professionals are required to positively act (to treat) in order to fulfill their moral agency. The professional’s ability to act is only as great as the resources available. Therefore, in order to promote professionalism, an organizational ethics framework must consider their influence on the healthcare professionals.

I. Conflicts between Identifying Health and Professional Ethics

While there is a struggle between the healthcare systems and minority populations, there is also a struggle within the system between ethical frameworks. The conflict between the two frameworks affects ethical climate within the organization and professional perspectives when encountering multicultural patients. For this reason, it is necessary to reconcile the differences and promote a professional code which fosters cultural sensitivity throughout the organization.

1. Applicable Relevance of Professional Ethics in Healthcare

Since the beginning of medicine, a professional code of ethics was established by providers. While some of the language and intention of this code has remained vaguely similar, the code has a wide opportunity for interpretation and application. Current bioethics situations more often involve individuals and families from a heterogeneous background consisting of different languages, beliefs, understanding of health and healthcare all within the United States western understanding of bioethics practices. Most specifically, for healthcare providers working in multicultural societies, professional codes can have limited application. In order to keep professional codes relevant in multicultural societies, it is important to acknowledge common
morality which transcends cultures. To achieve relevance, it will be necessary to address professional codes of ethics at a greater level than bioethics discipline.

The history of medical ethics suggests that professional codes are established and evaluated as a reaction to injustices against human dignity. Research experiments in World War II and over treating as a result of paternalism are examples of medicine impeding on individual rights. Prioritizing medical research over individual wellbeing resulted in patterns of injustices. As a reaction, professionals gathered in an attempt to provide an ethical framework as a guide to achieve mutual goals of medicine and protect individuals. Considering this as a motivation suggests that codes tend to reflect more reminders of healthcare provider intentions than actual ethics. It cannot be assumed that medical ethics can be determined solely by medical professionals for moral issues transcend the medical field. To position itself as proactive rather than reactive, these issues suggest an appropriate code of ethics will consider more than the medical ends.

While the reaction to patterns of injustices came as an attempt to rectify some of the problems, the medical professional code of ethics is rather limited. Its fundamental framework having been influenced by western thought, makes it conflict with cultures and moral codes. Professionals can find their own personal moral standards might conflict with the professional code of ethics. These individuals bring their pre-existing culture and religion to their practice which they use to interpret the professional code. While most codes still use the traditional idea to at least “do no harm” from the Hippocratic Oath, this requires the provider’s interpretation of harm. An understanding of harm is dependent upon culture, available resources, and medical frameworks. Furthermore, to help an individual’s health is then also dependent upon these and
other variables. Due to the dependent variables, a professional code of ethics creates an inherent tension for providers between their personal and professional codes.

Considering these conflicts between the distinct personal and professional codes of ethics, current medical ethics codes prove to be limited in their application especially when applied to pluralistic societies. This is due in part to the varying understanding of health and harm by both patient and provider. To reconcile this situation will require the participation of a committee reflective of the pluralistic society including a contribution by the served population. When the population contributes, there can be a better understanding of the intentions and the determination of health in the clinical setting. The professional code would have to exhibit characteristics which would allow for adaptability of the healthcare profession within the society and for the wellbeing of the society. By approaching the code in this manner, it would not be narrowly focused on a patient or only healthcare practices. Considering these suggestions, the professional code of ethics does not seem to be a code of ethics but rather a statement of intent.\textsuperscript{76}

To approach the issue of establishing health and healthcare in pluralistic societies, it is useful to start with the professional code of ethics. Healthcare providers are often understood as both the problem and solution to healthcare disparities because of their close patient interaction. So when an organization attempts to reorganize their plan of action or practices, it is often the provider who is expected to carry it out. It would be unreasonable to assume that all professionals are capable of acting within their professional code of ethics, leaving to be their personal moral values or code of ethics. If this were the case, it could be argued that the professional is not autonomous but rather merely an acting agent of their profession.

At its origins, bioethical recommendations were assumed to be neutral and consistent regardless of situational factors such as income, environment, and lifestyle choices.\textsuperscript{77} Current
approaches to bioethics claim to be multidisciplinary to develop well rounded discussions in order to come to the most appropriate ethical recommendations. The integrated global community contributes to growing culturally pluralistic societies. Bioethics as a discipline needs to mirror this change and adapt to remain relevant. Thus, bioethics must be not only multidisciplinary but also consider socioeconomic and environmental factors in order to produce appropriate recommendations. Working in cooperation with multiple frameworks will promote a more accurate representation of bioethical approaches and clinical issues.

2. Organizational Ethics Issues of Establishing Health and Health Care in Pluralistic Societies

Organizations must be inclusive to all individual it encounters both internally with its professionals and patients, as well as those maintaining their health outside the institution. As the national trend shifts towards healthcare systems, there are developing issues of establishing health and healthcare standards in unique pluralistic societies. Due to this trend, it is important to establish a common ground or common morality as a framework for healthcare practices. This framework would be developed with the intention to be inclusive of all who encounter the organization from their own professionals to patient's family members.

A common morality is one which can identify overlaps in moral frameworks resulting in a common ground which individuals can communicate with each other. This approach will provide an opportunity for understanding and possibly agreement despite other differences in moral judgments. Furthermore, this approach is most appropriate for establishing health and healthcare in pluralistic societies because of its inclusive characteristics making it ideal for the dynamic nature of healthcare organizations. Common morality is an ongoing framework which grows with cultural integration. Thus, it makes it most ideal for providers and patients alike who are those often underrepresented and marginalized. Common morality theories are disguised
on the global platform as guidelines, principles, or frameworks. Unfortunately, these frameworks and guidelines are limited insofar as they are difficult to enforce on a global scale and overgeneralization creates a large opportunity for interpretation. The global attempts to create common morality are important as an example of moral discussions which transcend cultural background.\textsuperscript{82}

The concept of culture can group individuals with similar beliefs and/or frameworks of understanding. Thus, the concept can be applied to providers and individual patients alike. The categorization used in a flexible manner can be beneficial for determining health and healthcare in organizations. It is significant that healthcare organizations have a cultural understanding of health in order to protect patient's perceptions of health while achieving reasonable standards of healthcare practice. Although medicine's objective science might not change, cultural values contribute to the interpretations of the objective information and therefore, contribute to understandings of health.\textsuperscript{83} Due to the inherent tension between provider and patient cultures, organizations should establish a normative framework to be one which is receptive to interpretations of health while acknowledging medical practices.

Organizations can use the widely accepted bioethical to develop a general framework applicable to medical practices which can be translated across health systems. However, such a framework does not directly equate to an ethical theory in and of itself.\textsuperscript{84} These principles can be used as a balance between culture and medical ethics within healthcare organizations. The principles can be used as the global platforms are where moral discussions can take place regardless of cultural differences. Thus, there is an attempt to relieve any tensions between provider and patient moral norms. At the points of convergence between patient, provider, and organization, a true understanding of health and healthcare can be established.\textsuperscript{85} Further, this
framework can provide a solution to address moral dilemmas, moral distress, and increase quality of care.

Cultural understandings of health and healthcare are beneficial to healthcare organization's establishing reasonable goals and moral frameworks. Medical ethics standards such as communication, truthfulness, informed consent from decisionally capable individuals, are developed from bioethics principles yet are experienced and observed through a patient’s cultural lens. Although healthcare organizations cannot establish their own morality, it is common for them to create a mission founded in common morality principles which are adaptable to target populations. Identification of points of convergence will be most useful when there can be a bioethics framework to assist in navigating the areas where health and healthcare are more difficult to determine.

The ability for a healthcare organization to adapt while maintaining its mission is essential to its success. Healthcare organizations are developing into multinational corporations serving diverse communities. Specifically, for the issues of consent and genetics, communities will have distinct interpretations of the risks and benefits since they have different understandings of responsibilities to their community. Further the varied definition of “health” in communities can create conflict between the professional’s duty and the patient’s requests. While medicine aims to make treatment options based on objective science, the ultimate treatment plan will be dependent upon the patient’s cultural background. For this reason, healthcare organizations and professionals will need to learn cultural humility to minimize ethical conflicts between traditional medical practices and the served pluralistic society.
3. Adopting Cultural Humility to Improve Organizational Ethics

Organizational ethics require cultural humility to improve care for their patients as well as professional creativity for their providers. Cultural humility is distinct from cultural competence and awareness as it is a lifelong, self-reflection process. The process is one which requires individual’s to examine their own biases and culture in order to be receptive of alternative cultural beliefs.\[89\] It is important to integrate this into the ethics to protect individual autonomy which is dependent upon reflection of the individual's culture. Morally, people have an obligation to respect another’s autonomy. This obligation has been practiced through various organizational frameworks from paternalism to the now heavily focused individual autonomy model. Respect for autonomy is arguably the primary principle for clinical practice in the United States. Yet, blanket respect for individual autonomy does not equate to respect for culture as is being observed in the United States now.

Culturally humility can help providers understand ethical justifications for difficult medical decisions as an expression of autonomy while balancing the medial realities necessary to sustain the healthcare organization.\[90\] Autonomy is best respected when the patient’s wellbeing is the center of clinical concern. While many providers would agree with this, there are countless examples of patient’s demanding unbeficial treatments often as a misunderstanding of medicine's relationship with their cultural needs. If confused with cultural tolerance, these demands could weaken healthcare organizations. Cultural skill in cooperation with the bioethical principles is necessary to system-level initiatives at organizational ethics. For a provider to treat effectively with cultural sensitivity can require him to go against his traditional practices while still being ethically appropriate. At some point in care, treatment plans can actually be counter to
the natural life cycle and therefore, become less compatible with the individual's culture and autonomy.\(^1\)

The necessity for cultural sensitivity in healthcare organizations is best described through an example of end of life stages. There are generally two options for patients at end of life: to continue or discontinue treatments. To opt for treatment or continued treatment is sometimes aggressive care plan. When a patient opts to continue treatment, they seek to continue the quantity of their life but not necessarily the quality as measured by medical professionals. A difficult part of continuing treatment is not always obtaining the quantity of life but refocusing the care plan on the patient’s cultural needs and ultimately, humanizing the aggressive care in cooperation with the culture.\(^2\) A patient who discontinues treatments tends to focus more on quality of life. By limiting or changing the direction of treatment options, the provider must also allow for cultural sensitivity in order to achieve reasonable levels of quality of life even if the provider believes there are reasonable alternatives. End of life cases offer extreme situations and thus, magnify the gravity of these situations.\(^3\)

A major point of conflict evident in bioethics legal cases is when families and providers differ on their perspective of the patient as can often be the situation for minority families. These situations raise questions about the expression of a provider's cultural sensitivity for non-decisionally capable minority individuals. Western understandings of bioethics there is a strong desire to continue treatment and avoid suffering. At the same time, the autonomous model allows an opportunity for patients and families to integrate their cultural understandings of end of life into the medical practice. At the point of conflict, cultural sensitivity allows for the common morality of understanding about decisions as complicated as end of life. If the patient or family
does not agree with the natural transition to the dying stage of life, then the provider's actions could be interpreted as a lack of cultural sensitivity.\textsuperscript{94}

Integrating cultural sensitivity into medical practices allows patient's autonomous wishes to more seamlessly cooperate with the medical realities. Patients might want to continue aggressive treatments until a culturally significant date or specific events such as wedding or birthday. After this point, the patient might be reasonably ready to discontinue such treatments and begin to accept end of life phases. Cultural skill is necessary to obtain appropriate goals of care which should aim respect autonomy and promote beneficence. The provider might have the authority to determine the criteria. However, the patient or surrogate decision maker has authority to determine when care is no longer beneficial to the patient’s cultural needs.\textsuperscript{95}

\textit{II. Establishing and Evaluating Healthcare Organization Ethics in a Pluralistic Society}

A moral agent’s actions are valued by a standard and subject to evaluation. Healthcare organization policies must meet ethical standards established and be attentive to the community’s needs. Both internal and external standards are necessary to consider when implementing policy. Evaluating these policies in the United States is specifically difficult as the nation has established and prided itself on its pluralistic perspectives open to all individuals. Determining appropriate policy and regulation for a healthcare organization in a pluralistic society becomes difficult as the policy should be narrow enough to have a specific purpose while broad enough to be appropriate in the changing climate. Generally speaking, healthcare organization policy should support the mission as this is what makes the organization a moral agent.\textsuperscript{96}
1. Promoting Professional Standards in Multicultural Societies

Various necessities to achieve higher quality care for minority populations in light of genetic technologies have been discussed. Finally, the need to promote uniform professional standards throughout healthcare organizations while allowing for interpretation will be analyzed. However, organizations need to be alert to the fine distinction between adaptable professional standards in multicultural societies and moral relativism. Moral relativism will result in an unsustainable healthcare environment and threaten quality of care for all patients. Goals of healthcare initiatives are developed to identify desired results from a program or approach. The target literature on healthcare disparities is focused on the clinical disconnect between providers and the patient. Therefore, majority of the efforts to reconcile this disconnect are also focused on integrating cultural awareness into provider practices which are already developed in the healthcare system. These efforts develop from a principle based approach and typically become the provider’s responsibility to improve patient care quality.97

The principle approach is a multilevel organizational ethics approach addressing, system, care process, and patient interactions aimed at improving quality. Therefore, this approach is applicable when there is already a system in place. Similar to the principles of biomedical ethics, the principles for addressing healthcare disparities are general and relevant across the wide healthcare spectrum. In this respect, the principles can be useful to address issues such as communication and/or access to care. They are both supplements to the current system and guiding principles to future organizational developments. Using the principle based approach helps develop these initiatives in a standard framework allowing for consistent multilevel integration. 98
An example of these initiatives is increased cultural communication and cultural integration procedures. Communication improvements provide significant influence on the quality of patient care. The provider is mainly responsible for improving communication in the immediate clinical interaction.\textsuperscript{99} It is intended to gain a better understanding of the patient’s background information including their religious beliefs, financial situation, and other influencing factors.\textsuperscript{100} Health information communication, both verbal and nonverbal, must be communicated in a manner which is consistent with the individual's ability to understand it. Providers should be sensitive to the nonverbal forms of communication such as personal space or silence and the messages these cues send to their patients. Awareness of a culture’s interpretation of these could contribute to the overall patient satisfaction and quality of healthcare.\textsuperscript{101} In order to improve communication, it is important to recruit professionals who are familiar with other cultures or are bilingual.\textsuperscript{102}

Integration can be accomplished by recruiting minority providers who create a communication bridge through various resources available. Culturally aware providers assist to further integrate minority populations into the healthcare system. Through this process, system-level efforts become more accessible environments to both providers and patients. Based on the brief description of the internal healthcare initiatives, it is evident that these tend to be closely dependent upon patient interactions. For this reason, cultural integration procedures are necessary for multilevel approaches. These efforts would require awareness of a target population thus, are effective at the local level of an organization but require system level initiation.\textsuperscript{103}

The efforts described present organizational approaches at the highest system level through to the intimate clinical relationship. These initiatives should seek to create organizational
consistency throughout the various levels in order to create optimal patient care in multicultural societies. Thus, the principle method within an organization can assist in consistently developing and applying these internal initiatives. Internal initiatives are necessary as care providers are finding a more diverse patient population and thus will be applied in daily care routines. Creating a culturally competent organization will pursue more holistic care plans to address individual needs.¹⁰⁴ Internal initiatives can be understood as reactive responses to healthcare disparities. External initiatives described next can be understood as proactive.

The argument has been critical of both professional and organizational ethics adaptability to be culturally sensitive and humble. However, these adaptations with technology should be approached with caution in order to avoid complete moral relativism. Promotion of a pluralistic society such as in the United States does not equate to moral indifference where there are no moral consequences and all actions can be morally justified. If cultural competence is not carefully integrated into the healthcare system, then there could be a loss of identity for the medical professionals, the organization, and medicine itself. This would result in complete lack of trust in the healthcare system.¹⁰⁵ Thus, through the development of culture in bioethics and normative healthcare practices, it is essential to draw a distinction between moral and cultural relativism. Some cultures might hold a belief that is immoral. Under these circumstances, the organization and providers cannot be expected to respect these beliefs or traditions.¹⁰⁶ Different cultures deserve tolerance from professionals but not ignorant obedience. At the same time, there are moral universals which require obedience. Therefore, cultural relativism does not equal to moral relativism.¹⁰⁷
2. Communal Genetic Information for Increased Quality Intervention: Concern for Cultural Privacy

Objective medical information can result in contrary provider practices discussed up until this point. Specifically, critics of genetic information argue that this can lead to a total reductionism of individuals. The fact that human beings shared 99.9% of their DNA promotes the idea that all human beings are comprised of the same physical components. It also supports that the smallest differences can create what is perceived as large variation among human populations. Considering this information, it is important to promote cultural sensitivity among healthcare professionals in order to avoid reducing all individuals to their biological factors. The differences make each human unique. At the same time, the fundamental components of human beings are vastly similar. This establishes the unique compromise between communal data collection and cultural sensitivity to improve quality care for minority populations. In regards to data collection, it is highly important that healthcare organizations foster an environment of cultural skill to avoid complete reductionism from objective genetic information.

Genetics introduces new light on old issues of medical intervention, and just healthcare access. Yet, genetics requires increase sensitivity to interpretations of these advances relative to cultural frameworks and moral principles. While the intention is justified- promote an understanding of health- providers must consider unintended effects of this research on the researched population especially minority populations. History has embedded a distrust in genetics research because it was so frequently performed on unknowing and unwilling participants such as in World War II. For this reason, genetics research requires the utmost concern for minority populations as to dissipate this distrust and pursue the objective science. Privacy is especially an ethical issue when discrimination can be an adverse side effect to disclosure of genetic information. The United States regulates privacy concerns through laws
such as the Health Insurance Portability and Accountability Act (HIPAA) which prohibits disclosing information to third parties without explicit consent from the individual.\textsuperscript{113} However, some researchers suggest that global collaboration will be necessary to reach the full potential for population genetics research. If this is so, compliance with ethics will be necessary to reach the full potential of population genetics.\textsuperscript{114}

An individual’s right to privacy is compromised by genetic technologies insofar as research results concern more than the consenting individual. As a result, disclosure and respect for privacy can present a conflict of interest for organizations.\textsuperscript{115} For this reason, informed consent for genetics can create a dilemma between individual wellbeing and the right to privacy.\textsuperscript{116} A population health approach is significant to research because genetic data is most accurate with large sample sizes yet these samples can have identifying characteristics which ultimately compromise an individual’s privacy and therefore, their cultural beliefs. This means that quality genetic intervention and research are dependent upon a number of people participating.\textsuperscript{117}

There are two determined subjects of genetics research. Primary research subjects are the individuals offering consent from whom the genetic material will be extracted. Secondary subjects are those who share the same genetic information of the primary participant. The threat to secondary subjects’ autonomy raises additional questions about genetics research as it puts privacy to an unconsenting individual at risk. Because of their relationship to an individual who has given consent, secondary subjects’ information can become public information. Private information can include family medical history offered by the participant to the researcher. Thus, among more traditional cultures if one individual consents to data collection, it can have large ramifications throughout their cultural community. From this respect, large data collection for
genetic research is particularly problematic among multicultural communities as it can introduce advanced western thoughts into an unwilling culture.\textsuperscript{118}

Genetic information offers an opportunity a new avenue to approach the healthcare disparity among minority populations who are significantly affected by diseases such as cardiovascular disease and diabetes. While this type of disparity is not in and of itself a result of lacking healthcare quality, failing to use the information appropriately is an ethical dilemma. There is an association between ethnicity and genetic traits which are a predisposition to diseases which can leave minority individuals at risk for adverse reactions such as unjust discrimination by insurers or employers.\textsuperscript{119} This is especially true if minority populations are unable to obtain therapy for their preconditions. Furthermore, it would be ethically problematic to suggest healthcare disparities are due to these genetic differences. Thus, healthcare providers should be aware of these associations to properly treat patients while sensitive to the biases which might result from the information.\textsuperscript{120}

3. Organizational Ethics Compromise for Genetic Technology Implementation in Minority Populations

Since genetic technologies are cutting edge and require ample resources such as finances and institutional support, they are often implemented in clinically advanced hospitals associated with large research institutions. However, these institutions are not as accessible, be it geographically, financially, or otherwise, as local health care organizations. Therefore, these technologies are potentially unattainable to the already marginalized minority populations and multicultures. Organizations must proceed in genetic technology pursuits with an understanding of the potential risks to minority populations such as just healthcare access and privacy and data collection which can be exacerbated by genetic information.
The United States outspends all other nations on healthcare yet; consistent high-quality care is not observed throughout the country. American populations tend to hope that increased technology use will resolve this discrepancy and close the disparity gap. Genetic technologies shed light on the complexity of healthcare access and quality care for organizational ethics. Generally speaking, genetics is objective information intended to be used to promote health through preventative or direct therapeutic methods. These advances present the opportunity to readdress understandings population health and disease in a population. Genetic advances occur within the context of healthcare organizations and are influenced by the professional and individual applications. Therefore, the implementation of genetic technologies should not go considered in isolation. Rather, the understanding health or disease should be considered in respects to the population or individual’s environmental factors including their culture.

Genetic manipulation such as therapeutic interventions could be argued as a highly western understanding of health insofar as, it is greatly dependent on the objective medical evidence and can lead reduction of the human to their biological parts. Furthermore, genetic screening or diagnosis could result in unintentional psychological distress for an individual and their relatives. It is already being observed that in vitro fertilization methods are available to a limited few who have the resources to afford the extensive intervention. For these reasons, genetics offers insight into future ethical issues of biotechnology, and the influence cultural interpretations can have on healthcare. These issues need to be addressed before genetic results contribute to healthcare professional biases and healthcare disparities which are already so gravely apparent in the United States.

It has already been discussed that part of the issue in healthcare disparity is a lack of healthcare access. Minority populations tend to receive lower quality care which often worsens...
the situation. Genetic technologies offer new options to manage care plans and achieve patient satisfaction. Yet, there remains to be a significant development in effective genetic technologies for major diseases such as cancer and cardiovascular disease. Furthermore, investments in research are put towards these diseases which, if proven to be effective, can have the largest impact. Meanwhile, orphan diseases which affect only a small percentage of the population are not receiving large investments for research or are only researched by an unexpected result from a larger research project. In order to do this, cultural sensitivity is required by the provider. Pain is often influenced by cultural perception whereas some cultures seek to bear the pain and others seek to avoid it all together. Current research movements in healthcare suggest there is a war against suffering and specifically, death.

Since health directly relates to an individual’s ability to participate in society and express their autonomy, just healthcare access is a human rights and social justice issue. Currently, the United States is attempting to reorganize the healthcare system to allow greater access with particular attention to minority or marginalized populations. More appropriate resource allocation is one purposed method to achieve more widespread healthcare access. Genetics will pose greater questions as to the access of technologies and healthcare especially with regard to privacy and confidentiality issues. In a capitalistic and autonomous society such as the United States, it seems unjust to share genetic information as it might be greater privacy risk for an individual than benefit. Thus, it is particularly difficult to ask this of an individual who is already vulnerable in the healthcare system to sacrifice their rights for the sake of another’s wellbeing even if it is ethically justified.

Potentially unequal distribution of genetic technologies should not deter healthcare organizations from pursuing research or integrating the technology into their practice. It does
suggest that there are precautions of pursuing genetic technologies which, if not addressed, can have undue burden on minority populations. For these reasons, appropriate treatment options should be initiated as soon as possible so that the patients can reasonably communicate and plan for their disease progression. It is arguably unethical to offer a medical intervention that is unattainable and thereby continues to marginalize minority patients. For this reason, it is necessary that with the shift to genetic technologies, there be sensitivity to just healthcare access as to not contribute to the healthcare disparities. A reasonable organizational ethics framework with regard to genetics will require an exchange between individuals and the community to protect each individual although sometimes the exchange might appear one sided.\textsuperscript{127}

There is little consensus on a resolution to healthcare access in the United States. However, it can be agreed upon that access to healthcare becomes a key component both for individual flourishing and for thriving communities. While research initiatives typically performed with consideration for public health, clinical medicine typically deals with the individual patient. Implementation of genetics in clinical practices requires organizations to acknowledge that at least this component of medicine will require collective participation for success.\textsuperscript{128} There are remain clinical reasons for providers to deny treatment options which are unrelated to the patient’s condition and therefore supporting the need for professional standards and ethics.\textsuperscript{129} Furthermore, considering that not all individuals might benefit equally, organizations need to consider the impact of implementation on trustworthiness.

\textbf{c. Trust & Organizational Theory}

When organizations fail to provide adequate care, they lack organizational integrity. The perceived lack of integrity results in decreased trust in the organization. Situations such as
adapting to legal changes, organizational governance, and cutting edge technologies contribute to the ability to the perception of adequate care. Further, such factors create an uneven terrain for the organization to develop policy and implement risky technologies. Organizational cooperation between both internal and external environments will maintain organizational trust in complex ethical climates.

I. Ethical Necessities for Maintaining Trust in Uncertain Environments

Interpretations of trust vary on context. Individuals who are trusting are typically in vulnerable positions and dependent upon the actions of other people. Further, when individuals find their selves in a position with few or no choices, if trust is broken the potential losses are often greater than the gains if trust is maintained. These types of situations are more common throughout healthcare than in other industries especially in end of life situations. Since these situations are unique to individual cases, it is essential for maintaining trust across the care continuum that there be a rational process for making ethical decisions at the end of life.

1. Natural law and proportionalism

Natural law is a bottom-up theory where humans inductively reason for moral justifications and principles. The theory suggests that human beings are subject to natural law because they are of the natural world. Thus, moral theories and values can be objectively reasoned to ascertain moral judgment on action. Natural law theorists argue moral judgments are verifiable in the physical world. Further, theorists argue that there is an overlap between law and morality. Thus, at some point, discussions of law must address moral principles. An individual can determine right and wrong actions by being social and participating in social responsibility. This theory emphasizes human’s will as rational and capabilities to live
morally. Natural law theory fosters human creativity as well as provides a justification for suffering which will be significant for bioethics purposes. Human beings can emphasize their creativity to determine moral justifications in society through inductive reasoning. As a result, moral judgments are more capable of developing over time. Therefore, morality is distinct from the general normative method.

The Catholic Church uses natural law to determine right and wrong as well as a method to justify human suffering. From a spiritual perspective, human beings are limited to the physical world which, by natural law theory, decays to regrow. Suffering and sickness is a reminder of human’s participation in natural law insofar as humans are capable of physical suffering and prosperity. With the increased complexity and use of technology in medicine, Catholicism began to reemphasize the importance of the principle of divine sovereignty. This principle establishes human beings as co-creators which foster their creativity and therefore promotes natural law theories. As a result of creativity, health care ethics practices are able to integrate the individual as well as the institution's role in the decision making process. Such integration will protect both the individual’s autonomy while maintaining trust in the organization.

In order to further develop this integration, an organizational ethics framework requires influence from the proportionalist perspective. Proportionalism justifies moral actions value based upon the moral value of the means, ends, and the actor’s intentions. As highlighted in PDE, the value of a morally valuable action depends upon the actor’s intentions. If the person’s intentions are justified, then the action has greater potential also to be justified. Proportionalist methods differ from both consequentialism and situationalism because it looks further than simply the ends to justify the means. At the same time, like consequentialism, a proportionalist method of justification allows for the acceptance of a wider variety of practices than traditional
deontology. Not only does the consideration of intention determine right and wrong, but also blameworthiness. Typically, if the intentions are justified by moral principles, then the practice can be justified. When intention is considered, then a person’s blameworthiness can be determined. In the case of determining to forgo treatments, the patient must not directly intend death. If they do, then the actions would more likely be considered to be an act of euthanasia.

For its application in healthcare ethics, proportionalism emphasizes the human’s creativity to relieve suffering albeit through research or through novel application of available resources. As previously determined, suffering allows for human creativity on both the patient and provider ends of healthcare. However, the proportionalist does not suggest either individual is the sole authority over life. This was determined because human suffering and fallacy is a reminder that humans are finite. The proportionalist method is distinct from traditional practices. Current proportionalist theory weighs heavily on natural law and reason. Therefore, this method emphasizes human’s will and creativity to live justly and in accordance with Catholic principles. Furthermore, proportionalism depends on more than intrinsic value of the action as suggested by the deontological theorists. The proportionalist method which is deduced from natural law theory attempts to strike a balance between being both a creature and co-creator. Or, in other words, proportionalism attempts to balance autonomy and divinity.

Natural law theory is useful to determine the value of an act. An act can be flawed in its pursuit or its intention. To purposely not pursue good is an act of unjustified conduct. However, since situational awareness is required to pursue good, it would be insufficient to create a list of good acts. Rather, individuals need a set of moral skills or values to determine good acts within a particular situation allowing the individual to develop law. Natural law theory justifies limitations as a means to promote human creativity and growth. As a result, humans develop the
ability to determine right and wrong from an understanding of natural order. Due to the objective reasoning of natural law theory and its use for understanding PDE, the theory has practical application for clinical bioethics. Insofar as uncertain environments influence trust in an organization, an objective theory is essential to developing logical processes and ultimately a framework for healthcare organizations.

2. Four Conditions of the Principle of Double Effect

The principle of double effect (PDE) can be used to provide justifications for moral decision making in uncertain environments. While the principle is widely applicable, it must be applied with caution as to not misuse the principle and thereby, come to an immoral end. The principle is based on dividing a moral act into object, circumstance, and end. A practical application of this PDE coheres the patient’s physical status with controversial healthcare treatments. The principle of double effect is applicable to justify an action which has two morally valuable ends. From a clinical standpoint, the proportionalist argues this method will help determine moral worth of an action as well as the proportionality to the patient’s condition.

Four conditions are required to fulfill the principle of double effect. All four conditions must be met in order for an action to be justified by PDE. First, the action itself must not be morally wrong. For example, murder is the unjustified killing of an innocent life. Therefore, murder always wrong. Murder cannot be justified by good consequences or circumstances.

The second condition is that the bad action cannot cause the good effect. In other words, the ends do not justify the means. Catholic moral theology has never justified a moral action by the ends in and of itself. In addition to supporting the first condition, the second condition creates a safeguard. Although the action might not be considered morally wrong, it cannot cause a bad
effect which causes the good effect. The proportionalist holds to be true that an acts value cannot be determined without examining circumstances surrounding it.\(^{148}\)

The third condition of PDE is that the agent must not intend the bad action. Again, this principle is a safeguard to protect unjust actions. Additionally, this condition reestablishes the limitations humans have in creation. Therefore, this condition is especially significant in end of life treatments. The third condition protects people from desiring a result that cannot be justified by immoral intentions.\(^{149}\)

The third criterion is significant once the action’s moral worth has been determined. Beyond the first two criteria, PDE emphasizes the patient’s intention behind the moral decision. When using PDE to determine the ethical value of a procedure, the patient must be aware of the morally negative consequences. Specifically, when considering end of life decision making, this may mean the patient understands that death is a potential result of the decision. A provider who was administering pain medication would be acting morally if pain relief was primary end even if a secondary, unintended end would be to hasten the patient’s death.\(^ {150}\) The patient must intend a justified end. Otherwise, the actions are immoral by the PDE criterion. Bioethicists use the distinction between intended and unintended results to describe intentions. But intentions are difficult to determine since they can be internalized. Furthermore, intentions require the patient to have a plan of action. The end is intentional if it is coherent with the other aspects of the person’s plan. Once the plan is established, the patient can further develop distinctions between the intended and unintended ends of the action.\(^ {151}\)

The fourth condition is that the bad effect must not outweigh the good effect. After the previous three conditions have been fulfilled, the proportionalist can morally justify the action based on this condition. Here again, the proportionalist is determined to interpret the moral
weight of an action. This condition is most significant when determining end of life care which will be discussed in a later section.\textsuperscript{152}

The PDE allows for moral justification of procedures which, in a more traditional sense of Catholic understanding may be morally impermissible. Newer methods develop the human’s co-creator authority as defined by the Catholic principles. At the same time, as mention in the second condition, the methods reestablish boundaries for wrong and right actions. PDE, as used by the proportionalist, does not promote relativism. Rather, the first condition reaffirms morally right and wrong actions. So, as argued, if an action such as murder is intrinsically wrong, then PDE can never justify murder.\textsuperscript{153} In addition to PDE conditions, Catholic healthcare ethics also has initiated the distinction between “direct” and “indirect” actions. This distinction is most useful when using the PDE methods. Should an undesirable effect be considered by the conditions to be an “indirect” action, then the action is morally permissible. However, it is considered a “direct” wrong if it fails a specific combination of the conditions. Proportionalist use the distinction between direct and indirect actions to justify some forms of euthanasia and abortions. However, these terms are becoming outdated because of the ability to distinguish the moral and immoral actions using PDE.\textsuperscript{154}

One example of these terminologies use is when applied to euthanasia cases. Catholic moral theology always considers direct euthanasia wrong. Direct euthanasia fails all conditions of PDE. The killing of an innocent life itself is wrong.\textsuperscript{155} The overdose of pain medication directly causes an unjustified end. The patient intentionally seeks death. Fourth and finally, the act of murder does not outweigh relief from pain. However, if the patient does not hasten death but seeks relief from extraordinary treatments, then the individual is justified in removing this treatment, even if death may be caused by removing the treatment. Therefore, PDE, as used by
the proportionalist, can provide an ethical justification for withdrawing or withholding treatments even if the patient knowingly intends to allow death.\textsuperscript{156}

3. Ethical Distinction between Killing versus Allowing Death

   The most obvious examples of uncertain environments are end of life situations. End of life situations are one which exhibit high potential for ethical dilemmas and professional moral distress. Legally, in the United States, physician-assisted suicide (PAS), and euthanasia are actively killing the patient. The majority of the states have maintained the laws which determine PAS and euthanasia unjustified killing and therefore, illegal.\textsuperscript{157} Thus, these situations can impact trust on an organizational, a professional, and patient level. A stigma surrounding end of life palliative care, or pain management, contributes to a blurred distinction between killing (i.e. euthanasia) and allowing death (i.e. hospice care). Such uncertainty requires an organizational response to ensure clinical practices are ethically justified and therefore, maintain trust.

   There are five different actions which can be classified as either killing or allowing death; withholding life-sustaining treatments, withdrawing treatments, pain relief that hastens death, physician assisted suicide and active euthanasia. PDE has already established the last two to be intrinsically wrong. Therefore, PAS and active euthanasia are unjustified killing and direct euthanasia. The proportionalist method can be used to justify hospice care (i.e. withholding/withdrawing treatment) has allowing natural death. The United States recognizes the right of the patient to request withholding or withdrawing life-sustaining treatments and pain relief therapies as allowing natural death. Additionally, by the patient’s request, the United States relieves the physician of legal obligations to actively treat for therapeutic intervention (e.g. chemotherapy in the final weeks) in situations where death is imminent.\textsuperscript{158}
The difficulty arises when determining a moral distinction between withholding life-sustaining treatments, withdrawing treatments, pain relief that hastens death and physician assisted suicide or active euthanasia. The moral distinction is also of utmost importance to maintain trust in uncertain environments. Determining the morality of the acts enables justification for the patient to request, or deny the treatment. Intentionality plays a major role in the moral worth. So, the third condition of PDE is most important in these circumstances. One method to determine the difference is awareness of intentions. If the patient seeks death as either the means or the ends, then the individual seeks to be killed. The proportionalist would argue this action is intrinsically wrong and therefore unjustified by PDE. However, if the patient seeks to relieve himself from unnecessary pains from treatment, then the patient is justified.159

At the same time, this does not also justify physician assisted suicide. Supporters of PAS argue they too seek to end the patient’s pain. Furthermore, supporters argue the means to end the pain are irrelevant. Therefore, if the patient seeks to end pain through death, then this would be morally permissible. In contrast, the proportionalist recognizes seeking death, as a means or an end, as morally wrong. Therefore, death as a direct treatment or ends is unjustified. Rather, this would be unjustified killing. But as previously argued, if the patient does not seek death, then a treatment can be morally justified. Following this logic, PDE then can establish a difference between killing and allowing death.160

As for the first three circumstances, ethical considerations surrounding them are based on the foundations of moral status and moral agency. Humans have the right to make their own moral decisions. Further, humans maintain moral status at minimum from birth until the moment of death. They are flawed, yet they maintain the right to exercise their freedoms. Freedom of choices is determined in the context of their relationship with their self and their identified
community. With this understanding, bioethicists can ethically justify an individual’s wishes to withholding and/or withdrawing treatments. If the patient is imminently dying, then it would ethically follow that the life-prolonging treatments are considered to be medical interventions. Therefore, they are extraordinary and the patient would be justified in requesting them to be removed to allow death.

Rather, one could argue medical interventions are inhibiting the natural life cycle. Therefore, these treatments can justifiably be denied by the patient. Furthermore, the provider can confidently respect these decisions without considering withholding the treatment as killing the patient. Of course, the acceptance of withdrawing or withholding treatments does not come without adverse reaction. When decisions are made in uncertain environments, the consequences of these decisions on future treatment plans must be considered. Thus, while it might be ethically permissible to withhold or withdraw treatments for one patient, organizations must avoid what is perceived as a “culture of death.”

**II. Cases of Compromise in Uncertain Environments**

The distinction between killing and allowing death is dependent on understanding each unique patient case. Since the cases are unique, there is a need to distinguish between cultures of death and ethically justified care plans that allow death. This distinction is increasingly more complicated as technologies are introduced into health care setting. These technologies test the application of ethical principles for justifying ethical decisions. Technologies have introduced additional opportunities and possibilities which contribute to ethically uncertain scenarios. This next section will discuss common
1. Avoiding a “Culture of Death” and Uncertainty

The acceptance of withdrawing or withholding treatments does not come without adverse reaction. When decisions are made in uncertain environments, the consequences of these decisions on future treatment plans must be considered. Thus, while it might be ethically permissible to withhold or withdraw treatments for one patient, organizations must avoid what is perceived as a “culture of death.”

Interestingly, the term “death” is widely used yet, there remains to be a clear definition. Some theories suggest death is an on-going process. A person’s cells die daily, most of these cells regrow, until the day when the whole body congruently ceases to function and death is medically declared. Other definitions suggest death is an event. There is a moment which a person loses their personhood and no longer resides in the body. Thus, the two interpretations of death suggest an objective, scientific understanding, and a more philosophical or spiritual understanding. Within the ambiguity, there are four defined criteria for death. The order in which the criteria in this argument has no implication on defining death. One criterion is the permanent loss of cardiopulmonary function. The second criterion is total and permanent loss of a functioning cortex. The third is the total and permanent loss of a functioning brain stem. Fourth is the total and permanent loss of a whole functioning brain.164

The introduction of technology into medical care impacts the ethical understanding of the four criterion of death. Consider that, new biomedical technologies enable a person to lose function in one of these areas but remain alive. Since this is the case then, death occurs by a process and is more than an event. A person can experience dying through a process of losing certain functions of the criterion. Because the person can experience death through the loss of functions, then it is difficult to determine when exactly the death process has occurred and
therefore, when a person is truly dead if other functions are still, in fact, active.\textsuperscript{165} Perhaps then, the definition of death varies depending upon the field in which it is being used. Medically, there is pressure to determine death to preserve resources which can include medical procedures and even harvesting organs.\textsuperscript{166}

In \textit{Evangelium Vitae}, Pope John Paul II warns against the slippery slope pronouncing people prematurely dead. The Pope feared the use of PDE as a justification for direct and involuntary euthanasia. \textit{Evangelium Vitae} was intended to remind the people they do not have the ultimate authority over life and death.\textsuperscript{167} Simply because humans cooperate with creation insofar as they are alive, does not suggest they are the ultimate authority. Furthermore, when they choose to practice euthanasia as a means of compassion they are actually doing a disservice to compassion. Pope John Paul II prefers to refocus compassion in pain relief to sharing in the patient’s pain, not avoiding it. As a result, then humans selflessly bear the burden of pain with the patient. In this process, the Catholic community can grow together through the suffering.\textsuperscript{168}

However, this does not also justify physician assisted suicide. Supporters of PAS argue the treatment is intended to seek to end the patient’s pain. Furthermore, PAS supporters argue the means to end the pain are irrelevant. Therefore, if the patient seeks to end pain through death, then this would be morally permissible.\textsuperscript{169} In contrast, the proportionalist recognizes seeking death as morally wrong. Treatment should be proportional to the patient’s condition. Therefore, death as a treatment or ends is always unjustified. Rather, this would be killing. But as previously argued, if the patient does not seek death, then a treatment can be morally justified. Following this logic, PDE then can establish a difference between killing and allowing death.\textsuperscript{170}

Simply because PDE provides an ethically justifiable distinction between killing and allowing death, this does not provide a justification for euthanasia. The United States has already
recognized that killing is only permitted in certain circumstances (e.g. self-defense). An individual has the right to respond to an imminent, unwarranted, and unlawful force with equal force.\textsuperscript{171} Thus, the common law uses proportionalism to justify the victim’s response to a threatening force. Currently, euthanasia is only legal in six states, California, Colorado, Montana, Oregon, Vermont, Washington, and the District of Columbia.\textsuperscript{172} Some scholars might argue that euthanasia is not killing but a justified death. Failing to provide the patient with an available treatment which they request is a failure to respect autonomy. Patients who are terminally ill and suffering to maintain relationships are, according to the justification for allowing death, permitted to relieve their pain even if it hastens death.\textsuperscript{173} However, euthanasia is not similar to self-defense killing that the United States permits since the force of directly inducing death is greater than the force threatening the individual (i.e. disease).\textsuperscript{174}

Further, euthanasia does not fulfill the third condition for the good outcomes do not outweigh the bad. The availability of these treatments places pressure on vulnerable populations. If euthanasia is permissible for certain conditions such as ALS patients for whom there are no reasonable alternatives, then, as Pope John Paul II warns, it could be justified for all who suffer such as handicapped, children, or the unconscious.\textsuperscript{175} More specifically, this could promote a pressure for autonomous decision making. Elderly patients may see their self as a burden to the family.\textsuperscript{176} This external pressure inhibits an elderly individual’s ability to provide authentic informed consent.\textsuperscript{177} In addition to affecting the patient, external pressures also affect perspectives of the medical profession. If euthanasia were legalized, proportionalists argue, this would cause distrust in the medical field. Patients could be concerned for their well being when put under the care of certain doctors.\textsuperscript{178}
Undoubtedly so, the proportionalist argues there are circumstances when euthanasia may be morally justified. However, in the case of the United States, the majority of the time, euthanasia is unjustified. Therefore, it has remained illegal. Using the proportionalist approach in combination with PDE, ethicists are able to come to ethically justified conclusions for distinguishing between killing and allowing death. This distinction is pivotal as medicine advances and is capable of practicing medicine at the most delicate levels. With the increased use of medical technology, there are better methods to manage pain or suffering especially towards end of life. The changes in medical practice and implications on our understanding of ethically complex situations will carry consistently through newly introduced technologies such as genetics.

2. Identifying Ethically Uncertain Environments in Genetic Conditions

Having argued that natural law theory supports PDE and proportionalist method as objective measures to provide ethical justifications, these frameworks and principles will be applied to ethical dilemmas for disease treatment. Specifically, for genetic technologies, society and science are at a slight disconnect. Thus trust in the healthcare organization is in a vulnerable position. Trust is essential to the sustainability of a healthcare organization’s status as a moral agent in society. Trust can be established on multiple levels: the clinical, organizational, and patient. Genetic technology science influences all three levels thus resulting in scenarios of uncertainty making trust vulnerable. The necessity for trust in organizational theory creates further conflicts of interest to either increase patient safety while compromising confidentiality.

One of the first and most widely publicized genetic intervention cases is Jesse Gelsinger’s case at the University of Pennsylvania. In the 1990’s, there was a high hope for gene
therapies to relieve conditions such as Ornithine Transcarbamylase Deficiency. In a research study conducted at the University of Pennsylvania, investigators were conducting a Phase I, dose-escalation study to determine a safe dose of gene therapy treatment. However, the trial was suspended and ultimately terminated when one subject, Jesse Gelsinger, died four days after being injected with the study drug. The study is infamous for flaws in the research protocol which resulted in changes to human subject’s protections in research.\textsuperscript{181} The case is known for influencing human subject’s protection in research. Specifically, the case made the University question its institutional review board processes, the level of detail required to describe risks in the consent form, and the transparency for disclosing investigator’s financial ties to the pharmaceutical company. This study highlights not only delicate relationship between organizations and research subjects but also, the uncertainty of gene therapy research and the necessity of appropriate organizational reactions to maintain trust despite these incidents.\textsuperscript{182} The potential hope for genetic therapies is to develop more individualized care for each patient. The intention is to increase patient safety and to relieve genetic burdens for patients and their families.

An organization focused on both implementing genetic therapies and maintaining a trusting relationship needs to consider the organizational, clinical (research), and patient perspectives. In the example provided, both the University of Pennsylvania and the principle investigator had significant ties to the drug manufacturing company.\textsuperscript{183} As moral agents, organizations and providers alike have the right to have stock in a company since it fulfills to business component of the institution.\textsuperscript{184} However, these ties are conflicts and should be managed as such when acting as an agent for the patient or subject. It would be ignorant to consider one aspect of technological developments without considering other developments.
which influence trust in society. While the conflict does not create the uncertain environment, it contributes to the loss of trust when such situations have negative outcomes.

Such conflicts contribute to organizational management of complex situations and misconceptions of genetic technologies. Over two decades into the genetic technology developments since Jesse Gelsinger and newspaper headlines only further contribute to the misunderstanding of genetic technology as its communicated from the organization to society. Headlines which contain information about a “gay gene” or “criminal gene” suggest there is a direct causal link from gene to expression. As a result, healthcare organizations begin the gene therapy conversation in the clinic at a disadvantage having to disperse of any similar misconceptions. Implementing gene therapies directly and drastically affects community’s trust in an organization as the technology has the ability to affect not just the current population but the future community as well.

Society is likely to become less trusting and more vulnerable of organizations when there is insufficient clarification about gene therapies. The potential for this situation increases with the influence of media publications. While embryo replacement therapy can be useful to combat mitochondrial disease, the media’s description of a “three-parent baby” adds fuel to the ethical controversy. Trust in gene therapies is similar to traditional health suggestions. When following the recommendations, patients expect to see positive results. There are a few progressive steps required before gene therapies emerge as accurate and effective clinical interventions. Public support will likely follow positive results in clinical trials, improved quality of transfer technology, and further investment.

Recently, a large ALS awareness movement argued against this approach as it appeared to minimize suffering of patients with ALS and their families. From a business and financial
perspective, the organization would want to invest in the area with the large returns especially in early stages of gene therapy. This would be a means to protect the society and appropriately provide for the surrounding communities as argued earlier. Although healthcare is on the path to individualize care, this does not suggest all patients will receive this specific care. Especially for gene therapies uses, there is not enough evidence which suggests such a widespread availability of therapy. An organization must maintain this balance and assure that there are no unreasonable expectations from either partner of the relationship in order to balance and maintain a trusting relationship.\textsuperscript{189}

As organizations progress and apply the framework to be recommended, they must consider the uncertain environments which will contribute to organizational trust and, as exemplified in both end of life situations and the Gelsinger case, the impact the decisions could have on the future of technology implementation. As indicated, a rational framework is essential to maintaining trust in the organization is uncertain environments since individuals who seek help tend to have limited options available. Thus, an ethical framework will be crucial to implementation of genetic technologies so that organizations can maintain trust in these novel and uncertain environments.

d. Organizational Ethics Framework

As argued, organizational ethics impacts all moral agents with whom the organization interacts both directly and indirectly. Thus, a framework is required to navigate the ethical dilemmas specific to genetic technologies. The organizational ethics framework that will be suggested is intended to provide an ethical balance between individual privacy and population
benefit with regards to genetic technologies. Specifically, this framework is developed with consideration of both clinical and research dilemmas from an organizational perspective.

I. Individuals, family, and society

The first element of the framework concerns aspects of consent. As discussed, genetic technologies alter the ability of individuals to provide authentic consent as there are unknown probabilities and risks. The requirement of obtaining consent creates dilemmas involving control over genetic information for both the individual and the relatives. For the individual, the might find their self-consenting to uncertainty if there is limited knowledge about their genetic data. For the relatives and society who do not consent to genetic disclosure, the individual’s results might impact the relative’s privacy, ability to consent, and overall moral agency.

Genetic technologies highlight both the relationship and unique qualities of personalized medicine. DNA-based risk assessments for common genes and genetic mutations are becoming more significant for therapeutic interventions. Further, family health history and environmental influences offer potential insight into the gene’s role in a diagnosis. Currently, family health history, while introduced in clinical practice, is a largely undermined resource for clinical care. Thus, the framework for genetic technologies will need to rely more heavily on family health history.

The framework emphasizes a cultural shift from privacy to confidentiality. The concept of privacy in genetics regards the control of information. However, since genetic information is always identifiable and highlights the deep connection between individuals, the concept of confidentiality is more accurate to describing reasonable standards for protecting genetic information. The concept of confidentiality restricts information to authorized persons only (i.e.
193 Because confidentiality is understood to be limiting access between individuals, as opposed to privacy which limits it to one individual, confidentiality is more appropriate to the framework. Confidentiality sets the framework’s security standards to be among a group of authorized individuals. This is crucial for genetic researchers who might request access to individual genetic data.

Using family health history will require cooperation on the part of the relatives. Family members place their self at risk of identification of genetic mutations or risk factors which contribute to genetic mutations. When results are actionable, a process must be in place to disclose such results if desired by the relative.194 However, this process is particularly difficult if the relative is not a patient of the institution as a notification can seem unwarranted or unexpected by the relative.195 Disclosure of results should respect the relative’s privacy, be transparent about the risk level, and should not take precedence over individual autonomy.

The organizational ethics framework will need to acknowledge that consent might not meet the ideal standards of knowing all the risks to a procedure but rather, there is a limit due to probability, risk, and uncertainty. For instance, genes are markers of genetic conditions but do not equate to the frequency or severity of a potential condition. Thus, there is a lack of direct biological correlations within the clinical application. Penetrance of genetic variation contributes to pharmacologic interventions such as determining effective cancer regimens. However, disease severity is a combination of both high and low penetrance.196 From a clinical perspective, it is not enough to know of the gene variation but also the penetrance level to determine the impact of genes.

At the same time, although an individual might be capable of providing consent and consider their decision-making process complete, it is not necessarily the case that they have a
right to access healthcare treatments which are not in their best interests according to medical standards. This would negatively impact the professional as their own independent moral agent and trust in the organization. If treatments deemed medically inappropriate are provided, this does not respect the principle of beneficence and negatively influences the ethical climate throughout the organization. Therefore, the framework is one which considers the right to healthcare access when determining the ethics of genetic implementation.

Alternative forms of consent will be worth considering to most appropriately allow opportunities for individuals to understand the risks and benefits of an option. Specifically, alternative types of consent might be more appropriate to protect individual autonomy while considering the impact of genetics on families and society. Regarding the return of research and clinical results, an open consent method might be most appropriate as individuals can control the level of disclosure they wish to obtain. An open consent approach as proposed by the framework will address the need for confidentiality is individuals can determine the authorities who access their data.197

II. Burdens and Benefits

Organizations must weigh the burdens and benefits of clinical success. A primary end for organizations and professionals alike as moral agents is to promote beneficence. However, without an understanding of the potential burdens and benefits for both individuals and populations, there will be difficulty determining when beneficence is truly promoted. Due to the controversy of “patenting life” or the “building blocks of life,” it is essential that moving forward with biotechnological patents, there are sound legal and ethical grounds to stand on.198
More specifically, since the ethical climate in western healthcare requires a shift from the individual autonomy model, the genetics framework must be capable of identifying a justification for burdening individuals for population benefit. Given the current ethical climate in American healthcare, there is a natural conflict between the burdens and benefits to understand genetic variability and susceptibility. Limiting these variables (i.e. a benefit) would require organizations to pursue big data initiatives and burden individual patients. Pushback from national efforts for population health such as the Affordable Care Act (ACA) highlights the United States’ hesitation towards individual efforts for population benefit. Even some organizations fought on moral grounds against parts of the regulations claiming that the mandate was inconsistent with the organization’s moral values which altered available to contraceptive interventions.

Understanding genetic variability is effective for preventing issues such as cardiotoxicity resulting from chemotherapy. Variation can impact the severity of toxicity of drugs thereby, influencing the appropriate dose of a drug. Knowing such information can increase identification of at-risk patients for conditions such as cardiotoxicity. To identify variations and susceptibility requires identification of gene alterations in at least 1% of the population. Research protocols are obtaining small sample sizes relative to the size of individuals affected by genetic variability and susceptibility by certain drugs. Therefore, much data is inconsistent or an incomplete representation. Pharmacogenomics efforts are aimed in part at identifying specific alterations and developing modifications to manage responses such as cardiotoxicity.

In a capitalist environment, such as the United States, organizational benefits can often include financial benefits of pursuing and developing technologies. As such, these benefits are seen to conflict with individual burdens. The financial benefits of genetic technologies are
exemplified in the organizational pursuit to patent and commercialize genetic technologies. Throughout literature, it is understood that patents and commercialization of genetic technologies will limit the availability of such technologies for therapeutic interventions. Such a circumstance has come to be known as the tragedy of anticommons in biomedical sciences. Specifically, patents protect developed genetic technologies by controlling access to such technologies. Because genetic technologies are developed on the most microscopic level and the patent process can have lengthy delays, institutions who dispute the first researcher to develop the technology result in highly publicized legal battles. Not only do the legal battles involve ownership of the technology, but these cases are also ones of social justice. Gene technology patents provoke debates about an individual’s property rights to their genetic information. This becomes and ethical dilemma since it is the individual and population who contribute their own data and risk their privacy and confidentiality.

The industries themselves are in an ethical standstill between the right to access and the right to patent. If health is a right, then it seems unethical for an organization to patent a genetic sequence if this limits individual access to healthcare decisions. Thus far, genetic patent cases determined have established that in its natural state, the genome should not be used as a means to financial gains. Therefore, the framework will need to focus on the proportionality of organizational benefit from patents and commercialization compared to the individual risks of providing data as well as the social justice issues of accessing such technologies. Not only are patents seen as restricting to individual patients but also researchers and clinicians which influence the potential impact of care provided.
III. Transparency

Organizations need to increase transparency to make information available, avoid unnecessary risks, and enable creativity and collaboration. Transparency has a variety of definitions throughout the literature but generally includes characteristics of openness, honesty, and accuracy.\textsuperscript{207} Transparency not only about the justified path to the decision made but also about the compromises required to make such decisions. Therefore, transparency will benefit the individuals, population, and organizations as it will allow for the deliberation process to be reproducible if necessary. Organizational transparency requires participation from the leaders and providers of the organization to create a culture of transparency.\textsuperscript{208} When healthcare professionals are transparent, it can expose both good and bad scenarios in the organization. Considering the complex dilemmas which are bound to arise because of organizational decisions, transparency to promote trust will be critical to an integration of genetic technologies.

Transparency is essential to maintaining trust in an organization. Research conducted after the Enron scandal in 2001, arguably one of the most notorious corporate fraud cases in U.S. history, suggests that people want companies to be open and honest about business. In the case of Enron, the leadership distanced themselves from the day to day operations promoting a culture that allowed professionals to conduct business without concern for ethical conduct.\textsuperscript{209} As such, people believe that companies which are open and honest have more concern for their stakeholders.\textsuperscript{210} Transparency is becoming increasingly more important as information is becoming more widely available and errors are harder to hide. When organizations exhibit low transparency, their stakeholders, be it patients, family members, or providers, lack trust in the organization. However, overall trust is positively correlated to transparency.
Transparency providers power to stakeholders in two ways.\textsuperscript{211} First it allows them to make their own decisions about the significance of the information. Because decision making processes are dependent on information, the information available must be true, substantial, and useful. Balanced information presents all sides of a situation to promote trustworthiness in the organization. However, in the age of transparency, consumers (i.e. patients) tend to distrust these claims because marketing strategies thrive on misleading claims or hidden truths.\textsuperscript{212} Further, presenting all sides of a situation does not suggest that information overload is appropriate either. Organizations must determine how much information to share with their stakeholders and the method of relaying the information to allow for a balanced interpretation.\textsuperscript{213} Of course, to determine how much information to share is dependent upon the organization knowing the intended audience of the information.

Second, stakeholders can hold organizations accountable for their actions.\textsuperscript{214} When organizations release information about their mission, care standards, research initiatives, stakeholders can observe and evaluate the organization based on the determined objectives. Thus, accountability requires that organizations release information that might be controversial or damaging and admit their mistakes. Again, balanced information must be provided either via the media or another resource for stakeholders to hold organizations accountable.\textsuperscript{215} In adverse situations, as exemplified in the Gelsinger case, organizations can regain trust through efforts of accountability. Accountability has become significant in healthcare for the purposes of integrity in quality and evaluation of safety. Hospitals have begun to develop accountability committees intended to protect both the patient and community. Specifically, these committees examine the financial responsibilities of the organization, specify guidelines, and apply necessary sanctions if such standards are not met.\textsuperscript{216}
From a healthcare organizational standpoint, organizations require transparency from both a clinical and research perspective. For clinical purposes, transparency regarding genetic technologies must acknowledge the limits of care. Studies suggest that being transparent can help develop best practices and save money especially after adverse safety events. Three years after implementing a policy to address safety events at the University of Illinois Medical Center, lawsuits decreased by 40% when compared to the 5 years prior. Being transparent about safety events and the limits to quality of care are determined by the organization’s efforts to promote beneficence. Personalized medicine does not necessitate that all medicine is personalized and these limits need to be clearly established given the patient’s circumstance. Organizations must maintain patient safety and quality of care as a priority. Due to genetic variability, personalized medicine has yet to be achieved as a standard of care in clinical care. Variability can negatively impact patient safety and quality of care insofar as it creates unpredictable outcomes.

With regards to research initiatives, organizations must pursue an alternative approach to minimize burden and maximize research output (i.e. promoting common good). Patents and commercialization influence trust as increasing the conflict of interest between hospitals and drug companies as institutions are creating policies to make these relationships more transparent. Further, it appears that only the organization benefits from patents and commercializing technologies since they financially benefit. The insurance market has shifted toward one of financial transparency. Thus, this shift is expected to carry over into research. Biobanks will prove to be most useful for research initiatives. To promote transparency in genetics research, the concepts of anonymization will need to be replaced with terms such as “coded” or “limited data sets” since genetic data cannot truly be anonymous. This is a level of
compromise that allows for transparency of the individual burden for population benefit. This level of transparency establishes a distinction between the individual’s rights versus the organization’s allowing the stakeholder (i.e. research subject) to make an informed decision about their participation. Thus, organizations must establish a level of trust in genetic biobanks as both a new concept and as a potential organizational resource.

e. Conclusion

The organizational ethics framework uses the elements of consent, conflict and compromise as tools to move forward and determine ethically justified boundaries in complex ethical scenarios specific to genetic technology implementation. As organizations depend on the trust of those who interact with the organization, the framework uses the issues identified between individuals and populations to establish a compromise and promote trust through transparency.

Transparency via logical deduction of the ethical justifications is supported using natural law theory and the principle of double effect. These approaches have already proven to be effective in ethically complex situations (i.e. distinguishing between physician assisted suicide and withholding/withdrawing treatments). Further, these approaches are effective since they allow for a logical and objective process to ethical dilemmas thereby, increase a moral agent’s ability to manage a situation properly. Thus, the processes increase transparency of organizational decisions which is critical to promoting an environment where other moral agents are capable of similar ethical decision making processes.

The ability for moral agents (i.e. healthcare professionals) to ethically assess a situation is essential to genetic implementation since the organization itself cannot carry out actions but is
dependent upon its agents to act in a manner which is consistent with the ends of the institution. These professionals currently experience moral dilemmas and moral distress which contribute to quality of care, patient safety, and professional satisfaction. Since the organization is comprised of a web of relationships between these moral agents, it must consider the impact of genetic technology implementation on all moral agents with whom it interacts and not only the individuals and populations whose genetic information is obtained.

Unlike the previous literature which focuses mainly on an individual or population perspective, this chapter discussed the relevance of organizations as moral agents in genetic technology implementation. As organizations are moral agents whose ends are to promote the common end, they are responsible for ethical implementation of genetic technologies. This requires that the organization consider the influence on their professionals, the clinical care provided, and their status as moral agents. Insofar as organizations need professionals to act out the organizational objective, it is essential to ensure that the framework allows for professionals to fulfill their own moral duties allowing them to provide quality care for patients. Thus, the problem identified by much of the literature requires a resolution at the larger organizational level. The following chapter will apply the framework to genetic therapeutic interventions in clinical care.

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2 Tom L. Beauchamp and James F. Childress, Principles of Biomedical Ethics, 7th ed. (New York: Oxford University Press, 2013), 64-68.


Steven D. Pearson, James E. Sabin, and Ezekiel J. Emanuel, *No Margin, No Mission: Health-Care Organizations*
116Tom L. Beauchamp and James F. Childress, Principles of Biomedical Ethics, 7th ed. (New York: Oxford University Press, 2013), 72-76.
177 Tom L. Beauchamp and James F. Childress, Principles of Biomedical Ethics, 7th ed. (New York: Oxford University Press, 2013), 137-140.
Chapter 4 Therapeutic Interventions with Genetic Technologies

The hope for genetic technologies is that they will be widely implemented into clinical care while maintaining high quality care, more precisely targeting conditions, and therefore, minimize costs. Currently, the majority of successful genetic screening and testing is implemented in the areas of cancer and reproductive technologies. The availability of these technologies while beneficial is also limited. There is a lack of standards for managing genetic data in clinical care and ongoing debate about how to handle the large amount of data. Successful clinical implementation will require more accurate testing with sufficient genetic data as well as an organizational approach to maintaining and promoting beneficence with the novel technologies. Considering their responsibilities, organizational need to further address advances in the areas of data collection, policy development, and standardization.

Individual and population data for the purpose of maintaining beneficence and patient safety complicates organizational responsibility for integrating and providing genetic technologies. The organizational ethics framework can help identify the relationship between the issues of implementing genetic technologies into clinical care. This chapter will present the ethical complexities of maintaining individual consent for genetic technologies due to genetic probability, risk, and uncertainty and the right to healthcare access. Following, there will be an assessment of conflicts between population benefits and patient risk of privacy. Finally, the organizational ethics framework will be used to develop a compromise between the limits of care available and maintaining high standards of quality of care for patient safety.
a. Probability, Risk, & Uncertainty

The lack of long-term data on genetic technologies begs the question of what known risks are available at the time of consent to the treatment. Due to the factors that affect genetic phenotype, there is a high degree of uncertainty about risks and benefits when consenting. These unknown risks ultimately affect the organization’s ability to promote the ethical principle of beneficence. At the same time, a balance needs to be met to ensure that there is justified healthcare access.

I. Consenting to Uncertainty

An aspect of authentic consent requires individuals to weight the risks and benefits of a decision. However, early implementation of innovations into clinical care can mean that sometimes, patients are consenting to uncertainties. These uncertainties beg the question as to whether consent is authentic if the risks and benefits cannot be adequately weighed by the patient.

1. The Principle of Do No Harm: Who defines “harm?”

In its earliest understanding, bioethics minimally emphasized the importance of the individual’s input of the decision-making process. Rather, providers were deemed the most knowledgeable. The paternalistic framework for ethics is one in that the providers make medical decisions for the patient since the providers are thought to be more knowledgeable and therefore, more qualified.¹ This framework is exemplified by and observed in the Hippocratic tradition of medicine. The provider maintains high reputation and authority throughout the community which supports their strong influence on patients and families. In this framework, providers are given ultimate weight in decision making. They are also left to discern what information is relevant to
disclose to patients. Ultimately, the provider was considered to have a higher status, and patient rights became indifferent to medical decisions. For these reasons, communication was not emphasized in paternalistic models such as the Hippocratic tradition. This difference would only continue to grow as the provider continued his practice.²

While the patient preference is not emphasized, the basic principle in paternalism is do no harm (DNH) also known as, nonmaleficence. The “do no harm” principle, can take many forms in clinical application. In a paternalistic but patient-centered model such as the Hippocratic tradition, harm is left to the provider’s discretion within the relative society. Providers are expected to determine the risk benefit analysis for patients. Although the practice is highly patient centered, it does not suggest the practice only concerns the patient. Instead, the provider must have concerns for the patient as well as, the art, and the society.³ Thus, the practice might have some useful application in clinical genetics. DNH principle might have roots in the paternalistic tradition and therefore seem absolute. However, physicians are still responsible for obeying laws and regulations maintain their practice. With the community’s beliefs as the assumed standards, then minimizing “harm” is relative to the society. Even if the provider has absolute values, he must make his practice applicable to the relevant context. The provider’s ability to make clinical care applicable to the relevant context will be especially useful for clinical genetics.⁴

From the perspective of ethical other frameworks, the principle of DNH might be interpreted as the minimum standard for practicing providers. To do no harm would be at least to minimize harm for the patient’s sake. This might include no medical action such as in end of life situations. In these situations, the action to transition from cure is care can sometimes be at the provider’s discretion.⁵ Interestingly, DNH also requires the provider to actively participate in the
patient’s wellbeing. In other words, to do good for the patient. If life is the good to be achieved or obtained, then in the paternalistic model, the provider might understand his duty to do as much as possible to preserve life. To not act would, in a sense, be to not promote life and therefore, do harm. With this understanding, paternalism developed into a vitalistic tradition in the mid-20th century attempting to do all things necessary to preserve life. Within the paternalistic moral tradition, there is a sense of beneficence and patient subjectivity despite doing no harm being the primary principle on the surface of the framework.

In the paternalistic framework, the DNH principle is left to the provider’s discretion with the patient and society as the center of focus. If from the provider’s perspective, the treatment is offering more harm than good, be it for the patient or society, than the provider maintains the authority which is justified by competence. By doing so, the provider determines the potential harms and weighs the risks and benefits of an intervention. While familiarity with medicine might help minimize complications, “harms,” for the purposes of consent, involve the medical complications as well as quality of life. Medicine is not an absolute science. Therefore, the provider is limited in his ability to cure or heal patients.

2. Probability and Avoiding Confusion with Definite

To argue conservatively, consider uncertainty as a factor in the decision making process is a risk. If the treatment goes well, there is an uncertainty of complications that can arise. However, it is insufficient to associate uncertainty of a disease or complication with a high probability of developing them. This holds true for genetics since genetic conditions are not always black and white. Rather, it is a continuum of probability. Our ability to predict probability is still less than ideally accurate. In 2009, in a test of about 200 associated markers, 7% of individuals were estimated to have triple the average risk when in fact they have less that the
average risk. With 400 associations, that number increases to 15%. What this information suggests is that there are a variety number of alleles which contribute to the overall probability of contracting a disease.\(^\text{10}\)

Specifically, the statistical power of predicting probability from one individual’s genome is often low for multifactorial genetic tests for which many alleles contribute to genetic phenotype.\(^\text{11}\) Statistical power for probability has increased with numerous genome-wide association studies which are pooled from population data. For instance, approximately 16 new genetic markers for diabetes were identified by pooled data.\(^\text{12}\) For clinical and policy purposes, this information is useful once the markers can be used to measure risk and probability. With these determinations, the appropriate standard of care policies can be developed.

Probability becomes a tradeoff between precision and size of the population for the condition. For example, breast cancer testing is among the more accurate genetic screening tests because it can affect women of all ages and races and therefore, has obtained sufficient data to increase accuracy. Generally, the more people identified increased the number of component tests.\(^\text{13}\) Panels of genetic testing for a multifactorial genetic condition can significantly increase precise prediction of probability. The ability of genetic tests to predict probability depend on population frequency, associated risks, and interactions.\(^\text{14}\) A genetic test panel for rare conditions can have a predictive value of almost 90% for some conditions if appropriately tailored for the condition.\(^\text{15}\) At the moment, an increasingly limiting factor in genetic prediction of probability is population risk information. This is especially the case for conditions for which minority populations are underrepresented in the data.

The variation in probability issues are prevalent and ethically concerning in scenarios of pre-implantation genetic screening (PGS) and Direct-to-consumer testing (DTC). PGS panels
often include tests that are either common in a population or are immediately actionable. For many couples who seek PGS, more information is better even if the information is only probabilities.\textsuperscript{16} For conditions such as Down syndrome, there is a false positive rate of less than 1\%. For the purposes of DTC, the reliability of results is often small and clinically insignificant. Often the results can even be misleading because of the inability to reliably predict the outcome.\textsuperscript{17} Rather, the results can be more significant for a researcher analyzing a natural history of genetic makers.

Of course, genetic predictability varies with each disease and condition. Therefore, from a policy perspective, it would be helpful for organizations to develop best practices for managing the varying levels of genetic testing and probability.\textsuperscript{18} Developing policies for genetic testing requires caution as limiting the availability of tests may be perceived as paternalistic. Specifically, organization’s must consider the impact of a tailored panel of testing to increase probability for less common conditions.\textsuperscript{19} All tests must achieve an acceptable standard of predictability or else, they would be unethical due to lack of beneficence. Of course, this standard might vary considering the severity of a condition and the possible medical interventions. All policy should aim to administer genetic testing more accurate probability prediction to reduce false positives which result in unnecessary, burdensome confirmation testing.

3. Genetic Counseling for Risk Assessment

Identifying the appropriate test and discerning relevant information from the results can be difficult due to gene probability and uncertainty. However, authentic, informed consent requires the individual to weigh the risks and benefits and determine that the ratio is within an acceptable range. For genetics, the number and types of risks essential to consent are still not
defined. Even healthy individuals are seeking genetic screening for disorders thereby begging the question of what risks a healthy individual should be aware of.\textsuperscript{20} Traditionally, for a clinical patient, the physical risks of a procedure are sufficient to determine that the consent process was fulfilled. Even today, there is a level of assumed trust between the provider and patient that eases the burden of communicating unrealistic risks for therapeutic intervention. In most cases, the known risks are manageable, even if additional interventions are required. However, genetic technology shifts the understanding of health and disease. Genetic counselors can assist in patient understanding of genetic testing results by aiding in pre and post-test process. Consequently, these counselors can aid in the patient’s risk assessment of testing and potential interventions.\textsuperscript{21}

The phrase “genetic counseling” is used to identify both a profession and an activity. The area of discipline was developed to address both the medical and social effects of genetic testing.\textsuperscript{22} As a profession, counselors are trained in both medicine and psychotherapy.\textsuperscript{23} However, in its practice, genetic counseling is still identifying adequate integration of psychotherapy as it requires professional ability to identify the patient’s cultural characteristics to design a plan relevant to the patient’s health behaviors.

As an action, genetic counseling focuses on genetic risk for the individual and family members, disease management, and potential reproductive options.\textsuperscript{24} Risk assessment is a critical component of genetic testing and intervention. In genetic counseling, risk assessment discussions begin with population wide data. As indicated earlier, the greater the amount of data on a condition, the more accurate probability of a risk. The analysis of genetic risk factors is heavily focused on Mendelian disorders which are caused by a single gene and have high penetrance.\textsuperscript{25} These disorders have known penetrance and physical effects. Since Mendelian disorders follow a
logical pattern of inheritance, as opposed to a de novo mutation, knowledge of one individual’s status can lead to questions of other family member’s status. However, increasingly, patients are seeking tests for non-Mendelian tests which result in complex risk assessment analysis. Pretest counseling for these conditions might include disclosure about less-well defined phenotypes, precision of rare conditions, and changes in screening panels as science develops.\textsuperscript{26}

To produce the most accurate prediction for both mendelian and non-Mendelian traits, family history is necessary. However, requesting family history for an individual patient test forces ethical issues of privacy and confidentiality as well as patient safety.\textsuperscript{27} For quality of care purposes, organizations must know their patient demographics to implement gene therapy interventions. Further, they are in a unique position when it comes to translating genetic risk and burden to a patient. While familial and population information is useful for the organization to meet needs of the community, a genetic counselor is responsible also factoring in confounding factors such as other genes, environment, and lifestyle choices and their correlation to potential patient burden of a gene therapy.\textsuperscript{28}

The genetic complexity makes determining the quality of care difficult as the expression, or lack of expression of a gene can depend on more than one gene, i.e. non-Mendelian. Only a small portion of genetic diseases are truly controlled by alleles of one gene on a chromosome, i.e. Mendelian. These are the disorders such as Huntington’s disease or cystic fibrosis. Although the gene might have been identified, research now suggests even alleles on the cystic fibrosis gene can affect the variation in expression of the gene. Further research suggests a higher frequency of a specific allele in Caucasian people. Yet, testing for this allele would not be definitive as people have cystic fibrosis with different alleles.\textsuperscript{29} For the other portion of genetic disorders, these are an expression of the gene’s relationship to the environment influences, gene-
gene interactions, and polygenic traits, traits which two or more genes contribute to the expression. Thus, as gene therapy precision increases, the task of unraveling these phenomena becomes more complicated.

To further complicate the matters, genes themselves change throughout a lifetime creating an unpredictable cofactor when calculating their expression. To maintain accurate safety data, long term follow up is required of individuals who participate in gene therapy trials. However, individuals and their data may be lost over time. For this reason, the statistics collected for populations are difficult to be determined as accurate and precise. Cancer statistics are evidence that the predictability of expression is complicated to determine without understanding the patient’s environment. Currently, most predictable cancers are breast, colorectal, and prostate cancers. Yet, even women who have the BRCA genes which are predictive of breast cancer can be at only a 5% risk of expression.

Beyond the physical risks, genetic testing also has psychological risks which are frequently undermined in many aspects of healthcare. Unique to genetic interventions is shared data. Because genetic data is shared, the relationship between family members is more present in the consent process. Setting aside the issue of who should consent, it begs the question as to whether familial impact should be considered a risk of genetic technologies. The answer to this question might be in the competence of the counselor. Healthy individuals frequently seek genetic testing and counseling to reveal reproductive risks. The genetic counselor’s discussion about these risks could be used as a door to discuss the impact on familial relationships. However, it is not always the case that individuals are obtaining genetic testing from their healthcare providers. The value of risk assessment with a genetic counselor is becoming increasingly more valuable as direct-to-consumer testing is becoming more widely available via
the internet. Studies of direct-to-consumer testing suggest that there are no changes in the consumer’s psychological status as a result of testing despite not having had an appointment with a genetic counselor.32

Because of their complexity, genetic risk factors and risk assessment is slowly making its way into clinical practice. While some individuals report no change in their psychological status after receiving genetic testing results, there are reports of some individuals making drastic, and sometimes unnecessary lifestyle changes.33 Either situation can be the result of genetic counseling. Of course, the need for genetic counseling is another resource contributing to the complex path to making clinical genetics accessible to all patients in routine care.34 With this data becoming more accessible, question of appropriate healthcare access are quickly requiring responses and action.

II. Genetic Technologies: Helping or Harming Problems of Healthcare Access?

A hope of genetic interventions is to develop patient-specific therapies or preventative care measures. However, this hope is only possible if there is genetic technology access in clinical care settings. A fear is that genetic technologies will increase disparity and limit healthcare access. Currently, access is constrained by contextual and organizational factors. These factors influence both inequitable and equitable distribution of genetic technologies.

I. Assessing Equitable versus Equal Access

UNESCO’s Universal Declaration on the Human Genome and Human Rights states that genome science should be made available to all with regards to the dignity and human rights of each individual. Further, in the context of research on the human genome, efforts should intend to “offer relief from suffering and improve the health of individuals and humankind as a
whole.\textsuperscript{35} Based on this statement, it appears that research efforts must have a two part endpoint: the individual and humankind. This statement can have various interpretations depending on the context. Most research efforts at least minimally contribute to generalizable knowledge which will contribute to the future of science. From a clinical perspective, improving genetic technologies for individuals and the population can lead to confusion between equitable and equal healthcare access.

Equal access is often generalized by describing a situation in that all individuals have the same amount of access to a service (i.e. healthcare). Equal access must be considered in relation to need, or else it can become unjustified.\textsuperscript{36} Therefore, when discussing the need for equal access, it often is preceded by a context of two individuals with equal healthcare needs, e.g. two individuals with diabetes. The comparison is not to be confused with individual resources such as lifestyle preferences. Inequality throughout similar income groups leads to broader issues of social justice and are, perhaps, a starting point for policymakers who aim to address equality in healthcare issues. For policymaking, the effort comes with some restrictions. Logistically, to attain equal access to healthcare for all individuals is difficult if at all desirable from an organizational perspective.\textsuperscript{37} If all individuals, regardless of condition had an equal right to healthcare access, then even those without diabetes would have a right to insulin medications. To aim for equal access is often associated with limitations both on individual availability of care as well as the provider’s ability of offer appropriate treatments.

Equitable access considers the average value of health. On average, the life expectancy in the United States in 2014 was 78.8 years.\textsuperscript{38} This number varied depending on sex, race, income, and other factors. On average, a healthier society is valued more positively. However, to get to a level when all individuals have the same life expectancy would require tradeoffs.\textsuperscript{39} The literature
tends to stratify access to healthcare issues by demographics such as age, race, or gender also known as predisposing characteristics. It is evident that people of different age groups require different amounts and kinds of medical attention. However, when factors such as culture or education affect variables of access such as insurance or routine care, it is inequitable access. Equitable access is based on age or gender. While these factors may influence the type of insurance and healthcare an individual has, it does not necessarily prevent them from obtaining healthcare. This is because equitable access is assumed to distribute a fair portion based on given factors. Genetic testing’s impact on the determination of appropriate health services has yet to be tracked and assessed but is rapidly becoming a concern for the purpose of healthcare access.

Idealistically, justice in healthcare would be a situation when all individuals with a particular condition or circumstance receive the appropriate care. Public health efforts are the epitome of distributive justice efforts in medicine. Distributive justice in public health scenarios allocates healthcare resources to competing individuals based on the basic rights of every human and not just earned privileges. However, it does not suggest that individuals receive equal shares but equitable shares provided their needs in relation to others. So while individuals are all equals with regards to rights, they are not equal with respect to health needs. The concepts of equity, equality, and justice are essential when considering larger ethical issues in public health.

Genetic testing itself could result in inequitable distribution. Result variability is present depending on age, ethnicity, or heredity. Clinical care providers have used breast cancer genetic tests for more than 20 years. However, recent systematic reviews are questioning the accuracy and reliability of these tests. Tests for breast cancer have been shown to be more inaccurate for individuals under 40 years old. Further, results of African-Americans, Turkish, Iranians, or Hispanic individuals have been shown to underestimate risk of developing breast cancer.
leads to questioning the appropriateness of genetic tests for these individuals insofar as it limits the effectiveness of their care plans. Variability of the tests is further complicated by new integration of risk factors in the breast cancer testing models. Each new factor integrated into the model requires reevaluating the accuracy of the model on the intended population. For this reason, determining the accuracy and validity of the test regardless of contextual factors is difficult.

The difficulty of determining accuracy and validity leads to the second issue with inequities which is implementation. Implementation, especially as far as breast cancer prediction is concerned, is based on patient information including family history. Family history is considered the largest indicator of risk factor behind age and gender for cancer and other chronic conditions. Accurate reports of family history are inhibited on the part of both the provider and patient. From a provider standpoint, there is no definition of family history to guide accurate collection of data. From the patient perspective, demographics such as socioeconomics and culture influence their ability to accurately report family history. Reporting also varies between types of cancers such as breast, prostate, and leukemia. Based on genetic testing limitations by variability and implementation, it appears inevitable that some populations are underrepresented when it comes to genetic testing. Therefore, while the genetic testing is intended to create equity in availability, it may inadvertently create inequity if risk assessment is inaccurate.

2. Organizational Perspectives on Clinical Implementation

Efforts to access and improve access to healthcare must consider the contextual factors such as ethnicity and environment but also the healthcare organization and community. For instance, major organizational factors that influence healthcare access are conditions which promote individual use, ease of use, provider awareness of medical conditions requiring
treatment. Health policy, either organizational or legislative, affect pricing, markets, and overall clinical resources. Structurally, organizations are capable of adjusting the organizational factors to maximize accessibility. Issues such as readmission or bed capacity all contribute to an organization’s ability to provide healthcare access to patients. These factors influence the probability that the benefits will help the majority population’s overall health and wellbeing.

An effective application of genomic science has the potential to reduce disparity between individuals. The ability is dependent upon the availability of technologies to improve health outcomes and the organization’s ability to integrate the technology into regular care plans. In the United States where healthcare is privatized and paid for either by insurance or the patient, availability is often associated with costs of treatment. Access to pharmaceutical drugs can be costly and therefore, considered limiting healthcare access. A commonly used example is the price of cancer therapies which can cost over $10,000 per month. Some countries like the United Kingdom and New Zealand, fully subsidize the cost of certain cancer therapies, so they are accessible to individuals who have genetic preconditions. Financial differences are contextual but disable individuals from receiving care as a result but are beyond the scope of the healthcare organization insofar as coverage is an issue of insurance.

Not only is there a financial barrier to accessing care but there is also one to developing treatment. The financial incentives to create biomarkers as diagnostic tools are lacking in comparison to novel pharmaceutical drugs. Even the pathways to becoming clinically valid tests for genetic diagnosis and preventative measures is lacking. From a pharmacology perspective, the pathway from research to clinical access is relatively clear. Drugs are tested in Phases I-IV. The FDA regulates each phase. Once sufficient data is available, the drug is approved, marketable, capable of becoming integrated into clinical care. However, for genetic
testing, the path is less clear. Most of the research on genetic testing is done in adult chronic conditions. However, a major challenge for genetics is the widespread small studies and the inability to duplicate results by making it harder to carry over genetic testing into clinical care.52

While some financial barriers are beyond the organization’s control, hospitals can modify their organizational features such as the processes of their healthcare delivery. Specific community hospitals might be tailored to better serve such populations. The unique differences between hospitals and healthcare organizations delivery models represent their values.53 Specifically, standardization of processes such as hand washing or pre-surgical checklists contribute to unifying the organization to deliver a systematic product, i.e. healthcare. While these standardizations are focused on safety, the issues of family history and changing genetic models briefly introduce provider setbacks for implementing genetic technologies and therefore, access.54 Primary care providers must deliver care with the aim to prevent disease through early signs. Further complicating the ability to deliver care are the avenues opening because of genetic testing and intervention. Providers must maintain their aims while navigating and making appropriate referrals for patients.55 Appropriate clinical referrals assist in the high quality of care as it connects patients with the right clinician for faster intervention. To make these referrals, there must first be an understanding of the biomarkers of genetic conditions.

From a clinical perspective, access to genetic technologies is dependent upon the provider’s communication and ability to manage information. Patients may be misled or misunderstand information about their risk factors as a result of seeking unreliable sources such as news media or the internet.56 Patients may not seek professional help until they have developed their attitude toward genetic testing. Since their personal experiences or culture often influence their attitudes, providers must have the skills to manage the patient’s personal
background while portraying accurate and appropriate information for access to genetics. This raises issues of the conflict for balancing individual understanding of genetic risks with the organizational duty to provide safety, effective care.

**b. Genetic Variability & Susceptibility**

Organizational motivation to provide cutting edge technologies to influence their ability to effectively and safely treat patients. These objectives are difficult to achieve with genetics since there are wide variability and individual susceptibility that can often not be accounted for when implementing the technologies. An inherent conflict between individuals and populations exist insofar information is shared between the two and influences treatment options.

**I. Organizational Management and Conflicts with Beneficence**

Organizations are not unfamiliar with the task of balancing individual and population rights to promote beneficence. In fact, this is an annual task for hospitals during flu season and other public health issues. For the purposes of genetics, the organizational concern for promoting beneficence is unique because of genetic technology is the broad application in clinical care.

**I. Provider’s Creativity for Promoting Beneficence with Novel Interventions**

Insofar as organizations are businesses and healthcare providers, there will be a conflict between the services provided and their decision making process. The result of this conflict is variation in the ability to promote beneficence to the patient. There are numerous examples when hospitals are in conflicts between their care and the business. Consider the example of provider flexibility. Practicing providers are granted flexibility in determining their care plan because each patient case is unique. Rarely are there procedures that do not allow for provider deviation or creativity in treatment. Cardiology is considered to be among the most standardized discipline
in the hospital. Healthcare organizations can have cutting edge technologies, specialists, and centers of focus. However, these patient appealing aspects are ineffective and in some instances dangerous without standardization and teamwork.

Increasingly healthcare providers like to find their specialty. There is an appeal to being the best at something even if it is only their niche as it makes providers different from other available options. Within this niche, the provider is capable of developing a standardization for their own practice. Standardization can increase their success rates, minimize medical error, and, as an added bonus, financially benefit the provider. Specializations are useful for patients and hospitals as they often require a team of providers to work on the particular procedure. These teams can become famous in the medical community for their low complication rates and increased experience. By increasing experience, hospitals promote beneficence throughout their organization that results in high-quality patient care.

Providers can specialize in a procedure and create their niche, but this does not necessitate that they are taking the best action for the patient. Some patients might be eligible for a less invasive and safer procedure but only be offered the invasive procedures because that is what the surgeon knows best. A pancreatic cancer patient might not always need radiation, but if they go to a provider who owns a radiation therapy machine, that is most likely going to be the treatment plan offered. Additionally contributing to patients not receiving appropriate care is a lack of standardization. The patient may not know or consider the six alternatives to treat pancreatic cancer thus, their choices are limited. Only about 10% of pancreatic cancer patients who are candidates for minimally invasive procedures are offered these. Part of this issue is because some providers might not know how to conduct these procedures (i.e. they lack
teamwork with other providers). Even among the most prestigious hospitals, there is variation in how certain conditions are treated. Often, the differences are from provider styles.\textsuperscript{60}

More invasive procedures often result in complications and therefore, prolonged and avoidable hospitalization for the patient. These are also known as medical errors. Medical errors that arise from a lack of teamwork in a hospital are most evident in Intensive Care Units (ICUs). ICUs tend to be high-stress environments where providers, especially nurses, tend to experience high moral distress. As a result of the high-stress environment, there is a high turnover rate of nurses in most ICUs. Lack of continuity of care negatively affected the teamwork throughout these units. Ultimately, patients tend to stay in these units longer when the unit lacks teamwork.\textsuperscript{61} When the patient is in the hospital for longer, more procedures are billed for, and the hospital makes more money.\textsuperscript{62} One study suggests that hospitals make about $10,000 more per surgical complication.\textsuperscript{63}

There are a number of factors which contribute to the patient’s choice in treatment options including, lack of teamwork among providers in different disciplines (ironically, because of their specializations) and lack of standardization. What is not often known by patients is that they can request a second opinion and choose their provider. Often, patients come into a hospital with a condition and perhaps a preconceived notion of how their condition should be treated. At the end of perhaps an unnecessary and invasive procedure, they are thankful to their provider for the care they received not knowing that they could have. Organizations can market their institution by having “Centers” which focus on a condition or “the best provider” for x, y, or z surgery.\textsuperscript{64} However, what is not the focus is how many of the procedures the provider does a year as compared to other institutions. An excellent cardio surgeon who performs hundreds of surgeries a year might be a horrible choice for a patient’s pancreas surgery.\textsuperscript{65}
2. Overscreen, overtreat, and overdiagnosis

With the conflicts that arise between organizations and provider standardization, organizations have begun to face issues of overscreening, overtreatment, and overdiagnosis. Screening for cancers is based on the idea that cancers with genetic markers have a consistent and traceable progression. Screening can be defined as the evaluation of asymptomatic individuals in a defined population to identify disease or assess risks. Ideally, screening should reduce the number of people who cannot be cured of their illness or condition as a result of delayed treatment intervention. Cancer screening is a common example of the value of screening. Incidence rates of cancers vary and change due to screening technologies. For cervical and colon cancer, incidences decreased. Meanwhile, for breast and prostate, incidences increased.

Despite the change in incidence rates, it does not seem that screening for cancer has had a significant change in mortality overall. The lack of change in mortality as a result of screening is due in part by the availability of effective treatments and early detection. Screening is more likely to be effective for slow growing cancers like cervical or colon. However, for faster-growing types of cancer, growth can occur in between screenings and therefore, it is ineffective. Adding perhaps unnecessary concern for screening are biopsies for pre-cancerous lesions. Upon biopsy results, providers might feel compelled to make a recommendation simply because the patient underwent a somewhat burdensome procedure. Not only to the screening biopsies for thousands of noncancerous lesions contribute to the uneasiness of patients, but it also results in millions, if not billions of dollars of unnecessary interventions. Overscreening can result in public confusion regarding the benefit of procedures.
An effect of feeling compelled to make a diagnosis can cause problems of overdiagnosis. Overdiagnosis is most harmful when it leads to invasive interventions in proportion to the diagnosis and prognosis. Additionally, it can contribute to aggressive clinical interventions such as treatment for minor problems. Part of this issue is that there is a fear among providers that lack of action would be failure to treat and ultimately result in a malpractice suit. Disease based screening (i.e. breast cancer screening) can lead to overdiagnosis leading to a decrease in effectiveness of screening. Genetic screening is difficult though because it assumes that if a marker is there (or not), that the individual has a higher probability of a condition and therefore, action might be warranted. However, returning of genetic results should not be confused with diagnosis. Genetic results are susceptible to variation, penetrance, and probability.

Among the most overdiagnosed cancer is prostate cancer. Low-grade, indolent tumors are often found among men aged 55 years and older who are screened for prostate cancer. The incidence rate has been steadily increasing over the past decade. Approximately 17% of men born between 2001 and 2003 will be diagnosed with prostate cancer at some point in their lifetime. Despite no change in grade or volume, approximately 90% of these tumors are treatment with radiation or surgery. At this point, an organizational response would be required to ensure a type of standardization to minimize unnecessary interventions. Using population level data, it is possible to individualize risk factors for different stages of screening and diagnosis and thereby, decrease overdiagnosis and, subsequently, overtreatment. Multiple longitudinal studies suggest that blood biomarkers correlate to individuals actually developing prostate cancer from a detected tumor. Thus, obtaining population data can benefit personal clinical care.
Prostate cancer is among the cancers where genetic markers can identify risks of developing the disease.\textsuperscript{75} While genetic markers are used to determine chemotherapy treatments, they are often not used during screening for diagnosis. However, markers could be used to minimize diagnosis and unnecessary interventions. The introduction of genetic screening then begs the question as to whether this will help or harm problems of overscreening, overdiagnosis, and overtreatment. Much of the literature on genetic screening appears to focus on newborn genetic screening. In such screening, newborns can be tested for a variety of diseases from blood disorders such as sickle cell to more severe conditions such as Trisomy 21, also known as Down syndrome.\textsuperscript{76} However, for purposes of primary care later in life, genetic screening has not yet been widely implemented into routine practice.

Despite the common practice of obtaining family history, only a few conditions, such as breast and ovarian cancer, are triggers for recommending genetic screening.\textsuperscript{77} The markers of these conditions are the result of decades worth of epidemiological studies. Over time, genetic screening will need to address both the depth of information that becomes available as well as the ambiguity of results.\textsuperscript{78} For the purposes of screening, diagnosis, and treatment, genetic information may be useful to way to reassess the purposes of screening. In other words, perhaps the definition of screening can be expanded to become more than an early detection tool. Longitudinal applications could be to make genetic screening as common as a physical examination. To implement effective and routine genetic screening, as exemplified by breast and ovarian screening, a prolonged analysis of epidemiological studies is required.

3. Fact Checking Medical Error: Root Cause Analysis

Issues of overscreening, overtreating, and overdiagnosis can lead to greater incidences of medical error simply by the fact that there is a higher rate of medical encounters. The term
“medical error” has a span of characteristics which make up its definition. It generally consists of either an act of omission, an error of execution, planning, or a deviation from the plan. These errors can occur either at the individual patient level or are larger system level issues due to a breakdown in a process or standard of care. In 2013, one study of medical error suggested that the rate was about 1.13% of deaths were a result of medical error. This would mean that approximately 400,000 deaths a year were caused by medical error. In 2016, Johns Hopkins Medicine concluded that medical error was the third leading cause of death in the United States.

Organizations have responded to medical error reports by root cause analysis (RCA). The Department of Veterans Affairs developed the process as part of their patient safety improvement initiative. The method has become so widely accepted that it is the preferred method of systematic analysis for hospitals by Joint Commission. Essentially, the process consists of three parts: what happened? Why did it happen?, and What can be done to prevent it from occurring again? Often, the analysis is used to identify one cause of the problem. Some changes are as simple as different packages or labels, moving drugs to a different shelf, or creating checklists. Common solutions to RCA incidents are re-education or rewriting policies. A higher level overview of multiple RCAs can help organizations identify system-wide issues.

An RCA review might prove to be difficult with regards to genetics. As noted earlier, genetic testing is still in its early stages and can be inaccurate or provide false-positives. Inappropriate or incorrect test orders has been identified as a frequent issue resulting in patient burden. Thus, organizations must be cautious of their use of genetic testing to avoid medical errors from misdiagnosis via genetic testing. Misdiagnosis from genetic screening is already reported in cases of pre-implantation genetic diagnosis. In these cases, genetic misdiagnosis can
be about 3 in 746 pregnancies for X-autosome translocation which can result in congenital abnormalities, mental retardation, and miscarriages. Once accurately diagnosed, genetic therapy technologies will be unique because of the long-term follow-up component. As genetic interventions become more common in clinical care, it will be critical for providers, educated in genetic medicine, to follow-up with patients and mitigate medical error.

Other clinical genetics issues identified by professionals include unanticipated adverse outcomes and inappropriate follow-up. Some issues may not be reported as medical error or may not even involve the genetic diagnosis but rather are caused by professionals untrained in genetics. In these cases, organizations may not have to reevaluate the safety of a test but rather, the education of their clinicians and standards of those who are involved in clinical genetics. For instance, responses to mitigate risk might include genetic counselor participation as a requirement for the return of genetics results.

Once implemented, a follow-up question for the RCA process is whether the risks of recurrence has been reduced by the changes. There is limited information about reevaluation of RCA in hospitals and organizations. It is insufficient and poor stewardship to identify a problem and implement a potential solution without evaluating the solution. Failure to reassess the risks would result in insufficient patient safety as well as waste hospital resources. RCA for genetics may become complex as both individual and population participation is critical to patient safety. This relationship expands the possible causes of an event and the solutions needed to effectively reduce risk reoccurrence.
II. Population Health versus Patient Risk

As exemplified by efforts for genetic screening and the individual’s risk of consenting to uncertainty, it seems that benefits from genetics originate from the individual. While the individual bears the burden of risks, the benefits are often delayed if ever available for their own clinical care. Therefore, beneficence for genetic implementation becomes a balancing act between population health and individual risk.

1. The Principle of Solidarity for Managing Population Benefit and Patient Risk Conflicts

The UNESCO Declaration principles are addressed to all persons and, for the most part, universally applicable to protect human rights. UNESCO’s Article 13: Solidarity and Cooperation calls for universal participation in practice of the principles of human rights. This article suggests solidarity is a prerequisite for cooperation. On the international level, this is limited by the freedom expressed within and by states. Thus, the higher good of Article 13 then is accessible freedom through global solidarity and cooperation identified by the individual. The individuals is the most primary and essential components of solidarity for, as argued, individuals comprise the societies for solidarity. The societies then establish the global communities at which the UNESCO Declaration most widely rings. Freedoms of an individual are dependent upon the neighboring individual’s respect for rights. More often, this is interpreted as restricting of the neighboring individual. However, the individual does not live in isolation and is inevitably affected by another’s choices.

Based on the traditional understanding, solidarity is only possible through the variation of cultures and the freedom to cooperate to obtain a common end. Theoretically speaking, solidarity should fill the voids of unjustified law against human rights. Individuals should seek the higher good regardless of backgrounds or other differences. That being said, solidarity does not
require equality. While Article 13 is focused towards to a common end, this does not necessitate participants to come from the same platform. An equal platform is exceedingly difficult to establish and maintain. Instead, the means to achieve the common ends need only be consistent with sustainability and availability relative to the state.\textsuperscript{92}

Considering UNESCO’s understanding of solidarity, the principle is only possible in cultures which acknowledge a common end, such as public health or the right to healthcare. From a theoretical standpoint, solidarity between the public and private entities should overlap in a manner which fills any potential voids of either functioning exclusively. On a more applied level, individuals must respect this common end regardless of differences in backgrounds or health needs.\textsuperscript{93} Solidarity does not require equality. The principle is focused on a common end but not necessarily a common platform. The common end must maximize improving citizen’s health while being conscious of sustainable healthcare practices.\textsuperscript{94}

Also, the principle of solidarity applied to genetics exemplifies the interdependency between individuals to obtain freedom from disease. For this reason, solidarity and cooperation are often associated with social responsibility. Since humans are social beings, the majority participation is required to achieve any level of effective genetic technology implementation. However, due to the interdependency, there are also inherent limitations of freedom. At its essence, effective and safe genetic technology cannot be successfully achieved if there are not limitations on another’s freedoms for the greater good.\textsuperscript{95} Interestingly, the principle of cooperation lends itself to the individual being the essential component for solidarity.\textsuperscript{96}

Considering the interdependence, solidarity in genetics requires a level of implicit trust across the system. When applied to genetics, this trust is among other individuals as well as the organization. Thus, it is essential for the organizational ethics framework’s success that trust is
woven throughout clinical care. In a sense, the solidarity is possible because of the nature of the unique system. It is a collaborative effort between the distinct groups of private and public funders who are citizens of Germany but have various motivations. The sense of belonging is essential to ensure solidarity and develop trust within the system. Importantly, it is not essential that all individuals in the system have the same values or morals. However, it is crucial that individuals participate in the model in the appropriate manner such as to be employed or pay taxes. These regulations imposed by the central government are considered an essential to the government’s role to promote health and development.

2. Preventing Conflicts of Interests for Quality of Care

As it has been presented thus far, there conflicts of interest manifest between the patient and provider. At the grander level of the organization, the organization’s and other institutions develop standards which create the climate in which the provider-patient relationship is expected to function. Considering the organization establishes the ethical climate with their standards, then limiting conflicts of interests for quality of care purposes requires organization action. Three areas which the organization could focus on to reduce conflicts of interest are specifying medical recommendations, determine appropriate patient demographics, and develop a relevant policy to the organizational climate.

There is something to be said for the business approach to healthcare to balance supply and demand to maximize profit margins. There is something similar to be said from the clinical perspective to maximize quality of care. As previously mentioned, the standard of care is the baseline level of care to be achieved in an organization. There are certainly instances when it might be in the best interest of the patient to actually limit the recommended amount of care.
While providers have an obligation to inform patients about appropriate treatment options, this does not imply that providers have a duty to inform about all treatment options for not all options are appropriate for a patient’s condition. In fact, instances such as when providers recommend non-medically relevant options, are when conflicts arise as the quality received is or becomes less than the acceptable medical standard. Currently, patients and their families are becoming unwilling to discontinue these treatments for various motives and organizations are being forced to continue the treatment against appropriate medical parameters.\textsuperscript{100}

From an organizational perspective, there are a limited amount of resources available for patients thus, creating a limited supply for treatments. To justly delegate the available resources, organizations are obligated to determine appropriate and most beneficial uses of the resources. Although the organizations are justified to have ties to medical research institutions such as pharmaceutical and/or technology companies this does not suggest that all patient cases will be appropriate for such care plans. The plan designed and influenced by the organization should fit the patient, not the other way around.\textsuperscript{101} Of course, medical recommendations should not be limited without consideration to the patient population their selves. Another business approach to achieving quality of care is to know the consumer. If the organization is intimately related to the community as moral agency suggests, then in order to establish trust and maintain quality of care, the organization must be aware of the community’s dynamic demographics.\textsuperscript{102} The provider’s right to not offer treatments should be medically based. Likewise, limiting medical recommendations to improve quality of care should also be medically supported.\textsuperscript{103}

Often associated with geography, organization are tailored to fit their surrounding community’s needs, however large that might be determined based on the demand. Reasonable interchange and multifunction of resources for patient population. Access to the appropriate
providers for the patient by traveling to more reputable hospitals. This is a patient choice and more observable in extreme situations with chronic or terminal diseases. Demographics affect the quality of care a patient can receive. When determining the appropriate demographics, the organization must be cautious to not unintentionally dismiss or exclude a cohort. Certainly, the organization, as a functioning business has to address the areas with the largest concerns for sustainable returns. In a sense, by determining community demographics for quality of care, there is an internal triage taking place to ensure the greatest concerns are addressed. Exclusion specifically related to demographics, by whatever motive, is perhaps one of the greatest hesitations of genetic advances.

Demographics are important to determine more accurate genetic risks for populations and individuals. However, patients do not always understand the distinction between risks and burdens. People are generally more accepting of voluntary risks than if they find their self-experiencing the burdens of the risk involuntarily. Thus, accurate risk burden assessment is an issue of informed consent and quality of care. One approach to improve quality of care, the organization should be capable to convey appropriate translation of risk and burden to patients in order that they are in a position to voluntarily take burdens of risks. Risk is a consequence of actions and the likelihood of the occurrence. The consequences are due to various environmental forces and lifestyle choices. Typically, risks are expressed in statistics or charts calculated in scales of large populations. There are two types of risk, perceived and actual risk. Perceived risk is the potential for a patient given the demographics. Actual risk is specific to the patient given their lifestyle choices and cooperation with medical intervention. Breast cancer screening might not consider the patient’s lifestyle factors and therefore is perceived risk. The qualitative evaluation process contributes to the patient experience.
When considering the burden of a disorder, it is largely relative to the individual patient. Generally, the burden is subjective to the individual patient’s previous life experiences and the availability of resources to help the individual manage the risks. Chances are, the burden is greater if there are less resources available for the individual. Because burden relies on a patient’s suffering is subjective to the individual’s experiences, a healthcare professional must understand the patient’s paradigms to understand what parameters of suffering are acceptable. Anyone in healthcare could speak of an experience when a person seemed to be suffering from causes greater than medicine’s reach.108

3. Approaching Issues of Just Healthcare Access for Genetics

The United States outspends all other nations on healthcare yet, consistent high quality care is not observed throughout the country. American populations tend to hope that increased technology use will resolve this discrepancy and close the disparity gap. Genetic technologies shed light on the complexity of healthcare access and quality care for organizational ethics. Generally speaking, genetics is objective information intended to be used to promote health through preventative or direct therapeutic methods. These advances present the opportunity to readdress understandings population health and disease in a population.109 Genetic advances occur within the context of healthcare organizations and are influenced by the professional and individual applications. Therefore, the implementation of genetic technologies should not go considered in isolation. Rather, the understanding health or disease should be considered with respect to the population or individual’s environmental factors including their culture.110

Genetic manipulation such as therapeutic interventions could be argued as highly western understanding of health insofar as, it is greatly dependent on the objective medical evidence and can lead reduction of the human to their biological parts. Furthermore, genetic screening or
diagnosis could result in unintentional psychological distress for an individual and their relatives.\textsuperscript{111} It is already being observed that in vitro fertilization methods are available to a limited few who have the resources to afford the extensive intervention.\textsuperscript{112} For these reasons, genetics offers insight into future ethical issues of biotechnology and the influence cultural interpretations can have on healthcare. These problems need to be addressed before genetic results contribute to healthcare professional biases and healthcare disparities which are already so vastly apparent in the United States.\textsuperscript{113}

It has already been discussed that part of the issue in healthcare disparity is a lack of healthcare access. Minority populations tend to receive lower quality care which often worsens the situation. Genetic technologies offer new options to manage care plans and achieve patient satisfaction. Yet, there remains to be a significant development in effective genetic technologies for major diseases such as cancer and cardiovascular disease. Furthermore, investments in research are put towards these diseases which, if proven to be effective, can have the largest impact. Meanwhile, orphan diseases which affect only a small percentage of the population are not receiving significant investments for research or are only researched by an unexpected result from a larger research project.\textsuperscript{114} In order to do this, cultural humility is required by the provider. Pain is often influenced by cultural perception whereas some cultures seek to bear the pain and others try to avoid it all together.\textsuperscript{115} Current research movements in healthcare suggest there is a war against suffering and specifically, death.

Since health directly relates to an individual’s ability to participate in society and express their autonomy, just healthcare access is a human rights and social justice issue. Currently, the United States is attempting to reorganize the healthcare system to allow greater access with particular attention to minority or marginalized populations.\textsuperscript{116} More appropriate resource
allocation is one proposed method to achieve more widespread healthcare access. Genetics will pose greater questions as to the access of technologies and healthcare particularly in regard to privacy and confidentiality issues. In a capitalistic and autonomous society such as the United States, it seems unjust to share genetic information as it might be greater privacy risk for an individual than benefit. Thus, it is particularly difficult to ask this of a person who is already most vulnerable in the healthcare system to sacrifice their rights for the sake of another’s wellbeing even if it is ethically justified.

Potentially unequal distribution of genetic technologies should not deter healthcare organizations from pursuing research or integrating the technology into their practice. It does suggest that there are precautions of pursuing genetic technologies which, if not addressed, can have an undue burden on minority populations. For these reasons, appropriate treatment options should be initiated as soon as possible so that the patients can reasonably communicate and plan for their disease progression. It would be unethical if these medical interventions only continued to marginalize minority patients. For this reason, it is necessary that with the shift to genetic technologies, there be humility to just healthcare access as to not contribute to the healthcare disparities. A flexible organizational ethics framework with regard to genetics will require an exchange between individuals and the community to protect each individual although sometimes the exchange might appear one sided.

There is little consensus on a resolution to healthcare access in the United States. However, it can be agreed upon that access to healthcare becomes a key component both for individual flourishing and for thriving communities. However, while research is typically performed with consideration for public health, clinical medicine typically deals with the individual patient. Implementation of genetics in clinical practices requires organizations to
acknowledge that at least this component of medicine will require joint participation for success.\textsuperscript{119} There are remain clinical reasons for providers to deny treatment options which are unrelated to the patient’s condition and therefore supporting the need for professional standards and ethics.\textsuperscript{120}

\textbf{c. Limits & Quality of Care}

Considering organizational issues of beneficence toward the individual specifically and the hopes for population benefits, a compromise between limits of available technology to maintain quality of care must be made. Specifically, this compromise will address patient safety and standard of care measures.

\textit{I. Patient Safety & Novel Technologies}

Healthcare safety is becoming an increasingly controversial topic because of lack of transparency and regulation throughout the hospital. Medical errors occur more frequently than anyone is willing to admit. The history and hype of genetic technologies make the future implementation even more scrutinized than other technologies. Specifically, synthetic biology has been highly criticized among genetic technologies for the development processes. Therefore, when implementing the technologies, organizations must have the utmost attention to detail when considering patient safety due to genetic variability.

\textit{1. Drawing a Crooked Line in the Sand: Knowing when the Enough is Enough}

The history of medicine is filled with examples of events when the pursuit for a cure caused more harm than benefit. Consider the lobotomy to cure mental illness or prescribing thalidomide for anxiety and insomnia.\textsuperscript{121} To think that medicine has progressed to the point where such grave harm is almost entirely avoided is unrealistic. This can be a difficult task for
genetic technology as there is already a stigma regarding gene therapies and the lasting effects on genetic variability. Specifically, there is concern that therapies which consist of synthetic biology blur the line between patient safety and scientific curiosity. Thus, to implement genetic technologies, organizations are obligated to ensure that innovative progress clinical care while maintaining patient safety.

Synthetic biology is the discipline of modifying an organism’s behavior to perform a specified task. The terms “nature” and “natural” often arise in discussions about synthetic biology. Critics argue synthetic biology will devalue nature and destroy the natural environment.\(^1\) This argument is based on unjustified predictions for, is a limited understanding of what is meant when using the terms “nature” and “natural.” Therefore, the ambiguity of “nature” and “natural” enable science to proceed forward with synthetic biology research.\(^2\) However, defining characteristics of nature is similar to defining characteristics of human beings. Nature is adaptable throughout time and space. The nature of an environment in the desert is not the nature found in the Arctic. Each area’s characteristics of nature are unique. By being unique, those elements that are not natural or native to the area are thereby, invasive. Yet, the invasive species can also be part of nature. Therefore, there is a fundamental constant which defines nature. At the same time, there are also observations which suggest nature is sacred or a part of the culture. Thus, one approach to defining the terms is to consider the perspective from which they are being defined. Nature is observed by both science and theology to determine its true characteristics. Both disciplines arrive at similar observations which recognize nature’s mystery. Yet, both disciplines can have different interpretations of these observations.\(^3\)

Theology’s perspective of nature leans more towards its awe and sacredness of nature. Typically, the closer an individual can come to nature the more apt the individual is to lead a
moral life because of nature’s relationship to God. The limitation of this interpretation though is that moral actions cannot be drawn from descriptive observations of nature. A metaphysical understanding of nature is necessary to extract moral guidelines. This limit presents difficulties when applying the theological perspective to synthetic biology as theology interpretations vary among individuals. The scientific interpretation of nature highlights the importance of nature’s adaptability. Nature’s characteristics are highlighted by whatever is most useful for the society at a specific time. Thus, nature’s definition can adapt both longitudinally, across time, and latitudinal, across cultures. This perspective is more applicable when it comes to considerations for synthetic biology. With adaptability allows for the opportunity of human capability. With each boundary stressed, new human capabilities develop a more knowledge for a different understanding of nature.

Darwin’s finches are an example of nature’s adaptability. Charles Darwin was a naturalist who is famous for his theory of evolution. In his research, Darwin noticed a pattern of different beaks in the population. This pattern was a correlation to the type of nuts and seeds available in the environment at the time. Darwin concluded, the birds with the appropriate beak for the kind of seeds available in the season, were the birds which were more likely to mate and survive. The finches’ anatomical characteristics were dependent upon nature. From this analysis of nature, there is a reduction from the awe of nature to cause and effect. Therefore, theology and science appear to be in conflict to define nature. The ambiguity of natural leads to a fear that science through synthetic biology will adopt the reductionist philosophy which reduces the awe of nature to biology and physics. This does not necessarily constitute reduced value in life. Rather, the reductionist perspective moves the mystery of life into the human capabilities of understanding.
Synthetic biology technologies allow for the creation of species synthesizing proteins. This method is often compared to the concept of using Lego’s to create new structures. The foundation remains the same, but the creation can often be a novel idea. Unlike the finches which adapted based on natural selection and environment, the organism is intentionally manipulated to fit an environment. This concept suggests humans are now manufacturing a species purpose. With this new capability, it appears that evolution can be dictated by humans. Perhaps an even more perplexing concept is the ability to copy other life forms. These capabilities foster questions as to the intrinsic value of life. Similar to the inconsistency of nature’s definition, there is an inability to define the characteristics of life. Some characteristics could include a germ line, independence, ability to react and interact with an environment. These criteria though suggest there is a boundary between the individual organism and another object. Unfortunately for the reductionist, this boundary is often hard to find. Furthermore, an organism can continue to change itself and react, yet there is an intrinsic value which constitutes that organism and maintains its identity. Therefore, the identity of the organism lies beyond its physical characteristics.

Even having an understanding of these characteristics, there still remains to be distinct clarity on the intrinsic value of the organisms. Higher levels of life cannot simply be manufactured in a lab as if it were a Lego car. Instead, there is a necessary set of conditions to be brought together to create the new organism with a potential of higher cognition. In the event that a novel organism is developed within a lab, this organism would be significant because it would have been unable to come into existence without the use of science. While reductionism can promote scientific creativity, the philosophy should not overshadow the value of life. Synthetic biology science does not consist of the capability to recreate the mystery of life.
in a lab. A reductionist perspective is a practical approach to develop research questions and provide empirical evidence of life characteristics. This perspective could actually promote a greater appreciation for life.\textsuperscript{134}

2. The Intention of Synthetic Biology: Enhancement vs. Therapeutic

The intention of synthetic biology provides an approach to overcome the reductionist argument. Synthetic biology has the potential to be interpreted as enhancement and/or therapeutic technology. Neither of these approaches suggests synthetic biology is intrinsically wrong. Two frameworks used to highlight this point are the top-down model and bottom-up approach to developing an understanding of synthetic biology. Therapeutic synthetic biology addresses a problem, determines the mechanism, and attempts to correct the problem by readjusting the mechanism.\textsuperscript{135} This model for determining solutions is a “top-down” model. Thus, synthetic biology is mimicking or recreating processes observed in nature. This approach to resolving a problem is not novel and in fact, has already been proven to be successful. While the synthetic biology solution is not novel to nature, the solution may be novel to science and even therapeutic technologies.\textsuperscript{136}

Therapeutic technologies have already attempted to recreate natural processes for human benefit. Take vaccinations as an example. They are a dead or weakened form of an infectious organism that is used to help the body build up an immunity.\textsuperscript{137} Biomedical technology has been able to successfully manipulate the natural biology for preventative measures. This is a similar concept that is being applied for therapeutic synthetic biology. While there are aspects of the human which were extracted from context and reduced to biology, the intention is to maintain prevent disease and maintain health.\textsuperscript{138} More commonly, the perception about manipulating biology is that humans are progressing.\textsuperscript{139} The intention of human progress leads to arguments
that synthetic biology is a form of enhancement. For the sake of the argument, let enhancement be broadly defined as a procedure aimed to increase quality of life or develop new traits. Some critics may consider Alzheimer’s treatments enhancement because it uses technology to manipulate biological processes. Even if this is true, this does not necessitate synthetic biology is immoral or wrong.

A practical application of therapeutic synthetic biology is potential to treat Alzheimer’s disease. In this treatment, scientists would be capable of administering synthetic biology to destroy amyloid-beta plaques which are cause for brain deterioration in these patients. The potential for this treatment is significant as the individual could be temporarily relieved of the burdens of Alzheimer’s. While the treatment might not cure or extend the individual’s life, the treatment could provide quality of life in aging. A major concern for therapeutic synthetic biology is the possibility of harming germ lines. At the current stage of synthetic biology research, this fear is an unreasonable prediction as there is limited significant evidence to support this concern. Therefore, this concern is not significant enough to discontinue pursuit of therapeutic synthetic biology.

In contrast to the “top-down” model, the “bottom-up” model is used to develop enhancement technologies would be to create novel life forms. Again, because of the ambiguity of nature’s characteristics, the boundary for a novel life form is difficult to determine. Subsequently, the limit for enhancement then is also hard to define. Typically, the bottom-up method suggests enhancement technologies would intend to increase experience beyond the average. This criterion though is insufficient as current, approved, technologies give humans experience beyond average. Take, for example, a doctor who uses an MRI to gather images of a
tumor’s progression. This could be defined as an above average experience. However, few would argue against the method because of its benefits for diagnosing and treating tumors.\textsuperscript{144}

Considering that approved technologies increase human experience, then there is an infinite continuum for enhancement technologies and therefore, an undefined line of unjustified enhancement. Currently with regards to technology, if the intention is to enhance an individual beyond necessity, then the enhancement is unjustified. Insofar as an organization is obligated to consider stewardship of their clinical care, then they are responsible for determining the type of synthetic biology is unnecessary.\textsuperscript{145} If so, perhaps the resources could be better used to resolve inequality of health issues. A limit on unjustified enhancement does not imply that because there is inequality in society that other parts of society are wrong at progressing. An organization is justified limits on technology highlight the need for an organizational framework to guide the process of determining where a treatment falls on the enhancement continuum.\textsuperscript{146}

Injustice in technology relates back to the availability of therapeutic interventions. If an individual does not receive a standard therapy within the society, then he is a victim of injustice. However, this discrepancy between societies does not imply that enhancements are immoral. Progress toward enhancement technology can help promote creativity in scientific advances. The “bottom-up” model for designing synthetic biology implies progress is essentially limitless.\textsuperscript{147} The desire for progress and creativity are, as mentioned, natural human characteristics. Either model requires organizational oversight to ensure the clinical technology fulfills the organization’s mission, limits conflicts, and maintains a high standard for patient safety.\textsuperscript{148}

3. \textit{Prolonging Life and “Conquering” Lou Gehrig’s: Cell Therapy Intervention}

It is human nature to seek a solution or cure for the disease. Amyotrophic Lateral Sclerosis, more commonly known as ALS, is no exception. As mentioned, the patients can
choose to use medications in attempts to prolong their life while seeking to relieve their suffering. Most prominent and contemporary direction for ALS intervention is cell therapies. Many of these therapies are still in clinical trial phases. In 2013, of the 1800 gene therapy clinical trials, about 360 were being done for specifically for neurological diseases. The mechanism of action behind the trials and availability of technology is a useful example of the need for organizations to compromise between conflicts and consent for clinical care purposes.

Around August 2014, ALS took the focus in social media and political movements support that the limited treatment options for ALS are a failure for medicine, science, and social equality. If the secular understanding of suffering is adopted, then ALS is the worst suffering because the individual is cognitively aware of their degeneration yet, still, loses their autonomy. Regarding end of life care, there is an underlying desire to either avoid suffering and to minimize the patient’s cognitive awareness of experiencing suffering. Current research movements in healthcare suggest there is a war against suffering and specifically, death. For this reason, continuing to “fight” against ALS is not uncommon among the public. In fact, continuing aggressive care plans can contribute to the individual’s total well being. As the voice for physician-assisted suicide gets louder, it is almost counterproductive to the fight against ALS.

Research suggests there is only one intervention clinically supported to delay death from ALS. Moreover, even that intervention prolongs the process by an average of three months. Patients with no preventative treatment options and incurable disease are likely more willing to experience higher risks in cell therapy trials. One study even had patients pay to participate in the study. There are few interventions which have been observed to have efficacy. Among the most promising cell therapy intervention for ALS patients are mesenchymal stem cells (MSCs)
which derive from blood or bone marrow. MSCs have been shown to have potential for diseases similar to ALS such as multiple sclerosis.\textsuperscript{153}

There are two approaches to stem cell application for ALS patients: replacement and protection. Replacement therapy would require the patient to have motor neurons replaced in the spinal cord. Using undifferentiated cells such as embryonic stem cells has resulted in the transplanted motor neuron’s ability to functionally develop axon terminals necessary for neuron function. However, the transplantation approach comes with difficulties. There is little support of complete differentiation of these cells in the research. Additionally, growing motor neurons as long as the spinal cord has proven to be difficult. As a result, the replacement therapy has little efficacy for the patient.\textsuperscript{154}

Continuing aggressive care plans when a prognosis seems so definitive can develop to a complicated situation. The plan would require providers to offer a great effort to understand the true nature of the patient’s total suffering. It is well documented and observed that many ALS patients suffer from psychological distress. Being a part of the scientific progress, even if not effective for their symptoms should be considered a means of PCE. To pursue aggressive treatment can offer the patient a sense of relief and control of their condition. Therefore, although it might not be physically beneficial, from the perspective of PCE, aggressive care might be mentally or emotionally beneficial to relieve a patient’s suffering. The aggressive treatments are a therapy for the patient on a level distinct from the biology.\textsuperscript{155}

When care is continued at end of life, there tends to be a natural narrow focus on the specific points of disease. Interestingly, in the fight against ALS, the narrow focus might be beneficial for medicine and the fight to win the battle. Since there is no definitive pathophysiology for the disease, it could be useful to highlight the distinct symptoms and
characteristics of the particular patient’s condition. For ALS patients though, continuing to pursue aggressive options can contribute to the sense of community and battle against the disease, thus, providing an alternative form of palliative care.\textsuperscript{156}

Simply because a patient is diagnosed with ALS, a terminal illness, does not necessitate that they are in end of life stages. The desire to continue aggressive treatment for ALS is not an unreasonable request.\textsuperscript{157} One motivator for people to consider physician-assisted suicide at end of life is a lack of autonomy. Ethically then, to limit a patient’s treatment plan only to provide palliative care would be no better at respecting autonomy than opting for physician-assisted suicide. It should be recognized though that the intention is not to avoid death through dependency on medicine. However, the availability to choose from options and attempt to seek continued aggressive care should not be removed simply because of a patient’s diagnosis and prognosis.\textsuperscript{158}

There are still clinical reasons for providers to deny treatment options which are unrelated to the patient’s condition. ALS is no exception to limiting care by means of compassion. For this reason, appropriate end of life planning should be initiated early on, so the patient has reasonable expectations of the disease timeline. The patient then could designate earlier what points in the disease progression might be unbearable suffering. As a result, the patient can better balance their aggressive care plans and maintain patient safety, while coping with the medical realities of their ALS.\textsuperscript{159}

\textbf{II. Standards of Care and Genetics}

Standard of care for medicine can vary but is consistent when considering safety and efficacy as well as patient preference. There is yet to be an established standard of care for
genetic technologies in clinical care for a variety of reasons. Therefore, it is the organization’s obligation to address this issue. Further, the standard of care should be established having considered the limits of care for the protection of consent and prevent conflicts of interest in care between patients and the greater population’s access to genetic technology. A compromise between the issues of individual consent and population conflicts will manifest in the form of standards of care for genetics.

1. Defining the Limits of Care

A healthcare organization is obligated to determine its identity which includes boundaries as a moral agent. Identifying where therapies are medically appropriate and inappropriate for specific patients and the public as a means to protect the organization’s ethical standards. The limits of care can be defined from the patient or clinical perspective. Ultimately, the organization determines the standard of care for specific patients which contributes to the establishment of the ethical climate in the organization. An organization is not sustainable if their providers are obligated to treat patients endlessly. This would cause issues of equity. Certainly, the provider has the right not to treat patients. This right is justified by either patient safety or a provider’s professional standards. The professional standards can include his individual moral agency independent of an organization such as his professional oath. Issues which could be argued as “moral risk” from the provider’s perspective, are a justified boundary to define the provider’s right to refuse to treat.160

The other approach to justifying the provider’s right to refusal would be supported by the patient’s condition or medical evidence. There are some instances when a provider might refuse to offer treatment if he finds the option no longer beneficial for the patient’s condition. This circumstance must be rooted solely in the patient’s condition for it to be justified and avoid
negligent situations. From an organizational perspective, this action would concern the appropriate use of resources for patients. By defining boundaries for providers, the organization also protects the community’s resources.\textsuperscript{161}

At the extreme end of the right for provider refusal, there are instances when a provider might be in conflict to provide services which are legal and standard care for what he believes to be medically justified reasons. Therefore, from an organizational perspective, the organization is morally obligated to ensure the authenticity and justification of any consistent refusals for the provider to treat. Additionally, to maintain trust with the public community, the organization is to be able to provide the services through other means. An organization’s collective actions give the total value of the institution. This is true be it a provider offer a service or not which is consistent with the organization’s mission.\textsuperscript{162}

From the legal perspective, patients have the right to access legal medical care. To not provide these treatments and procedures when medically appropriate can be deemed negligence on the part of the organization and providing providers. If a treatment is medically relevant, offered to a patient, and available to them, the patient has the right to receive this treatment insofar as the patient consents.\textsuperscript{163} As a result, legal standards might force upon the organization to care for a patient against the organization’s established standards and a provider’s beliefs. These standards ensure the dependency of collective medical practices by providers. So if a organization was unwilling to provide treatment for a patient who was unable to be transferred into another’s care, it might be legally obligated to care for that patient to uphold organization and provider standards of care.\textsuperscript{164}

There are unsustainable limits to the standard of reasonably available and access to medical care. Principle of justice supports that all individuals maintain the right to autonomy and
medical access. However, not all patients have insurance to cover the cost of medical care. In these cases, the law has established that organizations are legally obligated to provide services for these individuals in emergency situations. Often what is observed with uninsured individuals is the use of emergency services as a substitute for their primary care or as a last resort when their condition deteriorates beyond standard care measures. The patient’s access is provided but is not always truly sustainable from either parties’ experience.

A balance between the provider’s refusal and patient autonomy requests is the standard of care established by organizations such as the organization. Determining standard of care suggests that there are values given to health and the organization has an obligation to obtain the minimum standard but not exceed the highest standards. Standard of care can be influenced by factors such as availability of resources, insurance company, organization mission and belief, and/or federal regulations. The legal standard of care considers both ethics and organization available resources but not moral value of a procedure. These standards are established with the consideration to limit harm to the individual and other individuals. So if a resource’s availability is limited, the standard of care might be narrower to triage the resources use thus, affecting autonomy. Too much patient demand with negatively influence the community’s access to care. The organization is put in a position to limit patient’s autonomy for the sake of the greater community.

Because legal standard of care does not consider moral value of a procedure, the provider and patient are capable to interpret care measures to the patient’s context and often medically or scientifically supported. The normative standard can be individualized within the patient-provider relationship. The standard of care can be negotiated depending on intention. Of course, the organization maintains the right to limit treatments based on whether the intervention
conflicts with the organization’s moral agency. So while patients have the right to access appropriate, legal, medical care, this does not to imply that all organization are obligated to provide this care. Upon these circumstances, the patient then has the right to be educated about the standard of care and where the care is accessible.\textsuperscript{171}

2. \textit{Gene Therapy: The Front Line of Translational Medicine}

Gene therapies are like synthetic biology in that gene therapy manipulates physiology for an intended outcome. Further, these technologies may introduce germ line changes. Traditionally, gene therapies were designed for rare conditions which were difficult to treat with pharmaceuticals. Now, gene therapy can be used to slow tumor progression, combat viral infection, and stop neurodegenerative disease. This therapy is risky as it rests in an area between research and clinical care known as translational medicine. Translational medicine is summarized as moving research from bench to bedside.\textsuperscript{172} In this area, patients are bearing the risk of safety because, in terms of mirroring human biologics, animal models tend to be limited.\textsuperscript{173}

Gene therapy is at the front line of translational research because of its growing application in clinical medicine. Gene therapy is a broad area of treatment. Generally, gene therapy can be considered a treatment in which a gene which is defective or not present in a patient is replaced by either directly delivering the gene into the human or using a vector with the appropriate genetic information via nucleic acid transfer.\textsuperscript{174} This process is also considered gene transfer. Essentially, the vector helps create the appropriate expression of the missing or defective gene, and as a result, the person’s symptoms decrease. From an idealistic perspective, without mutations and adverse events, gene therapies could greatly increase patient safety as it would at least minimize, if not eliminate, harmful side effects from prescriptions. In total, the
therapy is a bottom-up approach. So once the genetic disorder is determined, the treatment can be manufactured unique to the circumstance.\textsuperscript{175} Somatic gene therapy is the administering of functional genes direction to the somatic cells, or nonreproductive cells.\textsuperscript{176} The intention of these interventions is to relieve the specific patient of a genetic disorder. Often times, the hope is that a patient will only need one treatment versus a series or a lifetime of treatments.

Gene therapy for hemophilia B has proven to be highly successful in recent studies. Hemophilia B is a bleeding disorder resulting from a genetic defect of encoding blood clotting proteins. Current treatment for the disorder requires lifelong intravenous injections of the clotting protein approximately every three days. These treatments can cost around $250,000 a year. Both the time and financial burden are not sustainable for patients. Inability to obtain treatments results in more bleeding episodes and decreased life expectancy.\textsuperscript{177} In one gene therapy study for hemophilia B with ten men, gene therapy resulted in long-term therapeutic relief. A one-time administration of gene therapy showed a decreasing in bleed episodes and severity. The majority of the adverse events reported in the trial were either unrelated to the intervention or not serious. As a result of the gene therapy, subjects could either discontinue other clinical treatments or increase the time between standard clinical doses. From a financial standpoint, the decrease in standard clinical interventions for these individuals allotted to a savings of $2.5 million.\textsuperscript{178}

Current limitations of gene therapies are gene delivery. The problem results in the inability to deliver genes accurately in order to begin and sustain genetic expression. Gene therapies use viral vectors that have been “turned off” or disabled from conducting any pathogenic changes. While this method is useful, it is limited by the body’s immune system, the natural defense system. Gene transfer is used to modify T cell for cancer therapy. A T-cell is a white blood cell that circulates throughout the body searching for infections or cell
abnormalities. A modified T-cell is engineered ex vivo to target a tumor. Due to the modified T-cell’s sensitivity, the engineered T-cells can target normal cells which results in “on target-off tumor” toxicities. In one study of modified T-cell transfer for cancer, nine subjects were treated with gene therapy. Five subjects experienced tumor regression. Another two subjects died in events that were deemed possibly related to the study. While five of nine subjects saw efficacy, the two deaths raise safety concerns for these types of interventions.

Given the examples of gene therapy for hemophilia and cancer, it is evident that there are different risks involved in this kind of care. There is always the potential that the genetic technology will not work at all. Another possibility is that the designed gene will produce mutant at some point in the treatment process. Further, gene therapies are risky because they are first in human and therefore, require strong laboratory data that the mechanism of action will be consistent in the human. The confidence that laboratory data will transfer to clinical outcome is called “translational distance.” Translational distance is influenced provider optimism and publication bias. An optimism bias is when investigators show their data as favorable. Favorable results ultimately get published and allow the investigators to continue with their research, i.e. a clinical genetic trial. Organizations must be alert and critical of the potential biases to minimize avoidable harms in translational medicine.

However, the circumstances of the trial being a first in human and the participants typically being in extreme situations raise the question as to whether the pre-clinical data should be held to the same standard as a pharmaceutical drug. For pharmaceutical trials, the FDA requires an established improvement in survival or symptom relief before approving a new treatment. For cancer therapies, a secondary objective such as a decrease in side effects of the drug may be used to provide sufficient proof for approval. This change affects the risk benefit
ratio of gene therapy interventions. The organization’s ability to translate information from the macroscopic to microscopic for patient safety becomes compromised. This limitation will inevitably be a compromise in genetic technology implementation for clinical care purpose until at least there is sufficient data to support patient safety. When doing this translation, an organization needs to emphasize the cofactors for gene expression including lifestyle choices.\textsuperscript{184}

These limitations will be essential to developing standard of care models and genetic policies for clinical care purposes. Translational medicine is intended to create continuity between research and clinical care. However, this gap is being filled with questionably safe genetic interventions. Therefore, organizations have an obligation to maintain patient safety standards while promoting this translational research.

3. Policy Making regarding Genetic Technologies

Majority of the discussion throughout the chapter discusses the strengths and limitations of current genetic technologies available. Among the most widely used genetic technologies used are for breast and colon cancer. However, there remains to be a discussion in the literature assessing organizational policy for managing the integration of genetic technologies.\textsuperscript{185} The framework of consent, conflict, and compromise can be used to frame the discussion for policymaking in a healthcare organization insofar as, the framework can encapsulate major issues of genetic technologies.

In this context, “policy” can be considered those that are developed throughout an individual organization as opposed to the government’s health policy. Three federal agencies influence genetic testing regulations: Centers for Medicare and Medicaid Services (CMS), the Food and Drug Administration (FDA), and the Federal Trade Commission (FTC). The CMS regulates the labs performing genetic testing by ensuring that the labs are compliant with Clinical
Laboratory Improvement Amendments (CLIA). CLIA certification legally ensures that the lab has met standards which qualify it to relay information about diagnosis, prevention, or treatment of human health.\textsuperscript{186}

The FDA regulates the safety and effectiveness of genetic tests as a medical device.\textsuperscript{187} The FDA also oversees and regulates the use of genomic information for pharmacogenomics and clinical application. These regulations are intended to ensure that the appropriate information about genetic markers is available on drug labels to minimize harm and maximize the drug’s safety and effectiveness. An example of this would be for chemotherapy drugs which have known genetic markers that influence the effectiveness of the drug.

Finally, the FTC has a narrow role to play regarding genetic policy and implementation. The FTC regulates marketing and advertisement of genetic testing. The Commission reviews advertisements to ensure there is not false or misleading information about genetic clinical implementation.\textsuperscript{188} Companies must carefully word advertisements so that they do not claim a genetic test can measure the risk of developing a disease. As discussed earlier, probability, risk, and uncertainties make it difficult to determine the likelihood of developing a disease or condition. Thus, testing should not be done in isolation without clinical professionals.

Federal institutions such as the CMS, FDA, and FTC regulate genetic technology implementation in clinical care. However, when it comes to policy development, this can be managed at the organizational level. The Institute of Medicine and other essential players in genetics and genomics advocate for stakeholder involvement when developing policy.\textsuperscript{189} The stakeholders are anyone who is influenced or affected by the policy. Thus, their involvement would require they be engaged in the process of policy development by supporting, opposing, or recommending changes to organizational policies. However, genetic policy development can
involve large amounts of complex data and information that many stakeholders are unlikely to understand even with basic genetic education.

The major issue of involving stakeholders in genetic policy development is identifying an appropriate representation of the population.\textsuperscript{190} Already, minority populations are underrepresented in availability of tests and data. Since genetic data can affect an unknown portion of the population, identifying specifically who is at stake is a challenge. However, it is crucial to the compromise component of the framework to include stakeholders as a balance between individual and population interests. For clinical purposes, stakeholders are actively involved on committees for newborn screening policies. Stakeholders who engage in policy development for NBS are usually patients or parents of children with rare conditions as well as members of advocacy groups and the scientific community.\textsuperscript{191} Thus this could carry over to other genetic policies if the policy is specific to a condition or test.

In order to compromise between individual consent and population risk, organizations developing policy on genetic and genomic implementation in clinical care must consider the not only the federal regulations, but also those who will most be affected by the policy i.e. stakeholders. Including stakeholders in policy development will increase the requirement of transparency throughout the process. In situations as complex and controversial as genetic technologies, organizational transparency is crucial to maintaining trust throughout the organization. Currently, there is little understanding about the methodology for integrating these opinions and perspectives into clinical care. However, the rapid expansion and development of genetics is making policy development a pressing issue to maintain patient safety and quality of care throughout the organization.\textsuperscript{192}
d. Conclusion

Organizations have yet to develop standard of care measures and policies for implementing genetic technologies into clinical care. These measures are crucial to maintaining patient safety, while balancing the population right to healthcare access and individual consent insofar as genetic interventions may vary throughout a lifetime and across populations. Due to variability and lack of regulations, premature implementation can result in overdiagnosis as well as unnecessary and burdensome interventions. In these circumstances, misuse of genetic technologies limits healthcare access for other patients. Further, an inability to create an effective method for genetic technologies in clinical care will negatively impact individual consent as it can cause confusion and unreliable information. Organizations have an obligation to avoid these circumstances to maintain and promote beneficence throughout clinical care. Specifically, promoting beneficence highlights the importance of transparency in the understanding of genetic probability, risk, and uncertainties.

While being cautious about the potential issues for genetic technologies, current application such as gene therapy highlights the significant impact this could have on patient care and healthcare delivery. As such, the organizational ethics framework helped identify the potential problems of genetics integration and is useful to evaluate current clinical advances as seen in cancer and reproductive technologies in relation to the organizational mission. Specifically, the framework allows for an adapting understanding of clinical genetics which is necessary as its application and scientific understanding changes. Organizations should be conscious of the delicacy of the integration process insofar as there is extreme criticism about the safety, purpose, and ethics of genetic technologies.
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Chapter 5 Research Protocols with Genetic Technologies

Most medical technologies have developed from some degree of research. For genetic technologies, research is bringing to life what seemed to be only science fiction a few decades ago. Genetic research has brought medicine to the point in history when the human genome can directly and purposefully be acted upon by humans. The available literature on genetic research highlights it as either novel and innovative for the purposes of translational medicine or boarding unethical forms of enhancement. The latter perspective might argue that genetic researchers are no more than body hunters searching for unique genetic sequences to develop human species altering interventions. The former can be understood as an attempt to bridge the gap between clinical care and research sciences.

This chapter will address the individual compromises necessary for genetic research purposes which are designed to understand and prevent population health issues. This section will implement the organizational ethics framework in the context of the research. Similar to the previous chapter, there will first be an analysis of the issues of individual consent in genetic research. Insofar as genetic information can rarely be anonymized, it is becoming increasingly more difficult to protect individual privacy in the research context. Considering the purpose of research is to develop generalizable knowledge, the second section will address the ethical dilemmas that arise from commercialization and patents of genetic technologies. Finally, the third section will analyze biobanks as a potential compromise between individual risks to privacy and the organization’s research endeavors.
a. Individual Privacy & Open Consent

The right to privacy is a long standing right and requirement for the traditional understanding of authentic informed consent. However, with the progress of genetic research initiatives and the understanding of relationships based on genetic information, the understanding of privacy is becoming more difficult to maintain. Confidentiality for genetic research is more appropriate as it allows individuals the opportunity to control access of their data albeit with some limitations. Due to this shift from privacy to confidentiality, individuals might find themselves offering a broad consent to genetic research which allows for dissemination of genetic data for specific research purposes.

I. Replacing Privacy with Confidentiality

The traditional understanding of informational privacy assumes that the individual maintains the ultimate authority for dissemination of their personal facts.¹ However, this understanding is limited in its ability to perceive the individual as a member of a community and the individual’s social responsibilities to the community. For purposes of genetics research and the unknown potential of a genetic sequence, genetic research initiatives need to shift their understanding from protecting privacy to promoting confidentiality.

I. Dilemmas of Maintaining Privacy in Genetic Research

Privacy is a situation when an individual attempts to control their information from another individual. The information being controlled is private information. With this understanding of privacy, the concept of privacy involves relationships.² Individuals who forcefully gain access to another’s private information have violated another’s privacy. To state that there is a violation of privacy assumes that there is a right to privacy. The right to privacy is
becoming increasingly harder to apply and maintain in situations of genetic research insofar as, genetic research requires collaboration between the researcher and research subject’s private information. The urgency of addressing privacy issues in genetic research became more so when it was determined that an individual could be re-identified by a single nucleotide polymorphism (SNP). Simply put, a SNP is a variation in a base pair in a DNA sequence. There are around 10 million SNPs in an average human genome and can be used as biological markers to locate genes.³

It was argued that the right to privacy is essential to maintaining the integrity of the informed consent process. Private contemplation of medical decision making protects individuals from undue coercion and burdens.⁴ Thus, the patient can safeguard their interests which subsequently protects medicine and research from paternalism. Researchers must obtain subject consent before disseminating or using a person’s information to avoid violating their rights.⁵ For the purposes of genetics, a balance is required between dissemination of information and individual privacy. Tradeoffs to balance privacy and access are already present in clinical care. A provider does not ask consent for every procedure (e.g. taking blood pressure during a physical exam) or when they read labs before reporting them to the patient. In most cases, asking for consent for every procedure would overburden the patient. Therefore, the patient trades their absolute privacy over all information for conveniences such as not to perpetually consent to each procedure or reading of labs.

Without similar types of trade-offs in research, researchers are expected to take on more responsibility to relay information to the participant. The researchers are to ethically and accurately conduct their study to ensure scientific validity. In return, subject responsibility involves complying with research procedures to ensure the success of the project.⁶ For genetics
research, the responsibilities are different from other types of research in that genetics research can involve as little as a cheek swab but the dissemination of results can have long term effects on the individual. Ultimately, because the proportion of participation to outcomes are different than that of most other medical research, the tradeoffs for genetic research still need to be established. However, for research purposes, some of these tradeoffs will be for the community’s convenience and perhaps not the research subject’s.\(^7\)

In large scale genetic research, individuals are perceived as members of a community. Individuals as members is evident in the International HapMap Project. This project collected blood samples from families and communities and put the genetic sequenced results online. The intention was to develop a map of the human genome to describe patterns of SNPs.\(^8\) The concept of public, online genetic databases is gaining popularity. The scientific community can use these databases to maximize sharing and subsequently, statistical power of their own research. For the individual, this means the risk benefit assessment is shifting because of the unspecified future potential of their genetic information. As a result of the potential scale of genetic research, consent forms for the research are more often including a note of disclosure regarding future potential of technology to identify individuals based on their DNA sequences.\(^9\)

Considering the unknown potential of genetics research, the concept of confidentiality is better suited to address issues of information access. Some interpretations of confidentiality suggest that in order for information to be confidential, all information should be concealed. This interpretation opposed that of anonymization which is when all identifiable information is removed from the data.\(^10\) Rather than information being concealed or consistently anonymized, research participants might find comfort in controlling the access of their data. Thus, confidentiality is a method to limit the use of data and therefore, is essential to maintaining trust
between the researcher and participant.\textsuperscript{11} However, a follow-up question that is begged by confidentiality in research is how much control individuals should be granted over genetic information that is volunteered.\textsuperscript{12}

To shift from an understanding of complete privacy in genetic research to a more practical approach, there must be a justification to shift from the right of privacy to confidentiality. First, confidentiality supports that the individual is a member of the community. The individual controls the amount of information shared with researchers as they would with other community members. The amount of information shared can sometimes depend on the payoff or, in the case of research, support in a cause. Second, disclosure risks are better understood shifting the risks associated with confidentiality from absolutely no risk (which is highly unlikely, if not impossible) to probabilities based on the combination of identifiable elements. Information such as voter registration, driver’s license identification, taxes, and property value are all publicly available but often mistakenly thought to be private.\textsuperscript{13} In fact, non-research related data is more often experiencing breaches of confidentiality than data collected for research purposes. In 2014, the online buying and selling website, eBay, experienced a cyber attack that resulted in 145 million customer accounts being hacked for information including names, email addresses, passwords, phone numbers, and physical addresses. Similar situations occurred in the same year JP Morgan Chase and Home Depot.\textsuperscript{14}

In research, loss or violation of privacy occurs when a researcher makes an unwanted intrusion on an individual’s life as a result of the research.\textsuperscript{15} A commonly used example of unwarranted interactions due to research participation is incidental findings affecting blood relatives of subjects (e.g. misattributed parentage).\textsuperscript{16} Genetic research initiatives support the idea that individuals are members of a community and that they control access to their private
information to participate in the community. The controlling of access suggests that while the right to privacy is essential for understanding relationships, confidentiality is most appropriate for genetic research due to the familial implications of incidental findings. To be approvable by the current common rule, research does not have to directly benefit the participant if the research is minimal risk. Rather, the research is approvable if it contributes to generalizable knowledge. This suggests that even federal research regulations emphasize a level of common good in ethical research practices.

2. The Common Good: Communitarianism vs. Liberalism

Consent for research is not only different because of the implications of the results but also because the intention of research is to contribute to generalizable knowledge. The generalizable knowledge does not have to have groundbreaking effects but rather, can eliminate an understanding of disease pathway through negative results. This information then can be used by other researchers to direct future research. Such information then contributes to the common good. The common good is an end toward which all individuals can strive. For research, the common good than would be to pursue generalizable knowledge for future generations. Generalizable knowledge cannot come without research which is made possible by the individual. In return, the individual benefits from the research. The ethics question at hand is how to justify the individual risk for population benefits. This question can be approached with an understanding of the common good. Once a common good is identified throughout a community, individuals can equally weigh the risks and benefits of participation in the research.

The common good, as defined by Pope John Paul II, is the good of all and each individual. Insofar as morality is not an individual issue, then individuals have a duty to promote the common good. It would be difficult to argue that individuals have an obligation to
participate in genetics research due to the duty to promote the common good. However, in some cases, participation would be altruistic as the burden undertaken by the research participant for the betterment of humankind. Therefore, there might be some research studies for which an individual’s participation would be highly valuable (e.g. orphan diseases). Thus, for genetic research purposes, the question to ask is what good will come from the results of the research? This is a daunting question as the possibilities for genetic research seem limitless and expanding exponentially.

Genetic research projects specifically focused on the common good are projects which involve protection of the diversity of the human genome. Often, those communities in need of preservation are isolated or have alternative views of scientific research. The community’s relational status or views do not necessitate that they are against participation in genetic research. Rather, before conducting the research, there must be an understanding of the community’s perceptions of the common good. Initially, Human Genome Diversity Project critics assumed that Native American communities who donate blood for research would perceive the donation as vampirism or biopiracy. However, Native Americans in Huston, Texas have interpreted blood donation as community service necessary of scientific progress. A blood donation for genetic science is understood as a gift or contribution to the common good. Native Americans noted that although defining “good” or “bad” outcomes is nearly impossible, the possibility of “good” outweighs the opposing potentials. That being said, blood abstracted specifically for research or for intellectual property would be problematic as it does not contribute to the common good.

There are two philosophical frameworks used to achieve the common good, communitarianism and liberalism. Communitarianism is a theory which suggests the individual has certain obligations to the community. An example commonly used to describe the tension
between the individual citizen and obligations to the community is the dugnad concept. This is a conservative theory which dates back to agrarian societies in which the citizens would help harvest the farm. In return, the farmer would treat the servers proportionally for their work by serving food and drinks. This method has been seen to foster solidarity and equality in society that can be relevant to research ethics in genetics. Collaboration between researchers and the sample population is required to successfully obtain a large sample size for significant genetic research results. Assuming the individual benefits from research, then he has an obligation to participate as the workers did on the farm. As a result of the collaboration, the society has the opportunity to have increased understanding of diseases and their own heritage. Should the citizen not participate in research, then he impedes society’s progress and causes harm to the other citizens. This increased understanding then promotes a society which fosters the individual’s autonomy. Through research participation, the citizens can become more partners in science and contributors to society than patients or participants in medical research.

At a minimum, individuals can be expected to not impede ethical scientific research. However, it seems a bit extreme to make it an obligation to participate in the research. Research conclusions are not as simple as gathering data and making conclusions. Rather, they can have long term implications on the society and the individual. When the individual’s private life becomes negatively affected by research participation, he is the one being impeded. Furthermore, if the individual fails to conform to the society’s standards then the individual and family are at risk for isolation. This can be exceptionally difficult for families who emigrate to a new society and/or cultural environment. Although they may move to a society which is less conducive to their autonomy, they maintain the right to practice their own cultures even if out of context.
The alternative to communitarianism is the liberalism perspective of the common good. A liberal perspective common good is the common good is based upon individual preferences. This interpretation supposes all individuals are free to determine a good life from equal opportunities as other individuals. The individual then, is capable of determining the society’s good values. As a result, the freedom to define the good life protects the individual’s personal interests. Therefore, society must be organized in a manner which can provide all individuals with an equal opportunity to determine their own good.26

The liberal perspective of the common good protects individual freedoms and attempts to resolve the issue of pressure to participant in societal norms. At the same time, the liberal common good requires equal opportunities for individuals. This requirement does not suggest all individuals should begin within the same demographics. That would be unreasonable.27 Rather, the liberal perspective requires categorized values for the individual to personally rank. For example, there are “basic liberties” which include freedom to thought, political view, and association. So, all individuals begin with the basic liberties which the individual is responsible to determine their priority.28

Both concepts argue in favor for individual autonomy. Yet, their methods to achieve the autonomy differ. The communitarian perspective requires the individual to conform to achieve freedoms. The liberal perspective promotes autonomy through the individual. The two theories conflict on the importance of privacy as freedom. If genetics research adopts the communitarian perspective, which it seems to be doing, then the individual’s confidentiality will be yield priority to research. The individual will be forced into a position where he has to defend his right to biological properties.29 Some states in the United States argue once the cells leave the person’s
body, the individual no longer has property rights over the material. What is at question is the concern for the physical material over participant’s private property.\textsuperscript{30}

Either framework can be used in genetic research. From an organizational ethics perspective, the application of the framework might depend on the community where the research is being conducted. For instance, the Native American community supported the communitarian perspective. Other American communities might find it more suitable if genetic research was framed from the liberal perspective supporting individual rights.\textsuperscript{31} As previously acknowledged, genetic information can provide information to the individual’s familial medical and ancestral history. Perhaps certain individuals in the family do not wish their information be available to the whole society. Therefore, by one individual providing access to information, it can make the rest of the family’s information available without their consent.\textsuperscript{32} The communitarian would argue the information is necessary for society. The liberalist would argue this is a breach of individual freedoms. The seemingly difference approached lead to issues of how and when to ethically obtain consent from individuals for genetic research.

\textit{II. Autonomy in Open Consent}

Insofar as genetic technologies introduce issues of privacy warranting a shift to confidentiality, it follows that to continue to pursue the current standards of privacy for consent can be problematic. The open consent process changes an individual’s ability to control access to their genetic information. Genetic information is particularly unique when it comes to applying open consent because unlike biospecimens or other types of data, genetic data can continue to be researched in perpetuity and has increasing potential with the development of technology to identify individual research participants.
1. Reassessing Informed Consent for Genetics Research

Thus far, a discrepancy between the individual’s confidentiality and the communal benefit in genetic research has been highlighted. If it is true that there is the inherent possibility of unintended disclosure within genetics research, then regardless of an individual’s preconditions (i.e. as a minority or vulnerable population), then, as a research participant, they should be treated as every other participant. In fact, then the only necessity for informed consent is for the individual to autonomously consent to participation. After consent is provided and the sample is obtained, risks to confidentiality are can continue beyond study completion. The development of genetic technologies has led to an ethical debate regarding the adequacy of traditional consent forms and processes for genetic research. Ethicists and researchers have re-approached the informed consent process specifically to address issues for genetic research purposes. The three main processes are broad, tiered, and participant centric. Each process has ethical strengths and weaknesses.

There is not an exception when protecting this right in international research. The means by which it is protected vary. There remains to be a movement to reconcile the issues previously mentioned. Currently, there are about three ways to generally approach informed consent in genetic research. The first and perhaps most traditional way to approach any research is blanket or broad consent. When offering broad consent, the participant allows the researcher to use the genetic information for all future purposes which have been subjected to IRB. This method is coherent with the communitarian society perspective. The board approach is similar to giving consent in the clinical aspect. A participant is given the study’s significance, risks and benefits, and data analysis procedures. From this, the participant can either consent or not to the research. This frees the researcher from having to return the participant for additional consent
of individual tests.\textsuperscript{37} Additionally, the researcher can distribute the material and data to other scientists directly or through publications.

A major limitation of this method is the inconsistency of the process.\textsuperscript{38} A specific case from an organizational perspective, broad consent for genetic research is sought from all individuals who walk through the doors of a hospital or healthcare facility to store and use a genetic specimen for future research. However, there is yet to be a guidance or solution to circumstances when an individual enters perhaps the main hospital and one of its satellite campuses, provides consent twice, and gives different responses. It is unclear which consent researchers should respect. Another limitation of this process, is the lack of participant involvement in the research. To gain information about studies using specimens, an individual would be directed toward a public forum. In some cases, the genetic information could be used for research which the individual would not have given consent.\textsuperscript{39} Broad consent would not protect privacy in genetic research. Nor would this method then promote trust in research. If the participant gives broad consent, then his material could potentially be used against his autonomy. So, although it may further the scientific community’s understanding and perhaps promote public health in other populations, the research does not directly benefit the participant.\textsuperscript{40}

Another approach to obtaining informed consent in genetic research is tiered consent. This consent form explicitly states three options for disclosing genetic data. The participant has the option to disclose genetic and clinical information to both public and scientific databases, some databases, or can restrict the conclusions to strictly the study.\textsuperscript{41} Similar to traditional informed consent methods, the participant has the opportunity to change the amount of information he wishes to release. This type of consent would offer a more interactive and liberal perspective of research. However, it would be difficult to fulfill this consent in large international
genetic research databases because individuals would need to be linked to the specimen. Often, linking the individual to the specimen negatively impacts participant confidentiality.\textsuperscript{42}

The third type of informed consent is participant centric consent. This method of consent was designed specifically addressing tensions of longitudinal and secondary studies in genetic research.\textsuperscript{43} The participant centric approach to informed consent is more interactive and personalized. The system is intended to create collaboration between the participant and the researcher.\textsuperscript{44} The participant can approach research in one of two ways. He could either have a refined preference for research or be less guided in his preferences. From these preferences, the researcher and participant collaborate to make the participant’s genetic material most beneficial to both the scientist and the participant.

Participant centric consent enhances the participant’s influence in research while maintaining confidentiality and allowing the participant ability to exercise autonomy. Again though, this type of consent may not be possible in circumstances of large genetic databases. First, this type of informed consent method requires the participant to seek out the researcher to be informed about current research undertaken. In some cases, especially international genetic research, research studies may be far from the population’s scope of understanding. Furthermore, seeing as certain diseases are in areas with population’s who have low literacy rates and communication access, it may not be possible to work one on one with the population’s individuals. Alternatively, perhaps even if the researcher could work with the individuals, the community would not approve of this because of the stigma the community has against western medicine.\textsuperscript{45}

All three alternative forms of consent have limitations. Alternatively, all three can also be adapted to best suit the community or individual background where consent is being obtained.
The major point to be addressed is for the organization to ensure that the appropriate information is being relayed to the individual so that they can make an autonomous decision to participate, or not, in the research. Thus, regardless of which informed consent process is adopted by the organization or research study, the level of participant confidentiality and potential downstream effects need to be disclosed.

2. Individualizing Informed Consent: Considering Genetic Variability

Having argued that there are various types of consent, then it would follow that there are questions regarding how to choose which form of consent is best for a specific genetic research initiative. Unlike clinical care where there is generally one, traditional approach, research projects allow for variation in the consent process depending on external factors such as risk level, individuals engaged, and even genetic variability. Since consent can be altered based on the external factors, then organizations must assess the ability and ethics of individualizing informed consent practices in genetic research.

Overall, research suggests that the lay community has a desire to understand genetic inheritance for their family’s sake. From the most basic observable evidence of family photographs, families can begin to conceptualize what it means for genes to be inherited. Public appreciation of genetics is becoming increasingly more complicated though because of the nature of the study. Individuals might believe they understand the nature of heritability because they can correctly identify Mendelian genetics.\(^46\) Often not considered by society are the environmental factors affecting gene expression. For this reason, and many more, obtaining authentic informed consent for gene therapies is unique and difficult.

For genetic technologies, burdens do not even have to be from a present force. People who suffer from genetic disorders might suffer simply for the future fear of the burden. Genetic
knowledge either lead an individual to a more active life, or, unfortunately, hesitate to act in fear of what suffering might come. The burden of knowledge for genetic information heightens individual vulnerability. When individuals find their selves inactive with fear of suffering, then their mind’s suffering manifests in a bodily disease.\textsuperscript{47}

Obtaining informed consent for genetic technologies poses a few difficulties which lead to an alternative form of informed consent. The alternative will be more effective to achieve the authentic intention of informed consent: be informed, voluntary, and made with competence. The informed aspect is the most questionable component of current standards when obtaining consent for genetic technology applications.\textsuperscript{48} To be informed, the individual must be made reasonable aware of the procedure itself and all the burdens and benefits of a particular treatment. Fulfilling the informed component for genetic technologies appears to be more difficult than other procedures. Although the gene’s expression might be macroscopically observable, more risks and benefits could be microscopic and even, unidentified by medical professions still. This does not suggest that genetic technologies are unsafe but riskier and continuous than other medical interventions.\textsuperscript{49} However, it does highlight the natural variability of genetics.

Another problem challenging informed consent for genetic research that is similar to clinical care, is the decision to determine from whom to obtain consent. Of course, if preventative tests are being done on a specific patient, it is important to obtain the information from that patient. But, if genetic information for research purposes, is not the sole property of one person, then informed consent could arguably need to be obtained from the patient’s family members. This is frequently the argument for the immediate patient safety concerns the consenting patient. But because genetics offers information to the extended family, then it might be in the best interest of future participants to disclose these implications in the genetic research
consent process. If the patient is given specific genetic information, then this could be an additional, unrecognized burden on the subject.\textsuperscript{50} Further personal questions arise about the subject’s responsibility to disclose the information to their family members and the familial rights of those members to provide, or not, an opportunity for authentic, informed consent.\textsuperscript{51} Interestingly, to protect confidentiality and individual vulnerability in informed consent processes, the alternative that has been suggested is open consent. The participant’s action to consent to genetic testing and therapy assumes a confidentiality between the patient and professionals. However, as the genetic revolution continues, more information might be available, and thus, additional contact might be necessary.\textsuperscript{52}

Around 1988, the protection of certificates of confidentiality issued by the Department of Health and Human Services was expanded to include biomedical, behavioral, clinical, and other research. Prior to 1988, the protections were limited to drug and alcohol abuse research.\textsuperscript{53} Certificates of confidentiality protect researchers from having to disclose identifiable information that was obtained by and maintained in the research records to “federal, state, local civil, criminal, administrative, or legislative” bodies.\textsuperscript{54} Identifiable characteristics protected by certificates of confidentialities include elements such as name, address, identifying numbers (e.g. study ID), fingerprints, or, perhaps most importantly for genetic research, a combination of items or data that could reasonably directly or indirectly identify a research subject. Factors like date of birth and zip code can make a person identifiable depending on the population of the community. Further, rare genetic conditions are also identifiable even on a national level.\textsuperscript{55} Certificates of confidentiality can be useful for genetics research since sensitive information can be revealed about the individual research participant and their family members. Without these protections,
genetic researchers could potentially be subpoenaed to court to reveal sensitive information or facing charges for withholding the same information.56

Specifically, certificates of confidentiality are useful from a research participant’s perspective because it assures the individual of the legal protections of the research. Thus, for more sensitive information like HIV status or illicit drug use research, participants can have peace of mind knowing that at least stigmatizing information cannot be used against them. Important to note is that certificates of confidentiality only protect information in the research record. If research results are placed into a subject’s medical record, the certificate of confidentiality does not protect the sensitive information.

b. Commercialization & Patents

With the sharing of information and resources, there will inevitably issues of ownership over the genetic findings from research. Historically, patents and commercialization were intended to encourage innovation. Critics of genetic technology patents argue that such patents inhibit research and development and restrict access to materials which cannot rightfully be claimed by one individual or company. The ability to patent and commercialize genetic technologies has led to both ethical and legal dilemmas influencing ownership, trust, and ultimately organizational policy.

I. Trust & Commercialization

In most areas of research and development, patents are tools for innovation. However, due to the common good aspects of genetic research, patents and commercialization on genetic materials are seen and not tools but restrictions to the technologies. When access is seen as
restrictive, it can create distrust among the research community. Conflicts of commercialization can lead to issues with regard to scientific integrity and the community’s trust. A participant’s consent has to consider open access to the research data when there may be conflict regarding commercialization and patents.

1. **Plant Patent Act: Cultural Changes on Views of Life**

   The Plant Patent Act (PPA) of 1930 began to take shape around the time of the Great Depression in the 1920’s. The United States was in need of industrial growth. Plant breeders dependent on the stock market and government funding, became concerned about their ability to continuously fund research. Essentially, plant breeders were practically applying scientific methods such as Mendelian genetics, to societal interests for financial gain. Throughout the case, plant breeders made some of the first arguments that would weave through the development of patents on life. First, breeders noted their dependency on governmental funding. If a patent was approved, the breeders would have a greater opportunity to stimulate private investors and thus, reduce dependency on the federal government. Second, the breeders mentioned their vulnerability to duplicates and eventually copiers resulting in what would essentially be known as a loss of their intellectual property.

   The (PPA) provided protection for farmers who had reproduced a manipulated selection of plants typically using Mendelian laws of hereditary. This act was proposed in a time of financial hardship and growing appreciation for inventors. Patented plants were designed with purpose to mass produce and commercialize. As city populations grew for work, the need to marketed food also became necessary. Thus, plant breeding came from necessity. There was no formal breeding process for plants and this is one aspect where biotechnology patents will develop in later years. The PPA did not require that the patent application describe in detail the
invention so that it be reproducible from the application. Rather, plant inventors were interested in gaining control over the plant variety regardless of the method the plant was developed. From the PTO’s perspective, the PPA was intended to encourage breeders to develop new plants which were to be an “improvement” over previous versions of other plants.  

The PTO eventually determined that plant breeding is not an invention of nature and its producer therefore be an inventor and/or discoverer. It only covered asexually reproducing plants such as fruits and some flowers. The PTO used “discover” not in the sense that the individual made a discovery in nature, but rather the individual was a cultivated a discovery. One implication of the act is that breeders are similar to inventors for they too can create novel designs. The PPA acknowledges anyone who invents or discovers and successfully reproduces a new plant variety. New varieties of plants became patent eligible similar to those of a new motor or machine and therefore, gave breeders similar rights as other inventors. In some senses, it could be argued that this act had poor boundaries to define its criteria for patentable plants and protection of intellectual property. The requirement was heavily influenced not by the novelty of the plant but hinged on human intervention. The act required minimal objective descriptions which made similar inventions susceptible to counterfeit patents.  

The PPA effects go well beyond the biotechnology industry and exemplify the relationship between university scientists and industry patents. Without the research component, there would be little evidence for industry markets to base their product. University scientists are in a position to have high publication rates which can contribute to patent applications. Furthermore, these scientists tend to be highly focused on the utility of their scientific endeavors as well as their contributions to the knowledge of science itself. Therefore, these scientists tend to settle on both the academic and industry sides of the fence. It is assumed that scientists
with this type of mentally and aim will provide an enhanced contribution to research and
development processes to advance industry materials. The distinction between the scientists who
conduct research for purely scientific purposes versus the scientists who conduct on behalf of a
utility or industry function will be significant as the patent argument develops and becomes more
complex.\textsuperscript{65}

The PPA was a social movement insofar as it transformed the legal system to
acknowledge purposeful manipulation of breeding also understood culturally at the time as
control of evolution. Unlike other patents that will be discussed, plant inventors took advantage
of natural laws or processes to develop or discover their inventions. Like other cases that will be
discussed, these patents came with cultural hesitations as it seemed that the inventors were
manipulating nature for human benefit and claiming it as their own property. Today, genetically
modified organisms include plant seeds to produce plants which are resistant to insects or
pesticides.\textsuperscript{66} There are a wide variety of patented plants with great amount of attention on
genetically modified foods. Although the efforts fell short, corn was genetically modified to
increase calories and feed the hungry. As a result of the ability to genetically modify foods, it is
estimated that upwards of 70\% of processed foods are genetically modified at some point in the
process from growth to table.\textsuperscript{67} The PPA was one of the first landmark cases which
acknowledged intentional human manipulation over nature as both beneficial and as property.

2. Incentives for Scientific Creativity and its Effects on Scientific Integrity

Research and development teams (R&D) depend on the scientific understanding of
information as well as the marketability of their efforts to fund future projects. Patents contribute
to overall profit for not only large organizational firms but also academic institutions. Therefore,
when discussing ethics of the right to patent a product as controversial as genes, it is important to
consider an appropriate balance between the scientific creativity and need for patents as a business. It is apparent that research institutions vary on their priorities to pursue research. Similarly, researchers vary the amount of time in a specific project which can potentially be swayed by the amount of value they or their institution place on the project. In either case, it is evident that the availability of patents does influence scientific creativity both in the market and academic institutions.

Perhaps most concerning area which patent availability influences scientific design and creativity is in academics. In times of economic hardships, universities are sought as potential avenues to stimulate technological development and growth. After the Chakrakbarty decision, the Harvard mouse was one of the first examples of the convergence of biotechnology, academic institutions, and patent law. The approval of the patented mouse was the beginning of a period in which academics was saturated with projects motivated by patents. Governmental influence encouraged universities and institutions to patent their designs in order to promote scientific creativity. Now, it is evident that commercial value and public attention contributes to scientific creativity. Patents can affect project selection, risk factors, and continuous approval of projects by both the researcher and organization. With greater commercial or scientific value/rewards such as a patent, a researcher might be more likely to take on riskier projects.

Because patents can influence scientific creativity, then the authenticity of scientific integrity must be brought into question. The availability of patents creates a pressure to move research from academic settings to the market or from public to private firms. Some might argue this would skew academic research making it become less reliable or less focused on development of knowledge. If researchers’ salary was subsidized by publications as well as patents, then the researchers would be more motivated to under reporting events or biased
results. Therefore, when the scientific integrity is called into question so too is the
trustworthiness of the institution. Since institutions and universities specifically, rely on public
trust, these organizations are expected to fully report adverse events which could potentially
change public support of the research. Reportable events are ones such as conflicts of interests
either by the researcher or institution. If either agent has a financial tie or motivation such as a
patent to pursue research, then it would be required that this information be disclosed to protect
scientific integrity.\textsuperscript{73}

On the other side of the argument, patents and commercialization of inventions or
research products do contribute to university funding. Thus, this funding can go back into the
research producing greater research results which could ultimately contribute to the taking on of
riskier research projects. University and industry collaborations have been credited with
developing some of the greatest research environments for students and future researchers.
Universities defend this stance because it would seem almost unethical to allow another
individual unassociated with the institution to patent a design which university resources
developed.\textsuperscript{74}

Researchers can approach their projects from two perspectives: upstream or downstream.
While upstream researchers build on their research and create a set up that allows for their next
project to be patentable, downstream researchers are focused on diagnostic and procedures in an
open and unpatented setting. The downstream model is more open to data sharing. This is not to
suggest that upstream model researchers do not share information but have more obstacle to
obtaining another’s information and might be deterred because of these obstacles. For this
reason, it’s argued that patents on genes increase prices to use another’s research, thus driving up
the price of research projects all together and thereby furthering the need for additional financial
avenues such as patents. Thus, the issue of the anticommons is becoming more present in biotechnologies. The tragedy of anticommons states that a restriction on access such as patents could severely inhibit research incentives. This trend is present in genetic sequence patents because so many fragments of the DNA sequence could possibly be patented. Taken from this perspective, genetic patents almost seem counter-productive to scientific creativity.

Because scientific creativity can be limited by some patents, and therefore research can also be limited, another ethical concern is for the protection of human subjects. Critics of patents for scientific creativity fear that industry relationships and patents will decrease the quality and rigor. Further it would be against federal regulations and ethical standards. This goes against both federal and ethical regulations which state that risks are to be minimized in human subjects research. Especially when taking into consideration more vulnerable populations, it seems most unethical to patent a genetic sequence which could be used in future research with vast benefits.

There seems to be an overall inconsistency between promoting research incentives and researchers’ rights to protect their products. Genetic patents are at the greatest risks of limitation by patents because of the methods to patent such as a fragment or whole gene. It appears that patents can drive up the costs of research projects and thereby motivate researchers to undertake more profitable and perhaps riskier, research endeavors. Most concerning though is the potential risk to human subjects which has already proven itself to be an issue for genetic research projects specifically.

3. Myriad Genetic Laboratories, Inc.

The distinction between naturally and non-naturally occurring products of nature was further pursued throughout another landmark genetic patent case of the BRCA1 and BRCA2
genetic sequences discovered by Myriad Genetics, Inc. The Myriad case is particularly interesting and landmark case for biotech patents because the company sought to patent two genetic sequences related to breast cancer diagnosis thereby affecting patient care. With these patents, it is suggested that Myriad attempted to create a monopoly of their genetic patents by preventing other laboratories from using the sequence in clinical care to screen, diagnose, and treat. This patent is unique as it was the first genetic patent that claimed rights over the results of international collaborations.

In its beginning, Myriad laboratories was a branch of the University of Utah focused on research and commercialization of genetics for major diseases such as cancer and heart disease. Their focus on major diseases was due in part by the collaboration of other researchers and the availability of genetic and medical databases. The genealogical branch of Myriad’s research has since expanded to a therapeutic arm of the corporation which is apparent in the motivation to patent the BRCA1 and BRCA2 gene. The BRCA1 genetic sequence associated with breast cancer was preceded by an international collaboration of laboratories which eventually lead to the Myriad laboratory identifying the genetic sequence. In 1998, Myriad gained patent rights to BRCA1 and BRCA2 genetic sequences as well as a number of the genetic mutation sequences on these genes also associated with breast cancer. Eventually Myriad gained worldwide patent rights to these genetic sequences.

The case of Myriad patenting BRCA sequences brought to light arguments of intellectual property. According to the PTO, ownership rights of intellectual property are equal to that of physical property. Certainly patenting genetic sequences would influence clinical care measures even if it is considered intellectual property. It would be unfair to not mention that other companies at the same time were attempting to patent the BRCA sequence for similar reasons. It
was apparent that the immediate reason to patent genes was to establish international control. Throughout the legal battle to gain patent rights to these genes, another company applied for patent rights over the most common BRCA gene sequence in normal women. Thus, this genetic sequence could be used as an alternative diagnostic route. The filing of such a patent brings about the argument that any mutation from the patented genetic sequence could be in itself another patent. However, if this were the case, there would eventually be a scientific gridlock of laboratories holding patents.

Throughout the media, the Myriad case was negatively portrayed as the problems which follow genetic patents. The company was considered a threat as it under mind nations with universal healthcare coverage. The media’s influence on public opinion will be significant to consider when moving forward in genetic patents especially when considering stem cell lines. The company has been accused of unreasonable pricing of diagnostic tests limiting therapeutic interventions and clinical care. Since the patent was approved, there have been numerous lawsuits attempting to revoke the patent rights. While few law suits have actually revoked the patent rights, Myriad’s control over the patent has been severely restricted. Between 2000 and 2013, Myriad’s rights to the gene patents were brought to both state and federal court various times. In 2013, the Supreme Court unanimously determined that isolated BRCA1 and BRCA2 genes were naturally occurring DNA segments. Therefore, without modifications, these sequences were not patentable.

What remains are the effects and interpretations of the Supreme Court’s decision to consider genes similar to BRCA sequences, ineligible for patents. For instance, it remains unknown how interpretations of description “product of nature” will be applied in future genetic patent cases. Myriad Laboratories attempted to patent a genetic sequence but not an entire gene.
Thus, there remains questions as to whether entire genes would be patent eligible. Interestingly enough, in the Myriad case, there were researchers who contributed to the overall end of determining the genetic sequence associated with breast cancer who did not want to be associated with the patent of the gene sequence. Reasons for the dissociation with the patent were often conflicts of moral or ethical interests. Thus, although the legal implications and justifications of genetic patents has been discussed until now, it is important to remember that law does not directly translate to ethics.

For policy’s purpose with regard to gene patents, gene sequences are treated more as chemical components or substances. In this respect, as Myriad did, genes can be patented in isolated and pure form. Naturally occurring, gene sequences contain many sequences which are cut and spliced out of the gene before it is replicated and copied for protein manufacturing. However, a pure an isolated form is one which contains only the parts which are copied for coding and therefore, not naturally occurring. In 2013, the Supreme Court determine that human genetics defined as genomic DNA is in fact, not patentable. The controversy surrounding the case has become an example of the effects of genetic patents sparking strong cultural and policy responses. Additionally, as it will be discussed further, case presents one of the largest acknowledgments of the dilemma between organizational research and individual clinical access.

II. Patents & Social Justice

The motivation for donating biospecimens and disclosing personal health information is to contribute to the common good for all people. The concept of patents though seems counter productive to this cause as it is understood to restrict access to innovation. Therefore,
organizations are responsible for ensuring a balance for restricting access and promoting social justice.

1. Applying the Principle of Utility

Genetic technologies have gained attention due in part because of the hope associated with them to provide improvements in clinical application such as prevention, diagnosis, and treatment options. The Myriad decision caused national confusion because of its potential clinical implications to provide diagnostic and therapeutic interventions. In addition to the clinical applications, the PTO requires inventors applying for patents must be able to support that their product is non-obvious, novel, and useful or beneficial. The legal system including courts have firmly held to the requirement that a patent is approvable if the product can provide some benefit to society. This belief has expanded from the macro-level inventions to more micro-sized inventions such as chemicals for drugs and now is being expanded again to genetic sequences. However, there have been examples exceptions where the U.S. Supreme Court allowed for a patent with a hypothetical utility. Therefore, there is an alternative avenue for gene patents.

The principle of utility can be argued from an individualist framework as one which the only laudable end is happiness. It is not necessarily the case that the principle gives moral value when it’s applied. Nor can it be solely stated that the happiness ends need to be truly rooted in individualistic ends. Rather, the ends could be community or individually focused. The principle of utility is one that hinges on prudence. Thus, when applying the principle, one should consider the benefits and risks to other individuals equally as he would to his own situation. When applied to patent law, the principle of utility then should be applied with the intention to minimize pains and maximize benefits for all individuals. Lacking moral value determinations
allows the principle of utility to be adaptable to patent law as it can change with cultural understandings of utility and benefit.

The patent’s utility requirement is a long standing requirement for eligible inventions.\textsuperscript{97} For pharmaceuticals and now biotechnologies, these industries attempt to patent as early in the process as possible and therefore, need to find utility in their earliest findings. This step is essential in the patent process for pharmaceuticals and biotechnology companies since the clinical trial phases often require extensive financial resources. Furthermore, the research and development phase for genetic is so sensitive both in time and resources. The PTO has had to adopt a more liberal or relaxed interpretation of the utility requirement.\textsuperscript{98} However, going back to the essence of the principle of utility and the purpose of patents, it seems that both concepts are being improperly applied to the protection of genetic research. If institutions benefit more by patenting early in the research phase, then with regards to genetics, it is often difficult to claim a direct utility of their inventions.\textsuperscript{99}

Around the time that the Human Genome Project was reaching their conclusions and after the decision in the Myriad case, the PTO introduced Utility Examination Guidelines focused specifically on biotechnology and DNA patent claims.\textsuperscript{100} These guidelines reinforce the need to satisfy the utility requirement for patent approval. As a result, it is argued the guidelines actually deter researchers from seeking patent approval and thus, discredit the incentive to patent to encourage creativity. However, the guidelines were mostly intended to prevent researchers from patenting a broad spectrum of DNA sequences and creating a monopoly over the sequence as Myriad was believed to do. The Utility Guidelines are an attempt by PTO to settle social justice issues allowing for a wider distribution of scientific discoveries. The utility requirements
set in place by the PTO guidelines on DNA sequences are similar to those of chemical components similar to those in pharmaceutical companies.\textsuperscript{101}

As exemplified throughout the patent cases described, there was a direct utility to the clinical practice or biotechnology as a discipline. However, when looking forward to future bio-patents, it cannot be ensured that all discoveries have known ends. For genetics, much hope has been placed on its application and utility to change disease management. This is unfortunate because already the principle of utility is unfairly being applied to unknown genetic discoveries. Thus, when applying the principle of utility to genetic patents, it is not as simple as seeing clinical ends for the research product.\textsuperscript{102} Rather, the genetic patent should be considered with regard to the risks of all individuals, being the industry companies as well as patients.

Thus, it could be the case that a great enough need has not been observed yet to allow for a further application of the principle of utility. As a part of research, patents can be used as incentive to continue genetic research beyond the development phase. Although it is arguable how consistent law and guidelines might be when making determinations, this is an essential policy shift for genetics. For these reasons, the principle of utility applied in PTO applications might have been useful to initiated acceptance of genetic and biotechnology patents. However, this principle might not be sustainable if the pursuit of gene patents continues. If still applied, the principle of utility will have both positive and negative consequences such as limiting incentive to patent which would increase publicly available knowledge.\textsuperscript{103}

However, the utility principle can be most difficult and in some cases, inappropriate for DNA sequence patents. First, as mentioned, it cannot be ensured that all genetic discoveries will have known ends. Second, some DNA sequences have multiple functions creating a legal dilemma as to what or how to patent these specific sequences. For it can be the case that a
genetic sequence is determined to code a specific protein. Yet, it is not necessarily the case that
the protein’s purpose is known.  
This argument follows the upstream model described earlier. While it was suggested that the model sets the stage for future patents, this could only be so if the patents were not dependent upon the principle of utility. The utility principle not only influences institutional decisions for patents but also has significant influence in individual decisions regarding genetic patents.

2. Diamond v. Chakrabarty: Patenting Non-Naturally Occurring Organisms

The first genetic patent was granted in 1980 in the U.S. Supreme Court case Diamond v. Chakrabarty. Through his research, Ananda Chakrabarty, a microbiologist, had a natural tendency towards practical applications of research. He was hired by General Electric to focus on environmental issues and reduce pollution. At the time, Chakrabarty recognized the high prices of proteins and low prices of crude oil. Putting these factors together, he modified bacteria DNA in such a manner that allowed it to digest a variety of hydrocarbon compounds. The microbiologist had a natural tendency towards the practical application of research. As a result, this bacteria became ideal for cleaning up oil spills. Chakrabarty’s patent application included the method to develop the bacteria, the carrier material used to modify the DNA, and the bacterium itself.  
The PTO initially determined the invention was not patentable. Although it was a novel design, it was not clear that eligible patents could be living creatures. By the time the patent application reach the Supreme Court, the question on hand was whether the living organism qualified as manufactured or a composition of matter as defined by the U.S. Patent Act.  
The Supreme Court’s decision actually overturned the U.S. Patent and Trademark Office’s decision to deny a patent of a genetically modified biological organism. The decision
stated that a patent could be obtained by “anything under the sun that is made by man.” Furthermore, the patent was for the bacteria and genetic changes themselves, not the method used to develop the bacteria. The bacteria was developed with a utility and therefore, was considered an improvement over the other bacteria and over other methods of cleaning oil spills.\textsuperscript{107} This distinction is significant as genetic patent and biotechnologies develop. It was evident by the determination that the Supreme Court purposely did not include considerations for potential risks of genetic implications as legal representatives tried to argue.\textsuperscript{108}

There was wide spread cultural fear and pushback with regard to this patent. One critic argued that a human being with a liver transplant was non-naturally occurring yet, it would be unfathomable to patent the individual.\textsuperscript{109} However, this decision carries forward the PTO’s previously determined criteria that the novel invention must provide improvement over previous versions. Thus, the improvement was a direct utility to man-made disasters. The Court stated that the patent law was non ambiguous in its language and that it is not intended to limit patents to non-living entities or dead organisms.\textsuperscript{110} Therefore, by allowing the patent, the Court defended itself in claiming that not only was the patent novel and legal, but it would also contribute promoting creative processes.

Following the decision in 1988, the PTO announced they would now consider non-naturally occurring, non-human multicellular living organisms to be patentable. This statement included animals. The animals could not merely be discovered by scientists but had to comply with the traditional sense of patents in that, they were man made inventions, manufactures, or compositions of matter.\textsuperscript{111} However, “non-naturally occurring” is not defined by the PTO nor, as it will be discussed, the Supreme Court. Throughout the next two decades, it became apparent that naturally occurring animals were being altered to meet the requirements for patents. What
was apparent though was that the decision to approve patents for genetically modified bacterium would be a significant factor in the United States’ place in the global biotechnology movement. If American companies could not patent genetic developments, then it would not be long before the country would fall behind in the biotechnology field.\textsuperscript{112}

Shortly thereafter, there were two more landmark decisions as a result of this case. First, Harvard University patented the first animal, a transgenic mouse used to test cancer-fighting drugs and carcinogens.\textsuperscript{113} After isolating a cancer causing gene, Harvard scientists injected a female mouse. Half of the mouse’s offspring developed breast cancer making these mice specifically useful for cancer studies.\textsuperscript{114} Second was patenting of the polymerase chain reaction (PCR). This is perhaps one of the most important patents to follow after the Chakrabarty decision was in the late 1980’s and early 1990’s. PCR is a process of amplifying and copying DNA sequences which allows scientists to produce an enormous amount of copies of DNA, in their own lab, in a few hours.\textsuperscript{115} This technique is highly valuable for molecular biologists and the study of viral diseases such as human papilloma virus (HPV) and HIV.\textsuperscript{116}

Unlike the PPA discussed earlier, the patent applications of novel creatures required reproducibility. Hence, the PCR patent will provide significant contributions for the future of genetic patents because of its precision and speed when reproducing genetic sequences. Without the Chakrabarty case, the above mentioned cases would be severely restricted if at all possible. Furthermore, these patents provide a utility similar to those discussed in the previous section. Ultimately, this case determination had two long term implications. First, it confirmed that novel, non-naturally occurring changes to organisms could be patented. This confirmation was criticized and confronted but eventually would be more or less accepted as biotechnologies developed. Second, the case determination established that naturally occurring products of nature
are not patentable. Thus, because both PTO and US Supreme Court have not defined “non-naturally occurring,” this distinction tends to be the driving force behind many future debates.117 Following the Supreme Court’s determination that genetic technology could be patented, issues of the patents affects on healthcare access began to develop.

3. Ethical Dilemma of Genetic Patents and Healthcare Access

Perhaps one of the largest outstanding issues for genetic patents is the restriction that patents puts on an individual’s access to the product. For years, critics have been arguing against genetic patents because of the fear that patents would affect diagnostic procedures. There is already a wide healthcare access disparity in the United States for a variety of reasons.118 The United States already exhibits some of the greatest healthcare disparities in the world.119 Considering the implications patents have on the industry and academic research, it is easy to see how industry might have a conflict of interest with their own invention. While on the one hand, it is commendable to develop the technology on the other hand, patents are an avenue for income to fund the projects. The industries themselves are in an ethical standstill between the right to access and the right to patent. The potential conflicts raise reasonable and serious concerns for the future of genetic patients. There are two scenarios which should be considered for healthcare access: the clinical and research sides.

Selling and purchasing healthcare resources is not a new phenomenon in the United States. However, political debates and cultural shifts have made healthcare resource allocation a pivotal national debate.120 For genetic patents, the debate rests again on the principle of utility. If health is a right, then it seems unethical for a company such as Myriad to patent a genetic sequence if this limited individual’s access to healthcare decisions. Strictly speaking from the business perspective, consumers deserve to be protected from monopolies as this limits markets
often by limiting choices and increasing prices. From a healthcare access perspective, clinical 
tests should be optimized to prevent misdiagnosis especially if misdiagnosis was due to using a 
cheaper, lower quality product. This issue is already observed for patients who require expensive 
pharmaceutical treatments and therapies.121 When the concept of purchasing and selling is 
applied to healthcare, it is extremely appalling in the United States as individuals pay for 
healthcare and believe in the right to choose their treatment options.

Second, from a research perspective, patents allow a research or organization to maintain 
property rights for 20 years. This can restrict use of the patent within the researcher’s own lab 
and allows organizations to freely set a market value to use the patent. If patents increase prices 
and a researcher must pay royalties to the patent owner upon a new discovery or invention, then 
this would potentially drive down research motivations.122 As a result, long-term beneficial 
inventions are not pursued. Furthermore, the litigation which followed the Myriad case 
highlights the value of research which was being negatively impacted by the genetic patent.123 
While gene discovery might be relatively cheap in the grand scheme of healthcare research, 
clinical trials remain expensive. Thus, the research process to approve genetic interventions 
becomes expensive.

If too many genetic patents are held by one company, then the intention of patents 
dissolves. Therefore, not only are patients limited in their access, but there might not even be 
inventions to access if patent monopolies control the genetic technology market.124 It appears 
then that patents have their own inherent limitations insofar as, to create a monopoly by 
patenting inventions would discredit the purpose of patents. That being said, there appears to be 
some value to arguments of patents can contribute to scientific creativity and ingenuity.125 
However, in order to maintain reasonable access to the clinical products, it is essential that the
genetic patents not be so protective as to restrict other researcher’s creativity in order to achieve high quality care.

A proposed resolution to the healthcare access issue which arises from patents is a patent pool between researchers. A patent pool is an agreement between two or more patent owners to license their patents to other owners. Thus, the researchers are still capable of protecting and regulating their research products however, there is further incentive to distribute their conclusions. As a result, the integrity of science is protected, intellectual property rights are respected, and the community aspect of research is promoted. Patent pools for genetic patents will eliminate the issues of restricting or excluding use from other researchers. Instead, the pool could actually contribute to a rapid increase in research and production as originally intended by patents by strengthening interdependency between researchers.

Additionally, these pools could reduce costs, another concern for individual or fragmented genetic patents. As mentioned, since genetic patents are so fragmented, this could results in redundant research costs only furthering the need for patents. However, the pooled approach is intended to be more economically sustainable. With regard to healthcare access, reasonable costs is a high priority. Finally, not only would patent pools be economically sustainable but would be more sustainable with institutional resources as it would provide another avenue to reduce redundant research.

It seems that if genetic companies seek to continue applying for patent applications on their genetic inventions, then it would require conditions to avoid the ethical dilemmas mentioned. If limited access becomes an issue, past experience suggests that transparency with regard to the cause is essential to maintain public’s trust in the healthcare system. Ultimately, these considerations would be beneficial for public and private sectors, for research and clinical
purposes. It is undeniable that biotechnology patents will require critical reflection of current legal frameworks. However, it would be unreasonable to dismiss the idea of patents all together without considering perhaps what some might consider more alternative routes to a traditional policy. It is not suggested that patent pools are the sole solution to issues described throughout this argument. However, it could be one reasonable tool to address the concern of genetic patents restricting healthcare access.

c. Biobank Research

The research community has formally used biobanks for decades. The goal of a biobank is simply to make information available for future research purposes. In clinical care, patients are offered an opportunity to donate leftover clinical specimens to biobanks and subsequently research. Similarly, research participants may be asked to donate extra biospecimens in addition to already collected samples for research purposes. However, due to the potential longevity of biobanked information as well as the potential future testing to become available for the banked specimens, dilemmas surrounding anonymization and protecting confidentiality are becoming pressing ethical issues. Organizations must address issues of anonymization of genetic information and their governing policies to ensure confidential access to the subject’s samples.

I. Anonymizing Genetic Information

Before electronic systems and genetic information, biospecimens could be anonymized by removing identifiable information such as names or dates. As technology continues to develop specifically with regard to genetic technologies, it is difficult to argue that genetic information will be truly anonymous even if, at the time of its donation, there are no identifiable
elements (e.g. names or dates) attached to the sample. Further clarification is needed to define the objectives of biobanks and the possible criticism for unintended use of samples so that organizations can efficiently and ethically maintain biobanks for research purposes.

1. Clarification of Biobanks and their Objectives

A biobank is the systematic collection of biological specimens and clinical health information of donors. Here forward, “specimens” will be used to mean both specimens and data unless specifically indicated. Biobanks can vary in both size and purpose. The largest biobank is the UK biobank which aims to collect samples and data from 500,000 British citizens. Smaller biobanks consist of a single group of patients at a hospital and perhaps their family members. Specimens collected can be any type that is collected for clinical care. Biobanks can consist of saliva, blood, or tissue samples. Ultimately, biobanks are useful for research about a particular population or disease. There is a common premise among biobank organizations that collective participation is required to make information readily accessible for future research.

It is necessary to distinguish biobanks for research purposes from the research itself. As defined by the Common Rule, “research” defined by the Common Rule is “a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.” A biobank is a collection of specimens maintained for future use. A biobank may encompass a systematic investigation but does not have to to meet the standards of a biobank. Biobanks in and of themselves do not have research ends. They do not have objectives that can be reasonably measured or validated that contribute to generalizable knowledge. Rather, biobanks collect information to make it readily accessible for researchers who have developed protocols. In this sense, biobanks are a resource for research. Further, for
the purposes of researchers who obtain the samples or data, if readily identifiable information is not in the data set or on the sample, then the research does not constitute human subjects research. Further complicating matters, based on the Common Rule’s definition of “human subject” as biobank donors die, they are also no longer human subjects. A subject must be a living individual.

Additionally, By the Common Rule’s definition, a “human subject” defined by the regulations is “a living individual about whom an investigator conducting research obtains (1) data through an intervention or interaction with the individual, or (2) identifiable private information.”138 Interestingly enough, while biobanks might be research, the protocols that use data from the bank do not necessarily have to meet the criteria for research as defined by the Common Rule. Insofar as there are research protocols which request de-identified data or samples from a biobank, by the Common Rule’s definition, the research might not be human subjects research if the data is not identifiable.

The Common Rule’s definition of a human subject depends on how the data is maintained in the biobank. Biobanks can retain specimens as anonymous (de-identified), coded, or identifiable.139 In more traditional biobanks, medical data is abstracted from a patient’s chart and maintained in a bank as solely a data set. Assuming that the individual does not have a rare condition, then, in this case, the data would be anonymous since the data set could not be linked back to the individual patient. Coded data sets are data sets that have a study ID which replaces PHI (i.e. name or initials). The study ID has a key that is linked to a master list that maintains the data with the individually identifiable data. With both the key and master list, a subject can be identified. The third method to maintaining data is as a simple, identifiable data set. In this case, a master list and key are not required to re-identify the individual.140 Further, when distributing
identifiable samples, it is not necessary to strip the identifiers from the sample as long as the biobank consent form indicates that the sample will be maintained in an identifiable manner.

Researchers most typically store specimens as coded samples so that if for no other purpose, they can ensure that data sets are accurate. Coded data is useful for longitudinal research insofar as continuous data collection is beneficial to the data set.\textsuperscript{141} Coding allows the potential researcher to collect data on a specific population, to re-contact the subject, or go back into the medical record to collect additional data points if the data set is incomplete. The researchers can continue to abstract data or confirm the accuracy of the data which can be requested when data is published in peer review journals. Genetic biobanks are unique insofar as they blur the line between the three methods of maintaining data. If an individual can be identified by a SNP in their genome as argued earlier, then presumably, samples can never be truly de-identified or anonymous.

Based on this understanding, biobanks do not appear to be research. If not research, then they do not require typical IRB oversight similar to other research protocols. However, some oversight is needed to ensure ethical transfer of materials and to protect the individual who donated the samples if the donation was provided with an intended use (e.g. Alzheimer’s research). Without this oversight, researchers may transfer specimens without oversight which can result in unintended specimen use. The implications of unintended use create an ethical dilemma involving the individual’s privacy and an organizational issue to help researchers manage the effects of unintended use.

2. Implications of Unintended Specimen Use

Since biobanks store data for future research, there is an opportunity for unintended use of the specimens. This type of research creates tension between the individual’s autonomy and
the research benefits. Once the participant donates the specimen to a biobank, it would be almost burdensome on both the researcher and participant’s part, to recontact the subject every time the material is transferred.\textsuperscript{142} Thus, a researcher may have a participant’s genetic information without the participant ever knowing exactly where the information is. However, seeing as this would distribute the participant’s information without his consent, this would violate the participant’s privacy. These risks have drawn attention to the concern for data protection in genetic research.

If specimens without identifiers are not human subjects, then theoretically, specimens can be shared without oversight. Without oversight, there is little regulation to confirm that specimens are being used in accordance with the donor’s intentions and what was consented to. Unintended use might be less of an issue for small biobanks that house samples from a small population. However, for larger biobanks and researchers who access specimens without identifiable information (i.e. without one of the 18 elements of PHI as defined by HIPAA), there are dilemmas to ensuring the specimens are being used with the donor’s intended use. Pending the biobank’s organizational structure, transfer of authority or changes in data management can all affect the link between the donor’s intended use and the specimen.\textsuperscript{143} If disconnected, the specimen could essentially be used for any research purpose. Some participants of genetic research may participate because they wish to donate to a specific cause. If the use of “their body” goes beyond this cause, then the individual, through the principle of autonomy, maintains the right to be contacted. Therefore, the clinical method could be particularly important for respecting culture in research. So, if a researcher continues research on the individual’s genetic information and a third party becomes aware, the participant can be negatively affected by the
research. So in this circumstance, individual consent for longitudinal genetic research values the individual’s freedoms before the society.\textsuperscript{144}

Unintended use of genetic specimens is an issue in two instances. First, unintended use is an issue when the consent form explicitly details how the specimens will be used in the future.\textsuperscript{145} If specimens are stored in a large, general biobank and a specific future use was not disclosed, then presumably no future use is an unintended use. However, if the consent form details use, for example, for a specific cause or with a specific test, then the future uses are limited. Interestingly, this limitation is one that is not imposed by federal research regulations. For the purposes of consent, among other elements, the research regulations require disclosure of risks, alternatives, and an optional element is a statement regarding new findings that may develop during the course of the research that will affect the subject’s willingness to participate.\textsuperscript{146}

The second circumstance which could cause an ethical dilemma for unintended use of specimens is when the use is inconsistent with the donor’s moral beliefs. Individuals who participate in research may limit their participation to research that is consistent with their moral values. For example, Catholics might not want to participate in research that contributes to abortions. However, an individual cannot be expected to have consistent beliefs with the entire research project (i.e. secondary objectives). The principle of cooperation is critical to mitigating this issue so that all individuals can donate to biobanks, if willing, even if a portion of the biobank resources are delegated to research the individual does not support.

Once the samples are obtained, typically, genetic data is no longer physically stored; rather, it is stored electronically in registries. Using electronic sources, researchers can share data faster, easier, further, and more often. This method is an efficient method for research because from different geographic regions without having to visit the area, the researcher can obtain a
larger desired sample size. The participant has the right to be aware of the research protocol and withdraw their information from the biobank or a subsequent research study at any time.\textsuperscript{147} However, if specimens are disseminated from a biobank, the biobank often does not maintain responsibility for actively withdrawing the specimen from research projects. Rather, biobanks may only be responsible for withdrawing and preventing any further research on the sample. This approach to research though does not protect authentic individual autonomy in the post research experience. Some research conclusions could be pivotal to the individual’s decision making or family. Although this type of information can create tension and undesired stress, it could also liberate the individual and make him more autonomous. As far as informed consent goes, in the situation of unexpected results, the individual should be able to weigh the risks and benefits of a particular trait or characteristic himself.\textsuperscript{148}

A researcher’s obligations to the participant in genetic study conclusions are unclear.\textsuperscript{149} Ultimately, there are two routes the researcher could use to develop their ethical perspective of using biobank specimens. First, he could remain simply the researcher. This route would leave him with minimal obligations. The researcher would be obligated to obtain informed consent as in any other study. Then, the researcher would be obligated to publish the research for public good. This type of interpretation would suggest the data and conclusions are public property. For the individual to learn about the conclusions, he is to seek them in a public forum.\textsuperscript{150}

The second route would be for the researcher to collaborate with clinical medicine.\textsuperscript{151} In this method, the researcher would be obligated to inform either the population as a whole or the participant as an individual about the conclusions if they would be clinically significant. The collaboration between clinical and research medicine would create a direct benefit for the
individual. Therefore, there would also be a greater responsibility upon the researcher to promote this benefit.\textsuperscript{152}

As recognized by GINA, the federal law, unauthorized use of genetic information can lead to stigmatization, discrimination, and familial distress.\textsuperscript{153} Some critics of genetic research informed consent argue a risk of research on biobanked samples is unwarranted informational dispersal. Therefore, a researcher has an obligation to the participant to disclose such risks during the consent process regarding unintended use of samples.\textsuperscript{154} International regulations focus more on the protecting of privacy rather than the discrimination of the participant. If the participant does consent to his material being stored, he accepts unique risks such as a breach of security in the system. Longitudinal studies promote new risks for the individual’s privacy. However, sharing conclusions or genetic data can be most beneficial for public health. For this reason then, there needs to be a balance between protecting a participant’s privacy or anonymity and the need to develop public health knowledge. Participants then need to trust the researchers to protect their genetic information. When participants are treated unfairly, they can experience unjust stigmas or discrimination. Currently there is no strict regulation on genetic research. Rather, the standards are more a patchwork of regulations for the researchers.\textsuperscript{155}

3. \textit{Return of Genetic Research Results}

Finally, in order for organizations to have successful biobanks, they need to address the return of research results from specimens obtained from biobanks. Not only does the return of results have implications for the biobanks, but this also contributes to standards of confidentiality and researcher responsibility. While traditional research results are returned if they are medically actionable, the longevity of biobanks makes the return of results more ethically complex.
Actionable results could be identified 5 months or 50 years after the specimen has participated and in some cases, recontacting the subject may be a breach of privacy or unethical.

Organizational, national, and international guidelines seldom address the issue of returning of incidental findings (IF) from research. In the event that guidelines do address IF issues, they are rarely consistent among another. At the moment, the return of IF results is fairly small in comparison to the results from potential, future research. Since there are a limited number of genetic tests which can accurately identify IF, the instances of these findings are less than what they will be in the future if validated tests continue to be developed and validated. For this reason, organizations must be proactive to develop a basic framework for aiding at least the decision to return IF, if not also a possible process and list of researcher responsibilities.

The issue of returning IF is complicated insofar as it places a degree of responsibility on the researcher to actively attempt to return the results. Thus, the first issue organizations must address when developing a guideline is to clarify whether researchers should return IF or are obligated to return them. The literature is inconsistent regarding the researcher’s ethical obligations. However, the Council of Europe states that research participants are entitled to know information about their health. Thus, there is a logistical dilemma regarding the process of returning results. Regardless of whether researchers should return or are obligated to return results, it is ethically imperative that the return of IF are done appropriately as not to overload a subject with incomprehensible scientific information. There are ethical recommendations for the return of IF which includes the researcher ensure that the results are validated, communicating the implications of such results, and ensuring that appropriate referrals are made. The recommendation for appropriate referrals is limited to only making the referral but does not obligate the researcher or participant to pursue the referral.
For the sake of the remainder of the discussion, assume that the ethical recommendations for the return of results are focused on communicating results to participants in a manner which they can understand the health consequences and are informed of potential next steps including informing family members, if applicable. If researchers are obligated to return results, then organizations must support the researchers in the ethical recommendations to return IF. Among the internationally available guidelines for research, only 23 were identified to explicitly discuss disclosure of IF. However, other guidelines could be interpreted to discuss the return of research IF by stating that results that relate to an individual’s health should be returned or available to the subjects. Among the 23 guidelines that explicitly discussed IF, only 3 of these guidelines specifically discussed IF results that originate from biobank data.159

The discussion about the return of IF results also introduces an ethical issue regarding the anonymization of research samples. From the participant perspective, participants are entitled to receive results about their health. If participants are entitled to results, then it would seem unethical to anonymize such data as the researcher would not be able to recontact the subject to disclose the results. Additionally, if subjects wish to withdrawal their information, they cannot do so if their samples are de-identified. From the researcher perspective, it is sometimes difficult to argue that a sample is ever truly identified as clinical data and geocodes can make a sample identifiable. In such a situation, then there might be questions as to whether the researcher has the overarching obligation to return an IF.

While the concept of a biobank is simple (i.e. storing of samples for future research), the actual process of developing and maintaining biobanks is complex. A well-established biobank requires long term storage facility, secure technology, continuous monitoring, as well as a labor force committed to conducting the protocol which includes consenting subjects and any
additional follow-up. Thus, returning of IF further contributes to issues of funding biobanks as it can require an extensive amount of resources to re-contact and follow through with the ethical process of returning results.\textsuperscript{160} When dealing with financial constraints, it is not uncommon for organizations to transfer their biobank specimens and data to a private biobank for access and equity in order to stay financially viable.

\textit{II. Confidentiality in Biobank Access}

While biobanks are developed to support sharing information throughout the research community, confidentiality remains essential to maintaining trust in this type of research. To maintain trust in biobanks, organizations must develop a proper system for governance, stewardship through benefit sharing, and bridging the gaps between laws, guidances, and the practicality of the research.

\textit{1. Organizational Governance as an Effort to Bridge the Regulatory Gap}

It should not be assumed that because a researcher or institution develops and maintains a biobank that there is ownership of the specimens. The concept of ownership and biobanks is highly controversial. Therefore, for the purposes of the discussion, governance can be considered an aspect of custodianship. Custodianship is a responsibility of taking care of the biobank until used for research.\textsuperscript{161} In addition to stakeholder trust in the biobank, adequate governance will also contribute to the scientific validity of samples and data emerging from the biobank. Standard operating procedures are critical to biospecimen handling and laboratory procedures to ensure samples are of the highest attainable quality.

A significant amount of work has been put into developing a network of biobanks that are readily accessible to researchers.\textsuperscript{162} Being that data collection can be global, and research
initiatives can be multidisciplinary, organizational governance over biobank research is critical to compromising between individual risk and population benefits. It is in a not too distant future that biobanks will likely have a search engine type function enabling researchers to effortlessly filter through data elements. For this reason, managing and protecting large amounts of data in ethically has quickly developed into a pressing issue for organizations which host biobanks. Biobanks are unique insofar as they are not governed by a typical command control structure observed in other parts of the organization. Rather, biobanks are networks of individuals from various organizations and backgrounds for the biobank itself. Additionally, from the purposes of government initiated biobanks, the biobank authority is in a sense, a shared authority between the participant (i.e. society) and the government. Thus, there is an element of social control which is not normally present. An example of shared responsibility is the Icelandic Health Sector Database which was government initiated. However, when over 20,000 Icelandic citizens opted out of the database, the government was forced to address issues of privacy to protect the citizen’s samples and data.  

Distinct from regulations, governance is an attempt to control or promote behaviors for a specific purpose. For the purposes of biobanking, governance can take form in the requirement to complete applications describing research goals and confirmation that data will be used in accordance with its donor’s intention. The procedures or regulations in place are formal methods of support for governance. Current research governance structures consist of Institutional Review Boards (IRBs), local, state, and federal regulations. Few international guidelines can be used for governance. However, some policies and guidelines such as the Nuremberg Trial principles have influenced governance. As a result of the Nuremberg Trial principles, the former governing bodies are structured to protect human subjects and their interests. The issue with the current
governance such as an IRB is that while they can review and approve a protocol that aims to withdrawal data from a biobank, it is difficult to confirm that the data is being used for its intended purpose and that the subject’s confidentiality is being adequately protected. In other words, current governing bodies do not often oversee how research is carried out and how the secondary data is being used for future research. Rather, these are the researcher’s responsibilities.

With so much responsibility dependent on the researcher, governance is difficult to enforce. Thus, governance of biobank research requires a reevaluation of the means to oversee data movement. Some governance systems have shifted towards an electronic based system which helps track the flow of information. However, a significant amount of information remains on paper which inhibits the transparency of data flow.\(^{167}\) This situation is similar to reporting of medical errors in clinical care. If it could harm the researcher’s reputation or impede the process, then organizations might have a difficult time motivating and subsequently enforcing a system to track specimen and data movement from a biobank. Of course, knowing information about data movement is important for the organization to maintain transparency in the biobank. Without this continuous oversight, participants may be less trusting of researchers when they say where or for what the participant’s specimen may be used form.

Recently, the NIH has made guideline changes to multi-center NIH funded studies.\(^ {168}\) For these studies, a central IRB must be the reviewing IRB for all sites. As IRBs are still implementing this new requirement, some hurdles have yet to be overcome. First, IRB oversight is only required in some instances but primarily if the research is human subjects. As discussed earlier, it is not the case that all researchers who put only data set into a biobank are engaged in human subjects research since the researchers might not be interacting with an individual or their
identifiable data to obtain the data set. Likewise, on the opposite end, it is not the case that all researchers requesting data sets or specimens from a biobank are engaged in human subjects research if the specimens do not contain identifiable information. Thus, at least for the purposes of IRB oversight, not all researchers are engaged in human subjects research, and therefore, IRB governance does not apply. Of course, as discussed earlier, whether a researcher is engaged in human subjects research and requires IRB oversight is a different dilemma to manage.

Another consideration for biobank governance is stakeholder participation. It is unarguable that a biobank’s success is dependent upon the patient or research participant’s willingness to donate leftover specimens to a biobank. For this reason, these individuals are stakeholders in the biobank, and their perspectives should be adequately represented and integrated into biobank governance. Overall, participants, both as patients and in research, have a positive attitude about biobanks. However, among the issues most noted by stakeholders are consent, privacy in data sharing, and the return of results. Multiple studies have noted that stakeholders put the benefits of data sharing above many risks. It does not seem that concerns for privacy influence an individual’s willingness to donate to a biobank. At the same time, individuals had minimal trust for biobanks that were for-profit, industry, or insurance sponsored.

Future issues for biobank governance will come when addressing transnational biobank networks. These biobanks will presumably require integrating local, state, federal, and international regulations. Currently, there are few regulations that can be effectively implemented to protect participants of biobanks. Therefore, organizations that house biobanks are responsible for ensuring that ethical research conduct is being undertaken and promoted.
Errors in ethical conduct may still occur when transferring data.\textsuperscript{172} In this sense, organizations and researchers are stewards of genetic material. As stewards, they must be sure that the individual’s rights are protected and that the community from which genetic information was obtained receives appropriate benefits.

2. *Stewardship of Specimens and Benefit Sharing*

Organizations and researchers are stewards of genetic information. They obtain specimens that belong to an individual to abstract genetic data. As defined by the common good arguments, the data’s ownership belongs to not only the individual but past and future generations. For communities that are either isolated or in a unique environment (i.e. one that is not easily accessible), are vulnerable to exploitation from genetic researchers. The research model exemplified when conducting research in these communities might find the concept of benefit sharing useful as a compromise between the individual and scientific benefit.

Benefit sharing is the process or act of sharing research benefits equitably. Benefit sharing typically comes into context when a research country goes into a host country to conduct research. A host country tends to have low-income and low-resources. As a result, these countries have a limited capacity to obtain accurate health information about their population or have limited resources to develop policies to protect their citizens in research. In order to avoid exploitation then, researchers are to address immediate health issues of the host country and provide a reasonable standard of care.\textsuperscript{173} The researcher’s nation can promise the host country incentives for consenting to research. Due to a lack of enforceable international standards, accessing human genetic information can go almost unregulated. The media has portrayed researchers who conduct research on small, indigenous communities as “body hunters.”\textsuperscript{174}
Suggesting that researchers are only seeking to gain access to rare genomic data and not truly aiming to provide benefits to those communities.

Material transfer agreements (MTAs) are among the few ways the host countries can ensure equitable sharing of benefits when participating in international genetic research. As part of an MTA, countries can require that they will only share biological specimens with other countries who abide by the otherwise unenforceable international law. Among the common benefits listed as part of MTAs that supports benefit sharing are monetary and non-monetary benefits. However, who should directly benefit from the research as part of benefit-sharing is not quite clear. Scientific research is not required by federal regulations to always contribute to individual well-being. However, generalizability is a component to defining research and benefits for generalizable knowledge are required as part of research. Even a single subject genome sequence can contribute to generalizable knowledge since it can be compared to other genomes and the variation could potentially occur again in the future.

Benefit-sharing is most often used and discussed in the context of international research. However, the general concept can be applied to national biobank research insofar as there are disparity gaps between communities. Organizations are in a position to bridge the gaps where unenforceable regulations can protect vulnerable populations. Specifically, similar to MTA requirements, organizations can raise the ethical standards by only engaging in MTAs with other organizations who uphold human genetic protection standards such as the UNESCO Declaration of Human Genome and Human Rights. MTAs not only protect vulnerable populations by ensuring reciprocating direct benefits, but the standards also help temper commercialization of products.
A general framework for organizations to consider when engaging in biobank research specifically with lower-income communities consists of 6 points: 1) respect participants and donors, 2) specifically by protecting confidentiality, 3) inform participants of potential risks such as incidental findings, 4) share materials and data in a transparent manner, 5) ensure quality of data and samples, 6) improve community awareness and participation, and finally, 7) define the role of private use of data and samples derived from the biobank. This framework is intended to, at a minimum, not leave the community worse off than when the research was initiated. Such a standard is the minimal requirement for protection of vulnerable populations in research. This basic framework intertwines the elements consistent with the larger organizational ethics framework discussed. Specifically, for genetics and biobanks, transparency is essential to maintaining trust with a vulnerable community. Additionally, the framework addresses the third component of the organizational ethics framework of compromise between the individual risks and the population benefits. There is equal representation of the needs of and responsibilities to communities and individuals who participate in biobanks. Finally, this framework also, if adopted by the organization, places both the organization and researcher at equal responsibility for promoting ethical research and benefit-sharing as a result of the research. With this general framework, the organization and research have a common ground to initiate a conversation to conduct research while protecting participants. A limitation of the framework is that while it is sufficient for a single biobank or even network of biobanks, it is still not an enforceable regulation.


The progression of privacy laws in the United States has followed developments of technology. Specifically, privacy laws have followed the increased use of electronic
technologies. Laws from about the 1980’s to the early 2000’s generally concern information access practices.\textsuperscript{180} “Information practice” is a set of practices established by the Department of Health, Education, and Welfare. The practices include the following: 1) it restricting the use of personal data record keeping that is secret, 2) ability for individuals to find personal information that is collected about them as well as, how the data is being used, 3) the ability to prevent information obtained for unintended use without consent, 4) to correct or amend identifiable information, and 5) organizations creating, maintaining, using, or disseminating identifiable data must ensure data is being used in accordance with its intention and must prevent any unintended use of the data.\textsuperscript{181}

Health Insurance Portability and Accountability Act (HIPAA)-mandated Privacy Rule, finalized in 2005, outlines the circumstances when an individual’s protected health information may be disclosed by a researcher or institution. The institution such as a health insurance company or a health care provider is a covered entity that is subject to the Privacy Rule. The Privacy Rule has defined “identifiable” by 18 elements which include characteristics such as medical record number, geocodes (i.e. zip codes or elements of address), social security numbers, or even implanted device serial numbers.\textsuperscript{182} If a specimen is stripped of the 18 elements of HIPAA identifiers or contains only minimal elements that cannot make an individual readily identifiable, then it is a de-identified sample.\textsuperscript{183} Interestingly, while genetic information is health information, it does not qualify as protected health information under the HIPAA Privacy Rule. The realization that genetic samples might not be coded with elements that make the sample readily identifiable but can be identifiable due to increasing technological advances raises the issue of how to protect this information. That being said, the Veteran’s Affairs treats genomic
data as personally identifiable information and therefore, protects the information in compliance with HIPAA.\textsuperscript{184}

Some countries have passed laws specifically to address the identifiable nature of genetic materials. In 2008, the United States introduced GINA, the Genetic Information Nondiscrimination Act of 2008. GINA is intended to prevent genetic discrimination from health insurers and employers. GINA is limited insofar as it prevents discrimination but not privacy protection.\textsuperscript{185} So a company might be able to access the information, identify the genetic difference or pre-condition, and subsequently use the information as motivation for certain decisions which are intended to mask discrimination. Additionally, GINA does not address issues of large scale data bases such as biobanks.\textsuperscript{186} There is yet to be a national standard to establish the right to privacy with regard to genetic sequence data.

As recommended by the Presidential Council on Privacy and Progress, a fostering participation in genetic research must consider three elements: the individual, information technology, and policy.\textsuperscript{187} Of course, respect for the individual requires at minimum confidentiality which can be influenced by information technology. Breaches of protected health information cause participant distrust or doubt in the security of their confidential information.\textsuperscript{188} For data, such as genomic sequences, that is stored electronically, preventing breaches of confidentiality is particularly critical since data can be analyzed by an unauthorized user without the data ever leaving the system. Thus, policy for confidentiality should be two-fold. It should address the proactive protection for data and the remedial actions if there is a breach of security.

One of the recommendations for maintaining privacy is to “ensure a consistent floor of privacy protections cover whole genomic sequence data… prohibiting unauthorized whole genome sequencing without the consent of the person from whom the sample came.”\textsuperscript{189} In other
words, there should be a seamless protection of specimens collected for biobanks regardless of how the specimens were collected (e.g. for research or for clinical care purposes). If collected clinically, data and specimens are protected under HIPAA. If collected for research purposes, they are protected under the Common Rule. Since genetic information can be obtained from specimens collected for either purposes, the regulations and governance should follow similar approaches for protection. Thus, specimens should be protected regardless of how they were collected.

d. Conclusion

Biobanks for genetic specimens are useful from a researcher’s perspective as it allows sharing of specimens thereby limiting the participant burden. At the same time, if proper oversight is not maintained, biobanks risk breaches of participant confidentiality. These breaches can decrease trust in not only the biobank, but the organization and the subject’s future participation in research. For this reason, proper governance is critical to maintaining biobanks to ensure appropriate use of specimens.

The organizational conflicts that arise when using biobank specimens or even donated genetic materials not part of a biobank used to develop patents and commercialized for profits. If genetic materials are common goods and specimens are donated to produce generalizable knowledge, then it seems counter intuitive to patent and commercialize genetic technologies if they restrict access. Since there are limited regulations surrounding the transfer and ownership of genetic materials, organizations must take responsibility for managing ethical transfer of specimens. Specifically, this can be accomplished by establishing material transfer agreements which will require researchers who use the biobank to confirm that they will uphold determined
ethical and legal standards. With better organizational management of biobanked specimens, patents and commercialization of genetic technologies can be tempered albeit still profitable for the organization.

Finally, biobanks do not resolve the issue of anonymizing genetic information and therefore, the issue of privacy would remain in genetic research. In summary, genetic specimens can rarely be completely anonymized and this will only become less rare as technology develops. However, using the organizational ethics framework, there can be a compromise between the inability to completely anonymize genetic information and the risks to privacy. Rather, informed consent standards in genetic research should only ensure that the researchers will protect confidentiality of subjects. Confidentiality is better suited for genetics research insofar as it assumes private or identifiable information is disclosed among a group of individuals but that the research participant will not be overburdened by this disclosure.
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Common Rule.


Chapter 6 Using the Framework to Promote Trust through Transparency in a Healthcare Organization

As the American Hospital Association states, “hospitals exist to serve.” Their ability to serve is impacted by stakeholder trust in the organization. In their mission to serve, organizations face issues of control of information on a daily basis. Some decisions do not have to be dramatic to affect the organization’s reputation with their patients, professionals, and community. Control of information will influence the overall ethical culture within the organization and ultimately stakeholder trust. The control and availability of information change the degree of transparency the organization allows. Thus, transparency is not only essential to genetic technologies but the entire organizational system. The final chapter considers the implications that the organizational ethics framework can have on promoting transparency not only in genetic technology implementation but also in the broader organization. Transparency is used in the framework specifically for addressing the risks and limitations of genetic implementation. The application in the framework can be used broadly in the organizational context to address transparency, patient safety, and trust. The aspects of consent, conflict, and compromise will be applied to these respective areas.

Transparency is often used in a negative context in order to motivate an agent to disclose information deemed to be below an acceptable standard. For hospitals, this may mean transparency about their rate of medical error, infection, or spending. A large portion of transparency literature is focused on cost-effectiveness. Consistently, the United States spends more of the GDP than any other nation in the world and yet, the healthcare outcomes do not reflect this spending. More importantly for organizations, patient satisfaction does also not directly correlate to spending. Therefore, healthcare spending does not appear to maximize cost-
effectiveness. Organizations can address issues of patient satisfaction with the framework since the foundation of the framework was developed with consideration of relationships and potential conflict. Therefore, the organizational ethics framework established in this dissertation can be used beyond the scope of genetic technology implementation to foster a culture of transparency and subsequently, increase trust in the organization.

a. Transparency in Healthcare Organizations

In healthcare, the criteria for transparency may vary depending on the individual. For instance, a clinician may want transparency surrounding a policy or standard operating procedure. Meanwhile, a patient might want transparency about whether a procedure will inhibit their daily life and the overall costs. Regardless of the criteria, transparency requires one agent to have control over information. For the most part, healthcare organizations are in control their degree of transparency. Organizations have an ethical obligation to transparency in instances when it can affect healthcare delivery.

Since transparency is an ethical obligation, an organization must be critical of the potential barriers to transparency built into the system. Barriers in genetic technology disclosure include respect for privacy, unknown risks, and genetic variability. Barriers to transparency include the associated risks both institutions and providers undertake when disclosing errors. Risks of decline in patient numbers, reputation, and financial costs are all incentives to not disclose errors. However, this disregards the ethical obligation to make information available to the consumer (i.e. the patient). Due to the multiple components of health care practices (i.e. insurance, hospital policy, and patient resources), creating a culture of transparency can be difficult. By being servants to the community, healthcare organizations not only have a duty to
be transparent, they have an ethical obligation to disclose necessary information to their stakeholders. As argued earlier, moral agents have an obligation to, at a minimum, not impede an individual’s decision making process be it a patient or a community of people.

In chapter 3 of this dissertation, the concept of transparency was applied to the stakeholders in genetic technologies. When applying the framework to the broader organization, the stakeholders become more diverse. These individuals can be not just those involved in the immediate care of the patient or subject; to all providers regardless of specialty. All patients regardless on the complexity of their case; all other organizations the healthcare organization might have relationships with (i.e. sponsors, benefactors, collaborating research institutions etc.). With transparency, each stakeholder can hold another accountable for their actions thereby creating a system of transparency.

Conflicts might arise when determining a method to approach transparency. There are essentially two perspectives similar to the framework (individual and population) which can be used to determine a method for approach. To foster a culture of transparency, an organization might approach an event by first questioning it was a system-wide occurrence or if it was an isolated event. This is not to dismiss all cases of human error. Of course, there are reasonable standards to which both professionals and patients alike are held accountable. However, the process becomes the problem and processes are often less complicated to change than people. Further, by shifting the focus on the process focus is taken off human errors. The framework leads itself to approaching transparency in a manner that assesses systems versus individual people as requiring the change. In doing so, organizations are in a position to create a culture of transparency. No longer does transparency have to be understood as resulting in disciplinary
action. With a framework with logical perspectives and objectives of compromise, transparency can foster an innovative and teamwork environment that enhances patient safety.

Cultures of transparency can lead to avoiding unnecessary risks and promote collaboration among the hospital community. Collaboration among clinicians, researchers, individual patients, and the larger population is already a component of the framework. For this reason, the framework’s application is most appropriate in the broader organizational aspect. A culture of transparency must dispose of the image of perfection. This image should be replaced with the organization’s reasonable limits of care. When limits of care are accurately defined, stakeholders can more easily identify when healthcare organizations are meeting or missing the benchmarks.

b. Enhanced Transparency in Patient Safety

Benchmarks in healthcare are critical for assessing patient safety standards. When benchmarks are missed, patient safety is potentially negatively impacted. Patient safety events are difficult to manage as they are often associated with financial distress and damages to the organization’s reputation. For this reason, transparency of medical errors is among the most taboo topics for organizational leadership to manage simply because it often involves a hospital admitting guilt of an error. However, all hospitals experience instances of medical error whether they care to admit it or not. Trust issues develop when organizations attempt to veil or entirely hide a patient safety event but the event becomes publicly known through alternative resources. Thus, transparency can promote safety in hospitals. The organizational ethics framework can be used to promote transparency in patient safety as the framework builds in acknowledgment of potential error. Genetic technologies are high risk, high reward interventions. Not only do these
technologies risk privacy, but also patient safety. In chapter 4, it is argued that although there is high reward, organizations must determine appropriate limits of care to maintain patient safety. For this reason, the framework can be an example of balancing the patient concerns with ethical obligations of organizational disclosure.

After implementing frameworks aimed at encouraging reporting and event analysis, hospital leadership is ethically obligated to address the noted concerns especially if the concern involves patient safety. Of course, it is not enough to simply address the immediate event. It is imperative for organizations to collect the relevant data from all similar patient safety events to contribute to generalizable knowledge for future patient populations. This process is exemplified in the organizational ethics framework in this dissertation. Individual data is used to contribute to generalizable knowledge about a population with similar genetic characteristics. In the broader application, collective information is beneficial to quality improvement. The framework developed in the dissertation is an example of the perspectives to consider when analyzing a patient safety event for the purposes of improvement.

Transparency causes hospitals to react to patient safety events and make appropriate changes to procedure to ensure the issue does not recur in the future. Transparency can help providers improve their benchmarks and patients make informed choices with regards to their care. Even transparency among healthcare organizations is beneficial to understand market competition. Difficulty may when healthcare organizations attempt to convey an image of perfection as opposed to one of openness. In a sense, the organization sets their standard too high that it’s unattainable thereby putting their professionals in a position to not meet their standards. The example of enhancement versus therapy discussed in chapter 4 can be used to highlight unreasonable expectations in clinical care. There is still room for improvement for hospitals to
create a culture where medical errors are identified and freely investigated for the purposes of improving patient safety. Importantly, error and conflict were built into the framework. It is inevitable that some agents within the organization might not be prioritized due to the restrictions of the situation. This can lead to issues of conflict if there is not transparency surrounding the decision making process.

In the decision making process, organizations must determine who or what is accountable for the error. As a result, an issue that often arises, which the organizational ethics framework addresses, is the imbalance of accountability. Providers might not want to disclose information for fear of damaged reputation similar to individual disclosure of genetic information described earlier. There is when it is important that a culture of transparency protects individuals who report errors. This fear can consequently inhibit a providers’ motivation to be transparent about their practices. At the same time, it would be unethical to not discipline the necessary individuals in the event that an error occurred due to purposeful disregard.

Organizational conflicts arise when there is a breakdown of communication in the event that a provider does face disciplinary action. If a discussion does not take place explaining the reason for the action, then it can be perceived that an individual was disciplined for a systems failure. The communication aspect of organizational ethics will remain to be a complicated issue. In the age of information, transparency is determined by who obtains and interprets the information first. At the same time, organizations need to have prudence to understand what information is helpful to their served community and what might be harmful in their decision making process. While it is imperative that organization addresses patient safety concerns and is transparent about these issues, too much information can impede trust in the organization. The
framework can be used in the broader scope to define a balance about necessary disclosure and too much information to maintain trust.

c. Trust in Healthcare Organizations

Chapter 5 discussed the need for trust in organizations specifically when it comes to fiscal responsibility. The need for trust in an organization spans far greater than only fiscal responsibility but to all aspects of healthcare delivery. Transparency promotes trust because it increases accountability. When organizations are transparent about medical errors, they are held accountable to regulatory bodies and the served community to resolve the root cause of the problem. Transparency in healthcare organizations requires communication, relationship building, and opportunity to voice opinions. All of these factors are present in the framework in some form. For instance, in aspects of consent, effective communication is required to relay relevant information. Conflict might occur when identifiable information is used to assess a problem. Finally, compromise is an opportunity for relationship building. To achieve the final compromise, there must be a level of trust in mutual objectives. Granted, these objectives may vary depending on the agent.

Specifically for genetic technologies, transparency can be a balancing act in an of itself. The standards of consent require providers and researchers to relay the amount of information a reasonable individual would want to know to make a decision. Individual rights and privacy are among a top priority in United States healthcare. Privacy is considered essential to informed consent since it is understood to be the individual’s primary protection from undesired burdens. Given the complex nature of genetic technologies, an organizational promise for privacy is becoming less appropriate. Further complicating the situation is novelty of genetics since it is
difficult to determine when enough information is sufficient to determine transparency. Further, providers might need to be transparent with Genetic research initiatives are developing at exponential rates.

A major contributor to the speed of development is the method for storing data. “Big data” was discussed in Chapter 5 of this dissertation. Big data creates a conflict with individual rights insofar as it creates potential for a breach of confidentiality. When individual confidentiality is compromised, individuals are less likely to trust an institution with their private identifiable information. Transparency in the potential risks of genetic research is essential to the continuous development of genetic technologies and the integration of these technologies into clinical care. Specifically, the limits of privacy’s application focused on balancing individual privacy and population interested. The contemporary approach to healthcare suggests that the autonomous model is most appropriate for clinical care. However, given that genetic data has elements of shared information, a shift is necessary to integrate an understanding of community dependency into clinical care decision making.

A healthcare organization is distinct from a business seeking to obtain financial success. The bottom line in healthcare organizations is to promote patient safety and community health for future generations. The organization is dependent upon both the delivery of healthcare and patient satisfaction. Inevitably, both components depend on the organization’s ability to ensure appropriate resources are available, including cutting-edge technology such as genetic technologies. As questions about genetic technologies have been approached from an individual and population perspective in bioethics discourse, this dissertation fills the need to assess the organizational perspective. An organizational ethics framework consisting of consent, conflict, and compromise was developed. This framework was used to evaluate the impact of genetic
technologies in both clinical care and research initiatives. In the case of clinical care, traditional medicine favors the individual patient. Meanwhile in research initiatives, generalizable knowledge, or population interests, are the minimal requirement for undertaking ethical research.

In summary, the organizational ethics framework for genetic technologies can be used in a broader application for the entire organization. For the broader application, it can address need for transparency at the individual and system levels. For the purposes of genetic technologies, it is critical to determining and maintaining an ethical balance between individual privacy and population health. The chapters of this dissertation analyzed the implications of genetic technologies on an organization’s ability to promote both the patient and population wellbeing.

Chapter 2 presented concerns of genetic technology access if healthcare practices were to continue in the manner of individual autonomy. Chapter 3 developed the organization’s role in addressing the tension between individuals and populations. Specifically, this chapter developed the organizational ethics framework as a response to the moral obligation for organizations to act responsibly with cutting-edge technologies. Chapter 4 implemented the framework into the clinical care setting in attempts to highlight how the framework can be used to justify standard of care methods. These measures are crucial to maintaining patient safety and therefore, trust in the healthcare organization. Finally, chapter 5 discussed the importance of confidentiality in genetic research biobanks. The practice of confidentiality lends itself to authorized disclosure of information.

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