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Catholic Ethics in the World of Clinical Research: A Study of Social Responsibility

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Introduction:

After the many global tragedies of the early 20th century, an emerging sense of social and moral urgency catalyzed the nations of the world to attempt to develop ethical standards for clinical research. Seminal documents such as *The Nuremberg Code*, *The Declaration of Helsinki*, and *The Belmont Report* attempted to bridge the chasm that allowed such tragedies. *The Belmont Report*, specifically, suggested universal ethical principles that later evolved into what is widely known now as the four core bioethical tenets: beneficence (the duty to promote the welfare and good of others), nonmaleficence (the obligation to avoid causing harm), justice (the requirement of equal and fair treatment), and autonomy (the right of individuals to make independent, informed choices). More nuanced guidance would later be offered in the form of the four principles for clinical research in the 21st century, such as those outlined in *The Oxford Textbook of Clinical Research*: collaborative partnership, social value, scientific validity, fair participant selection, favorable risk-benefit ratio, independent review, informed consent, and respect for participants. However, while these ubiquitous principles have directed the creation and revision of numerous research guidelines, their instructions on the inherent social responsibilities of clinical research remain ambiguous.

To fill this void, Catholic Social Teachings founded on the three-fold cornerstone of human dignity, solidarity, and subsidiarity offer a basis for a new principle of social responsibility. The three core principles of Catholic Social Teachings emerge from a comprehensive framework grounded in natural law reflect the secular concept of common morality. This foundational alignment allows for their universal application beyond the confines of the Church. Accordingly, this research assesses the essential components of clinical research while also exploring the foundational documents that led to the principles approach; by doing so, it highlights the deficiency in these principles' ability to address social stewardship. Incorporating the new principle of social responsibility will enrich our current ethical framework for clinical research and will enable us to truly fulfill humanity's goal after World War II.

I. What is Clinical Research:

To effectively discuss the embedding of social responsibility as a principle within clinical research, one must first understand the hierarchical structure and detailed processes of research. This

understanding involves appreciating and managing research risks and extends to institutional review boards, regulations protecting vulnerable populations, and the informed consent process. This background knowledge is a prerequisite for the exploration of foundational guidelines that regulate clinical research, which ultimately demonstrate the need for social stewardship.

a. Understanding Research:

Understanding research as a modern scientific inquiry begins with the topography of its hierarchical structure. The term research is formally outlined by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in *The Belmont Report* as a systematic inquiry aimed at hypothesis testing to draw conclusions contributable to generalizable knowledge. The Commission further sought to create a clear distinction between research and medical practice, defining the latter as an intervention solely aimed at improving the well-being of a patient.[1] Furthermore, medical practice entails a fiduciary relationship between a physician and their patient, requiring heightened scrutiny whenever research activities intersect with this unique connection. The bisecting of this special relationship between physician and patient occurs in what is labeled clinical research.

Clinical research refers to human-centered investigations used to advance the medical sciences and broadly encompasses two distinct yet interrelated components: clinical studies and clinical trials. A clinical study is a form of research that is primarily focused on gaining insights into a particular disease or medical condition, including disease patterns, outcomes, and potential risk factors.[2] Clinical studies are observational by design, centered on understanding a particular disease rather than developing or testing medical treatments. They are frequently utilized in the fields of epidemiology, public health, and sociology. In contrast, clinical trials are prospective or forward-looking research aimed at developing, testing, or expanding a therapeutic treatment and forming a reliable basis to evaluate the efficacy of a health-related intervention.[3]

The reliability of clinical trials relies on three crucial characteristics: a quantifiable outcome, the use of a control group, and a protocol for treatment assignment.[4] A quantifiable outcome in a clinical trial

can range from straightforward binary results, such as a 'yes' or 'no,' to more intricate measurements.[5] For example, it could encompass complex variables like the degree of symptom reduction in patients, taking into account subtle differences in patient responses. A control group in clinical research provides a critical comparison point, enabling the observation of differences between various interventions. Control groups are typically conceptualized as the comparison between an experimental group receiving the active treatment and a placebo group, which receives a non-active substitute. Finally, employing a predetermined method for assigning participants in clinical trials significantly diminishes the potential for investigator-induced bias.[6]

The drug approval process is the most widely recognized type of clinical trial. Before a new molecular entity (NME) can be approved for marketing within most countries, it must be reviewed for safety and efficacy by regulatory authorities. The approval process for an NME typically unfolds in a multi-phase sequence, formally encompassing phases I through IV. The initial step, phase I, primarily aims to evaluate the safety of the NME in healthy human subjects and to assess its pharmacokinetics.[7] Following a successful phase I trial, an investigative drug is then studied in individuals who have the disorder for which the drug is being developed.[8] Phase II of the drug approval process serves as a proof-of-concept stage for the NME.

After phase II trials have established the potential that the NME may be able to effectively treat individuals with the relevant disorder, regulatory approval typically requires at least two statistically significant clinical trials that confirm this finding. Phase III trials, therefore, involve the enrollment of hundreds to thousands of participants across multiple study sites to show a statistically significant result of the investigative drug.[9] Upon completion of a phase III trial and a favorable review by regulatory bodies, the NME may be approved for marketing in its target country. However, post-marketing surveillance, known as phase IV, will be necessary to continue monitoring the NME's safety throughout the life of the drug’s marketing and sales.[10] Clinical trials are invaluable tools that contribute to generalizable knowledge used in healthcare to better treat illness, as shown above with the drug approval process. However, their dual nature encompasses not only benefits but also risks.

According to bioethicist David Resnik, risk is the potential hazard of harm, such as loss of function, life, or money.[11] In terms of clinical research, risks to participants may be categorized broadly into five groups: medical, psychological, social, financial, and legal.[12] Within these categories, there exist various potential harms, including disability, discrimination, and mental distress. Furthermore, all research inherently involves elements of unforeseen risks. Accurately assessing risks for research participants is then not a precise science, given the possibility of unanticipated harms, individual participant perceptions of potential risks, and the specific context in which the research takes place. Therefore, risk evaluation is a form of quantitative ethical judgment, as it requires one to assess the worth of the risks in light of the benefits.

As an analogy, consider a clinical trial for the development of a new pharmaceutical to treat congestive heart failure. This investigative drug could be very promising at slowing the progression of heart failure but also carry the potential of severe side effects, including death. For some individuals with early-stage heart failure, this trial may be deemed too risky for them to participate in, regardless of the possible benefits. Still, for others with advanced heart disease facing limited treatment options, the risk of mortality from participating in the trial might be viewed as a less significant drawback, bearing in mind their current health situation.

b. Addressing Research Risk:

Historically, United States federal regulations regarding risks for human research did not assume their current form until the 1980s, following several scandalous revelations in previous decades. During this era, the Common Rule was incorporated into the regulations of the FDA and 17 other federal agencies.[13] The Common Rule established a comprehensive oversight system, mandating that researchers obtain institutional review board (IRB) approval before the commencement of any research with federal funding. It also set forth standardized procedures for IRBs, including protocols for reporting and addressing unforeseen issues that may arise during research.[14]

The task of an IRB is to assess the appropriate amount of risk and how said risk will be managed in research involving human subjects. As prescribed by the Common Rule, risk assessment for an IRB

requires identifying foreseeable harms, estimating their likelihood, and meticulously weighing the risks against the benefits.[15] An IRB holds the decided responsibility of evaluating both objective information (risk identification and probability) of the proposed research and subjective elements (risk-benefit analysis) to determine ethical and scientific appropriateness.[16] Therefore, the powers of IRBs span approval, rejection, suspension, and termination of research activities.

In addition to IRB requirements, the Common Rule incorporated specific safeguards for populations considered vulnerable and particularly susceptible to research exploitation. Vulnerability protections, outlined in sub-parts B to D, extend to pregnant women, fetuses, prisoners, and children.[17] Additionally, the Common Rule specifies detailed requirements for obtaining informed consent to safeguard all human research participants. Informed consent is an individual's autonomous decision to participate in research or permit a medical intervention. It is both a legal and ethical mandate that healthcare professionals and researchers secure the informed consent of their patients or participants before initiating any medical intervention or research. Bioethicists Tom Beauchamp and James Childress define autonomy as self-determination absent of external interference and limitation of meaningful choice. To truly respect an individual's autonomy is to empower them to make their own decisions.[18] As such, informed consent is the practical implementation of autonomy.[19]

The consensus of the bioethical community is that there are five necessary elements for a researcher to obtain valid approval of an individual. First, an individual must possess decision-making capacity (DMC), defined as the ability to comprehend, reason, and communicate an informed choice.[20] DMC is dynamic and can be affected by age, disability, and distress, among other conditions. Moreover, a direct relationship exists between the complexity of a choice and its level of risk to DMC: as the complexity and risk of a choice escalates, so does the necessary threshold of DMC required for an individual's decision to be considered valid. Conversely, the threshold of DMC required for a decision decreases as the complexity and risk are lowered. For example, an elderly individual with dementia may not have an appropriate level of DMC necessary to consent to an experimental treatment but could have a DMC level appropriate to determine when and what they eat at a skilled nursing facility.

Secondly, the informed consent process requires that potential research participants are given comprehensive information about the study, presented in a language and at a reading level suitable for their understanding. The provided information must cover key aspects of the research, such as the study's objective, rationale, duration, associated risks, benefits, and other pertinent details.[21] Within the process of disclosing relevant information to participants, there are three general standards: the professional standard, the reasonable person standard, and the subjective standard. The professional standard involves communicating information that a creditable professional in the field would typically disclose to a research participant. The reasonable person standard is, as it sounds, the communication of information that a reasonable person would want to know before authorizing their consent to research, and the subjective standard necessitates that a researcher tailor the information disclosure to align with what a specific person would likely wish to be informed about prior to the start of a study.[22]

Third, any potential participant must be able to comprehend the information that is provided to them. Oftentimes, research subjects can develop a misunderstanding of their involvement in clinical research, confusing the goal of the study with the treatment of their disorder rather than the advancement of scientific knowledge. This misunderstanding is known as a therapeutic misconception.[23] As outlined in *The Belmont Report*, therapeutic misconceptions can be prevented through clear communication by researchers and the correction of any misunderstandings. Fourth, any consent that is provided must be voluntary, free from coercion or undue influence. Coercion involves the application of force or intimidation to compel an individual to comply with a request.[24] Finally, fifth, the individual must agree to participate in the research. Consent can be obtained through either written or verbal means or by proxy, depending on the context.

While informed consent is a central component of most modern clinical research, there are some situations that may justify conducting research without obtaining it. The Common Rule permits an IRB to waive the requirement of informed consent in research that is deemed to be of minimal risk.[25] Minimal risk stipulates that the probability and level of potential harm are not greater than the risks that an individual would normally encounter in their daily life or during a routine physical or psychological

examination.[26] For instance, a study involving the review of medical records at a hospital could fulfill the minimal risk requirement or research that is performed on de-identified human biological samples retained from previous medical procedures. The discretion of an IRB on these matters should be guided not only by regulatory statutes but also by ethical principles and guidelines, which will be described in section II.

II. Current Principles and Guidelines of International Research:

When research involves human subjects, ethicists widely agree that adhering to legal and ethical standards are crucial to retain scientific validity and to protect participants. While cross-border guidelines undoubtedly protect research participants and promote human rights, they may also reflect a social incompleteness that undermines their utility in a pluralistic world. Section II will undertake an examination of the predominant ethical guidelines in research. The analysis will begin with an exploration of three widely recognized guidelines and treaties: *The Nuremberg Code*, *The Belmont Report*, and *The Declaration of Helsinki*, evaluating their relevance and application in today's global research landscape. It will then move on to discuss their foundational tents, rooted in the four primary bioethical principles and the eight research-minded principles of *The Oxford Textbook of Clinical Research Ethics*.

a. International Guidelines and Treaties

Transnational research standards can trace their roots back to the mid-twentieth century, following the conclusion of World War II, in the 1947 *Nuremberg Code*. *The Nuremberg Code* served as a new basis of international law to prosecute the unethical researchers of the Nazi regime.[27] The Code delineated ten essential principles for human research that must be followed regardless of the geographical location in which research takes place. The first and perhaps most revolutionary principle of *The Nuremberg Code* is that of voluntary consent, which is explicitly regarded as critical for all research involving human test subjects.[28] The first principle ostensibly resembles the bioethical principle of respect for autonomy, elaborated decades later in *The Belmont Report*.

The second principle defines the ultimate goal of all scientific research: to produce valid, generalizable knowledge. Principle three states that the anticipated benefits of research performed on

humans should outweigh foreseeable risks. According to the fourth principle, human research should be designed and performed to avoid unnecessary physical and mental suffering. The fifth principle affirms that research should not occur if there is a high foreseeable probability of death or disability. The sixth claims that the level of acceptable risk involved in experiments should never exceed the magnitude of the problem the research is attempting to address. The seventh principle is that precautions should be implemented in the research to protect participants from injury, disability, or death. The eighth principle refers to the competency of those performing the research in question, stating that all researchers must be scientifically qualified to perform said research. The ninth principle requires that human subjects should be free to quit their studies at any time. Finally, the tenth principle posits that the primary investigator should be prepared to terminate the research study at any point if they believe the experimentation is likely to cause injury, disability, or death.[29]

The most significant strength of *The Nuremberg Code* is its philosophical rationale for its principles approach, which is grounded on the theory of natural law guided by reason.[30] Consequently, the Code's wide-reaching pertinence has established it as the foundation for all subsequent ethical guidelines and codes of conduct in research since its 1947 adoption. Yet, because of its Western origins in a United States army tribunal, some ethicists still question its ability to retain global authority. As *The Nuremberg Code* can be conceptualized as the first modern ethical guideline on research involving human participants, *The Declaration of Helsinki* arguably follows it as the second.

In 1964, the nascent World Medical Association codified what would become a seminal document for ethical standards of research performed with human participants, known as *The Declaration of Helsinki*.[31] Over the following decades, *The Declaration of Helsinki* would go through multiple revisions, with the most recent seventh revision occurring in 2013. The Declaration expanded on the ten principles of *The Nuremberg Code* to cover topics absent in the 1947 document. Notably, it addressed the lack of consent requirements from participants deemed incompetent and the utilization of control groups in clinical research.[32] For instance, subsections 28 to 30 of the Declaration address the involvement of incompetent individuals in research, stipulating that consent for their participation must be granted by a

legal representative. Furthermore, it added obtaining their assent, when feasible, is imperative, among other detailed requirements.[33]

The strength of *The Declaration of Helsinki* lies in the novel authority and obligation it places on researchers and physicians as opposed to governments. The preamble of *The Declaration of Helsinki* articulates this obligation unequivocally, emphasizing that physicians are bound to these standards. They must adhere to both the ethical and legal requirements of their own country and the corresponding international standards; no ethical or legal provision can override the protections established.[34] Further, the successive revisions to *The Declaration of Helsinki* ensure that it is a dynamic document that can evolve to the ethical needs of the time, unlike *The Nuremberg Code*, which is a stagnant guideline. Apart from the establishment of explicit regulations governing international human research, the principles delineated in *The Belmont Report* offer a more conceptual basis for the rationale of ethical standards applicable to research indirectly mentioned in both *The Nuremberg Code* and *The Declaration of Helsinki*.

In 1978, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research published *The Belmont Report* on the moral principles of human research. The United States Congress created the Commission with the passage of the National Research Act of 1973 after public outrage over the infamous Tuskegee Syphilis Study. This horrific study took place between 1932 and 1972 and was funded by the Department of Health, Education, and Welfare to understand better the etiology of syphilis within the African American community. The study was to observe the natural progress of syphilis in an experimental group consisting of 399 African American men who, therefore, did not receive treatment for their syphilis or were informed that such treatment existed.[35]

When the study gained national attention in 1972, following a report by the Associated Press, the United States government initiated efforts to establish ethical guidelines for the oversight of federally funded research in order to prevent the recurrence of questionable experiments. The result of the National Research Act was *The Belmont Report*, which outlined a principles framework from which federal

research regulations were revised. The Report describes three principles that must be considered when research is performed on human test subjects: respect for persons (autonomy), beneficence, and justice.[36]

The authors of *The Belmont Report* stressed the importance of protecting research subjects, especially those deemed vulnerable. Still, shortcomings exist in *The Belmont Report* as it does not address how to weigh these principles against one another when they inevitably come into conflict.[37] Despite its narrow objective to formulate ethical guidance for policy advisement in the United States and its practical shortcomings, *The Belmont Report's* uncovering of three comprehensive bioethical principles has broad research appeal. For this reason, those principles have been elaborated on, transcend national boundaries, and have since become influential in shaping ethical standards for human research.

b. The Ethical Principles of Biomedical Research

Picking up on *The Belmont Report's* groundwork, the ethical principles that now serve as the cornerstone of all major research standards: beneficence, autonomy, and justice were further developed and expanded upon by bioethicists Tom Beauchamp and James Childress, with the addition of nonmaleficence. Briefly, the definitions of the four principles are as follows. The principle of beneficence is a moral obligation to act in ways that benefit others. Further refinement of beneficence is broken down into positive obligations for individuals to confer benefits and utility, carefully balancing risks and benefits to secure optimal outcomes.[38] Nonmaleficence is a moral principle that mandates individuals to refrain from inflicting intentional harm upon others.[39] This requirement is equivalent to the Hippocratic Oath's maxim, "First, do no harm." Beauchamp and Childress argued that the distinction between nonmaleficence and beneficence was necessary because of the moral distinction between the two.[40] A duty to avoid causing harm to others is noticeably different from an obligation to help others.

At a basic level, autonomy refers to the right to make independent decisions free from external influence or restrictions that obstruct genuine choices.[41] Respecting an individual's autonomy is more than refraining from decisional interference; it is also about acknowledging and empowering that person's right to make choices based on their values and preferences. The principle of autonomy is not absolute; its application must be navigated within the confines of the legal system in which individuals find

themselves. Respecting autonomy grants individuals the right to make choices, yet it does not impose a duty upon them to exercise that choice.[42] Lastly, the concept of justice asserts that the treatment of individuals and access to the distribution of resources should be equitable.[43] In practice, the principle of justice not only upholds the theory of fairness and equality but also demands that disparities be rectified.

In the field of research ethics, while the four fundamental principles offer a solid foundation, they can sometimes seem too theoretical or abstract for practical application. Their utility can also be questioned on the grounds that they are too expansive.[44] In fact, Beauchamp and Childress themselves recognize that the four principles alone are not sufficient to solve all ethical dilemmas. Identifying this, *The Oxford Textbook of Clinical Research Ethics* has taken a step further by distilling these concepts into eight more specific, research-focused principles. This refinement attempts to ensure that the core ethical values are not only preserved but also made more relevant and applicable in the context of actual research scenarios.

The first of these principles is collaborative partnership, which emphasizes the importance of ensuring that communities where research is conducted are not merely protected from exploitation but are also actively involved in the decision-making process.[45] Achieving a genuinely collaborative partnership consists of acknowledging and respecting the culture of the local community where research occurs. This, in turn, will facilitate mutual respect between the community and the researchers. The second principle is social value, an extension of philosopher Immanuel Kant's categorical imperative that one must act in such a way as to treat each person as an end unto themselves and never a means to an end.[46] In practice, the concept of social value equates to treating research as an instrument capable of generating knowledge for the improvement of humanity, not for the sole benefit of an individual, corporation, or country. Without social value, research places participants at risk without adequate benefit. The third tenet is scientific validity, which is related to scientific value, as it emphasizes that research outcomes must be both valid and reproducible. As described in section I, this entails a quantifiable outcome, the use of a control group, and a protocol for treatment assignment. If research does not retain validity, it parallels the

scenario where research lacks social value: participants might endure potential harm without justifiable cause.[47]

Fair participant selection obligates researchers to use only the objectives of their study as the primary factor in the determination of participant selection.[48] Social status should not be a factor in the selection process, nor should any other discriminatory characteristics. The subsequent principle, favorable risk-benefit ratio, asserts that the potential benefits to research subjects should outweigh the potential harms. However, this principle does not entirely exclude scenarios where the ratio is equivalent or slightly skewed towards harm, provided that the overarching social value justifies the risks.[49] As a matter of beneficence, risks and benefits should be examined for each individual participant.

The sixth principle, independent review, mandates that individuals not involved with the research study should examine all research protocols. These reviewers are expected to minimize their conflicts of interest, and the outcomes of their review should be transparently disclosed, which is especially critical to respect the diversity involved in multinational research appropriately. The seventh principle, informed consent, as outlined earlier in the paper, is a multi-pronged process required to respect the autonomy of participants. The final principle of *The Oxford Textbook of Clinical Research Ethics* is respect for participants. This principle obligates researchers to treat individuals with respect during the entire research process and extends this obligation beyond the study's conclusion.[50] Pledges of confidentiality are required to be maintained during and after the study, and participants should be alerted to any breaches that may compromise their private information or health.

While these various principles have become ubiquitous and have had a significant impact on the protection of global research participants, their instructions on the inherent social responsibilities of clinical research remain ambiguous. For example, while the principles of social value and respect for human participants reflect components of social stewardship, they do not fully encompass the topic. Social responsibility is more complex than the creation and spread of generalizable information (social value) and the protection of an individual’s autonomy as a research participant (respect for human participants). Social responsibility in research entails a comprehensive commitment to ensuring that

research delivers multifaceted social benefits, including economic, health, and human rights advancements to local, national, and global communities.

III. Social Responsibility: Applying Catholic Social Teachings to Research:

The concluding section of this paper systematically examines the central thesis that the four bioethical principles of Beauchamp and Childress, tailored to the research contexts in *The Oxford Textbook of Clinical Research Ethics*, primarily advocate for ethical practices in methodology, participant protection, and scientific integrity. However, this interpretation presents a significant oversight as it lacks a comprehensive framework for social responsibility. These principles, while reflecting aspects of social responsibility, fundamentally fall short of fully embodying it.

Social responsibility in research extends beyond procedural ethics; it encompasses a profound appreciation for the intrinsic dignity of each participant, ensuring equitable distribution of research benefits and aligning research endeavors with the welfare of the local communities. This section, therefore, argues for a more complete approach to ethics in clinical research, one that integrates these broader societal considerations alongside traditional ethical principles and adopts a new ethical tenet of social responsibility.

a. The Three-Fold Cornerstone

The three-fold summation of Catholic Social Teachings was first formally articulated by Pope Saint John Paul II in *Ecclesia in America*, stating that the Church's social doctrine rests on the threefold cornerstone of human dignity, solidarity, and subsidiarity.[51] Before the Church's social teachings were formally organized into a tripartite model, they were thematically present in several previous papal encyclicals, which were rooted in the broader tradition of the Church's response to evolving social conditions, particularly since the Industrial Revolution. Key examples include Pope Leo's *Rerum Novarum* and Pope Pius XI's *Quadragesimo Anno*.[52,53] The modern packaging of Catholic Social Teachings by Pope Saint John Paul II was later reaffirmed by his successor, Pope Benedict XVI, who expressed that the fundamental principles of human dignity, subsidiarity, and solidarity are invaluable tools to the support of the laity's development of the Church and society.[54]

Catholic Social Teachings serve as a guiding framework for assessing the moral dimensions of society, offering pertinent criteria for making such evaluations. Beginning with the greatest of the three tenets, human dignity is the inherent value with which each person is endowed by their creator.[55] Human existence holds this intrinsic worth on one part because we are formed in the image of God and set apart from all other creatures, endowed with a reflection of divinity, not equivalent to God, but mirroring His supreme goodness.[56] As a manifestation of God's benevolence, life also holds intrinsic worth because existence itself is a gift. *The Ethical and Religious Directives for Catholic Health Care Services* analogize this viewpoint in terms of stewardship.[57]

Within the realm of clinical research, human dignity can be conceptualized as built on two pillars: respect for life's sanctity and the preservation of individual integrity. Respecting the sanctity of life is a negative obligation, entailing that one must abstain from deliberately causing the death of any innocent individual.[58] The preservation of individual integrity holds that each individual, regardless of age, race, sex, socioeconomic status, or medical condition, deserves to be considered an end unto themselves and not a means to a greater scientific goal.[59] Additionally, those performing clinical research are obliged to be attentive to and care for the physical, psychological, and spiritual well-being of their subjects.[60] For researchers, these pillars of human dignity translate to a commitment to abstain from direct involvement or cooperation with any act deemed intrinsically immoral. To illustrate the point, research on euthanasia or elective abortion is intrinsically wrong because it could be construed as endorsing or facilitating the practice of deliberately voiding an individual's dignity.

The second leg of the tripartite model of Catholic Social Teachings is solidarity. Solidarity is a commitment to the common good and a spirit of unity among all people.[61] It implies a brotherly covenant to the disadvantaged through individual and collective actions. According to Pope Francis, solidarity is a willingness to lose oneself for the sake of others.[62] Solidarity pulls at the fraternal fabrics that connect all of humanity toward the common good. This portion of the three-fold model necessitates a fostering of collaboration and partnership that transcends borders, disciplines, cultures, and socioeconomic factors.

Every decision made during a research study, from its conception to its conclusion, is an opportunity to respect, contribute, and embrace this shared thread of humanity.

The last of the principles of Catholic Social Teachings is subsidiarity, referring to the appropriation of societal resources and activities to support community life.[63] Subsidiarity is a prescription that calls for society to be ordered in such a way that balances individual liberties with the broader community interests, ensuring that neither are neglected. According to Pope Benedict XVI, the principle of subsidiarity does not ignore an individual's freedom but rather enhances it by promoting the assumption of personal responsibility.[64] True embracement of subsidiarity requires that any activity capable of being decentralized should be transferred to the local level. In research, subsidiarity goes beyond the encouragement of local involvement in research decision-making and actually mandates it. Questions of authority regarding participants must be followed as a bottom-up approach, starting with the individual participants, then with the local community, and finally with the state. This last piece of the tripartite model obligates the equitable distribution of risks, as no single community or group of individuals should bear the entirety of the research risks. Those who do bear any risk burden should directly benefit from the research.

The relevance of integrating the threefold summation of Catholic Social Teachings as a principle of social responsibility in research must be addressed if one is to claim its universal application. Catholic moral philosophy asserts that natural law informed by reason forms the foundation of a divine, objective ethical framework. The Catholic Church articulates natural law as humanity's engagement with the divine goodness of God. God's gift of human dignity is the sole reason for individual rights and responsibilities under this scheme. Further, natural law stipulates that man, created in God's image, can participate in His providence by using reason to differentiate between right and wrong, good, and evil.[65] Reason can never be in conflict with morality, as both originate from the divine. The conscience is the arbiter of reason, where the moral quality can be judged.[66] Thus, the Catholic Church espouses that there are shared human archetypes of values and norms that transcend location and culture and provide common grounding through rational thought.[67]

The principles of human dignity, solidarity, and subsidiarity resonate deeply with the universal ethos of the four core bioethical principles and by derivation the eight research principles of *The Oxford Textbook of Clinical Research Ethics*. Ethicists Tom Beauchamp and James Childress, the originators of the four primary bioethical principles, address this phenomenon of shared ethical norms as common morality, which alludes to an ethical awareness that all humans share regardless of geography, culture, or religion.[68] Common morality, as devised by Beauchamp and Childress, is not relativistic. Moral conclusions are thus made through common morality through rational coherence and grounded in fundamental ethical truths.[69] It can be observed, for example, that all cultures over human history share common ethical rules, such as not to lie or steal. Taking the core bioethical principle of autonomy as another example, one can observe that it appears to be deeply ingrained in the post-Enlightenment individualistic traditions of the Western world. Yet, Beauchamp and Childress explicitly argued in their formation of the principles that autonomy is not Western-centric, holding that it retains universal value through flexibility in cultural interpretations.[70] Specific interpretations and practices of morality via the bioethical principles may differ from culture to culture, but the underlying shared norms remain the same. Common morality does not deny global diversity but recognizes an omnipresent human paradigm of ethics.

Common morality and natural law are both grounded on the unmeasurable value of human dignity, prominently reflected in *The Universal Declaration of Human Rights*.[71] Through its preamble and various articles, this historically important document stresses the intrinsic dignity and worth bestowed upon every individual by virtue of existence. *The Universal Declaration of Human Rights* illustrates a global and secular convergence of fundamental moral principles. The presence of common morality and natural law is also evident in *The Nuremberg Code* and *The Belmont Report*, explored earlier in this paper.[72] These documents, along with the striking similarities between natural law and common morality, serve as evidence that a principle of social responsibility based on Catholic Social Teachings is universally applicable in clinical research.

b. The Need for a Principle of Social Responsibility:

The primary ethical consideration when conducting research involving human subjects is the prevention of exploitation. Exploitation in clinical research primarily manifests in two forms: the instrumentalization of human subjects and the inequitable distribution of benefits and risks.[73] *The Oxford Textbook of Clinical Research Ethics*, through its eight principles, attempts to provide a principles approach to minimize the probability of exploitation as defined above. Still, it lacks in one key area, the social obligation of clinical research. By their own admission the authors of *The Oxford Textbook of Clinical Research Ethics* state that their eight principles cannot eliminate all ethical dilemmas within research.[74] The comparative analysis that follows of the eight research-derived principles alongside the three-fold model of Catholic Social Teachings will reveal a noticeable deficiency in the depth of guidance for social stewardship. This discrepancy clearly demonstrates a necessity for the introduction of a ninth principle dedicated to social responsibility.

Beginning with the maxim of collaborative partnership: a concentration on the relationship between the researcher and the community stakeholders, one can observe a reflection of the threefold leg of solidarity. However, the construct of collaborative partnership does not encompass the full intricacies of solidarity, which includes a more covenantal commitment to the welfare of the poorest and most vulnerable members of society, as well as a more profound sense of global interdependence.[75] In Catholic Social Teachings, solidarity is not just a principle of collaboration but a moral virtue that calls for a transformation of relationships to one that seeks justice and the upliftment of the entire human community, especially those who are marginalized.

As described earlier, social value instructs all research to contribute to the generalizable knowledge of humankind. Social value aligns closely with the social principles of subsidiarity and solidarity. Yet those two pillars of Catholic Social Teachings go beyond merely viewing research as a means to a greater end for humanity. For instance, solidarity dictates that research-derived knowledge be equitably accessible, especially to the individuals and communities from which the research was made possible. Complementary to subsidiarity in this context, solidarity emphasizes the full sharing of both tangible and intangible resources among all members of humanity.[76] Communities must stand to benefit

from their participation in research, exceeding temporary health or financial benefit. Tied to the principle of social value is the concept of scientific validity. Scientific validity, or the reproducibility and generalizability of research conclusions, similar to social value, resonates with, yet inadequately captures, the social tenet of subsidiarity. Scientific validity fails to address the mandate of limited resource stewardship. Resource stewardship not only includes the management of material resources but also the management of participant and community involvement. As Pope Benedict XVI alluded to in his address to the participants in the 14th session of the Pontifical Academy of Social Sciences, the tenet of subsidiarity requires balancing individual interests and the greater community.[77]

A derivation of the ideal of justice, fair participant selection stipulates that participant selection should remain objective to the requirements of the research.[78] However, solidarity implies a responsibility not just for the objective, in this case, fair selection, based on research requirements, but also for the inclusion of those who are often overlooked or underserved by research, such as individuals experiencing poverty or those with rare diseases. The marginalized of society deserve an opportunity to participate in clinical research despite the logistical challenges they may pose to researchers. Moreover, researchers are petitioned to have a preferential disposition for the inclusion of the vulnerable. If they are to fulfill the principle of solidarity, they must prioritize not only the needs and rights of this population, but further offer real benefits to these individuals during and after the completion of research.[79]

A favorable risk-benefit ratio is anchored on four key benchmarks: risk identification, risk minimization, maximization of benefits, and the favorable skewing of the risk-benefit ratio towards benefits.[80] This research tenet too often represents the hedonic calculus of utilitarianism, which does not represent the larger spiritual and social dimensions of research required of the principle of human dignity. To respect the dignity with which each person is endowed, all research must consider and prioritize this inherent feature of humanity; the axiom of the greatest benefit to the greatest number is a dangerous oversimplification of the favorable risk-benefit ratio. The next of the eight components is an independent review, which is needed to mitigate conflicts of interest in research and to uphold public accountability.[81] The threefold principle of subsidiarity would extend *The Oxford Textbook of Clinical Research Ethic's*

idea of independent review to promote a sense of responsibility and ownership for not only the research participants but also the local community. Under this new framing, a review of proposed research must take into account the values, culture, and needs of the community. Pope Francis has emphasized the principle of subsidiarity from an organizational standpoint, highlighting its significance in contributing to the common good.[82] Applying this to a research context requires the identification of the common good through an independent review that must precede the commencement of any research initiative.

Informed consent is the responsibility of researchers to obtain appropriate approval from participants prior to their involvement in research and resides with the principle of respect for participants to form the informed consent process.[83] Both concepts are an extension of the bioethical theory of autonomy, which itself is based on human dignity. Therefore, the maxims of informed consent and respect for participants embody the recognition of human dignity through the lens of autonomy, but autonomy is not the complete fulfillment of human dignity. Respect for human dignity within research requires fidelity to the truth, objective and divine, and an explicit duty to avoid falsehood, misleading information, and biases.[84]

The principles of Catholic Social Teachings in the three-fold model provide a wider lens through which to view research ethics, encouraging a more comprehensive form of social responsibility that seeks the welfare of humanity at all of its various levels. It should be evident that the existing principles within *The Oxford Textbook of Clinical Research Ethics*, while reflecting aspects of social responsibility, do not fully address its scope. This gap requires a ninth principle, that of social responsibility built upon Catholic Social Teachings, to cover this partial moral blind spot.

Conclusion:

In conclusion, the evolution of research ethics post-World War II, marked by pivotal ethical developments such as *The Nuremberg Code*, *The Declaration of Helsinki*, and *The Belmont Report*, have been instrumental in uncovering and establishing universal bioethical principles with a global scope. These foundational documents laid the groundwork for ethical conduct in research, focusing on shared values, such as respect for persons, beneficence, and justice. *The Oxford Textbook of Clinical Research*

Ethics further adapted these principles into practical guidelines for researchers. However, the eight principles of *The Oxford Textbook of Clinical Research Ethics* fail to appropriately address the broader concept of social stewardship, necessitating a new ninth principle of social responsibility.

Catholic Social Teachings, grounded in the same foundation of natural law equivalent to the secular development of common morality, emphasize a threefold social responsibility model to bridge this gap. This model is founded on the principle of human dignity, which encompasses respect for life and personal integrity, combined with solidarity, a dedication to the collective welfare of humanity, and subsidiarity, which advocates for societal support of the community. These teachings, as a tripartite model, promote an approach that goes beyond the limitation of the current eight research principles focused on methodology, participant protection, and scientific integrity. This critical deficiency is only corrected by the integration of the new ninth principle of social responsibility. The inclusion of social responsibility will not only enrich our current ethical framework for clinical research, but it is imperative to truly fulfill the goals set by humanity after World War II.

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