The Ethical Quality of Biomedical Research: Virtues and Vision

Dr. Peter A. DePergola, II, University of Massachusetts Medical School
THE ETHICAL QUALITY OF
BIOMEDICAL RESEARCH: VIRTUES AND VISION

1. INTRODUCTION

Research in biomedicine often involves collecting data from human subjects with the intention of advancing the knowledge and practices necessary to prevent and control disease. As such, it raises numerous questions as to which safeguards ought to be implemented so as to preserve the dignity of research participants, including the integrity of researchers themselves. Naturally, the questions induced are predominantly ethical. As research becomes more complex, its ethical demands become more critical; the development of the former commands increasingly amplified degrees of respect for the latter. As a result, one must necessarily ask: What makes biomedical research ethical, and how can the ethical quality of research be strengthened in light of healthcare’s current business culture?

The aim of this brief essay is to respond, however incompletely, to the aforementioned question. To do so, it will be broken up into four parts. In the first section, I will argue that ethical research in biomedicine is both informed and informative to underscore the nature of research as necessarily knowledgeable about the means and methods by which it attempts to secure its particular end, as well as respectful of its duty to provide the essential information by which subjects in research may consensually participate in a way that is meaningful and morally justifiable. In the second section, I will argue that ethical research in biomedicine is both valuable and valid to highlight the nature of research as necessarily socially advantageous inasmuch as the knowledge gleaned from its implementation ought ideally to lead to the improvement of healthcare generally, as well as scientifically complimentary insofar as the data it produces can be trusted to have been authentically generated, reliably interpreted, and ethically implemented.

In the third section, I will argue that ethical research in biomedicine is both fair and favorable to accentuate the nature of research as requisitely impartially equitable in its assignment of eligibility in selecting research participants so as to ensure that the objective goals of particular research are met, as well as propitiously justified in the weight and balance attributed to potential risks by systematic rational analysis and careful circumstantial consideration, particularly where the limits of knowledge and the degrees of benefit are uncertain. In the final section, I will argue that the corrective vision for the moral astigmatism of biomedical research to date is primarily to be found in the need for

---

a harder line to be drawn between therapy and research. In so doing, I will pinpoint two underlying causes of the failure to distinguish between the two: the first being a misunderstanding of vulnerability and its relationship to both research and healthcare, and the second an inattentiveness to what is referred to as therapeutic misconception.

2. ETHICAL RESEARCH AS INFORMED AND INFORMATIVE

2.1 Scientific Knowledge

Biomedical research is ethical to the extent that it is both informed and informative. This means, first, that the nature of research is necessarily knowledgeable about the means and methods by which it attempts to secure its particular end, and, second, that it is respectful of its duty to provide the essential information by which subjects in research may consensually participate in a way that is meaningful and morally justifiable. Ethical research as necessarily knowledgeable hints at the pivotal and pressured role science plays in contemporary society, namely, the trustworthy beacon of perspicacity to be relied upon to indicate and thus guide the future medical treatment of human persons who will all suffer from morbidity and, ultimately, mortality. Ethical research must be scientifically precise, and ensure that it possesses all of the data necessary to proceed prudentially.

Ethical research as knowledgeable also underscores the notion that research should be more than merely wealthy in the scientific knowledge required to competently begin and complete a particular study. Being an excellent scientist is a good start, but one must be a moral scientist too, and this means proceeding with one’s research in the right ways and at the right times. In ethics, answers are important, but how we arrive at them is more important. Hence, that appropriate means and methods are employed to achieve empirically desirable results is an exposition of the knowledge necessary for ethical research to take place. Anything less will lack the information, no matter how “scientific,” which in turn effects genuinely positive results.

2.2 Informed Consent

Ethical research as respectful of its duty to provide essential information alludes to one of the most essential elements of research in biomedicine—indeed, in biomedicine as a whole—namely, informed consent. Though informed consent is today recognized as one of the foremost components of importance in the physician-patient relationship, the place of informed consent in therapeutic research is a relatively new phenomenon. It commenced with the abuse of subjects in World War II and in clinical trials such as Tuskegee and Willowbrook, continued to reign influential during the second half of the twentieth century when physicians became, as it were, strangers at the bedside, and peaked with its formal induction into the American legal system as the development of defensive medicine progressed. The primary ethical purpose of informed consent is to

---

protect human persons from being abused, and the primary justification for seeking it within the research context are for autonomic and welfarist reasons.\(^5\)

Informed consent includes at least three vital elements that secure its justifiable employment. The first is information. The requirement that consent be informed demands that the researcher provide relevant scientific and clinical information in a way that the subject can thoroughly understand and thereby be enabled to make an informed decision about whether to participate.\(^6\) The second element is voluntariness. The requirement that consent be voluntary demands that the researcher make every effort to ensure that the subject’s consent is, in fact, voluntary, thereby enabling the subject to make a decision that is free of coercion, manipulation, and the like.\(^7\) The third element is competence. The requirement that research subjects be competent demands at least two things: first, that subjects themselves possess the cognitive capacities required to understand, evaluate, reason, deliberate, and communicate, and, second, that researchers be held responsible for ensuring that subjects are, in fact, capable of making autonomous decisions; put negatively, researchers will be held responsible for the oversight of defective decision-making abilities in subjects.\(^8\)

### 3. ETHICAL RESEARCH AS VALUABLE AND VALID

#### 3.1 Social Benefit

Biomedical research is ethical to the extent that it is both valuable and valid. This means, first, that the nature of research is necessarily socially advantageous inasmuch as the knowledge gleaned from its implementation ought ideally to lead to the improvement of healthcare generally, and, second, that it is scientifically complimentary insofar as the data it produces can be trusted to have been authentically generated, reliably interpreted, and ethically implemented. Ethical research as necessarily socially advantageous highlights the fact that research does not exist for itself.\(^9\) Biomedical research is, in other words, a means to the achievement of something greater than mere data collecting; most notably, it provides knowledge that in turn allows for greater insights into the nature and course of disease, and the most effective methods by which to treat, slow, and cure it.

The value of research is embedded in its social quality; it aims to extract knowledge so as to better care for the society in which it is formed and fostered. If research were merely an end in itself, it would expose subjects to risk for no purpose and waste valuable medical resources in the effort to serve itself.\(^10\) As members of a care profession, however far removed, researchers must ensure that any and all studies conducted ultimately serve the greater good, and can thereby be justified in the

---

providence of service to society at large. Research is valuable prospectively, that is, for what it could ultimately accomplish. In other words, before research is able to produce anything of particular use for society, its value lies also in what it aims to achieve. Thus, in the effort to improve health, research derives its value not simply from that which it discovers, but from whom it can serve by means of those discoveries.

3.2 Scientific Complementarity

Ethical research as scientifically complimentary in the integrity of the data it produces is indicative of society’s expectation of it, namely, that it be valid so as to allow for authentic generation and reliable interpretation, and that these two moral prerequisites, as it were, lay the groundwork for its licit implementation. For reasons similar to social valuation, the requirement of scientific validity in research makes clear that risks with no potential benefits are, at best, both unreasonable and unreliable in design. The scientific and statistical design of the research, and the methods employed to achieve it, must reasonably achieve the objectives of the individual study and must also satisfy the normative requirements of ethical research generally. Research is required, that is, to employ achievable objectives that are able to be morally justified, including proportionate sample sizes and unbiased methods by which to secure accurate analytical measures. Any alterations of this model must possess tenable justifiable benefits to the research community.

Scientific complementarity also ensures that the design of a particular study is able to produce transparent results that are, in turn, able to be interpreted in a way that is useful in the context of biomedicine. The knowledge gleaned should be implemented on the basis of its identificatory abilities (i.e., whether an intervention is effectual or ineffectual), social, cultural, and economic supportive benefits (i.e., whether an intervention is appropriately sensitive to the adaptations it may be required to make in the context of biomedicine), prospective growth power (i.e., whether an intervention provides a solid foundation from which to base further research), and data generalizability (i.e., whether an intervention is able to realize the social and scientific objectives for which it sets out and produce informative material that is able to be universally inferred from a group of particulars). Ethical research must also achieve its objectives while ensuring that healthcare to which subjects are generally entitled is not denied, and it must similarly protect again requiring the application of services that are contextually unreasonable. Finally, for ethical research to be considered valid, it must, in the end, be structured in such a way that is practically achievable given the social, political, and cultural climate in which it is being carried out.

4. ETHICAL RESEARCH AS FAIR AND FAVORABLE

4.1 Impartial Equitability

Biomedical research is ethical to the extent that it is both fair and favorable. This means, first, that the nature of research is requisitely impartially equitable in its assignment of eligibility in selecting research participants insofar as it ensures that the objective goals of particular research are met, and, second, that it is propitiously justified in the weight and balance attributed to potential risks by systematic rational analysis and careful circumstantial consideration, particularly where the limits of knowledge and the degrees of benefit are uncertain. Ethical research as requisitely impartially equitable emphasizes the imperativeness of selecting subjects fairly. Subjects in research are to be selected based on their eligibility free of all extraneous sociological circumstances. Grounded in scientific objectives, minimizing risk and vulnerability, maximizing benefit, securing collaboration, and ensuring practicality, ethical research aims to liberate itself from the temptation to target particular communities while simultaneously intentionally excluding others.16

Impartial equitability also ensures that valid science is performed by virtue of the population selected for research. Groups and individuals must be chosen on the basis of whether they can fulfill the objectives of the individual study, not because they belong to a particular community, culture, race, or the like, and the rationale on which to base selection must be exclusively scientific in nature.17 Securing minimal risk is also essential to the selection process in research; hence, pertinent personal and clinical data are highly relevant to who should be included in research studies (e.g., those with an abnormally depreciated white blood cell count should not be subjected to drugs that have a high likelihood of rapidly deteriorating immunological function at a potentially dangerous rate). Researchers should select subjects on the basis of the measure by which they can benefit society and themselves by their participation in experimentation. Essential accordant details such as mental capacity, age, medical status, personal relationships, social disadvantages, political lot, and financial depravity should also be considered prior to the selection of subjects so as to safeguard against the exploitation of vulnerable individuals and groups.18

4.2 Propitious Justification

Ethical research as propitiously justified in the weight and balance attributed to potential risks stresses its preconditioned mandate to supply an overtly positive ratio between potential harms and benefits. It cannot not always be said, of course, that benefits will surely and clearly outweigh the risks involved in a particular study; indeed, oftentimes potential risks outweigh potential benefits. In these cases, moral justification is to be found in the social benefit to be promised by the individual net risk. Since clinical research is dependant upon many uncertain factors, including drugs, clinical machines, and idiosyncratic procedures, certainty may in fact dissipate with each enhanced stage of

research, particularly in its early phases.\textsuperscript{19} Still, this is not itself an adequate reason to halt research; it is only to say that proceeding with caution and humility is essential to the ethics of research as it steps into the realm of the unknown.

Propitiously justified research also commands that the risks of research be typified and reduced accordingly. Based on scientifically verifiable data, research should identify the class, likelihood, and degree of potential net risk. Here, potential risks not immediately physically present should be considered, including those psychologically, socially, and financially related.\textsuperscript{20} Equally as important as typifying the potential net risk involved in a particular study is the identification of the class, likelihood, and degree of potential benefit. It must be noted that benefit analysis in research primarily includes those factors most immediately related to the potential health and well-being derived from the study itself; potential benefits to be weighed and balanced in one’s consideration of participation in experimentation ought not, for example, to include being financially rewarded for one’s social sacrifice, nor receiving a vaccine one’s insurance would not have otherwise covered the cost of.\textsuperscript{21} Ethical research also requires that the net risk and benefit affecting particular subjects be compared. Comparative analysis between risks and benefits with individual subjects allows insight into ratios by which can be determined respective moral weight. In other words, each increased risk should be accompanied by a proportionate prospective benefit. Contextual considerations pertaining to individual subjects must also be considered inasmuch as they are relevant to the assignment of risk. Thus, the presence of riskier diseases may de facto justify riskier research.\textsuperscript{22}

\section*{5. CORRECTIVE VISION: DRAWING A HARDER LINE BETWEEN THERAPY AND RESEARCH}

\subsection*{5.1 Vulnerability in Relation to Research and Healthcare}

The corrective vision for the moral astigmatism of biomedical research to date is primarily to be found in the need for a harder line to be drawn between therapy and research. What lies at the core of the failure to distinguish between the two is, first, a deep-seated misunderstanding of vulnerability and its relationship to both research and healthcare. Vulnerable persons at risk in biomedical research are those individuals or groups who, for whatever reason, do not possess the capacity to fully grasp the information necessary to give informed consent. Children, for example, are one such vulnerable group. Unable to comprehend the consequences of what is being asked of them, they are neither freely nor fully able to consent to experimental studies. Other vulnerable groups include those whose first language is dissimilar to that of the research team, the unemployed, the homeless, the uneducated, the sick, the poor, the intellectually challenged, the imprisoned, the elderly, and the like. Each of these population groups, and many others with them, may lack consensual capacity by virtue of an underlying

\textsuperscript{19} Emanuel et al., “An Ethical Framework,” 129.
\textsuperscript{20} Emanuel et al., “An Ethical Framework,” 129.
\textsuperscript{21} Emanuel et al., “An Ethical Framework,” 129.
\textsuperscript{22} Emanuel et al., “An Ethical Framework,” 129.
anxiety, lack of confidence, general uncertainty, or preoccupation with the hope of a solution to their social or personal plight. Differences in culture, gender, ethnicity, and religion may also be considered vulnerable attributes in particular research contexts.  

Unlike general healthcare, which centers around and is prided upon the providence of care to the patient, the aim of clinical research is to produce useful scientific knowledge by which society at large may benefit. Research thus faces the perpetual challenge of balancing the competing interests of society and the individual who participates in experimentation. Researchers may therefore find themselves inherently conflicted as they attempt to generate socially beneficial knowledge while contemporaneously treating the individual subject entrusted to their care. Subjects rightly trust in the providence of treatment by researchers, and the fiduciary relationship thereby established, whether intentionally welcomed and fostered or not, may lead to increased vulnerability. The result can be vastly morally dilemmatic. Conducting research in the biomedical or social context is inherently different from conducting research in every other context inasmuch as subjects enrolled in biomedical and social research studies expect to and do receive care. To be sure, social, economic, medical, and other perspectives pertaining to vulnerable populations can and should be examined so as to produce greater understanding and appreciation of their valuable contribution to biomedical anthropology. The essential moral dilemma, however, is whether it is appropriate to invite clearly vulnerable persons to participate in research when their expectations are neither thoroughly transparent nor comprehensively apprehended by researchers. A clarification and understanding of the intentions not merely of the aims of the study but of the subjects in research is of utmost importance, and a lack of general attentiveness to and appreciation of this glaring potential risk in research has led to what is referred to as therapeutic misconception.

5.2 Therapeutic Misconception

Therapeutic misconception is most succinctly described as the illicit notion that decisions about one’s treatment while a subject in research will be based on one’s idiosyncratic medical condition and needs. It is the product of the lack of general attentiveness to the intentions of the individual subject in research, thus exacerbating preexisting vulnerability or, worse, de facto breeding it where it did not formerly exist. The subject in research may also fall victim to therapeutic misconception on the basis of an unreasonable personal assignment of potential benefits to be accumulated from the particular study in question. The rationale underlying this strand of misconception is the failure to appreciate the fact that a course of treatment may be given at random, not, as mentioned above, applied on the basis of an assessment of potential net benefit.

---

configured by the researcher. An example would be a subject’s enrollment in a research study of the pathophysiology of diabetes in adults of middle age, misinterpreting the fact that it possesses no therapeutic intent. Therapeutic misconception, hence, poses an enormous challenge to the ethics of informed consent.

Addressing therapeutic misconception and dispelling the vulnerability it unnecessarily exacerbates or breeds requires a systematic approach. At least four suggestions may prove helpful. First, researchers would themselves do well to become better educated on the moral difference underlying the providence of general healthcare and treatment provided in the context of clinical research. This suggestion may sound overly simplistic, perhaps even insensitive, but the fact that therapeutic misconception continues to surface hints that it is neither. Second, researchers can be further trained as how best to explicate the difference between the providence of general healthcare and treatment provided in clinical research in more readily intelligible ways. Here too, researchers should make strident efforts to underscore the differences between the aims of general healthcare and clinical research and the reasons that ground them.

Third, a clearer, more concise consent form, which includes a comprehensive yet broad summary as an appendix, should be used. Explicating in simplistic detail the departure from general healthcare, subjects may better grasp the nature of research, and thus be freed to provide full consent. Fourth and finally, consultative services from a trained, impartial bioethicist may be of use with subjects who are participating in high risk research or studies that target particularly vulnerable individuals or groups. This advisory instrument can be implemented to secure that subjects are protected from the unforeseen effects of decisions based on personal or communicated misunderstanding.

6. CONCLUSION

In biomedical research, the successful production of data useful for the advancement in understanding of disease and the practices by which it can be controlled and prevented is important, but the means and methods employed to achieve that understanding is more important. In addressing the questions of what makes biomedical research ethical and how the ethical quality of research can be strengthened in today’s society and culture, then, several factors require thoroughgoing consideration. The aim of this brief essay was to explore the moral virtues and vision of contemporary biomedical research with the intention of pinpointing the areas in which research currently possesses strength, weakness, and room for growth. Practicing the strengths, acknowledging the weaknesses, and implementing the requisite changes to ensure growth will lead to a more ethically mature research in biomedicine.

---

Biomedical research is ethical to the extent that it is informed and informative (based on precise scientific knowledge and providential information required for fully informed consent), valuable and valid (based on social advantageousness and scientifically complimentary data production), and fair and favorable (based on equitable selection of subjects and propitious justification in potential risk assessment). Finally, a deep-seated misunderstanding of vulnerability and its relationship to both research and healthcare and the failure to take necessary measures to prevent therapeutic misconception in the research context lie at the heart of biomedical research’s moral astigmatism to date. A fourfold approach, including increased education and further training for researchers, the use of a clearer, more concise consent form, and the implementation of consultative services from a bioethicist, may prove useful in the attempt to draw a harder line between therapy and research.

REFERENCES


