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Is There a Duty to Serve as a Subject in Biomedical Research?

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Abstract
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Most contemporary discussions of the ethics of human subjects research focus on the adequacies and inadequacies of informed consent in combination with peer review by institutional review boards (IRBs) for protecting subject welfare. Little has been written about the moral reasons that ought to lead someone to participate in research in the first place.

The strong impression conveyed by all the scholarly attention to consent and committee review is that the main problem in the area of human experimentation is the prevention of the practice of murder or mayhem against those poor unfortunates who fall into the maw of biomedicine. While it is true that one does occasionally encounter the grousings of a researcher or two concerning the possible negative effects ethical concerns have had on the pace of biomedical research, the major preoccupation of those writing about the ethics of research appears to be the protection of subjects who wind up in research settings solely as a consequence of infirmity, insanity, or inanity.

I do not mean to suggest that research subjects would be better off without the dual protections of informed consent and IRB review. While there are many reasons for doubting the sufficiency of these mechanisms for protecting the interests of those who serve as subjects, there can be little doubt that the current regulatory provisions in the United States have done much to eliminate the more egregious examples of moral atrocity from the domain of human experimentation. Nevertheless, the frequent claims that the current system of regulations and protections is a success because it has prevented the recurrence of the flagrant moral abuses of the past is a telling comment about the nature of the moral concerns that originally fueled the establishment of these protections.

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Moral Scandals and Their Prevention

A review of the articles and books written during the 1960s reveals the importance of examples of subject abuse by biomedical researchers in setting the tone of ethical discussion. The Nuremburg trials of the physicians and scientists involved in barbarous medical experimentation during World War II played an especially central role in determining the direction of subsequent discussion concerning the ethics of experimentation. Nazi medical experiments exemplified what crass utilitarian concerns and total disregard of subjects rights and welfare could lead to if followed faithfully and systematically.[1] The airing of research abuses in the landmark studies of Henry K. Beecher, Paul Freund, Jay Katz,[2] and many others drew public and academic attention to the serious problem of subject abuse in our own research settings.

The tradition of motivating concern about the ethics of human subject research by focusing on the serious harms that have befallen subjects continues today in both the anthologies and textbooks of bioethics.[3] It is easy to understand the current emphasis on the protections of informed consent and peer review in light of the role played by moral scandals in focusing public attention on the ethics of human experimentation.

The desire to protect individuals against blatant abuses of medical authority and power led many scholars and physicians to emphasize the central role of autonomy in human experimentation. Lawyers, philosophers, and physicians agreed that voluntary choice, as evidenced by written informed consent, was the best protection against abuse in medical contexts.[4]

The desire to assure the welfare of research subjects eventually resulted in the complex array of state and federal regulations that now govern human subjects research in the United States. However, the provision of these safeguards does not in any way address the basic issues raised by the need to involve human beings in research: who will serve and why?

What is Known About Subjects?

Unfortunately, very little is known about the composition of the pool of persons who actually participate in biomedical research in the United States. The available data shed little light on the way in which subject participation is obtained, and, more im-

portant, on the specifics of how the benefits and burdens of biomedical research are distributed in our population as a whole.

There is some reason for concern about the makeup of the subject pool. One of the few available studies of subject participation suggests that:

> . . . studies involving greater therapeutic benefit for the subjects are more likely than those of lesser benefit to be done using subjects the majority of whom are private patients, whereas studies with minor or no benefit for subjects are most likely to involve mostly ward or clinic patients.[5]

While it is difficult to obtain hard data on the socioeconomic background of those currently participating in research there is at least some reason for concern that the poor and disadvantaged bear a disproportionate share of the research burden.

A number of authors have also noted that the underrepresentation of females of reproductive age in research trials may have a deleterious effect upon the health and welfare of the members of this group. Similar concerns have been voiced about the relative absence of elderly subjects, children, and even fetuses in research trials of new drugs and procedures.[6]

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There is little reason to doubt that the brunt of contemporary research in biomedicine falls upon those who are ill, institutionalized, or both. The benefits enjoyed by the public as a whole of improved medical care, better drugs, and increasingly powerful technological therapies have been acquired at a cost that has not been shared equitably among all the members of our society.

If it is true that some individuals or groups never or rarely participate in medical research, if many Americans behave as "free riders" when it comes to obtaining the benefits of medical research, then discussions of the ethics of research should not be limited to considerations of the adequacy of current protections of subject safety and welfare. While it is morally laudable that our society has instituted these protections, their moral value is greatly diminished if some groups within our society are far more likely to need to avail themselves of them than are others.

Bad Science and Skewed Subject Pools

Justice is not the only reason that compels attention to this question. Important methodological reasons also point toward the need for the broadest possible public participation in biomedical experimentation.

The biases introduced into research findings by the selective use of volunteers or nonrandomized subjects are poorly understood but much discussed by those designing research protocols. A number of recent studies have shown that unblinded randomization and nonrandom assignment can have a deleterious impact on the adequacy of controlled clinical trials.[7] If double-blind randomization is the method of choice in clinical trials, then it is surely of the utmost importance that such trials draw their subjects from a statistically representative sample of the general population. A system that relies primarily on the recruitment of subjects from among those who are sick, institutionalized in one way or another, or who volunteer, cannot rest easy about the reliability and soundness of its research conclusions.

It is not even clear that participation in most blinded randomized clinical trials is ethical. There are few trials where the researcher can believe with certainty that there is no difference among the treatment arms of the trial. In such cases it may not be ethical for the physician to solicit volunteers if there is reason to think that one form of treatment might be preferable to another.[8] Yet the need to conduct randomized clinical trials even on widely disseminated and accepted procedures in medicine is well known. In such cases informed consent does not appear to be consistent with the requirements of therapeutic ethics since it is often difficult to ethically justify entering patients randomly in one arm of a clinical trial knowing that one treatment appears preferable to another but with less certainty than is required to satisfy the traditional canons of statistical significance.[9]

Can A Duty to be a Subject be Generated?

There have been a few attempts in the past decade to locate a moral basis for participation in biomedical research. The arguments for participation have taken two forms: (1) There is an obligation to participate, which is incurred because the benefits of biomedical research are available to all; and (2) there is a tacit "cross-generational" social contract that compels each person to participate.

Physicians such as Walsh McDermott, Louis Lasagna, and Leon Eisenberg have argued eloquently the view that participation is justified by the fact that the results of biomedical research are public goods. None argues that the state has a right to force participation in research in the name of the social good. Rather, they argue that health, safety, and knowledge constitute public goods—goods that accrue not to a majority of the members of a society, but to all members of society.[10] The duty to participate in research, on this view, derives from the fact that the production of public goods requires public participation.

The counterarguments have been persuasively made by, among others, Hans Jonas and Charles Fried.[11] These authors note that (a) it is not self-evident that health, safety, and knowledge are public goods, and (b) the moral pull exerted by the desire to have public goods is counterbalanced by the far more powerful moral force of respect for individual autonomy.

Certainly in our society it would be difficult to argue that the benefits of biomedical research are equally available or even desired by all citizens. Nor is it evident that anyone need feel an obligation to produce any and every public good no matter how valuable that good might be.

But even if one were to grant that health and safety were public goods, it is not clear what the relationship is between biomedical research and these goods. As Jonas correctly notes, research aims at improving or advancing health and knowledge and, while one might be obligated to engage in activities that maintain public goods, it is hard to see why such an obligation would extend to the improvement or advancement of such goods.

The other means of generating a duty to participate in research is by positing some version of a "social contract."[12] Since those now living have benefited from the participation of previous generations in biomedical research, we owe our own participation in research to future members of society, born and unborn, as a way of discharging this debt. By accepting the benefits of scientific and medical knowledge in the form of better therapy, diet, lifestyle, and so on, we affirm, obliquely but overtly, our duty to those individuals whose past sacrifices made these benefits possible. We incur a powerful moral obligation of reciprocity to bear additional burdens so that future generations may reap similar benefits.

But it is not at all clear that those persons who participated in research in the past did so believing that they were creating a debt that had to be discharged by those who reaped the benefits of their participation. Indeed, such

a view diminishes the sacrifice of previous generations of research subjects by stripping their actions of any suggestion of altruism.

Many of those who participated in dangerous and deadly experiments in the past did so out of a desire to benefit humankind. It is simply a conceptual mistake to think that a duty to reciprocate is the obligatory response that must be made to a gift that was freely given—at most, we are obliged to be grateful for a gift.[13]

It would, of course, be naive to think that those who participated in biomedical research in the past all did so out of pure altruism. Many subjects were compensated for their participation; some others were coerced or tricked into participating. However, it is hard to see how any obligation is generated among the existing members of a society who have obtained the benefits of research produced as a result of either compensation or duplicity.

Furthermore, it is not clear that a contract exists unless someone has directly benefited from the actions of those involved in previous forms of biomedical research. The only persons with a contractual claim on the living would be the members of past generations who gave of themselves with the thought that such giving had to be reciprocal. Unless these claims are cashed in, it seems mistaken to speak in a general way about abstract duties to society or to past generations and simply wrong to generate duties to participate in research on the basis of hypothetical claims by future generations.

The counterarguments against a duty to serve as a subject in biomedical research seem to have been so persuasive as to have made the topic otiose. While there have been discussions in recent years of the moral acceptability of involving prisoners, children, retarded people, and other classes of so-called "vulnerable" subjects in research, these discussions have hinged almost exclusively upon the reliability of the informed consent mechanism for protecting these classes of persons from abuse rather than over the issue of an individual's duty to serve in research.[14] However, if inequities exist in the ways in which the benefits of human subjects research in the biomedical sciences are allocated, and if some research requires involvement that cannot be justified on the grounds of immediate personal benefit, then other grounds should be sought in support of a duty to participate in research.

One way of generating a moral duty to participate in biomedical research is to acknowledge that the public status of the goods or benefits of research—knowledge, health, and safety—is questionable, but to insist that those individuals who actually accept the benefits of such research incur certain obligations, central among them a duty to participate in research. H. L. A. Hart describes such obligations as arising

> . . . when a number of persons conduct any joint enterprise according to rules and restrict their liberty, those who have submitted to these restrictions when required have a right to similar submission from those who have benefitted by their submission.[15]

John Rawls[16] has coined the term "fair play" to describe these types of obligations. He argues that those who benefit from participation in various cooperative social schemes—for example, the creation of a food co-op, a block patrol, or even a political state—have obligations to each other when called upon to bear the risks or burdens that involvement in cooperative endeavors often entails. The members of a cooperative group can legitimately expect each group member to accept the burdens and risks of participation in such enterprises if the members have profited from the activities of the group. The members of cooperative enterprises are on sound moral footing in chastising and excluding any "free riders" that are discovered taking benefits but shirking responsibilities.

The notion of fair play, which properly governs the actions and ethical evaluations of the members of voluntary associations and organizations, requires that a distinction be drawn between those who derive benefits from various social enterprises as knowing participants, and those who simply have such benefits forced upon them without their consent. For example, Robert Nozick[17] has persuasively argued that no obligations can be said to be incurred by persons who inadvertently or unavoidably derive benefits from social schemes and cooperative endeavors that they neither approve of nor consent to.

Nozick argues that even if I am lucky enough to benefit from the security afforded me by the existence of a block patrol in my neighborhood, I incur no obligation to pay for or serve in such a patrol merely because I happen to live in the locale where this group is active. I incur no obligations or duties to the members of social groups merely because they choose to make me the beneficiary of their group largesse. Nozick maintains that the principle of fair play is only binding upon those who explicitly consent to participate in cooperative enterprises and social schemes.

This principle of fair play can, however, be restricted in a way that avoids the kinds of difficulties Nozick raises. No doubt it is true that innocent beneficiaries of group activities incur no obligations toward other group members. But one need not give explicit consent to be recognized as a full-fledged participant in a group activity or enterprise.

If someone is constantly, continuously, and knowingly receiving benefits as a result of some cooperative social activity and if such a person also makes no effort to avoid receiving such benefits when it is possible to do so with little inconvenience, then it seems reasonable to argue that someone in this situation has tacitly consented to membership in the group's activities.[18] If, for example, I set up a receiving dish on top of my house in order to obtain the broadcasts from my neighborhood cooperative television satellite, it will hardly suffice as a reason not to pay the required monthly charge for me to argue that I am an innocent and unwilling beneficiary of the group's largesse. My conscious and purposeful efforts to get the benefits of television broadcasts would seem to obligate me to pay the fees that the group has agreed to levy upon all of its members even if I never actually consent to membership in the cooperative. Those who knowingly seek out and obtain benefits from social enterprises appear to bear a general obligation to share in the costs, if any, of creating these benefits.[19]

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The Teaching Hospital As A Social Cooperative

One way of viewing the institutions and organizations of biomedical science is as social cooperatives—often vast ones, but, nonetheless, enterprises that depend upon the voluntary cooperative efforts of many individuals to produce specified benefits. They also generate burdens and costs that have to be shared according to some fair scheme. Consider the example of a relatively small biomedical cooperative—the teaching hospital.

Physicians often state that patients who receive care in such institutions have an obligation to serve as subjects for teaching and demonstration purposes. If patients do fully understand the nature of the institution, I believe that these physicians are correct.

SUMMARY: There is a strong case for arguing that biomedical research constitutes a form of voluntary social cooperation. The hospitals and institutions in which research usually occurs are quite analogous to other forms of social cooperation where the obligations generated by fair play demand equal participation in sharing the benefits and burdens of voluntary social activity. Any competent person who voluntarily seeks out and takes the benefits of care resulting from biomedical research can legitimately be said to be a consenting participant in the enterprise and, thus, the bearer of a duty to share in the costs of producing the desired goods.

Those who freely choose to receive care in the context of a teaching hospital do incur an obligation to serve as the subjects in various teaching activities. The teaching hospital is one form of a scientific social cooperative—physicians, scientists, and patients organize themselves into a social unit to promote certain ends and to obtain certain benefits. Those who receive the benefits of such a scheme can legitimately be said to incur certain duties as a result. Fair play requires that those who *knowingly* and *willingly* seek out and accept the benefits of better care, closer attention, and the higher levels of medical skill that are often available in a teaching hospital incur a general obligation to serve as the subjects of medical teaching.

Of course the distribution of the burden of service as a teaching subject must be fair and equitable. But as long as this is so those who willingly accept care in such settings fall under the requirements of fair play that govern all forms of voluntary social cooperation.

Of course, it should be quickly added that a sense of fair play among the participants in these kinds of hospital settings requires that some burdens not be assignable. For example, no one is obligated to serve as an illustration of the effects of lethal drugs on human beings. Because those who knowingly receive the benefits of care in a teaching hospital incur a duty to serve does not mean that such a duty abrogates their other rights, including the basic rights not to be seriously harmed or killed.

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Most of those who work in teaching hospitals do not believe that they have the right to demand participation in teaching activities whenever they see fit. Despite their belief that patients have a duty to make themselves available for teaching purposes, physicians will often exempt certain patients for both physical and psychological reasons from such activities. Patient consent is usually obtained, as it should be, with respect to both the specific teaching activity and the convenience of the patient. Those who choose to receive their care in teaching hospitals incur a duty that can be discharged in a manner most consistent with their wishes and their convenience as long as, at some point, the duty is discharged.

The Obligation To Serve As A Subject

Is it not the case that those who benefit from or receive care in hospitals and health care facilities that openly identify themselves as research institutions incur an analogous duty to participate in research? Fair play seems to require that those who reap the benefits of greater therapeutic knowledge and skill that are derived from biomedical research should be called upon to bear the burdens and costs of pursuing such activities. There is no more reason for tolerating free riders in research contexts than there would be in any other voluntary social cooperative. As long as all patients freely and voluntarily choose to receive care in research settings, and as long as the burdens of being a subject are fairly allocated among all who benefit, a general obligation to be a subject appears to exist.

There are important restrictions on those who demand the discharge of this duty. They must (a) openly disclose the nature of the institution; (b) recruit among all those who are sufficiently competent to have chosen to receive care in a research context; (c) not compel participation in studies that pose significant risks to health or well-being; (d) obtain consent from all individuals who are asked to participate since the determination of significant risk requires the involvement of each individual; (e) assure that all subjects have a fair chance of obtaining the benefits derived from research; and (f) ensure that all potential subjects have freely chosen to receive the benefits of better health care.

If it is accurate to say that biomedical research and its constitutive hospitals, organizations, and practitioners constitute voluntary social cooperatives, then a number of interesting ethical consequences can be drawn. First, biomedical scientists must recognize the distinctive nature of their enterprise and fully inform those persons who have an interest in reaping its benefits about the choices they have and the burdens and costs they are likely to incur. Second, as members of such social cooperatives, biomedical scientists must also be considered eligible for bearing the costs and reaping the benefits of the enterprise—the duty to serve in research is one that is owed both by patients and researchers. Finally, the existence of duties generated by the principle of fair play should not abrogate the obligations of researchers to respect the basic rights of those who choose to be in such settings.

A duty to participate in research does not void the rights of subjects to choose and consent to specific research protocols. Nor does the existence of a duty to serve as a research subject diminish in any way the need for prior peer review of research protocols. Just as the proposition that a fetus has a right to life does not settle the question of what to do when rights conflict; the demonstration of an obligation to serve as a research subject does not settle the question of how conflicting obligations in this context are to be resolved. But the fact that conflicts between subjects' duties and rights can arise does not weaken the case for positing a duty to discharge the burdens incurred by freely accepting the benefits of a particular social activity.

There is a strong case for arguing that biomedical research constitutes a form of voluntary social cooperation. The hospitals and institutions in which research usually occurs are quite analogous to other forms of social cooperation where the obligations generated by fair play demand equal participa-

tion in sharing the benefits and burdens of voluntary social activity. Any competent person who voluntarily seeks out and takes the benefits of care resulting from biomedical research can legitimately be said to be a consenting participant in the enterprise and, thus, the bearer of a duty to share in the costs of producing the desired goods.

Possible Objections to the Argument

There are a number of possible objections to this claim. It is not always clear that those who benefit from biomedical research voluntarily choose to do so. Nor is it clear exactly what level of participation in research will suffice to discharge the general obligation.

Some people may have no choice about whether they will or will not avail themselves of the services of any given biomedical institution or practitioner. Since, as Nozick and other critics of the concept of fair play have been at some pains to point out, those who receive the benefits of cooperative social activity without choosing to do so incur no obligations as a result of being benefited, such people are not under any general obligation to serve as subjects.

It is sometimes difficult to ascertain whether those who utilize research hospitals or receive care from physicians who are engaged in biomedical research knowingly choose to do so. Some patients come to research institutions not by choice but simply because no other facilities are available to care for them. Others become sick suddenly and have little say in who will treat them or in what setting. People who receive care in these kinds of circumstances do not appear to be under any general obligation to serve as subjects in biomedical research since they cannot be said to have either had or made a choice about receiving the benefits of such research.

But these situations are relatively rare. For the most part those who seek health care consciously and often conscientiously seek out the "best" or "most advanced" hospitals and clinics. In fact most consumers of health care attempt to locate those practitioners who are the most up-to-date and those institutions with the most up-to-date in equipment and facilities. This sort of medical consumer, surely the majority of those receiving medical care in this country, can hardly be described either as having no choice or as not intending to choose the benefits of biomedical research in seeking care when they receive care in institutions that have research as one of their primary goals.

Implications of the Argument

If it is true that those who knowingly and consciously seek out the benefits of care in research institutions incur, as a consequence of being bound by the principle of fair play, a general obligation to participate in biomedical research, then there are strong moral arguments against complacency about the composition of the current research subject pool at many institutions. If it is true that the sick, the poor, or the young are bearing a large portion of the burden of biomedical research, then measures should be taken by IRBs and researchers to redress these imbalances by making every effort to include all of those who freely choose to receive the benefits of research among those who serve as subjects.[20]

Admittedly, there are many persons, both healthy and ill, who do not seek care from physicians or institutions that avowedly identify themselves as committed to biomedical research. Nonetheless, it is surely true that many hospitals, nursing homes, and private physicians make regular use of the knowledge that is gained as a result of biomedical research. Does the general obligation to participate in research extend to these persons?

Furthermore, many patients in research institutions must pay for their care. If a general obligation to participate in research can be said to exist, what behaviors suffice to meet or discharge such an obligation—payment, participation as a subject in a controlled clinical trial of a new drug, having one's blood drawn for tests?

Both questions raise issues that go beyond the scope of this article. If cash payments are to be allowed as a method for discharging the general obligation to serve as a subject in research contexts, then surely policies about this option must be discussed and debated by all the members of the research enterprise—subjects as well as researchers. And if the scope of the general obligation to participate in research is to extend to all persons who receive any sort of health care, then patients will have to be much more informed about the various costs and burdens of having health care available.

These are provocative and important issues but they should not be allowed to distract the reader's attention from the main point of this article: in identified research settings, knowing beneficiaries of care incur a general obligation to participate in research. How, when, and in what manner this obligation ought to be discharged are all subjects for future debate and deliberation. But, if my arguments are valid, they are questions that those who design or participate in research ignore at their own moral peril.

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[19]A useful summary of other efforts to generate an obligation to participate in biomedical research is provided in Levine, R.J.: *Ethics and the Regulation of Clinical Research*. Baltimore: Urban and Schwarzenberg, 1981, pp. 85–87.

[20]This would mean that IRBs ought to take far more seriously than they often do the requirements of 45 CFR 46.111a (3) which charges IRBs with ensuring that the "selection of subjects is equitable."