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# Ethical Issues in the Use of Human Subjects

Stanley Hauerwas

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## 1. The Variety of Ethical Analysis

The ethical issues surrounding human experimentation are complex and, I suspect, some of them are irresolvable. I am going to try to describe how ethicists tend to frame the ethical concerns involved in the experimental use of human subjects. However, I must ask you to keep in mind that there is no ethically neutral way to describe a moral problem. Indeed the very designation of a "problem" depends on prior moral presuppositions. For example, different positions concerning the use of human subjects are often thought to be determined by whether a deontological or teleological pattern of moral justifications is dominant. Yet this very way of construing the dispute may conceal a more fundamental disagreement about how to describe morally what human experimentation involves. Thus while I am trying to act primarily as a reporter, you should suspect that my commitments color the way I describe the ethical issues involved in the use of human subjects in research.

## 2. Protection of the Individual Versus the Benefit to Mankind

Perhaps the most basic as well as the most heated issue surrounding the use of human subjects in research is the assumption by some that the primary ethical question is whether the benefits of any research are sufficient to justify certain risks to the subject. In other words many in the research community seem to assume that the question of the moral justification of research on human beings is a matter of providing more information about comparative benefits and risks. The experiment is thought justified if it has been carefully designed and can be shown that the actual or potential benefit outweighs the risk.

Others, however, have argued that this way of stating the moral issue is to already beg the principal moral question. They argue that

the teleological assumption — that is the idea that the good consequences outweigh the bad — involved in this kind of ethical cost-benefit analysis fails to do justice to the basic commitment to respect and protect each human person. Put differently, it is argued that no amount of benefit can ever justify using one person as a means for the good of others. Those who assume that the ethical issue is one of balancing some risks against future goods fail to see, therefore, that respect for the integrity of the individual cannot be balanced by the benefits gained — no matter how the benefits might be understood. Thus Jay Katz argues that what must be recognized is that there is an inherent value conflict in the conduct of human research — “the quest for the acquisition of knowledge for the benefit of present and future generations on the one hand; and the respect for the dignity, autonomy, and inviolability (unless consented to) of the subjects of research.”<sup>1</sup>

Those who argue that the protection of the human subject is the overriding ethical issue for human experimentation do not intend this demand to deny any use of human subjects in research. Rather they argue that any experiment must provide proper safeguards for the human subject. If such safeguards cannot be provided, then the experiment cannot be done even if it would have great benefit for present and future generations. Ethically this means that no basic value can be overridden for a higher good except if it can be shown that another basic value is at stake. For those who see themselves serving the future of mankind through the office of science, this position appears unduly restrictive.

If the Conference on Experiments and Research with Humans sponsored by the National Academy of Science in 1975<sup>2</sup> was any example, I am afraid that we have a long way to go before this conflict is resolved. (Moreover, it is hard to see how we can expect it to be solved in this context when it has not been resolved at the level of ethical theory.) For neither side seems to be able to speak to the concerns of the other. Scientists cannot understand how anyone can fail to appreciate the benefits to be gained through science for the good of mankind. Talk of the “inviolability of the individual” appears as an irrational commitment that is holding back important developments for the cure of disease or opening up new vistas of human understanding.

Those concerned with the protection of human subjects as the overriding value, however, tend to think that research scientists naively assume that what is good for science is also good for mankind. Just as what is good for business is not necessarily good for America, they argue that the assumed importance of science for human betterment, both morally and materially, must be shown rather than simply asserted. For scientists often seem to assume that their activity can be justified on the simple utilitarian grounds of the greatest good for the

greatest number. Yet utilitarianism as an ethical theory remains problematic because it fails to account for some of our central intuitions about what we can justly do and not do.

Even though I am sympathetic with those who have argued for the priority of protection of the human subject, I think they have not as yet provided convincing grounds for their allegiance to the individual. Ramsey's contention that "no man is good enough to experiment upon another without his consent,"<sup>3</sup> seems to strike a chord within us, but it is not clear why this is the case. Of course it is possible to argue within the framework of liberal political theory that we simply have a "right" not to be subjected to the interests of others. This response continues to assume that we have a clear idea of what "rights" involve or how they can be justified. But this is not the case.

As Alastair MacIntyre has recently observed, "It is an interesting paradox that those eighteenth century writers such as Jefferson or Robespierre who believed that they intuited timeless truths about the rights of man did so in a vocabulary that had historically come into existence as a child of late medieval legal usage and which does not seem to be found in the precise senses in which they used it until a hundred and fifty years or so before their own time. But it is easy to understand why it did emerge as a central moral as well as legal concept. The central preoccupation of both ancient and medieval communities was characteristically: how may men together realize the true human good? The central preoccupation of modern men is and has been characteristically: how may we prevent men interfering with each other as each of us goes about our own concerns? The classical view begins with the community of the *polis* and with the individual viewed as having no moral identity apart from the communities of kinship and citizenship; the modern view begins with the concept of a collection of individuals and the problem of how out of and by individuals social institutions can be constructed."<sup>4</sup>

If MacIntyre is right about this, and I think he is, then in an interesting way the appeal to "rights" to protect research subjects presupposes the same individualistic presuppositions as utilitarianism. This may reveal that, while appearing antagonistic, the debate between the teleologist and deontologist on this issue may be a debate between brothers. Or, more accurately, it helps us see that to construe the issue of the use of human subjects in terms of a choice between teleological or deontological ethical theories is misleading. For the issue is what kind of risks should we as citizens and recipients of the benefits of health science be willing to undergo to further the general well-being of our community.

But if this is the right way to frame the question it cannot be answered in terms of the current discussion, but rather must await the development of a new sense of political community and resulting political and ethical theory. For only then can we stand back from

abstractions such as "the good of mankind" or "the rights of the individual" and be clear about what ends and values science can and should serve. With the articulation of such ends we may well find the grounds to say why each of us should be willing to serve as research subjects for the good, not of mankind, but of the communities in which we exist.<sup>5</sup> Because we do not share these values, however, the only way we feel that we can protect ourselves from one another is by insisting on the procedural rule of informed consent. In other words, what we have here is the typical liberal strategy to substitute procedure for the *absence* of debate on substantive norms and values.

### 3. Therapeutic and Non-Therapeutic Experimentation

It can be objected that I have overstated the unclarity of the moral values and ends that give direction to contemporary research. To be sure, there is an important distinction between therapeutic and non-therapeutic experimentation that suggests we have a clearer idea of what we are doing in therapeutic cases. But we also know that this distinction is often easier to draw in theory than it is in practice. For example, there are good grounds to think, in spite of the wide practice of kidney transplants, that such procedure is still an experimental technique.<sup>6</sup> Furthermore, it remains unclear if random clinical trials should be viewed as therapeutic or non-therapeutic even though medical progress depends on such testing.<sup>7</sup> For the issue is: medical progress for whom — the immediately sick person or future patient populations?

The question of who the doctor's patient is or should be is often not easy to determine, but it is complicated by the realization that we are no longer sure what health and illness mean. As Charles Fried has suggested, "The concept of good health implies a concept of the good life, and the goodness of life includes a large number of other factors besides simply its length."<sup>8</sup> Thus the doctor's primary duty is not the prevention of death, but rather the preservation of bodily integrity necessary for the realization of a reasonable and realistic life plan.<sup>9</sup> But we have little consensus about what kind of medicine should be developed since we are unclear what constitutes a "reasonable and realistic life plan." But concretely this means we have no way of determining whether we should develop heart transplant procedures in order to provide some with opportunities not normally thought to be a possibility. For the expense of providing those opportunities for some must lessen basic medical care for others.

Even if we knew better what health means or should mean it is unclear how this would help us direct the research not directly associated with therapeutic ends. For example, some of the hard cases involving the use of human subjects in research are clearly non-therapeutic — that is the research aims to obtain information of use to

others and thus does not pretend to treat some illness that the experimental subject might have. Thus the justification for using human subjects in such research is made more intense because the design and ends of such experiments are remote from the therapeutic context.

#### 4. Informed Consent

Of course many assume that the requirement of "informed consent" is a sufficient safeguard to protect subjects involved in therapeutic and non-therapeutic experimentation. Informed consent at least means that the doctor or the experimenter must give the subject the facts necessary to make an informed choice. That means that if the subject is ill he must have a clear sense of the diagnosis of his illness and the prognosis without treatment. Also the patient must have an idea of the benefits and risks of the treatment as well as the hazards and advantages of alternative forms of treatment.

Fried summarizes the rules that define informed consent as: "1) A fair explanation of the procedures to be followed, and their purposes, including identification of any procedures which are experimental; 2) A description of the attendant discomforts and risks reasonably to be expected; 3) A description of any benefits reasonably to be expected; 4) A disclosure of any appropriate alternative procedures that might be advantageous for the subject; 5) An offer to answer any inquiries concerning the procedures; and 6) An instruction that the subject is free to withdraw his consent and to discontinue participation in the project activity at any time."<sup>10</sup>

As it stands, this sounds fine, and it surely acts as a break on some of the abuses that might occur if we did not require it. The problem, however, with informed consent being used as the overriding justification criterion for experimentation is that few believe it is really possible to obtain. For many doctors, informed consent is that slip of paper that is a necessary (but as we have discovered, not sufficient) condition to avoid malpractice. But even if the doctor or researcher is committed to informed consent it is not clear if it describes a genuine choice. As a famous heart surgeon once told me, for a patient to make an informed decision to undergo heart surgery would mean he would have to study with him for at least three years (and that was assuming the patient had completed medical school). Though this certainly overstates the case, one may still ask whether informed consent is a workable moral requirement.

Even if informed consent were a clear possibility it is still not a sufficient condition to justify human experimentation. In some form or other, informed consent is probably a necessary condition for the use of human subjects, but simply because some may consent to make themselves subject to an experiment does not mean that they should so consent. For persons can misuse themselves even if they do so

voluntarily and with full knowledge. There are some things that we should not do to ourselves even for the good of others. To absolutize informed consent does not resolve the issue of whether we ought to allow ourselves to be subjected to certain kinds of risks in the name of human good.

Nor should this kind of problem be limited to those experiments which involve the greater physical risk to the subject. Indeed, I think that the issue is even more important in relation to the kind of experiments in the social and psychological sciences where deception is necessary to the experimental design. It is important to remember that we can morally harm without physically hurting.

Even if we can make informed consent a workable criterion for human experimentation there remains the problem of what we do about particular test populations. Should prisoners or the poor be subjected to human experimentation? Many argue that because of their disadvantaged position any informed consent they might give, in spite of elaborate safeguards, is inherently coercive. However, Katz suggests that this attitude, especially toward the poor, betrays a stereotypical and degrading view of them.<sup>11</sup> To be sure, it may be necessary to exercise special care in respect to prisoners and the poor, but to deny them the opportunity to participate in the joint venture of our community to better our condition is to deny them the respect due them. (The situation of the poor may be significantly different than that of prisoners, however, insofar as the latter have no power to protect themselves. This may also be important in the use of students in research for while they appear free, they are in fact in a disadvantaged position since their future depends on being able to please professors. At the very least, this means that the manner of obtaining informed consent is very important in contexts where the one consenting lacks the power to withstand the suggestion that he volunteer. This is especially the case when the "power" is unarticulated and informal.)

Of course, for this last point to be viable depends on the actual existence of that joint venture. Yet, in fact, we know that doctors and medical researchers have gone to great lengths to avoid exposing the general population to the risks necessary for medical advances. This is not the place to speculate about the reasons for this, though I suspect it has much to do with the paternalistic attempt of doctors to protect us from the risks involved in normal medicine, but until medical experimentation is seen as an opportunity — and perhaps even an obligation — for everyone, I find it hard to justify the continued use of prisoners and the poor as experimental subjects. Moreover, if we were willing to widen the opportunity for more people to participate in scientific research, it would necessitate the healthy development of making the scientific community take the time to explain what they are about. Or put more positively, it would help us see the stake we all

have, and the risks we should assume, for the development of certain kinds of research.

The ethical issues raised by the use of prisoners and the poor seem simple when compared to the problems involved in the use of children and other non-competents. In order to develop certain kinds of drugs or procedures we can do all the animal and adult testing we want and still we must finally test on children — i.e., a test group who by definition cannot give informed consent. Paul Ramsey has argued that no one, parent or guardian, even with the best intentions, has the moral status to consent for a child to be made the subject of medical investigation solely for the accumulation of knowledge (except when epidemic conditions prevail). To quote: "When there is no possible relation to the child's recovery, a child is not to be made a mere object in medical experimentation for the good to come."<sup>12</sup> If it is objected that this severely restricts possible advances in childhood medicine, Ramsey argues that the moral progress of the race is more important than the scientific. Thus, testing on children is the paradigm instance that at times it may be necessary to choose between morality and knowledge even though we normally assume that we do not have to choose between them.

(Without developing it I at least want to suggest that not enough attention has been paid to the ethical issues involved in using animals in research. It may well be that we will learn more about what moral issues are involved in human research if we think more about our assumption that we can subject animals to almost any peril or pain for the good of men. Our inhumanity to our fellow man may well be a correlative to our unjustified insensitivity to those not of our species.)<sup>13</sup>

### 5. The Basis of Informed Consent

In conclusion I think it is interesting to ask why we have come to think that informed consent is so important. Above I have quoted Ramsey to the effect that no man is good enough to experiment upon another without his consent, but it is not clear why this is the case. Of course many would argue that no man has the right to force another to do what he does not want to even if it will have positive benefits for others. In the framework of the libertarian political ethic this response has some plausibility, but as I suggested this assumes an individualistic assumption that avoids asking what ends medicines and collateral research ought to serve.

In this connection Charles Fried's recent analysis of the basis of informed consent seems to me to be particularly suggestive and illuminating.<sup>14</sup> Fried argues that our commitment to the individual subject is based on the idea that the ethical life is primarily anchored in the concrete relationships in which we are involved. In other words, Fried suggests that the sense of care we should have for others is not based



on impersonal moral principles, but grows out of our more or less direct commitment to particular significant others. Thus we feel that we have obligations to our wives, children, and friends, which are qualitatively different from obligations to those with whom we are not in such relationship. Moreover, we feel that whatever our obligations to a stranger may be, they cannot override our obligation to those with whom we share a special relationship. If Fried is right, our obligation to the stranger is based on our prior commitment to particular friendships.

Fried goes on to argue that the kind of relationship between a doctor and his patient is of this primary sort. Thus the ethos of medicine assures the patient that the doctor's concern for him or her is absolute — that is it would be immoral for the doctor ever to lower the quality of care of one patient for the good of another even if the "another" were a greater number. The requirement of informed and free consent for therapeutic as well as experimental procedures refers to one attempt to safeguard our fundamental commitment, then to primary relationships. It is to be noted therefore that the concern with the "rights" of the human subject is not necessarily based on the inviolability of the individual, but rather grounded on the community possible between those who wish to be friends.

But if Fried has properly identified the relationship which underwrites the doctor's sense of commitment to each individual patient, it must be asked how this commitment translates into the non-therapeutic experimental context? If this is not the kind of relationship between the scientist and the human subject then even more careful procedures must be developed in the research context to protect the subject. For we must see that what we have is not a joint venture for medical progress or human goods secured through such progress, but a relationship between strangers in which one side has been given more power than the other in the name of science.

## REFERENCES

1. Katz, Jay, "The Poor," *Experiments and Research with Humans: Values in Conflict* (Washington, D.C.: National Academy of Science, 1975), p. 154.
2. For the proceedings of this conference see the above publication.
3. Ramsey, Paul, *The Patient as Person* (New Haven: Yale University Press, 1970), p. 59.
4. MacIntyre, Alastair, "How to Identify Ethical Principles," unpublished paper prepared for the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.
5. Fox and Swazey put this well as they suggest that "the social and cultural meaning of dialysis and transplantation is also integral to the questions these procedures have raised about the basis and significance of human solidarity. The nature and importance of our relationship to one another is a core issue in every society, system of ethics, and religion. Dialysis and transplantation have reempha-

sized how central it is to medicine as well. This has occurred in a period of generalized crisis even whether and how an advanced society like our own can achieve a more trusting intimate, inclusive, and transcendent form of solidarity." *The Courage to Fail* (Chicago: U. of Chicago Press, 1974), pp. 330-331.

6. See for example, pp. 60-108 in Fox and Swazey.

7. Fried, Charles, *Medical Experimentation: Personal Integrity and Social Policy* (New York: American Elsevier Publishing Co., 1974). Randomized clinical trial is the therapeutic investigation "in which the allocation of a patient to a particular treatment category or its alternative — sometimes an alternative therapy, sometimes a placebo, that is no therapy at all — is done at random." p. 7. Of course part of the problem with this procedure is that the patient is drafted into it without his knowledge since part of the value of the trial depends on the patient not knowing other therapeutic alternatives are available. It is assumed that this is justified since in such an experiment no technique has shown itself to be superior to another.

8. *Ibid.*, p. 50.

9. See for example Leon Kass, "Regarding the End of Medicine and the Pursuit of Health," *The Public Interest*, 40 (Summer, 1975), pp. 11-42.

10. Fried, p. 42.

11. Katz, "The Poor," p. 154.

12. Ramsey, p. 12.

13. For a more extended discussion of this issue see Peter Singer, "Animal Liberation," *New York Review of Books*, XX, 5 (April 15, 1973), p. 17.

14. Fried, pp. 67-78.

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