How the Belmont Report Fails

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On July 12, 1974, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research was created. One of its charges was to identify the basic ethical principles underlying research involving human subjects. In fulfilling its charge the Commission published the **Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research** on April 18, 1979. Since then the Belmont Report has become the ethical standard for the treatment of the human subjects of research. The mechanism by which abuse of human subjects of research is prevented is the institution of Institutional Review Boards (IRBs), which require researchers to submit their research proposals for their approval. IRBs frequently make use of the highly publicized and widely accepted standards enunciated in the Belmont Report. Thus the Report has tremendous practical significance for the oversight of research on human subjects.

The Belmont Report is a bad ethical theory. The Report is a needed response to an important and practical issue: how do we guide and regulate medical and behavioral research. In view of the abuses of research subjects which have occurred during World War II on concentration camp prisoners and on poor black men in the Tuskegee syphilis study, no serious person would suggest that we simply trust researchers to exercise her own judgment. As a result specific local codes and guidelines have sprung up to protect society at large and potential research subjects in particular. The Belmont Report is an attempt to provide a theoretical background adequate to evaluate actual and proposed codes of conduct for researchers. As the Report itself states "Broader ethical principles will provide a basis on which specific rules may be formulated, criticized and interpreted." In order to serve this function of rule evaluation the Report offers three basic ethical principles: respect for persons, beneficence and justice. I wholeheartedly agree that we need some more general principle or principles to allow us to evaluate specific codes of conduct offered to guide research. However, the Report’s formulation of these three principles is completely inadequate to the task.

Ethical theory does not come to us inscribed on tablets of stone. It is something we invent and reinvent as time and circumstances change. Good inventions are good because they are good for something. We must be clear about what ethical theory is for in order to recognize a good ethical theory when we see one. An ethical system, like a legal system, is necessary for regulating human behavior so that we may live together harmoniously. An ethical system differs from a legal system in being more basic and less formal. Ethical authority resides in a shared system of rules understood and enforced by everyone in general and by no one is particular. The system represents a kind of ethical common sense.

Ethical theory is the rational clarification, defense and critique of the rules of ethical common sense. Applied ethics is the extension of clarified common sense to new issues and conditions. Since ethics is essentially rule-based applied ethics consists in the rational critique of proposed subsidiary rules applied
to special circumstances--among these being research with human subjects. The Belmont Report understands ethical common sense as consisting of three ethical principles: respect for persons, beneficence and justice. Assuming that the Report has picked the most relevant rules, what we need then is a clarification of the rules and their relationship to each other. This clarification will guide us in evaluating specific rules concerning the treatment of the human subjects of research. These corollaries of the general rules should be evaluated according to the contribution that they make to our ultimate goal of living together in harmony as members of a moral community.

We want to be able to explain to both the general public and to the researchers themselves why we believe that research conducted in accordance with a particular code is morally acceptable and why research that violates the code should not be allowed. The Belmont Report states that its "objective is to provide an analytical framework that will guide the resolution of ethical problems arising from research involving human subjects." General principles for the evaluation of specific rules must be both clear and uncontroversial to do the job we want them to do, viz. resolve ethical problems. If the principles are unclear then people will be unable to agree on how to apply them. If the principles are overly controversial then no useful consensus can be reached about whether it is really good to conform to the code. The two criteria of clarity and plausibility stand in constructive tension to one another. It is easy, too easy, to construct a clear code if we are indifferent to its plausibility to a wide range of people. Moreover, it is all too easy to propose principles with which no one will disagree by formulating them in positive but hopelessly vague language. The Belmont Report tends to be excessively vague about the rules and even more vague about the relationship holding among the rules.

Substantial disagreement about values is an uncomfortable fact for ethical theory to deal with honestly. Substantial disagreements can be papered over with verbal agreement. For example, suppose the issue before us is tax policy. It is easy to obtain verbal agreement that a system of taxation should be "fair." But such a general principle for the evaluation of specific tax proposals is useless given unresolved and substantial disagreement about the meaning of "fairness." Does fairness mean that the burdens are shared equally, shared in proportion to ability of pay, shared in proportion to benefits received or something else entirely. Conservatives argue that to make the tax system fairer we must make it less progressive. Liberals argue that to make it fairer we must make it more progressive. Verbal agreement between liberals and conservatives that the tax system should be "fair" contributes nothing to the debate. Clarity demands that we specify what we mean by "fairness" prior to determining whether or not any given taxation system is fair. A cheap consensus can be reached by sacrificing clarity, but a cheap consensus isn’t worth much. Good ethical theory must aim at both clarity and consensus. This is hard but all good things are hard.

Many readers come to the Belmont Report with little prior training in ethics. They come to it because they are involved in doing research on human subjects and seek help from the Report on how to think clearly about the issues arising from this research. I fear that the quality of the guidance that they are receiving from the Report is of poor quality. In what follows I will substantiate my charge that the Belmont Report is too vague, especially in regards to the relationship of the principles to each other, to offer any help in the resolution of the difficult questions that arise concerning research on human subjects. Some readers friendlier to the Report than I am will wonder if I am not demanding more of an ethical theory than is reasonable. So in the conclusion of the paper I will try to show how an ethical theory could simultaneously satisfy the joint demands of clarity and persuasiveness.
Respect for Persons

The Belmont Report’s treatment of respect for persons divides into what is required of us if we are to show proper respect for the autonomy of fully competent agents and what is required of us concerning the protection of human beings possessing diminished autonomy. Concerning normal or fully autonomous agents the Report says this:

To respect autonomy is to give weight to autonomous persons’ considered opinions and choices while refraining from obstructing their actions unless they are clearly detrimental to others. To show a lack of respect for an autonomous agent is to repudiate that person’s considered judgments, to deny an individual the freedom to act on those judgments, or to withhold information necessary to make a considered judgment, when there are no compelling reasons to do so.3

Thus the Report distinguishes three ways in which we might fail to show respect for autonomy. The latter two ways are basically correct, but the first of the three makes little sense. There is no reason why my respect for someone’s autonomy means that I must “give weight to her opinions” and not “repudiate that person’s considered judgments.” Suppose someone believes that smoking cigarettes is good for her health and that that is her considered judgment. In what sense must I give such a judgment weight? Respect for persons does not require that I fail to recognize foolish opinions for what they are. The respect that I owe to others, foolish or not, concerns the second two considerations mentioned. Respect for another person requires that I should give her considerable latitude to act on her beliefs and judgments no matter how foolish I take her opinions to be. In deciding whether or not to agree with the opinions of another person I show her no disrespect by giving all weight to the relevant evidence and none at all to the fact that it is her opinion. But, in order to respect others, I ought to be very chary of interfering with people’s efforts to act on the basis of their opinions, foolish or not. In addition I ought to try to provide people with the information necessary to make reasonable decisions. In the case of the person who believes that cigarette smoking is good for her health, respect for her may require that I at least inquire as to whether or not she has been exposed to the relevant evidence on the subject. Far from having an obligation to “give weight” to foolish opinions, a clear recognition that some opinions are simply wrong is a preliminary to identifying cases in which respect for the person should lead us to give her more information. These problems with the first point about autonomy are minor in comparison with those that I shall mention shortly. We could assume that the “weight” mentioned in the Report concerns the freedom of the individual to act on her opinions rather than the epistemic respect we owe to the opinions themselves. I shall accordingly interpret the Report’s mention of giving weight to opinions as a mere slip of the pen.

There are more serious problems that are not so easy to overlook. “To give weight” does not tell us how much weight should be given. Nor does the qualification mentioned at the conclusion of the passage "when there are no compelling reasons" give us much help in determining what would constitute a compelling reason to override the agent’s choice. The qualification mentioned earlier “unless they are clearly detrimental to others” promises to clarify matters but this promise quickly evaporates upon careful inspection. Is the likelihood of detrimental effects on others just an example of a “compelling reason” or is it the only “compelling reason”? What would other “compelling reasons” be? Are there any limits to how detrimental the effects of others have to be in order to override an agent’s autonomy? If so, what are these limits? That we should allow other people to make choices is a truism that no one would deny. But this truism is of little help in resolving the difficult ethical problems that arise concerning the
limits of autonomous choice. The Report offers us nothing that would help us determine which limits are justifiable and which are not.

Individual researchers or members of IRBs, untrained in ethics, who are coming to the Report to acquire a more sophisticated appreciation of the ethical issues surrounding respect for persons, will come away with little. A brief survey of the problems will show some of what is missing from the Report. The principle of respect for persons can conflict with itself. This can come about in at least three ways. First, a person’s decision at one time may conflict with her decision at a future time. Suppose a person wants to make a decision now and asks that we not allow her to change her mind in the future. Should I respect her right as an autonomous agent now to make that decision or should I respect the right of the future self to change her mind? Odysseus asked his crew to tie him to the mast so that he could hear the Sirens singing and asked that they not listen to his pleas to be untied once he heard the song. Should Odysseus’ right to make a decision now to be tied up give him to the right to make the decision to give up his right to be untied later? Should patients be allowed to commit themselves to a painful course of treatment in such a way as to override their right to opt out later on? A second way in which autonomy can conflict with itself is in cases in which the right of one person to make a decision interferes with the right of another to make a decision. Spouses and business partners tie their fates together in such a way that their choices are intertwined in the present. A decision to move to North Dakota by one spouse conflicts with the possible choice of the other spouse to stay put. Respect for the autonomy of one person can thus come into direct conflict with respect for the autonomy of another. Further, there are times when an autonomous agent faces a present choice that will restrict the autonomy of another agent by preventing her future choices. When Amish parents decide to restrict the amount of education that their children receive to basic literacy, they are making a choice now that limits the range of choices their children will be able to make in the future. In all these cases autonomy clashes with autonomy and something more than a principle which enjoins us to respect the right of individuals to make choices will be necessary to give us guidance in how to proceed.

Moreover, respect for autonomy can conflict with other ethical considerations. The simplest and most relevant sort of conflict arises between respect for autonomy and possible harmful effects on other people. Simply put, sometimes an action that the agent wants to perform would harm another person. In general there is widespread appreciation for the fact that my right to do as I please can be limited by other people’s rights not to be harmed by my actions. However, this is not to say that the interrelation of these rights is clear. Surely my right to swing my fist is overridden by your right not to be hit in the nose. But it is equally clear that my right to wear an ugly tie is not overridden by your sartorial preferences. Drawing the line between reasonable and unreasonable restrictions on the right of agents to act is no easy exercise. Such issues cannot be ignored when the subject is human research. The driving force behind research with human subjects is the desire to acquire knowledge that will be of benefit to people in general. This goal comes into potential conflict with the rights of individual subjects of research. These individuals are at the very least asked to volunteer their time to the study and at times they are asked to risk their health, well-being and even their lives for the benefit of others. Potential conflict between the interests of the research subjects and the interests of society at large are not incidental to the ethics of research with human subjects. It is at the very heart of the subject. Yet the Report has almost nothing to say about the resolution of this core conflict.

The Report’s comments on our obligations to persons having diminished capacities for rational deliberation and choice are even more confused.
Respect for the immature and the incapacitated may require protecting them as they mature or while they are incapacitated. Some persons are in need of extensive protection, even to the point of excluding them from activities which may harm them; other persons require little protection beyond making sure they undertake activities freely and with awareness of possible adverse consequences. The Report fails to distinguish between the need to respect the autonomy of agents with diminished capacity from the need to protect these agents from harm. The latter would seem to be an instance of what the Report calls Beneficence. The obligation to protect people from harm is distinct from the obligation to allow them to make their own choices. Police have the obligation to protect both the fully capable and the incapacitated from criminals; firefighters have a similar obligation to protect everyone from fires. The appropriateness of such protections does not depend on the extent of anyone’s ability to rationally deliberate. Are the duties of researchers to protect their subjects any different in this regard? The obligation to protect individuals from harm may come into conflict with our obligation to respect their right to make decisions for themselves. When it does, as in the case of seatbelts or motorcycle helmets, we have to decide whether or not autonomy should be trumped by beneficence in such cases. There are, however, cases in which respect for an agent’s autonomy, as distinct from concern for the agent’s welfare, can arise for agents whose capacity for rational deliberation is diminished or nonexistent. These are cases in which the agent’s past or future autonomous decisions would be interfered with by actions we take in the present. For example, suppose a person makes a will at the age of fifty while in full possession of her faculties. Respect for that decision requires us to disallow attempts by the same person to change her will at a later date if age or disease has severely diminished her capacity for rational choice. Similarly, we might not allow a boy to become a castrati in order to preserve his beautiful singing voice because we believe that when the boy becomes a fully autonomous adult he may not approve of his youthful decision. Our respect for his right to make decisions in the future leads us to protect him from making this decision now. The existence of agents with diminished capacities is certainly a source of ethical problems. Who should decide for such agents? What criterion should the decision be based on? How much consideration should be given to the diminished agent herself? These are all questions that thoughtful people will ask in connection with research on human subjects. The Report’s vague principle of respect for persons offers no substantial guidance towards making these decisions. Worse, vagueness muddies the waters making resolution of ethical problems harder. A concrete example of an ethical problem that may arise will show how unhelpful the Report is. Suppose in conducting research on a new treatment for cancer that a research subject, despite its being explained that there is only a small chance that the treatment will be effective in his case, comes to believe that the treatment will certainly be effective in his case. Should the experimenter be satisfied with this or should she go over the information again to try to see to it that the subject comes to believe the truth, viz. that there is a chance but only a small chance that the treatment will be effective? Does respecting the subject’s autonomy mean allowing him to continue in his unjustified but comforting belief or does it require that he form a correct belief about his chances of recovery so that he can make a rational choice as to whether or not to participate in the research? Such a situation is not an idle speculation. Research has shown that human research subjects are often misinformed about the potential value of the research for their own cases. Vague talk about “giving weight” and “no compelling reasons” offers no guidance. A person whose ethical intuitions favor not interfering with the patient’s unreasonable optimism will be able to quote the Belmont Report in support of his opinion "to show a lack of respect for an autonomous agent is to repudiate that person’s considered judgments." On the other hand a person whose ethical intuitions favor a more proactive approach to informed consent will find support for her
opinion in the Report’s claim that illness can lead to the complete or partial loss of the capacity for self-determination. And note the following statement: “Respect for …the incapacitated may require protecting them …while they are incapacitated.” The Report’s vagueness exacerbates such ethical disputes; it does not help to resolve them.

Beneficence

The Belmont Report formulates the principle of beneficence into two general rules: “(1) do not harm and (2) maximize possible benefits and minimize possible risks.” As they stand the rules are in need of considerable clarification. Who should we strive not to harm? The research subject or society as a whole? With respect to this issue the Report cites the Hippocratic Oath and the views of Claude Bernard. Both restrict their attention to harm done to the individual patient or research subject. Such harm is forbidden and is not to be balanced by possible benefits to other persons. The Report’s answer with respect to the first rule seems unambiguous: it means “do not harm the individual research subject.” With respect to the second rule similar questions arise. Whose possible benefits and possible risks are we asked to consider? Again a reading of the Report offers a plain answer: the possible benefits and risks which we must weigh against each other concern not just the research subjects but people in general now and in the future. The Report reminds us that “effective ways of treating childhood diseases and fostering healthy development are benefits that serve to justify research involving children.” So both rules are clear with respect to the question of whose harm or benefit is relevant. The first limits the relevance to the individual research subject. The second includes everyone. The second rule is vague concerning the balancing that takes place between the risks and the benefits of the research. Research costs time and money. How many millions of dollars is it worth to cure a disease, to prolong the lives of patients suffering from a disease, to improve the quality of life of patients suffering from a disease? As difficult as comparing economic costs with potential benefits to patients may be, it is perhaps even harder to compare different kinds of benefits to patients. Suppose a new course of treatment promises to prolong patients’ lives at the expense of their quality of life. Is such a treatment beneficial or the reverse? How about a treatment that shortens the patients’ life but significantly reduces his pain? Such comparisons are a rich source of ethical dilemmas, but the Report offers no hint of how we are to resolve them.

Putting aside the difficult question of comparing different kinds of benefits and harms let us return to the Belmont Report’s two rules of beneficence. One natural way to read these two rules is that the first stipulates that a necessary condition for research on human subjects is that the research does no harm to the subjects themselves. The second rule adds an additional necessary condition: the research should promise benefits to society now and in the future that outweigh the costs to all concerned. Since we have already precluded any harm to subjects the costs to be considered here are only costs to other members of society, which will include other people suffering from the disease in question. On such a reading the Report would be offering clear ethical guidance. It would be recommending that no amount of benefit to society at large could ever justify any harm done to the human subjects of research. Can we ever impose costs on the subjects of research and justify them by the benefits that might accrue to others? The reading I am considering would give a definite negative answer to this question. This would be clear, however it is also clear that the Report does not intend this reading of its two rules. Using the example of research on childhood diseases the Report says “A difficult ethical problem remains, for example, about research that presents more than minimal risk without immediate prospect of benefit to the children involved.” The Report notes that people disagree about whether such research is ever permissible and have presented arguments on both sides. The Report does not claim that its rules will resolve the disagreement. “Here
again, as with all hard cases, the different claims covered by the principle of beneficence may come into conflict and force difficult choices.”\textsuperscript{12} Earlier the Report had claimed that the two general rules were “complementary expressions of beneficent actions.”\textsuperscript{13} Now however it is clear that far from being complementary the two rules are contradictory. Researchers are being told by the first rule to do no harm to subjects of research while the second rule requires them to balance the harms done to those subjects against the benefits to society as large.

Charity bids me to make one final attempt to make sense of the two rules together. Perhaps the intention is to attempt to balance the costs and benefits of the research (the second rule) while giving special weight to the risks imposed on the subjects of the research (the first rule). That something like this is actually intended is indicated by the Report in section on Assessment of Risks and Benefits: “In balancing these different elements, the risks and benefits affecting the immediate research subjects will normally carry special weight.”(emphasis added)\textsuperscript{14} However, notice the claim is qualified by the word “normally.” Evidently there are cases in which the effects on the research subjects do not carry any special weight or even any weight at all. The next sentence confirms this impression. “On the other hand, interests other than those of the subject may on some occasions be sufficient by themselves to justify the risks involved in the research, so long as the subjects’ rights have been protected.” (emphasis added)\textsuperscript{15} Nothing in the Belmont Report gives IRBs any guidance on when a given research proposal is a normal case in which the research subjects’ interests carry special weight or when it is a special occasion when other people’s interests are sufficient by themselves. Nor does the Report give any indication of how much special weight to give the subject’s interests even in normal cases.

Moreover, the Report fails to harmonize beneficence with respect for persons. This is something of a surprise since it is widely recognized that deontological ethical principles like respect for persons stand in some considerable tension to consequentialist ethical principles like beneficence. It is not easy to harmonize consequentialist considerations with deontology. Some ethical theorists, like Kant, opt for a purely deontological ethics and reject any attempt at compromise with consequences. Others, like Mill, seek to make one set of considerations primary and show how a decent respect for the autonomy of rational agents is consistent with a fundamentally consequentialist approach. The Belmont Report opts for neither strategy and just ignores the tension between deontology and consequentialism. The tension arises in quite simple ways. Suppose an agent decides to embark on some course of action that is likely to harm herself and others. If I take deontological considerations are primary I am apt to let her act on her decision because respecting her autonomy is more important than preventing harmful consequences. On the other hand if my basic ethical instincts are more consequentialist I will be apt to intervene to prevent the imminent harm her actions threaten because I consider such harm to be reasonable grounds for overriding her autonomy.

The difference between deontological and consequentialist approaches may appear too purely theoretical to have practical significance but this is not the case. Take informed consent as an example. There is a subtle but significant difference is the way informed consent is understood depending on whether the basic approach is deontological or consequentialist. A consequentialist insists on informed consent primarily because the person who feels the effects of the experimental treatment, nausea or headaches for example, is the person in the best position to tell us how bad it is. Similarly, the person whose life might be prolonged or cut short is in the best position to judge how valuable more or less of his life would be. A deontologist, on the other hand, looks at informed consent quite differently. Assuming the subject to be fully competent her consent to the study is what is important. The fact that she has freely consented to
the personal costs that the experiment imposes on her justifies us in going forward. In short the consequentialist will emphasize the *informed* part of informed consent while the deontologist will emphasize the *consent*. Such differences in emphasis will make a practical difference when we have to decide whether informed consent has actually been obtained of some particular subject. The Belmont Report tries to satisfy both kinds of ethical intuition. Deontologists will find support for their intuitions in the first principle. Consequentialists will find support in the second. However, the Report is completely silent as to which principle we should rely on when the two principles give conflicting advice. So the Report is too vague to resolve such disputes.

**Justice**

Everyone will agree that justice is important. But disagreements about justice are commonplace. This is why serious philosophers from Plato and Aristotle to Rawls and Nozick have devoted considerable attention to trying to formulate clear and convincing theories of justice. The relevance of justice to the ethics of research is not immediately obvious but the Report makes a good case that it is. On the individual level suppose there is a research study that will provide a promising new treatment for a form of terminal cancer. It would be unjust to offer patients an opportunity to participate in the study solely on the basis of personal likes or dislikes. On a social level it also seems unjust to select only those deemed “inferior” for risky research. We do not need any ethical theory to see that the treatment of poor black men by the Tuskegee study was wrong. Ethical common sense will suffice for this. Where we need ethical theory, in this case, a theory of justice, is to guide us in the harder cases about which there is some controversy. Different hospitals serve different social and economic groups. The decision to conduct a particular study at one hospital rather than another thus carries with it the consequence that more members of one group will be exposed to the risks and benefits of the study than another group. How do we determine whether the choice of a particular hospital as the locus for the study is unjust? In a private market economy the wealthy will have better access to any new treatments that will come about as a result of medical research. Is unequal access to medical services itself unjust? If so, what significance does the unjust distribution of medical services have for medical research? These are hard questions that mere ethical common sense cannot answer. A sharp ethical theory will allow us to make cuts in the hard cases where common sense ethics is too blunt a tool. Does the Belmont Report offer us a concept of justice any sharper than crude common sense? It does not.

The Report notes that there are differences of opinion about the just distribution of burdens and benefits. It mentions five such without comment as to which is correct or properly applicable to the burdens and benefits of medical or behavioral research. “These formulations are (1) to each person an equal share, (2) to each person according to individual need, (3) to each person according to individual effort, (4) to each person according to societal contribution, and (5) to each person according to merit.” First it must be pointed out that all of these are too vague to be used as they stand. For example, what does “an equal share” mean? Does it mean an equal chance of receiving the benefit or does it mean that everyone must actually get the same benefit? Similar questions should be raised and answered with respect to all five formulations before they would be usable. The Belmont Report neither raises these questions nor answers them. But let us set that aside for now and pretend that they have all been raised and answered. Once this is done, it should be obvious that the differences among these are not merely verbal. If we look at different distributions of benefits we will get very different answers as to their justice according to these different formulations. For example, if I give benefits to those who are most in need of them I am not giving everyone an equal share. Yet IRBs are given no guidance by the report as to which of
these formulations to use. What happens when different members of an IRB choose different formulations? What is to prevent IRBs from adopting formulations arbitrarily—perhaps they apply (2) on Tuesdays and (5) on Fridays?

Despite the theoretical vagueness and confusion that infects the Belmont Report’s concept of justice the Report itself does not hesitate to draw sweeping conclusions. “Finally, whenever research supported by public funds leads to the development of therapeutic devices and procedures, justice demands both that these not provide advantages only to those who can afford them and that such research should not unduly involve persons from groups unlikely to be among the beneficiaries of subsequent application of the research.”(emphasis added)12 My general political persuasion prompts me to agree with the first conclusion here, but intellectual honesty leaves me perplexed as to how the Belmont Report’s vague and conflicting pronouncements on justice could possibly support such a claim. Public funds support the construction and operation of airports but only those who can afford tickets can use them. Public funds support a system of universities but only those who meet admissions standards can use them. Public funds support regulation of banking and investment services but only those with capital can make use of those services. Could any of the vague formulations of a principle of justice mentioned by the Belmont Report decide which of these practices are compatible with justice and which are not? Concerning the second conclusion I am in even more of a quandary. First, the presence of the qualification “unduly” renders the second conclusion vacuous. Of course anything that is undue is wrong. This is like defining theft as wrongful taking or murder as wrongful killing. What we want is clarification of when such actions are wrong. IRBs attempting to implement the Report’s concept of justice are left relying on their subjective and variable intuitions about when involvement of groups with limited access to medical services is due and when it is undue.

What is the Role of Basic Ethical Principles?

As we have seen the Belmont Report cites three basic ethical principles as its core ethical theory. The Report makes two quite different suggestions about the role of basic ethical principles. The Report notes that IRBs establish and implement codes, rules and guidelines to determine under what circumstances research on human subjects is ethically acceptable and should be permitted to proceed. The first suggestion about what basic principles are for is that they “provide a basis on which specific rules may be formulated, criticized and interpreted.”18 That is to say, basic ethical principles could serve as metarules, which would guide people in formulating the specific rules that they would actually use in ordinary day to day decision making. They would also serve to justify the specific rules and to defend them against criticism from researchers who thought they imposed excessive restrictions on their freedom to do research or against criticism from members of the public who thought the rules provided insufficient protection for human subjects. The more basic principles could also guide us in the interpretation of the specific rules when these turned out to be insufficiently clear to provide guidance in new and unanticipated cases. In short the basic principles could serve as a sort of constitutional law that would govern the more specific laws needed in everyday life. The suggestion is a good one but the Report does not really take this suggestion seriously. Throughout the Report various possible applications of the basic ethical principles are discussed but none of these take the form of critiquing, defending or interpreting specific guidelines. Every application discussed in the Report takes a different form: the basic ethical principles are used directly to render judgments about the acceptability of specific forms of research on human subjects.
Surely this is problematic. If we take the basic ethical principles as superceding specific codes or
guidelines, then this is bound to create difficulties. Suppose a given research proposal is deemed
consistent with the local code or guideline governing such research but the IRB decides that it is
inconsistent with the basic ethical principles and disallows the research. Surely the principal investigator
will be indignant that research consistent with the IRBs guidelines is being refused on these grounds.
Moreover, allowing the basic ethical principles to overrule the guidelines in the other direction is also
problematic. Suppose a research proposal that violates local guidelines is allowed to proceed on the
grounds that the proposal is in keeping with the more authoritative basic ethical principles. Suppose
further that some human subject takes herself to have been harmed by this research. Should the IRB feel
confident that it can justify overriding its own guidelines on the basis of an appeal to these basic ethical
principles? What, one wonders, are specific guidelines for if they can be overridden by “higher”
principles? What protection do they offer human subjects? What guidance do they give to researchers? It
seems safer and far more sensible to look to the specific local guidelines rather than to basic ethical
principles for answers to specific questions. Especially given the extreme vagueness of the principles in
question. One of the great values of publicly stated explicit rules is that they provide people with the
security that there is a common understanding concerning what sorts of actions are acceptable and what
sorts are unacceptable. With a good clear set of rules I can feel secure against criticism and second-
guessing by others. I can justify myself by reference to the public rules and that settles the matter.
Moreover, a sense of fairness is assured. If I know that others are held accountable to the same set of
rules then I am more willing to voluntarily abide by them. But if the clearer and more specific rules
governing the treatment of human subjects can be overridden at any time by a set of vague “higher” rules,
then the value of specific rules is lost. It seems to me that using basic ethical principles to apply directly
to actions is a terrible idea. Using them to explain and defend specific rules is quite another matter.

Not only are the basic ethical principles of the Belmont Report vague and implausibly construed as
superceding specific local rules and guidelines, but the relationship of these rules to each other is never
articulated. In any system having multiple rules questions inevitably arise about their relationship.
Suppose a research proposal is deemed consistent with respect for persons but inconsistent with justice.
Is the proposal acceptable or not? Suppose the principle of beneficence seemed to require going forward
with some very promising avenue of research, could respect for persons veto this judgment? One way of
interpreting the relationship among the principles is to take them each as being necessary conditions for
the moral acceptability of the research. A conflict with any of the three would be sufficient to render the
research unacceptable. Another very different way is to set the principles into an ordered hierarchy. For
example, we might make respect for persons supreme, make justice second to respect for persons, and
place beneficence at the bottom of the list. In such a case any conflict between respect for persons and
justice would be decided in favor of the former. Any conflict between beneficence and justice would be
decided in favor of the latter. Any ethical theory weighty enough to be helpful in the resolution of
practical ethical issues would have to clarify the relationship of the basic principles. The Belmont Report
does not even attempt to do this. In the absence of such clarification researchers will not be able to guess
how their IRB will interpret or apply the basic principles. Individual members of IRBs will disagree
among themselves as to which basic principle to apply in given cases. And IRBs as a whole will be
unable to determine whether or not they are being consistent in their application of these principles from
one day to the next. In such a situation the public will have less reason to place its trust in the integrity
of IRBs.

The deficiencies of the Belmont Report as a moral theory are multiple and severe. The basic principles
are excessively vague, the relationship of the basic principles to specific guidelines and actions is misconceived and the relationship of the principles to each other is never clarified. Any one of these defects would be sufficient to invalidate the Report as a guide of human research. Taken together they are altogether damning. We can do better than this and we ought to do better than this. The treatment of human subjects of research is too important to be left to the vagaries of subjective feelings. I suspect that no matter how bad the Belmont Report is shown to be that it will continue to be widely cited and used as authoritative until a better theory is available. Having critiqued the Report so thoroughly I feel obliged to make some positive suggestions. In the final section of this paper I will attempt to spell out how we could do better.

Fixing the Belmont Report

I will begin this section by stating what I think is right about the Belmont Report. The Report is on target when it identifies respect for persons, beneficence and justice as plausible and important ethical considerations that must be taken into account in regulating research on human subjects. They are indeed part of ethical common sense. The problems with the Report concern clarifying those principles, their relation to each other and their applicability to particular cases. In this final section I will try to repair these deficiencies. An ethical theory that could be usefully applied to practical issues such as the treatment of the human subjects of research must be both plausible and clear. If the theory is implausible, then people will not trust the conclusions that are based on it. If the theory is unclear, then people will not agree on what conclusions can be drawn from it. In order to get an ethical theory that is both plausible and clear I propose that we begin with commonly accepted ethical principles and clarify them as needed.

Ethical common sense approves of respect for persons, beneficence and justice, and so do I. There is sufficient agreement among reasonable persons that these things are ethically important and so they form a basis upon which a reasonable ethical consensus can be arrived at concerning research with human subjects. I think that the Report is doing something right by picking out these principles. However, I do think that beneficence plays a different role in our moral thinking from the other two principles and that our ethical theory should take this into account. In the beginning of this section, for ease of exposition, I will write as if all three principles played exactly the same role. The explanation of the unique role played by beneficence will be delayed until the end. A final preliminary qualification is that while as ethical theorists we aim at reducing vagueness we cannot eliminate it entirely. The Belmont Report as it stands is so fraught with vagueness and ambiguity as to be useless. My goal is eliminate the ambiguity and reduce the vagueness to tolerable levels.

The three principles should be understood as indirectly and not directly constraining the behavior of researchers who wish to use human subjects. The principles rule out some research proposals as unacceptable in a doubly indirect way. The principles serve as an overarching constitutional law that oversees the institution of specific local guidelines for research. It is these local codes of conduct adopted and enforced by IRBs that effectively determine which human research projects may proceed and which are halted. As discussed above whenever there are multiple principles care must be exercised in explaining the relationship of the principles to each other. I propose that each of the three principles be understood as necessary conditions. To make respect for persons a necessary condition is to say that no amount of public benefit could justify a research proposal that violated the autonomy of the research subjects. To make justice a necessary condition is to say that no research proposal that distributed benefits or burdens according to race would be acceptable. But the determinations would be mediated by
the existence of specific codes of conduct. Very specific rules would need to be adopted concerning informed consent. The specific rules would detail exactly what information had to be conveyed to subjects, how that information would be presented, how the determination would be made that the subject really gave informed consent. Special provisions would have to be established for cases dealing with children, the terminally ill, prisoners, etc. Serious ethical thought needs to be done when we are designing these local codes of conduct. It is at this stage that we must ask ourselves what kinds of rules would genuinely protect the autonomy of research subjects and prevent injustices. The application of the specific rules to individual research proposals will be straightforward and no special pleading will be allowed if we really take these principles as necessary conditions. For example, a researcher will not be permitted to argue that the rules governing informed consent should be ignored in her case because of the huge potential benefits to society of this research. Necessary conditions do not allow for exceptions. The principles are understood as being necessary conditions for any acceptable code of conduct for researchers and the provisions in the code should be read in the light of this as more specific necessary conditions with which researchers must comply in every case. For example, suppose the code specifies that when there are serious health risks to the subject the subject must be tested to determine that they really understand the risk prior to consenting. Such a specific requirement would have to be justified by appeal to the principle of respect for persons, but once adopted no study that proposed waiving this requirement would be permitted under any circumstances.

Having clarified the relation of the principles to particular actions and to each other the more difficult task remains of clarifying the principles themselves. In any system there are tradeoffs due to the relation of the various parts of the system. In making the ethical principles necessary conditions I have chosen to make this part of the system very tight and restrictive. This allows and even requires a corresponding loosening of some other part of the system. Since our principles are being understood as imposing requirements, rather than as mere desiderata that could be overridden by other factors, we should be careful not to make those requirements unreasonably restrictive.

The principle of respect for persons that is relevant to research with human subjects can be stated as follows: autonomous adults should never be subjected to any significant risk of harm without their informed consent. As a corollary to this an additional principle can be formulated: humans who are temporarily or permanently incapable of exercising their autonomy should never be subjected to any significant risk of harm without the consent of an autonomous adult acting as guardian of their interests who can consent on their behalf. These principles, I hope, are clear enough as they stand. This is not to say that working out specific codes to embody these principles is an easy matter. The codes will have to detail some standards for what is to count as a significant risk. They will have to describe effective procedures for insuring that consent is both genuine and informed. Further the difficult questions of how to determine who is autonomous and who shall be recognized as the guardian of the incompetent person’s interest will have to be worked out. These principles do not suffice to deduce the details that will be embodied in the procedures covering informed consent, but they will serve as a touchstone for evaluating those details. Working out such details as these is not to be done by ethicists in their armchairs. The primary responsibility will lie with people having a significant amount of practical experience working with human subjects. But it is also important that the codes and procedures be worked out in advance and not applied in an ad hoc way to particular cases by researchers having a vested interest in having the research project proceed. For this we need properly constituted review boards.

The Belmont Report was at its worst in dealing with the issue of justice. As mentioned above it
explained justice by alluding to five mutually contradictory concepts of distributive justice seemingly with no awareness of the problem far less any attempt to solve it. In retrospect this is not surprising. Concerning the principle of respecting an individual’s right to make informed decisions regarding their own health and safety there is broad consensus in society. Concerning justice however there sometimes seems to be little more than agreement over the word. To incorporate justice into a moral theory which we intend to actually use it will be necessary to settle on some conception of justice that is modest enough to be relatively uncontroversial. A principle such as health benefits must be made equally available to every member of society will be heartily endorsed by some and condemned as socialism by others. A concept of justice that we want to use to guide research into human subjects cannot enshrine a liberal vision of the good society at the expense of the conservative vision. A modest minimalism must be our aim. Such a principle is the following: the benefits and burdens of research on human subjects should not be distributed according to arbitrary characteristics like race, gender, religion or socioeconomic status. It seems to me to be neither possible nor desirable to attempt to ensure that the benefits and burdens of any piece of research are equally distributed among all groups of people. Medical conditions do not affect groups evenly. In free market economies some people cannot afford some forms of medical care. Some treatments are more effective with some groups than with others. What to do about these inequalities is not something that liberals and conservatives agree on. However, I think liberals and conservatives agree that we should not look at a study that offers immediate benefits to the research subjects and decide to select subjects because they are white. Nor should we look at a study that carries risks to the participants and decide to select subjects because they are black. This much is uncontroversial. In addition it seems perfectly feasible to work out detailed rules ensuring that researchers are not selecting research subjects on these grounds. Again the details would have to be worked out at the local level. Suppose for example that in one community there are two hospitals that can be used for research studies. One of these serves a predominately middle class white population and the other serves a predominately low-income black population. In such a situation it seems reasonable to require that studies be assigned at random to the two hospitals. This is obviously oversimplified but it shows how local IRBs could adapt the principle to their particular situation. What would not be implied from this minimalist concept of justice is that a study could not be done if the research subjects were disproportionately members of one group. Because diseases do not affect all groups of people evenly sometimes it is impractical or even impossible to conduct research on all groups equally. Research into diabetes or AIDS necessarily focuses on people with these medical conditions. If these diseases disproportionately affect some groups then it is inevitable that the research subjects will not reflect the population as a whole. That does not make such studies unjust. The Tuskegee syphilis study was not unjust because it was a study in which the subjects were black. It was unjust because the subjects were treated badly because they were black.

I have postponed a discussion of the principle of beneficence until now because it is significantly different from the other two principles and has a unique role to play. While I think that justice and respect for persons are general moral requirements binding on all people, I do not think that people are morally required to be beneficent in every circumstance or even in typical circumstances. One is generally obliged not to harm others but I think there is no parallel obligation to help others. Helping others is certainly morally good, but if there is any duty to help others it is what ethical theory calls an “imperfect duty.” The imperfect duty to help others is highly unspecific. It does not specify under what conditions I must help or whom I must help or when I must help. It allows every individual a great deal of latitude in deciding when to respond to the needs of others. It condemns only those who never respond. Commonsense morality, as I see it, assumes that it is both normal and proper for ordinary
human beings to spend most of their lives pursuing their own private interests. Morality imposes a few necessary limitations on the pursuit of happiness—do not deceive, do not kill, do not steal, etc. The moral person is one who pursues her own interests within these restrictions. Consequently, I do not think that medical or behavioral researchers should be expected to have the interests of other people as their main concern. This is unrealistic. These researchers will be pursuing tenure, promotions, grants, research assistants, prestige, and all the normal inducements their institutions offer. To suppose anything else is utopian. Admittedly, self-interest is dangerous. It tempts us to overstep the bounds of morality and violate the rights and interests of others in the pursuit of our own, but it is not in itself illegitimate.

Ethical common sense places a negative but not a positive obligation to consider the welfare of others. I am obliged not to harm other people in specific ways—I cannot kill them, do them bodily injury, or destroy their property. In special emergency situations I may be obliged to offer positive assistance—to be a good Samaritan—but such situations are limited to preventing losses not in actively improving people’s lives. In so far as human research aims at the betterment of people it is a good thing, but it is not morally required. As such it cannot overcome our other moral rules, including the rule to avoid harming others. So human research that harms the individual human subject is never justified by the potential benefits to other people. The Report is wrong in suggesting that benefits to others, if sufficiently great, could outweigh harm to the individual subject. But how then are we ever to proceed with research that involves significant harm or risk of harm to human subjects? If such research could never be justified then we would be giving up great potential benefits. Such research can be justified, not by the benefits we foresee, but rather by the fact that it is permissible for autonomous research subjects to freely and knowingly subject themselves to harm or risk of harm for the benefit of others. Risk without personal benefit to the individual is a form of heroism which can never be coerced, but which can be allowed. The most difficult cases are those of risk without personal benefit where the subjects are children. Can it ever be acceptable to ask parents to volunteer their children for such research?

As we have argued, there is no general obligation to produce benefits for other people and benefits for others cannot justify sacrificing the individual without her consent. Ordinary situations merely require us not to harm others. There is no corresponding obligation to help anyone. Researchers are not saints and in doing research their primary motivation is self-interest not the good of mankind. However, research with human subjects is not a normal everyday situation. Research subjects are volunteers. The goodwill of the public is essential to the continuation of our practice of doing research on human subjects. People volunteer to participate as human subjects for many reasons, but most would not do so unless they believed that the study promoted the common good. Research subjects are a bit naïve about physicians and scientists. They believe them to be unselfishly seeking truths that will benefit the human race. They forget or underestimate the extent to which these research studies are designed to promote the careers of the researchers. Since the researcher’s self-interest is a significant part of the motivation for doing research and since the public’s continued cooperation with human research depends on their belief that the research will foster the common good, it falls to an objective third party—the IRB—to insure that each piece of research will in fact promote the general welfare. Researchers are not morally wrong for wanting to do a study whose only value is that it will result in a publication with their name attached. But IRBs need to be wary of such research and to forbid it when they see it. Otherwise this information will eventually leak out to the general public and the public trust upon which all such research depends will begin to vanish. Thus, we should articulate a third necessary condition for research with human subjects. The research must promote the common good. It is important that the determination of whether or not a given study actually promotes the common good be done by an objective third party, the IRB,
and not by the researchers themselves, since the natural and proper self-interestedness of the researcher will inevitably distort such evaluations.

The Belmont Report fails. In this paper I have tried to document its deficiencies and to suggest improvements. Research with human subjects continues and will not cease due to the lack of a good ethical theory to apply to such cases. This fact makes it all the more important that we continue to devote serious efforts at succeeding where the Belmont Report fails. If there are deficiencies with the positive suggestions I have offered at the conclusion of this paper, as undoubtedly there are, it is my hope that others will repair them.

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Notes


2. Belmont Report, p.3.


18. *Belmont Report*, p. 3.