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What's Right About the Medical Model in Human Subjects Research Regulation

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Abstract:

Critics of Institutional Review Board practices often base their charges on the claim that IRB review began with and is premised upon a "medical model" of research, and hence a "medical model" of risk. Based on this claim, they charge that IRB review, especially in the social and behavioral sciences, has experienced "mission creep". This paper argues that this line of critique is fundamentally misguided. While it remains unclear what critics mean by "medical model", the point of contemporary human research subjects regulation remains the same across all domains of research. That point is to protect the autonomy of human subjects, primarily through the use of informed consent. In fields as different as biomedical self-experimentation and ethnography there is the danger of losing sight of subjects' autonomy. Critiques of the so-called medical model are sometimes libertarian and sometimes utilitarian in spirit. Either way, such critiques have not yet demonstrated that these philosophical schools of thought have the resources to guard against the potential risk of harm that lexically prioritizing the autonomy of human subjects does. Precisely because IRB review recognizes that human subjects research occurs in different fields using different research methods, IRB review requires researchers to explain their particular methods, the particular risks of harm created by these methods, and the implementation of procedures by which subjects may autonomously consent to precisely those risks.

What's Right About the Medical Model in Human Subjects Research Regulation

Bioethics experts Paul Weindling and Volker Roelcke suggest that current bioethical thinking may use an incomplete picture of the historical context of the Nuremberg code. Volker Roelcke writes: “rather than being the result of a coercive state, Nazi medicine illustrates how medical researchers and their representative bodies [...] co-operated with and even manipulated a totalitarian state and political system relying on expert opinion, in order to gain resources for the conduct of research without any moral and legal regulation.” He states that Nazi doctors “followed the intrinsic logic of their scientific disciplines and used the legally and ethically unrestricted access to human beings created by the context of the political system and the conditions of war.” - WHO Bulletin, on the occasion of the 60th anniversary of the Nuremberg Code (Theiren 2007)

Introduction

A prominent strand of criticism of the current IRB system contends that today's “Common Rule” -- the foundational U.S. regulation for research on human subjects regulation -- presupposes a "medical model" for research on human subjects and regulation thereof (Van Den Hoonaard 2001, 38; Hoeyer

2005; Nelson 2004). Critics assert that this makes the IRB system inappropriate, even ethically corrupt, particularly for regulating research in the social and behavioral sciences. These critics warn that IRB review unduly threatens academic freedom, especially for qualitative researchers who employ “inquiry models that take explicit account of alternative epistemologies,” epistemologies that do not “focus on objectivity and causal connections, as well as generalizability” (Lincoln 2005, 171).

These complaints have bite only if the so-called medical model erroneously introduces a mistaken conception of the ethical perils posed by research on or with human subjects. Whatever the merits of the claim that qualitative research involves fundamentally different epistemologies than quantitative research does, it does not follow that a different way of knowing necessarily, or even probably, changes the ethical threats to human research subjects. To assess the grounds for concern expressed by champions of academic freedom in social and behavioral and/or qualitative research, we must ascertain the ethical threats targeted by the current Common Rule and check whether these threats relate only to the “medical model.”

The major threat addressed by the Common Rule is compromise of a human research subject's autonomy. The Common Rule relies on a number of measures, especially informed consent, to prevent researchers from disabling or ignoring subjects' capacity for agency or self-determination

when it comes to participating in the research project. The relevant conception of autonomy is neither idealized nor utopian. It does not equate autonomy with decisionmaking from an entirely pure standpoint, one completely unadulterated by context or personal traits. Whatever the possibility or worth of that conception of autonomy, it is not the conception that underlies today's principles of respect for human subjects as reflected in The Common Rule. Today's principles emerged from an awareness that a much less rarified conception of autonomy is in play when researchers make humans their subjects. On this conception, the decision to participate in research should be just that: a decision, a relatively conscious, relatively uncoerced choice to involve oneself in an activity not ordinarily encountered in one's daily life, and therefore to encounter risks different in degree and kind than those one would otherwise face. A researcher is not expected to create a Kantian hyperworld for human subjects. After all, researchers themselves do not live in such a world. In addition to IRB oversight, researchers operate under other constraints, for example, whether they have financial support to pursue their work and whether they can obtain sufficiently talented helpers. The Common Rule expects and requires researchers to make good faith efforts to understand the risks and harms their research may pose to potential subjects and to convey that understanding to potential and ongoing subjects. Essentially, this means

treating the subject as having a certain equality with the researcher: an equality of autonomy when it comes to research.

Such equality demands that, as the researcher may decide whether and how to conduct her studies, the subject may also decide whether and how to participate. Researchers do not embark upon their work without an opportunity to consider how it may harm them. Researchers can choose to abandon their projects. A researcher respects a subject's autonomy, his status as a self-determining agent, by according the subject the same meaningful opportunity to choose to participate and then to continue participating in the enterprise.

Whatever methods a researcher uses, whatever the degree of risk posed by these, whatever the kind of possible harms involved, the question of a subject's autonomous participation remains the same. Different methods, different degrees of risk, and different kinds of harms may have to be explained differently in order for somebody to authentically authorize her participation in research. But to be authentic, authorization must rest on knowledge of the particulars of the project.²

The Emergence of a Principle of Robust Consent

As is well known, the origins of the Common Rule lie in the Nuremberg Code, itself a product of post World War II war trials that assessed the

criminality of research on human subjects performed under the auspices of Adolf Hitler's Third Reich. In these trials, neither prosecutors nor defendants concerned themselves with today's categorization of research into biomedical, social, and behavioral. The Nuremberg prosecutors focused on a more relevant distinction: between research and the other conduct at issue in the war trials. Most of the acts for which defendants were prosecuted involved the infliction of pain, injury, and death, as did the research for which some defendants were on trial for conducting. Yet scientists, doctors, and their aides were not prosecuted for torture or murder. They were prosecuted for criminal research on human subjects, done for so-called "anthropological purposes" (Nuremberg Military Tribunals 1946-1949, I:37).

This research followed a "therapeutic pattern" (Nuremberg Military Tribunals 1946-1949, I:37):

Experiments concerning high altitude, the effect of cold, and the potability of processed sea water have an obvious relation to aeronautical and naval combat and rescue problems. The mustard gas and phosphorous burn experiments, as well as those relating to the healing value of sulfanilamide for wounds, can be related to air-raid and battlefield medical problems. It is well known that malaria, epidemic jaundice, and typhus were

among the principal diseases which had to be combated by the German Armed Forces and by German authorities in occupied territories. ... To some degree, the therapeutic pattern outlined above is undoubtedly a valid one, and explains why the Wehrmacht, and especially the German Air Force, participated in these experiments. (I:37)

Furthermore, experiments were performed to develop a new branch of science, the science of efficient genocide. The prosecution termed this science “thanatology” (Nuremberg Military Tribunals 1946-1949, 38). “The thanatological knowledge ... supplied the techniques for genocide. ... This policy of mass extermination could not have been so effectively carried out without the active participation of German medical scientists” (I:38).

The scientists and doctors prosecuted at Nuremberg included prominent professionals, their stature established before the rise of the Third Reich.

Outstanding men of science, distinguished for their scientific ability in Germany and abroad, are the defendants Rostock and Rose. Both exemplify, in their training and practice alike, the highest traditions of German medicine. Rostock headed the

Department of Surgery at the University of Berlin and served as dean of its medical school. Rose studied under the famous surgeon, Enderlen, at Heidelberg and then became a distinguished specialist in the fields of public health and tropical diseases. Handloser and Schroeder are outstanding medical administrators. Both of them made their careers in military medicine and reached the peak of their profession. Five more defendants are much younger men who are nevertheless already known as the possessors of considerable scientific ability, or capacity in medical administration. These include the defendants Karl Brandt, Ruff, Beiglboeck, Schaefer, and Becker-Freyseng. (Nuremberg Military Tribunals 1946-1949, 1:68)

These prominent administrators, scientists, and doctors did not simply engage in thoughtless killing. The experiments conducted by the German medical establishment in conjunction with the Third Reich served therapeutic medical ends, such as an understanding of the effects of chemical warfare and extreme climatological conditions on aviators and others, and a social end, the development of thanatology, the efficient elimination of segments of the population deemed undesirable.

The Nuremberg prosecutors did not concern themselves with whether thanatology was a biomedical science or a social or behavioral one. This is because the prosecution focused on how the human subjects were treated qua subjects by those who used them for their research purposes, as those purposes were understood by the researchers themselves. The Nuremberg prosecutors did not rest their case on the distastefulness of the purposes of the researchers or on the epistemological style or value of the research design or even on the pain and suffering experienced by the human subjects. The prosecutors focused on the failure of the researchers to treat those they experimented with as autonomous individuals capable of giving or declining consent to participate in a project being imposed upon them, not one they themselves devised or adopted as their own.

The prosecution emphasized two features of the experiments performed under Hitler's auspices. First, that doctors, scientists, and medical administrators sought knowledge and understanding when they studied what happened to people they exposed to malaria or plunged into ice cold water for extended periods. Second, that researchers and administrators ignored subjects' objections to participating and efforts to stop participating, even when the subjects understood that a refusal to participate would put them in line for execution or reassignment to wretched working conditions within a concentration camp. Prosecutors concentrated on the meaningless of any

formal consent given by subjects and the researcher's refusal to respect requests to discontinue participation.

What came out of “The Doctors Trial” at Nuremberg was an official statement that put meaningful consent at the heart of human research ethics.

The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonable to be expected; and the effects upon his health or person which may possibly come

from his participation in the experiment. (Nuremberg Military Tribunals 1946-1949, 2:181)

Consent does not prevent injury or pain. It does not guarantee the worthiness of the researcher's goals or her field of inquiry. Consent does, however, force notice of the separateness of persons, an ethically important fact closely associated the exercise of autonomy.

The Separateness of Persons

The separateness of persons signals the differences between different people's ends and the distinctiveness of what goes into each person's flourishing. The separateness of persons does not necessarily mean opposition between their ends. Nor does it imply isolation or lack of relationships with other people. Nor does separateness presuppose any particular power dynamics between different individuals. Separateness is simply a feature of ethical life. Because of separateness, we cannot simply conflate one person's ends or well-being with another's. People may share ends, their well-being may be bound up with one another, and they may be aware of this mutuality and connection. But shared ends are shared by separate persons, and mutual well-being involves the flourishing of separate individuals.

When a person is caught up in the pursuit of his or her own ends, it is psychologically easy for him or her to discount other people's ends, to downplay tension between realizing his or her own ends and respecting others', and to give unwarranted priority to his or her own flourishing. This is a matter of more than simple selfishness. It is a problem of perspective. Our ends constitute a lens through which we see the world, making expedients salient and masking potential obstacles, sometimes to the point of making those potential obstacles invisible. Having a ready supply of human subjects serves a researcher's ends qua researcher; devoting time and energy to ensuring subject autonomy, not so much. Fully informed subjects may decline to participate at all, possibly elevating informed consent from an inconvenience to a serious impediment. The separateness of persons is hard for researchers to keep in mind not because of something inherent in any academic discipline or experimental design, but because of many of the traits that distinguish successful researchers. Consider some of these traits: passionate inquisitiveness, commitment to discovery and learning, ambition, self-directedness, ability to focus. For a person with these qualities, one's own ends loom particularly large. The separateness of others from one's own projects tends to recede from view.

Philosophically, threats to the separateness of persons come from two directions. One is from utilitarianism. Utilitarianism collapses all individuals

into one aggregated bearer of a single end, maximization of utility, however utility is then understood (Rawls 1999, 24). The other threat stems, perhaps somewhat surprisingly, from libertarianism. Libertarianism's individualistic focus might suggest that a libertarian would never lose sight of the separateness of others. But libertarianism's individualism is essentially first personal. It threatens the separateness of others because of its elevation of the significance of one's own self and one's own ends. Libertarianism invites the individual to adopt a perspective from which the separateness of others represents only a problem to be brushed besides, rather than an ethically salient fact to be respected.

When researchers complain that ethical and legal regulation interferes with their academic freedom, they voice a libertarian complaint.

What we are suggesting is that what is being taken out of an individual's hands is the ability to make decisions as an autonomous researcher working within the healthy parameters that the academy previously had established. Instead, in a litigious environment, guidelines are developed that seek to ensure that the institution is not liable to any risk. The individual professor no longer fully decides the research design, who to protect, where to conduct research, or what to ask.

The institution determines the answers, and if the individual disagrees, then the research shall not be done. (Tierney 2007, 397)

This is the libertarian voice, objecting to state-based regulation. Traditional libertarianism is especially wary of the state, which the libertarian sees as the major threat to individual autonomy. Libertarians traditionally have been less concerned with other sources of threat to individual autonomy and freedom. Thus, the libertarian researcher's does not focus on the threat to others' autonomy that the researcher and his methods may pose. Without further argument, however, it is difficult to conclude that the only ethically significant threats to individual freedom arising in the research context derive from the state's regulation of researchers, whether direct or through delegation to bodies within a researcher's institution.

Closeness Can Threaten Separateness: Ethnography and Self-Experimentation

The problem of losing sight of separateness does not correlate with whether a method calls for intimacy or formality between researcher and subject or whether it requires physical proximity and interaction or physical distance with no direct interaction. Certainly, other people's separateness can go

unnoticed when we situate ourselves so far from them that we cannot make them out distinctly. To us they become dots on our own horizon, blending with the context in which we pursue our own ends. But there is another path to effacing the separateness of others. This is the path of closeness, of intimacy. Consider the ethnographer self-consciously devoted to a hermeneutic fusion of horizons with those she goes to observe.

For ethnographers, the primary data-gathering tool consists of the relationships that we forge with those whose lifeworld we are trying to understand. Few of us start with specific hypotheses that we will later test in any systematic way. ... We cannot inform our subjects of the risks and benefits of cooperating with us for a number of reasons. First, the risks and benefits for subjects are not so different from those of normal interaction with a stranger who will become a close acquaintance, an everyday feature of a lifeworld, and then disappear, after observing intimate moments, exploring deep feelings, and asking embarrassing questions. There is the risk inherent in any fleeting human relationship—the risk of bruised feelings that come from being used, the loss when a fixture in a social world disappears, or the hurt of realizing that however

differently it felt in the moment, one was used as a means to an end. This risk is magnified by a certain unavoidable deception in every ethnographic investigation, a certain pretense that comes from trying to have both researcher and informant forget that what is going on is not a normal, natural exchange but research—not just everyday life as it naturally occurs but work, a job, a project—”No really, I’m interested in what you have to say, think, feel, and believe for more than my own narrow instrumental academic purposes.” To some degree, we cannot specify risks because we do not know what we will find, what interpretive frameworks we will develop for reporting what we do observe, and how the world around us will change to make those findings seem more or less significant. Finally, we cannot define risk because few of us believe that being an ethnographic informant is a risky business. We believe this despite considerable anthropological and sociological evidence to the contrary. (Bosk 2004, 253)

This remarkably frank, self-reflective assessment of the practice and point of ethnography highlights how getting too close to somebody else encourages both parties to ignore or forget their separateness. While this happens in

ordinary life, it becomes a matter for human research ethics when a researcher goes out of her way to forge the intimate connections, not for private or essentially personal reasons, but for the sake of pursuing knowledge intended to be shared at large. At that juncture, the researcher occupies a different relationship to those with whom she is forging intimacy than they are forging with her. It is this research oriented relationship, I argue, the researcher must share with the subject if the subject's autonomy is to be preserved.

A similar problem of preserving subject autonomy in the face of intimacy arises in a research setting that may well seem radically different from the ethnographer's: the context of self-experimentation by physicians and other biomedical researchers. In that framework, potentially problematic closeness of subject to researcher and (vice-versa) arises because the subject and the researcher are the same person, although each persona may occupy very different facets of that person's makeup. How can a researcher gain sufficient perspective on the aspects of herself not caught up in the research program to know that her decision or agreement to experiment on herself does not stampede the parts of her with projects and ends detached from, and perhaps endangered by, the ends of her research? Just as ethnography calls for a fusion of horizons between the observer and the observed, and

therefore a deconstruction of boundaries, a similar deconstruction is demanded when biomedical researchers experiment on themselves.

Some biomedical researchers have recognized this explicitly. Consider David Clyde, a physician and parasitologist who worked on developing a vaccine against resistant malaria in the 1970s. (Shiff et al. 2003). Clyde experimented on “prisoner-volunteers” just when concern was mounting over a prisoner's ability to genuinely consent to be a human subject given the coercive atmosphere of prison settings (Altman 1986, 161). Clyde himself did not have this worry but he did maintain that at least one scientist must go through the experimental process with the prisoners. Clyde specifically wanted to find out “about any side-effects such as lingering taste, nausea, insomnia, which, being subjective, were difficult to elicit by questioning others” (Altman 1986, 161). In other words, Clyde wanted to know about the effects of the vaccine from the inside out, by inhabiting the perspective of the subject as well as that of the researcher. Presumably, Clyde found value in reporting his own subjective experience of malaria despite his reservations about gaining understanding through others' self-reports of their experience of experimental vaccines.

Other biomedical researchers evidence the deconstruction of the subject-researcher boundary by noting that even when they are obviously experimenting on themselves, they do not conceive of themselves as research

subjects. Consider Dr. Scott M. Smith, who investigated the use of curare to be used in conjunction with anesthesia (Utah Society of Anesthesiologists). In 1946, Smith wanted to know whether curare eliminated the sensation of pain as well as stilling muscle movement. This required receiving increments of curare and signaling to observers whether he experienced pain or other sensations while under the influence of the drug.

In the hope of getting a clear-cut answer to his questions, Smith decided to take a dose three times larger than he had ever administered to a patient. “It may sound funny,” he said, “but I did not think that I was experimenting on myself. I believed the drug was safe because I had used so much of it already [on other people, without their knowledge] and had observed its action. And there was an antidote – neostigmine – available. (Altman 1986, 82)

Thirty years after the experiment, Smith observed that he never considered performing it on somebody else, and that even if it had occurred to him to do so, he “doubt[ed] [he] could have convinced anyone else to participate” (Altman 1986, 82).

Whereas Clyde self-consciously used self-experimentation as a tool for ascertaining “subjective” effects of a drug, Smith's use of himself as a research subject seemed to distract him entirely from the fact that he was self-experimenting. Both men's experiences and their interpretations of them illustrate how self-experimentation closes the gap between researcher and subject. Clyde lost his distrust of subjective self-reporting when he reported to himself; Smith lost his sense of what constituted research on a human subject. Just as the ethnographer relies on a sort of perspectival sleight of hand, so does the biomedical self-experimenter. The illusions relied upon may yield revelations but they can also obscure important aspects of what is actually happening.

Altering one's perspective to achieve closeness to research subjects (yourself or others) may or may not interfere with scholarly value of one's findings. Regardless, such closeness and conflation of perspectives can distort both the researcher's and the subject's perception of the risks and harms associated with the experiment. If people become research subjects without an appropriate appreciation of such risks and harms, they cannot be participating autonomously. To be the author of the decision to participate in a potentially dangerous situation that you would not ordinarily encounter, you need to appreciate that the situation is indeed out of the ordinary and that it

might cause you physical, psychic, or economic injury. You must be positioned to see these features.

This is the point of informed consent. Informed consent implements the separateness of persons. The process of obtaining informed consent is a mechanism for communicating information, fostering understanding, and provoking the subject to consider the methods, risk level, and type of potential harms to which she may expose herself should she choose to participate. Informed consent is not an end in itself. It is a tool for highlighting the subject's separateness from the researcher even when both are embodied in the same person, and then using that separateness as a way to confer a perspective on the research and the subject's role in it such that the subject has a meaningful opportunity to authorize her participation.

Conclusion

Nazi sanctioned research gave rise to the Nuremberg Code's lexical prioritization of subject autonomy over other ends and values. One major threat to subject autonomy, obfuscation of the separateness of persons and the ethical significance of that fact, can arise in settings as apparently different as ethnography and biomedical self-experimentation. The central aim of IRB regulation is to preserve subject autonomy whatever the research settings.

It is not entirely clear what critics of today's Common Rule mean by a "medical model" or its influence on current regulation of human subjects research. If by "medical model", critics simply mean an approach to human subject research that gives subject autonomy priority over other interests and values, their beef is not with anything peculiar to medical research or to biomedical experimentation. Their beef might be with giving subject autonomy that lexical priority. If so, they need to make the case that some other end or value trumps subject autonomy or at least should be weighed against it as a possible reason for permitting researchers to experiment on human subjects without providing them as full and meaningful an opportunity as possible to authorize their own participation.

IRB regulation based on the protection of autonomy via informed consent procedures is not totalitarian nor intolerant of variety in research methods and fields of study. Indeed, IRB regulation treats social, behavioral, and scientific research with equal gravity. When one person examines another for the purpose of scholarship and public knowledge, the possibility of encroaching upon the subject's autonomy does not vary according to the disciplinary categories that may be relevant for other purposes. IRB review based on the Common Rule focuses on safeguarding autonomy in context. IRBs consider the specifics of protocols from different disciplines. To the extent that different methods or fields vary in how they may interfere with

subject autonomy, the Common Rule allows researchers to tailor their informed consent procedures to those specifics.

Perhaps those who charge that the “medical model” is irrelevant to social and behavioral research have a slightly different concern. Perhaps they believe that the major ethical problem arising from human subject research is the infliction, or risk of infliction, of *physical* injury. The current Common Rule does not directly protect against this specific problem. It does attempt a certain kind of protection for subjects, but not direct protection from physical harm. Current regulation aims to create a situation where subjects can meaningfully decide for themselves which risks of whatever harms to undertake. The need to regulate for this purpose arises whenever research poses a significant degree of risk of injury, whether physical, emotional or financial, whether tangible or intangible. Injuries and risks are not exclusive to medical research. An accidental dissemination of personal data collected in a survey may lead to emotional and financial injuries more extreme than some nontrivial physical ones. Interviews with those who have lived through years of civil war or been subject to war crimes may cause intense psychological discomfort or mental anguish. The point of making autonomy central to human subjects research regulation is to ensure that potential subjects understand such risks, and then choose for themselves whether to participate in research. The significance of autonomy does not vary according to the type

of possible injury, although risks of different kinds of injury may require different techniques for ensuring autonomous participation in human subjects research.

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2. Just how particularistic the knowledge must be is debatable. Researchers may collect data that they intend to save for future use, for the study of problems not now specified or even known. Whether subjects can meaningfully consent to contributing to data-gathering of this kind is beyond the scope of this paper. But this question arises only after we recognize the connection between particularized knowledge about research and meaningful participation in it. Thanks to Jerry Menikoff for drawing my attention to the problem of the degree of generality sufficient to ground genuine consent, a point raised at Menikoff, Jerry A., Wang, Vivian Ota, Feldman, Heidi Li, and Reece, Gwendolyn, "When People are Research Subjects: Ethical and Policy Questions," 37th Annual AAAS Forum on Science and Technology Policy, Washington D.C., April 26, 2012.