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A Relational Perspective on Ethics-in-Science Decisionmaking for Research with Vulnerable Populations

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<b>A Relational Perspective on Ethics-in-Science Decisionmaking for Research with Vulnerable Populations</b> by Celia B. Fisher	<b>1</b>
<b>Some Overlooked Aspects of Consent Form Readability</b> by Mark Hochhauser	<b>5</b>
<b>Reducing Postmortem Examination Refusal by Families of Research Subjects</b> by Jennifer M. Phillips	<b>10</b>
<b>CALENDAR</b>	<b>9</b>
<b>ANNOTATIONS</b>	<b>11</b>

## **A Relational Perspective on Ethics-in-Science Decisionmaking for Research with Vulnerable Populations**

by Celia B. Fisher

In the wake of recent revelations concerning the government radiation studies<sup>1</sup> and concerns that diminished public trust in human subjects research may jeopardize the willingness of our most vulnerable citizens to become research participants, the President has appointed a National Bioethics Advisory Commission to review the adequacy of current federal guidelines for the protection of human subjects. This article advances the argument that to insure that such protections are indeed adequate, revised research regulations will need to reflect the perspectives of those who design, implement, and participate in research. In the everyday practice of science, investigators often find

that guidelines designed to protect vulnerable children and adults inadvertently create institutional obstacles that limit participants' autonomy and access to research protocols that may advance scientific understanding and treatment of their disorders. Moreover, healthy adults, adults with physical or mental disabilities, children and adolescents, and individuals from diverse economic and cultural backgrounds react differently to controlled procedures, and their perspectives can differ from those of well-meaning decisionmakers. Creating federal regulations without considering the expectations of and special relationship between investigator and participant thus risks decreasing the adequacy of ethical procedures. Constructing national guidelines that emerge from careful consideration of investigator and participant perspectives will facilitate collaborations between scientist and subject that enable the construction of the best ethical procedures possible within each unique research context.

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## **Limitations of Traditional Moral Ideologies Applied to Ethics-in-Science Decisionmaking**

Researchers applying the scientific method to describe, explain, and enhance the status of individuals with physical, psychological, and social vulnerabilities are encountering ethical dilemmas to which current federal regulations offer incomplete answers. In such work scientific and ethical duties often appear to have mutually exclusive goals. Whereas scientific responsibility involves a search for truth through experimental controls, ethical duties are directed toward protecting participant welfare through means that often appear to jeopardize such controls.<sup>2</sup> When the goals of science and ethics appear to conflict, investigators studying vulnerable populations draw upon their own moral compass, the advice of colleagues, and recommendations of institutional review boards (IRBs) to make decisions about ethical procedures that will have immediate and possibly long-term impact on individual subjects, their families, and the communities they represent.

Historically, these decisions have been grounded in two metaethical traditions.<sup>3</sup> According to the first tradition, utilitarianism or consequentialism, the morally right action is the one that produces the most pleasing consequences.<sup>4</sup> Utilitarianism can thus promote a value structure in which potential benefits of science to society take on higher priority than concrete and measurable risks to research participants. In the second tradition, deontology, the moral rightness of an action is evaluated without regard to the consequences.<sup>5</sup> Although the Kantian tradition has been interpreted by some as promoting an inherent respect for the dignity of persons and thus would appear to encourage scientists to seek to incorporate the perspective of participants into their ethical decisionmaking, in practice its focus on the universality of moral principles often leads investigators and IRBs to believe they can determine which research pro-

cedures are ethical without consulting members of the population that will be studied. Thus, even though both utilitarianism and deontology are important theoretical resources for ethics-in-science decisions, applied in isolation from subjects' own understanding of the research context these moral frameworks have the potential to minimize a scientist's special relationship and subsequent moral obligations to individual research participants, fostering a psychological distance between scientist and subject.<sup>6</sup>

In the absence of knowledge concerning what research subjects think about ethical alternatives, investigators have incomplete moral guidance when confronting such questions as:

- Does prevention research requiring public identification of risk factors in persons with cognitive, physical, or psychological disorders violate their privacy or lead to social stigmatization?
- Is requiring guardian consent always in the best interest of minors or individuals with cognitive impairments?
- Under what conditions is it ethically responsible to use placebos, control groups, and randomized assignment to evaluate the efficacy of a treatment for persons identified with physical or mental disabilities?
- When is payment for research participation coercive for the cognitively impaired or those from impoverished backgrounds; and when is withholding of such payment inequitable?

**The Justice-Care Perspective**

Moral arguments for the duty to consider participant perspectives in ethics-in-science decision-making derive from a synthesis of principle-based justice ethics and relation-based care ethics. The justice perspective emphasizes moral agency based upon principles of mutual respect, beneficence, and

fairness.<sup>7</sup> It stresses impartiality and distance from both the scientist's own interests and her or his connectedness to participants. The ethics of care emphasizes the duty to interact with research participants on their own terms and to respond to their needs as they extend over time.<sup>8</sup>

In recent years there has been growing recognition in philosophical and scientific circles that a morality based on justice can and does coexist with a morality based on interpersonal obligations.<sup>9-12</sup> A justice-care framework recognizes that ethical principles can mediate our understanding of participant perspectives without placing a priority on the investigator's interpretation of these principles over the moral frameworks of others, and that respecting research participants involves responding to them on the basis of their own self-conceptions.

**Participant Perspectives.** The justice-care perspective, by integrating the perspectives of both justice-based and interpersonal-based ethical frameworks,<sup>13-16</sup> supports several moral arguments for including the views of prospective research participants and their families in federal regulations and ethics-in-science decisionmaking. First, formulating regulations and ethical judgments solely on the bases of opinions expressed by experts in the scholarly community and IRB members risks treating subjects as "research material" rather than as moral agents with the right to judge the ethicality of investigative procedures in which they are asked to participate. Second, failure to consider prospective participants' points of view leads to a reliance on scientific inference or professional logic. This in turn can lead to the acceptance of research procedures causing significant participant distress or to the rejection of potentially worthwhile scientific procedures that subjects and their families would perceive as benign and/or worthwhile. Third, consistent with the community consultation model advanced by ethicists and investigators concerned with ethical practices and policies for clinical research on HIV/AIDS,

engaging prospective participants in partnership in the design and implementation of research: (1) assures that adequate consideration is given to the ethical values of beneficence, respect, and justice; and (2) increases the probability of community support and cooperation.<sup>17,18</sup> Finally, understanding the point of view, needs, and expectations of others can enhance an investigator's own moral development through a better understanding of the reciprocal relationship between the participant's expectations and the scientist's obligations.

**Investigator Experiences.** Another aspect of this relational perspective is the importance of grounding ethics-in-science principles and federal guidelines in the practical, day-to-day experiences of researchers. As my colleagues and I found in a recent NIMH survey, investigators striving to meet the dual obligations of protecting participants and producing valid scientific knowledge have developed innovative ways of identifying and minimizing research risks without forfeiting the integrity of their studies.<sup>19</sup> Researchers studying vulnerable populations can provide ethicists, policymakers, members of IRBs, and citizens an enhanced understanding of the ethical challenges that arise during the actual design and implementation of human subjects research, the barriers that current ethical guidelines sometimes place on good scientific and ethical practice, and the practical and innovative steps that have been taken to meet these challenges. *The practice of science without guidance from ethical principles is morally blind, but the establishment of federal guidelines without relevance to real world application will be empty.*

**Understanding Participant Perspectives: A Co-Learning Model**

If one believes that knowledge concerning participant perspectives is essential to good ethical decisionmaking, how does one go about generating this knowledge? To engage individuals in a morally



ambiguous study for the purpose of eliciting their reactions is ethically problematic, since it exposes persons to what the investigator believes may be procedures that potentially violate their autonomy and welfare. To give prospective participants open-ended questions concerning research ethics is equally problematic, since it asks individuals to provide spontaneous and decontextualized responses to moral questions which require informed deliberation.

Over the years my colleagues and I have developed empirical methods based upon a co-learning model of scientist-participant relationships. Individuals in our studies learn about how the scientific method is applied to examine questions of societal import and are introduced to areas of current ethical concern. We, in turn, learn what prospective participants think about specific ethically relevant issues, their views on whether certain types of studies should be conducted, and the moral frameworks applied to their decisions. We have established dialogues about guardian consent procedures with Latin-American mothers, about confidentiality in research with urban adolescents, and about randomized clinical trials and deception research with young adults.

**Adolescent perspectives on confidentiality: A case example.** Our endeavors have challenged stereotypes about how participants view ethical procedures. For example, in one study we found that urban high school students do not endorse maintaining confidentiality when during the course of research an investigator discovers a teenage subject is a victim or engaged in behaviors adolescents themselves perceive as serious problems.<sup>20</sup> Teenagers often indicated that upon such a discovery a researcher should tell a concerned parent or adult. Students responses thus indicated that *they saw the investigator as having a moral role in relationship to their problems*. Their views raised heretofore unasked ethical questions concerning the consequences if scientists fail to fulfill this role. For example,

an investigator's failure to help may unintentionally communicate to a troubled high school research participant that his or her problem is unimportant, that no services are available, or that knowledgeable adults can not be depended upon to help children in need.

**Additional areas of ethical inquiry.** A relational ethic of scientific responsibility and care that considers the interpersonal dimensions of the scientist-participant relationship can lead to the examination of other underexplored areas of ethical inquiry.<sup>21-24</sup> An ethical attitude that seeks information on prospective participant perspectives can lead to moral discourse on the following questions:

1) Is the current emphasis on harm avoidance sufficient ethical justification for conducting research on mentally infirm or marginalized populations if it places the ethical burden on participants or their guardians to demonstrate that they have been harmed, and away from the investigators who need not demonstrate that their research will result in any good?

2) If research findings can have direct impact on public attitudes and policies directed toward individual research participants, their families, and communities, to what extent should group stigmatization be considered in determining research risks, and should the nature of such risks be described during informed consent?

3) Who should represent participant and community interests on IRBs, and do community leaders always represent the views of their individual constituents?

4) When do tests of competency for consent to research decisions place an unjust burden on those with identified mental deficiencies?

5) How can risk be better defined across diverse populations so that norms based upon healthy or advantaged persons do not overinclude or exclude vulnerable populations from research?

6) What role should the altruistic benefits of research participation play in the cost-benefit calculus for research presenting greater than minimal risk?

7) Given the scandals surrounding the Tuskegee and Willowbrook studies, the government radiation and UCLA schizophrenia experiments, and the recent controversial adolescent violence research initiative,<sup>1,25-28</sup> how can scientists win the confidence of vulnerable persons and their appreciation of the potential positive value of research?

### Ethical Challenges of the Relational Perspective

Including participant perspectives and the practical concerns of scientists conducting research with vulnerable populations in the establishment of federal guidelines raises its own ethical challenges.<sup>29</sup> For example, when including participant perspectives in the ethical evaluation of federal regulations, bioethicists need to address issues raised by the potential *tyranny of the majority*. Principles of respect, beneficence, and justice, informed by participant and investigator perspectives, can guide policymakers in their struggle with the question whether a particular procedure can be justified if a substantial or even small *minority* of prospective participants believe the costs of participation outweigh potential benefits or that procedures selected are in conflict with individual moral frameworks.

Consideration of participant or investigator opinion also runs *the risk of accepting descriptions of ethical decisionmaking as prescriptions for ethical decisions*. The fiduciary nature of the scientist-participant relationship obliges the investigator to take ultimate responsibility for the welfare of research subjects. A relational perspective based upon the ethics of both justice and care proposes that an understanding of participant views can assist, but not substitute for the ethical decisionmaking obligation of individual scientists and policymakers as moral agents. Thus the opinions of those from the scientific and participant communities need to inform, but not dictate federal guidelines and ethics approval or disapproval of research practices.



Conclusions

Attention to the interpersonal nature and obligations inherent in the scientist-participant relationship expands ethics-in-science decisionmaking to include the importance of intersubjectivity, particularity, and context, and moves scientists toward a reinterpretation of their own moral agency.<sup>30</sup> The relational perspective enhances the ability to engage scientists and research participants as partners in creating federal guidelines reflecting both scientific and interpersonal integrity. Scientific ethics is a process that draws upon our human responsiveness to those who participate in research and our awareness of our own boundaries, competencies, and obligations. If becoming a moral subject is the critical moral task for all persons,<sup>31</sup> then recognizing that morality is embedded in the investigator-participant connection is the essential moral activity of human subjects research.



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