

# 21 The Regulatory Environment for Science: Protecting Participants in Research

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The federal government has had a long-standing interest in research as a means for improving the well-being of our citizens. As a result, it supports a diverse range of research involving people. This research includes nonmedical research such as behavioral and social science research as well as biomedical research.

The federal government also has responsibilities in areas such as social science that the citizens of our country endorse. For example, the National Science Foundation (NSF) supports data collection efforts, such as the Panel Study of Income Dynamics, that enable our elected and other government officials to plan effectively for education, housing, medical care, and concerns in a wide variety of areas. In addition, research on cognition, learning, memory, language, perception, and social and economic behavior helps us understand, among other things, how humans deal with complex tools and environments ranging from computers and the Internet to workplaces and playgrounds. These are just a few examples of the enormous breadth and complexity of research that the National Science Foundation supports. To be effective, systems for human protection in research must understand this complexity and deal with it flexibly. This is an awesome undertaking.

The majority of NSF-supported research that involves human participants is *basic research in the behavioral and social sciences*. However,

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a number of Directorates also fund research involving human participants. Examples include work in the areas of *computer science* (such as in the area of human-machine interface design), *education* (for example, research on the science of learning), *engineering* (such as studying the societal and economic impact of developments in nanotechnology and other technologies), and *mathematics* (including research on the development of math and science literacy). Most of this research is non-biomedical and all of it is nonclinical. NSF also supports a large amount of *international research* (again, this work is mostly non-biomedical).

*Those involved in research and its oversight have the dual responsibilities of advancing knowledge and protecting human participants.* Approaches to the protection of human participants should be designed so that they include the kinds of expertise that are appropriate for the particular work that will be conducted. These approaches should ensure that the review and oversight is proportional to the risk of harm, in order to avoid expenditure of time and effort with no gain in public safety and a loss in research capacity. Review procedures should be guided by sensitivity to the kind of research, the local conditions in which it will occur, and the actual risk of harm.

Protecting participants in research is a priority at the National Science Foundation. We support research involving human participants when a responsible party determines that the project complies with the federal government's "*Common Rule*" (*Code of Federal Regulations*, Title 45, Part 46). For the sort of research that NSF funds, adherence to the guidance of this rule has proven to be extremely satisfactory both from the perspective of providing adequate protection to research participants and from an internal administrative point of view. At present, we see no need to change this "Common Rule" for the kind of research that we support. Although this seems to be the dominant view across agencies, it is by no means universally agreed upon and remains an active topic of discussion.

It has become clear, however, that universities, institutional review boards (IRBs), researchers, and policymakers are not always aware of the existing institutional flexibility and delegation of authority stipulated in the Common Rule, particularly as it applies to research in the social and behavioral sciences, and to other non-biomedical research. We encourage the National Human Research Protections Advisory Committee (NHRPAC) and the Office of Human Research Protections (OHRP) to craft the solutions that are needed to remedy this confusion. We are working with them and other agencies to improve this situation.

*International collaboration* is crucial for conducting research in the modern world and is also an important part of the NSF mission. Sensitivity to varying cultural considerations is essential to this enterprise and should be mirrored in the approaches that are adopted as well as their administration. We must take extra care to make sure that we increase opportunities for international collaboration and not introduce new, unnecessary roadblocks. Our dual goals are to protect participants in research and to enhance the strength of our nation by promoting research in science and education. These goals need not be in conflict. We are disappointed that recent changes in the requirements for IRB approval for foreign collaborators have more and more frequently resulted in delays of funding or cancellation of plans for minimal-risk research (such as recording foreign speech for cross-language linguistic analysis).

We are active participants in ongoing efforts to help ensure the protection of participants in research. To do this properly, we must make sure that the approaches being considered are flexible enough to address the concerns of all research communities, including non-biomedical research, particularly in the area of the behavioral and social sciences and international research. To that end we are working cooperatively with OHRP, its director, Dr. Greg Koski, (see Chapter 20 in this volume) and his staff. Our participation includes representation (in the form of a NSF *ex officio* representative) on the National Human Research Protections Advisory Committee. We also participate in the National Science and Technology Council Committee on Science, Humans Subjects Research Subcommittee, and its Behavioral and Social Working Group. We are eager to participate in the improvement of this system, while also bringing to the attention of all relevant decision-makers the particular concerns of NSF, and of the many diverse communities that we support through research funding.

A quick overview of some of the crucial issues relevant to non-medical research is provided in the following “Top Ten List.” This list is not intended to cover all of the important issues that are presently being deliberated. Rather, it represents my personal perspective on some of the points to consider as new guidance and policies are developed.

1. It would be useful to *conduct research and collect data on the human research protection process*. Agencies such as the National Institutes of Health, NSF, and OHRP could help in the process of seeking and providing funding for research on this important topic. An example of a research topic is the issue of informed consent, especially in

nonmedical settings. For example, there is a need to experiment with ways to make informed consent more effective.

2. Ethnographic studies, other field research, survey research, oral history, etc., often involve special concerns related to *informed consent*. We need to develop innovative approaches that emphasize a “process” for obtaining consent, going beyond the single-minded concern with a consent form. Documented informed consent from individuals may not be feasible, but it may be very important to make sure that the community as a whole is aware that the research is going on, what it entails, who is responsible, etc. IRBs need to have informed expertise available to them to evaluate this issue.

3. *Guidelines should be developed* that discuss the potential kinds of harm in behavioral and social science research and that clarifies the differences between low risk and high risk research.

4. It is essential that *IRBs have the expertise that is tailored to the kind of research* they will be considering. If an IRB is going to evaluate behavioral-social science research, it should have a sufficient representation of behavioral-social scientists.

5. The OHRP should take *proactive steps* to counter the increased regulatory burden caused by the recent upheavals in the human research participants enterprise.

6. *The OHRP staff should have a behavioral-social scientist devoted to facilitating the process* for behavioral-social science researchers running into bureaucratic problems because of the misinterpretation or lack of understanding by IRBs, universities, etc., of regulations as they are applied to behavioral-social science. Examples include a lack of understanding of expedited reviews and issues related to informed consent. The behavioral-social facilitator should be readily available and should be seen as *working for this research community*.

7. The new requirements *for foreign IRB approval for minimal-risk research* have created unique, and unfortunate, difficulties that are resulting in long delays in getting research started and, sometimes, the cancellation of research plans. Given that many foreign countries do not recognize behavioral-social science in their IRBs and that much behavioral-social science research occurs outside institutions, the appropriate IRB is often that of the U.S. home institution. Usually, no reduction of risk is obtained by holding up such projects in order to insist on creating new IRB structures in the foreign setting.

8. The issue of *balancing risks* needs to be taken seriously. The purpose of the regulations is to limit the potential of research to harm par-

ticipants. Minimal-risk research should not be given the same degree of oversight as high-risk research. Major resources should be devoted to overseeing higher-risk clinical, biomedical research. This should be coupled with a significant reduction in the oversight of lower-risk research.

9. The solutions crafted in this enterprise need to be flexible and easy to change, and should impose minimal regulatory burden. Wherever possible, those engaged in this process should go beyond a “regulatory” approach to find other ways of promoting ethical behavior.

10. We should *always* remember that *the protection of participants in research should be our highest priority.*

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## Readings and Web Sites

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Note: Below are some URLs for further exploration on matters concerning human subjects.

The NSF Human Subjects Web site is at: <http://www.nsf.gov/sbe/bcs/common/humsub.htm>

The official NSF version of the Code of Federal Regulations 45CFR690.101-124 can be found through <http://www.access.gpo.gov/nara/cfr/index.html> by searching on "45CFR690.101". The similar NIH version is at <http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm>

The Office of Human Research Protections (OHRP) (part of the U.S. Department of Health and Human Services) can be found at: <http://ohrp.osophs.dhhs.gov> This office is in charge of IRB registration and assurance filing, and is presently developing a variety of new policies and procedures, including new federal-wide assurance procedures, training requirements, and international considerations. Information on the new federal-wide assurance procedures can be found at: <http://ohrp.osophs.dhhs.gov/irbasur.htm>

The National Human Research Protections Advisory Committee (NHRPAC) provides input to OHRP, and can be found at: <http://ohrp.osophs.dhhs.gov/nhrpac/nhrpac.htm>

The Office of Research Integrity (ORI) created OHRP. Its Web site is at <http://ori.dhhs.gov> It has links to the recent congressional interactions with ORI related to "PHS Policy on Instruction in the Responsible Conduct of Research": <http://ori.dhhs.gov/html/programs/congressionalconcerns.asp>

The National Science and Technology Council (NSTC) Committee on Science, Humans Subjects Research Subcommittee (HSRS), is an interagency group. A roster of the members is at <http://ohrp.osophs.dhhs.gov/references/humansubcomrost.htm>

The National Academies Institute of Medicine (IOM) (<http://www4.nationalacademies.org/iom/iomhome.nsf>) is conducting ongoing studies that include several components, including a fast-track study related to the accreditation of human research review programs, and more long-term studies related to other issues of human subjects protections. A public meeting was held on January 22, 2001, in Washington, DC, to solicit public input on the accredita-

tion issue. The URL related to the ongoing studies of this committee is at <http://www.iom.edu/IOM/IOMHome.nsf/Pages/human+research+protections>

The National Bioethics Advisory Commission (NBAC) was established by President Clinton in 1995 to advise the Administration about bioethics and human subjects protections. It has issued a report, "Ethical and Policy Issues in Research Involving Human Subjects." The NBAC Web site is at: <http://bioethics.gov/>

Researchers conducting behavioral and social sciences research often have questions about the applicability of their research to federal regulations protecting human subjects (research participants). A document from NIH addresses many such issues and is posted at <http://obssr.od.nih.gov/IRB/protect.htm>. It is also available as an Adobe Acrobat file at <http://obssr.od.nih.gov/IRB/protect.pdf>

