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The Regulatory Environment for Science: The protection of participants in social/behavioral/non-medical/ non-clinical research

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(*Note*: The opinions in this document are those of the author and do not necessarily represent the position of the National Science Foundation.)

There has been longstanding Federal interest in research as a means for improving the well being of our citizens. As a result, the Federal government supports a diverse range of research involving people. This research includes behavioral and social science research and other non-medical research as well as biomedical research. The Federal government has responsibilities in areas such as social science that the citizens of our country endorse. For example, the National Science Foundation 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 for concerns in a wide variety of other areas. 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 couple of examples of the enormous breadth and complexity of research that is supported by the National Science Foundation. To be effective, systems for human protection in research must understand this complexity and deal with it flexibly. This is an awesome undertaking.

At the NSF the majority of the research that we support that involves human participants is *basic research in the behavioral and social sciences*. However, research involving human participants is also funded in a number of other Directorates. 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. As you can see, most of this research is non-biomedical and all is non-clinical. We also support a large amount of *international research* and, again, this work is mostly non-biomedical.

Those who are involved in research and its oversight have the dual responsibilities of advancing knowledge and protecting human participants. Human participants protection approaches 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 assure that the review and oversight is proportionate to the risk of harm to avoid expenditure of time and effort with no gain in public safety and a loss in research capacity. Sensitivity to the kind of research, the local conditions in which it will occur, and the actual risk of harm should guide review procedures.

The protection of participants in research is a priority at the National Science Foundation. We support research involving human participants when the project has been determined by a responsible body to be in compliance with the federal government's "*Common Rule*." For the sort of research that our agency funds, adherence to the guidance of this rule has proven to be extremely satisfactory from both the perspectives 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, researchers, and policy makers 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 NHRPAC and OHRP to craft the solutions that are needed to remedy this confusion and are working with them and other agencies to improve this situation.

International collaboration is crucial for conducting research in the modern world and is an important part of the NSF mission. Sensitivity to varying cultural considerations is essential to this enterprise and should be mirrored in both the approaches that are adopted and their administration. Extra care is needed 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. They 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 been resulting in delays of funding or cancellation of plans for minimal risk research, such as the recording of foreign speech for cross-language linguistic analysis.

We are active participants in the 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 activities. To that end we are working cooperatively with the Office of Human Research Protections (OHRP), its Director, Dr. Greg Koski, and his staff. Our participation includes representation on this committee, NHRPAC (the National Human Research Protections Advisory Committee), in the form of a *NSF ex officio* representative. Among other activities, we are also active participants in HSRS (the National Science and Technology Council (NSTC) 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 our Agency, and of the many diverse communities that we support through research funding.

Top 10 Points to Consider

10. It would be useful to *conduct research and collect data on the human research protection process*. Agencies such as NIH, 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, such as with the suggestion of obtaining informed consent after an interview, when that is more appropriate.

9. Ethnographic studies, other field research, survey research, oral history, etc., often involve special concerns related to *informed consent*. There is a need for innovative approaches that emphasize a "process" for obtaining consent rather than a 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.

8. *Guidelines should be developed* for the protection of participants in research in behavioral and social sciences that show the differences in risk and procedures from clinical research.

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

6. *Proactive steps* should be taken by OHRP to counter the increased regulatory burden caused by the recent upheavals in the human research participants enterprise.

5. It would greatly help our communities if there were *a social-behavioral scientist on the OHRP staff 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, issues related to informed consent, etc. The social-behavioral facilitator should be readily available and should be seen as *working for this research community*.

4. 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 much behavioral-social science research occurs outside institutions, the appropriate IRB is that of the US home institution. No reduction of risk is obtained by holding up such projects to insist on the creation of new IRB structures in the foreign setting.

3. The issue of *balancing of risks* needs to be taken seriously. The purpose of the regulations is to limit the potential of research to harm participants. 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 coupled with a significant reduction in the oversight of lower-risk research.

2. The solutions that are crafted in this enterprise need to be *flexible*, 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.

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

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The protection of research participants in social / behavioral / non-medical / non-clinical research.

Readings and Websites

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Note: Here are some URLs for further exploration regarding Human Subjects matters.

The NSF Human Subjects webpage is at: http://www.nsf.gov/sbe/bcs/common/humsub.htm.
The official NSF version of 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,

OHRP is the Office of Human Research Protections (part of DHHS). It can be found at:
http://ohrp.osophs.dhhs.gov/
They are in charge of IRB registration and assurance filing, and are also presently in the process of developing a variety of new policies and procedures, including a new Federalwide Assurance, training requirements, international considerations, etc.
Information on the new Federalwide Assurance procedures can be found at:
http://ohrp.osophs.dhhs.gov/irbasur.htm

There is a national advisory committee that provides input to OHRP. It is called NHRPAC (the National Human Research Protections Advisory Committee), and can be found at:
http://ohrp.osophs.dhhs.gov/nhrpac/nhrpac.htm
Philip Rubin (Director of the Division of Behavioral and Cognitive Sciences (SBE-BCS)) is the NSF *ex officio* member to this committee. He is also the chair of the HSRS Behavioral Sciences Working Group.

ORI is the Office of Research Integrity (that created OHRP) (http://ori.dhhs.gov/). Here are 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

HSRS (the National Science and Technology Council (NSTC) Committee on Science, Humans Subjects Research Subcommittee) is an inter-agency group. Here is a roster of the members:
http://ohrp.osophs.dhhs.gov/references/humansubcomrost.htm.
We have several NSF connections. Stuart Plattner (SBE-BCS) is the NSF representative. Rachelle Hollander (SBE-SES) is on the Helsinki Charter Subcommittee. Philip Rubin (DD SBE-BCS) is the chair of the Behavioral-Social Working Group (BSWG). Stuart Plattner maintains a listserver for the HSRS-BSWG group.

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 Jan. 22, 2001, in Washington, D.C., to solicit broad public input on the accreditation issue. Here is the URL related to the ongoing studies of this committee:
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 is about to issue a report, "Ethical and Policy Issues in Research Involving Human Subjects." The NBAC website is at:
http://bioethics.gov/

"Protection of Participants in Behavioral and Social Sciences Research". NIH, Office of Behavioral and Social Sciences Research : http://obssr.od.nih.gov/IRB/protect.pdf .
Researchers conducting behavioral and social sciences research often have questions about the applicability of their research to the Federal regulations protecting human subjects (research participants). Basic questions arise including even "Am I conducting research that involves human subjects?" This document addresses many such issues. The document is posted at http://obssr.od.nih.gov/IRB/protect.htm
and is also available as an Adobe Acrobat file: http://obssr.od.nih.gov/IRB/protect.pdf .