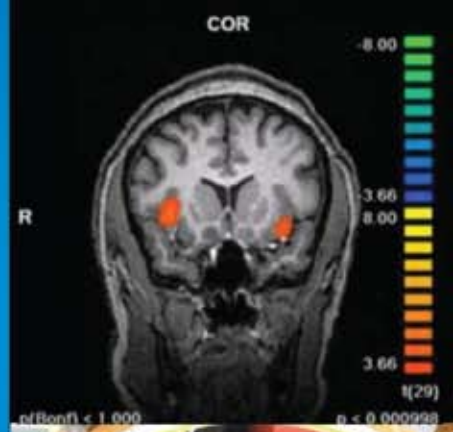


# Expedited Review of Social and Behavioral Research Activities

*Social and Behavioral Research Working Group*
*Human Subjects Research Subcommittee*
*Committee on Science*
*National Science and Technology Council*

*June, 2008*

**About the National Science and Technology Council**

The National Science and Technology Council (NSTC) is the principal means by which the Executive Branch coordinates science and technology policy across the diverse entities that make up the Federal research and development enterprise. A primary objective of the NSTC is establishing clear national goals for Federal science and technology investments. The NSTC prepares research and development strategies that are coordinated across Federal agencies to form investment packages aimed at accomplishing multiple national goals. The work of the NSTC is organized under four committees: Science, Technology, Environment and Natural Resources, and Homeland and National Security. Each of these committees oversees subcommittees and working groups focused on different aspects of science and technology. More information is available at *http://www.ostp.gov/nstc*.

**About the Human Subjects Research Subcommittee**

The Human Subjects Research Subcommittee (HSRS) of the National Science and Technology Council's Committee on Science has the goal of promoting the protection of individuals who participate as subjects in federally funded and regulated research. Representatives from all of the Federal offices and agencies involved in human research meet on a bimonthly basis to help coordinate the policies and practices of the Federal government's oversight of human research. The Subcommittee's involvement began with the development of the *Federal Policy for the Protection of Human Subjects in Research*, generally known as the "Common Rule," and continues in its mission to facilitate consistent implementation of this Common Rule across the Federal government.

**About this document**

This document discusses the expedited review procedure allowed under Federal regulations for certain categories of research involving human subjects. These categories of research are identified in a list published by the Secretary of Health and Human Services and the Food and Drug Administration in the *Federal Register*. The list is amended, as appropriate, by the Secretary and the Food and Drug Administration, after consultation with other departments and agencies, and republished in the *Federal Register*, and made available by the Office for Human Research Protections on its website at *http://www.hhs.gov/ohrp/* . Readers of this document need to be mindful of whether the list of categories of research eligible for expedited review have been amended and re-published since the time of issuance of this document.

**Cover Information**

Cover images clockwise from top right: Functional magnetic resonance image portraying an axial view of the brain (credit: James Rilling, Emory University); an optokinetic drum used to study the perceptual and physiological causes of motion sickness (credit: Frederick Bonato, Saint Peter's College); an electrophoresis unit used to conduct DNA fingerprinting (credit: University of Arizona); a developmental study on the capacity of infants to perceive and evaluate social interactions (credit: Karen Wynn, Yale University); a researcher uses a sphygmomanometer to screen a subject for signs of hypertension (credit: James Gathany); an American epidemiologist interviews malaria control workers for a Pakistani toxicologic study of malathion, a poison used against mosquito populations (credit: Edward Baker); a Tibetan woman participates in a study on nitric oxide in the breath of high altitude populations, and its significance to human adaptation in a low oxygen environment (credit: Cynthia Beall, Case Western Reserve University).

# Expedited Review of Social and Behavioral Research Activities

Social and Behavioral Research Working Group
Human Subjects Research Subcommittee
Committee on Science
National Science and Technology Council

June 2008

EXECUTIVE OFFICE OF THE PRESIDENT
**NATIONAL SCIENCE AND TECHNOLOGY COUNCIL**
WASHINGTON, DC

Dear Colleague:

Since 1991, the *Federal Policy for the Protection of Human Subjects*, also known as the Common Rule, has applied to research studies sponsored by many Federal agencies. The policy is designed to ensure that human subjects in research are treated with respect, and that they are protected from exploitation and unnecessary risks of harm. Social and behavioral research studies have greatly improved our understanding of human behavior in many areas, including health, education, economics, and crime, strengthening the available evidence for the development of better policies and practices. The *Federal Policy for the Protection of Human Subjects* ensures that important research can go forward in an ethical manner.

This document explains how the *Federal Policy for the Protection of Human Subjects* allows for the review of many types of social and behavioral research studies under an *expedited review procedure,* allowed by law but not taken to full advantage. It offers suggestions as to how institutions might implement successful expedited review procedures, identifies various types of common social and behavioral research studies that fall within the categories of research eligible for expedited review, and offers some illustrations of those types. The goal of the document is to help researchers, administrators, and reviewers recognize research activities that are eligible for expedited review so that they may avoid needless misunderstanding and delays in the review process.

This report will contribute to the understanding of when proposed social and behavioral studies qualify for expedited review under the *Federal Policy for the Protection of Human Subjects*, and enable researchers and institutional officials to improve the process of appropriate review for such studies, enhancing their effectiveness, while preserving the highest protections for human subjects in research.

Sincerely,

John H. Marburger, III

# Introduction



As human subjects research has advanced over the last several decades, Federal guidelines and policies intended to protect those who volunteer as participants in Federally funded research have evolved. In 1991, these policies culminated in the *Federal Policy for the Protection of Human Subjects*, known as the Common Rule, now adopted by 17 Federal agencies that fund human subject research. By definition, the Common Rule applies to a wide range of human subject studies, including both biomedical research studies (e.g., interventional clinical trials), as well as social and behavioral research studies. A primary mechanism through which the Common Rule ensures that appropriate measures are taken to protect human subjects is the Institutional Review Board (IRB). It should be noted that the Common Rule exempts some biomedical and many social and behavioral research studies from its regulatory requirements, including the requirement of IRB review.[1]

Even before the widespread adoption of the Common Rule, researchers in the social and behavioral science research community expressed concerns regarding the impact of these regulations in their field. In contrast to the physical risks associated with biomedical research protocols, the risks associated with social and behavioral research are frequently limited to concerns of privacy or confidentiality, or subjects' reactions to questions about sensitive topics. While the importance of human subjects' protection in these areas cannot be minimized, the nature and assessment of risk is somewhat different. A National Academies report that focused on the protection of human subjects in social and behavioral sciences also recognized this issue, and highlighted the importance of appropriate review commensurate with level and type of risk.[2]

The Common Rule explicitly acknowledges the concept of "minimal risk" in certain categories of research, and allows for review of these types of studies without convening a meeting of the IRB, through use of expedited review. Ideally, expedited review is intended to enable institutions to conserve administrative resources, provide timely reviews, and focus the convened meetings of their IRBs on the review of research activities involving greater risks or ethical complexities. In practice, institutions supporting social and behavioral research have yet to fully utilize the expedited review option for a variety of reasons.[3] Many investigators are not certain if their protocols are eligible for expedited review, or may not know how to best demonstrate a study's potential eligibility in their IRB application. Guidance for investigators on expedited review varies widely in the level of explanatory detail at individual institutions, and IRB administrators and chairs may differ in their own interpretations of the scope of activities eligible for expedited review procedures. As a result, important research programs may experience unnecessary delays.

---

1 45 CFR 46.101(b)(1-6)

2 Panel on Institutional Review Boards, Surveys, and Social Science Research, National Research Council of National Academies, *Protecting Participants and Facilitating Social and Behavioral Sciences Research* (Washington: National Academies Press, 2003).

3 De Vries, R., DeBruin, D.A., and Goodgame, G. *Ethics review of Social, Behavioral, and Economic Research: Where should we go from here?* Ethics and Behavior 14(4), 351-368; 2004.

The purpose of this document is to improve clarity and provide suggestions regarding the expedited review of social and behavioral research studies, so that the benefits and use of expedited review can be maximized within the research community. The document addresses the following four questions, so that researchers, IRB administrators, and IRB members can share a common understanding of how those determinations are made:

- What is "expedited review"?
- What is "minimal risk"?
- What kinds of social and behavioral research studies are eligible for expedited review?
- What factors influence the successful implementation of the expedited review procedure?

In answering these questions, this document reviews the criteria for determining whether a proposed research activity is eligible for review under the expedited review procedure, and it identifies some strategies that institutional officials may adopt to improve the efficiency and quality of the expedited review process at their institutions.

# I. What is "Expedited Review"?

The Common Rule allows institutions to review certain kinds of research proposals under an "expedited review" procedure[4]. Expedited reviews are performed as an alternative to review by the full Institutional Review Board (IRB) at a convened meeting. The expedited review procedure is carried out by the IRB Chair, or by one or more experienced IRB members appointed by the Chair. The expedited reviewer(s) has all the same authorities as the full IRB to approve, modify, or attach conditions to proposed research activities, except the authority to disapprove a research activity[5]. Institutions using the expedited review procedure must have procedures for notifying IRB members of research activities approved under the expedited review. Expedited review involves applying the same criteria for approval of research activities that are required for review by the full IRB, as specified by the Common Rule[6].

Human subjects research activities covered by the Common Rule must satisfy two regulatory conditions in order to be eligible for expedited review. The first condition is that the proposed research activity involves no more than "minimal risk" to the research subjects. The second condition is that the proposed research activity must be included in a list of eligible research categories established by the Department of Health and Human Services and the Food and Drug Administration for this purpose[7]. Explained in detail in section III of this report, this list applies to proposed research activities supported or conducted by any of the Federal agencies that have adopted the Common Rule, and includes several categories that are directly relevant to social and behavioral research. Institutions have the option to use the expedited review procedure to review research studies that satisfy the two eligibility conditions, but they are not required to do so.

4 45 CFR 46.110. The regulations also allow using the expedited review procedure for the reviewing "…minor changes in previously approved research during the period …for which approval is authorized" (45 CFR 46.110(b)(2),) but this option is not the focus of this document.

5 In the event that a proposed research activity cannot be approved, modified, or amended to secure approval under the expedited review procedure, the proposed research activity may be disapproved only after review in accordance with the non-expedited review procedure of a convened meeting of the full IRB (45 CFR 46..110(b)(2).)

6 45 CFR 46.111.

7 45 CFR 46.110(a), and *Categories of Research That May Be Reviewed by the Institutional Review Board (IRB) through an Expedited Review Procedure*, Federal Register (November 9, 1998, Federal Register (63 FR60364-7), available at: *http://www.hhs.gov/ohrp/humansubjects/guidance/expedited98.htm*

# II. What is "Minimal Risk"?

In order to be eligible for expedited review, a research activity must be determined to be no more than "minimal risk," a regulatory concept defined in the Common Rule as follows:

> *Minimal Risk* means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests[8].

Social and behavioral research studies may involve the possibility of various kinds of harm or discomfort. Harm or discomfort may be physical, psychological, or social; other harms may be economic, legal, or moral. Some social and behavioral research studies are designed to obtain sensitive personal information about people, the disclosure of which may be a major source of risk in social science research. Strengthening procedures to protect the confidentiality of acquired sensitive information decreases the risks of research studies involving sensitive information by decreasing the probability that subjects will experience harm or discomfort resulting from the disclosure of such information. Any effective strategy used to avoid, prevent, ameliorate or protect against the occurrence of harm or discomfort in a research study lowers the total value of the probability and magnitude of harm or discomfort – that is, the *potential for negative effects* - of the proposed research study. The reviewer should take into account any protective measures included in the research design as part of the process of determining if the proposed research involves no more than minimal risk. However, some social and behavioral studies involve more than minimal risk, even though they include such protective measures.

The judgment that a research activity involves "minimal risk" depends on a comparative assessment that the potential for negative effects to the human subjects of the research must be judged to be no more than the potential for negative effects ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. Assessing the potential for negative effects of research involves considering the *probability* of harm or discomfort – the chances that the subjects will experience harm or discomfort, and the *magnitude* of the harm or discomfort - that is, how great or small the harm or discomfort would be, in terms of such factors as the kind of harm, duration, intensity, reversibility, etc. The potential for negative effects is the product of how likely it is that the subjects will experience harm or discomfort and the degree of harm or discomfort subjects would suffer if the harms or discomforts were to occur.

The definition of minimal risk provides three alternative standards against which the potential for negative effects of the research may be compared to determine whether the research involves minimal risk:

1. the probability and magnitude of harm or discomfort ordinarily encountered *in daily life*; or,

8 45 CFR 46.102(i).

2. the probability and magnitude of harm or discomfort ordinarily encountered *during the performance of routine physical examinations or tests*; or,
3. the probability and magnitude of harm or discomfort ordinarily encountered *during the performance of routine psychological examinations or tests*.



Depending on the nature of the specific research activity, one or another of these three alternative standards may be most suitable. The particular risks of the research activity may not be identical to those of any of these three standards; however, these standards serve as guides for the types of possible harm or discomfort that are determined to be of minimal risk to subjects. The routine-physical-examinations-or-tests standard may be most appropriate for evaluating the potential for negative effects of medical research activities. The routine-psychological-examinations-or-tests standard may be more suitable for evaluating the potential for negative effects of behavioral research projects carried out in psychological laboratories. One of these two standards may also be suitable for evaluating the potential negative effects of survey or interview research in which sensitive personal information is obtained, since routine physical or psychological examinations and tests frequently involve such information.

The daily-life standard may be most appropriate for evaluating the potential for negative effects of social and behavioral research studies that take place in natural settings, where individuals' participation in research as human subjects is intertwined with everyday life. The physical-examinations-or-tests standard and the psychological-examinations-or-tests standard both offer the advantage of establishing a relatively precise measure of the potential for negative effects involved. This is not so simple for the daily-life standard, which requires taking into account a larger array of human activities, including activity in the home, transportation to school or work, the experiences of school or workplace activity, ordinary social or recreational activity, or routine exercise, etc. But while the variations among and between these activities make it more difficult to precisely assess the potential for negative effects ordinarily encountered in daily life, the resemblance between these activities and the activities of human subjects in many social or behavioral research studies may make the daily-life standard more directly suitable for determining whether the potential for negative effects involved in those social or behavioral studies meets the standard of minimal risk.

Determining whether a study involves minimal risk or not involves comparing the potential for negative effects of the research for the subjects of the particular research study with the potential for negative effects of individuals engaged in everyday life or undergoing routine physical or psychological examinations or tests. The potential for negative effects of a particular study may vary depending on whether the subjects are children, adults, members of a vulnerable population, or people chosen for a specific condition, background, or social status. Similarly, the potential for negative effects for the population of individuals whose ordinary daily lives or routine physical or psychological examinations or tests serve as the basis for comparison also varies depending on those individuals' age, vulnerability, health, culture, and social environment.

The minimal-risk standard is sometimes interpreted to require comparing the potential for negative effects for the subjects of the research activity to the potential for negative effects of everyday life or routine physical or psychological examinations or tests for the same specific population of individuals outside of the research, which is sometimes called the 'relative standard'. Alternatively, the minimal-risk standard has also been interpreted to require comparing the potential for negative effects for the subjects of the research activity to the potential for negative effects of everyday life or routine physical or psychological examinations or tests for a population of normal healthy individuals, sometimes called the 'uniform standard'. Whatever standard or population is chosen as the appropriate basis for comparison with the potential for negative effects of the research for the subjects in the research study, it is important to avoid an interpretation that leads to taking unfair advantage of a population of individuals who are already vulnerable in some way. The assessment of minimal risk should be sensitive to the concern that the impact of the assessment of minimal risk should not serve to exploit the research subjects in violation of the principle of justice.

# III. What Kinds of Social and Behavioral Research Activities are Eligible for Expedited Review?

The Common Rule references a list of nine categories of research involving human subjects that may qualify for expedited review[9] which vary in applicability to social and behavioral research studies. The first four of the nine categories primarily pertain to biomedical research studies, and concern the use of drugs or medical devices, the collection of blood samples or biological specimens, or noninvasive procedures routinely employed in clinical practice. These will not be discussed here, nor will the last two categories, which concern the circumstances under which expedited review may be used for the continuing review of research activities originally reviewed by the full IRB at a convened meeting. Categories five, six and seven are most relevant to social and behavioral research studies, and are as follows:

5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)
6. Collection of data from voice, video, digital, or image recordings made for research purposes.
7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

These categories are relatively broad and potentially include a wide variety of different kinds of social and behavioral research studies. As noted, the categories also include some research studies that are exempt from the Common Rule, and do not require either expedited or full board review. Because the wording of the categories is not elaborate, it is not always obvious what kinds of research studies fall within each category. Some fairly common types of social and behavioral research activities do qualify for expedited review under one or more of these categories, assuming that they also meet the standard of minimal risk. A number of these types of research activities, accompanied by brief illustrative examples, are as follows[9].

9 45 CFR 46.110(a), and *Categories of Research That May Be Reviewed by the Institutional Review Board (IRB) through an Expedited Review Procedure*, Federal Register (November 9, 1998, Federal Register (63 FR60364-7), available at: *http://www.hhs.gov/ohrp/humansubjects/guidance/expedited98.htm.*

A. Secondary analyses of existing or future data sets, such as databases containing medical records, criminal justice system records, education records, or survey data. These analyses may include studies where one or more data sets are combined.
For example:

An analysis of student educational records to explore the relationship between student mobility from district to district and student academic achievement for students from various economic and ethnic backgrounds. [Category (5)];

A study of prison administration records to explore the relationship between inmates' individual background characteristics, type of criminal violation, and acquisition of a Graduation Equivalent Development (GED) credential[10]. [Category (5)];

A study of medical records and survey data to compare people's weight with the cultural attitudes of different subpopulations toward diet and exercise. [Category 5].

B. Observational studies of human behavior and characteristics where personal identifiers are recorded and the data are not particularly sensitive in nature.
For example:

A study using video recordings to examine communication styles used by cooperating employees in a variety of business organizations. [Category (6)];

A laboratory study comparing patterns of eye movement and reading comprehension performance among novice and competent readers. [Categories (6) and (7)];

C. Experimental studies of human behavior, attitudes, opinions, and decisions, where the experimental manipulation consists of subjects reacting to hypothetical or contrived situations that are not expected to have significant lasting effects on the subjects.
For example:

A study in experimental economics in which people play an economic game that involves offering and/or accepting amounts of cash provided as part of the experiment. [Category (7)];

A study of adults' ability to identify accurately the perpetrators of staged thefts. [Category (7)];

A study attempting to validate a previously tested measure of extroversion/introversion with members of a previously untested cultural group. [Category (7)].

10 In its guidance document, "Guidance on the Use of Expedited Review Procedures," the Office for Human Research Protections (OHRP) recommends that: "… (3) expedited review procedures NOT be used for research involving prisoners. However, if an IRB chooses to use expedited review for research involving prisoners, OHRP recommends that the prisoner representative of the IRB be one of the designated reviewers." Readers should note that this is a recommendation, not a requirement, and that OHRP clearly recognizes this in the second part of its recommendation, which is directed toward how expedited reviews should be carried out if the institution does elect to use the expedited review procedure.

D. Survey research where the respondents are approached in a natural setting, either personally or through a communications medium (e.g., by mail, telephone, or the internet), and participation is voluntary.
For example:

A research study using telephone surveys of persons who provide their names and information about their background characteristics, political beliefs, and voting behavior. [Category (7)];

An online internet study in which undergraduate students view a video clip about economic theory and then respond to computer-simulated scenarios about individual spending decisions. [Category (7)];

E. Evolving research activities (such as ethnographic studies or focus group research) where the research activity is refined in various ways in response to earlier data collection, and the topics are not especially sensitive.
For example:

An ethnographic field study using un-structured interviews to explore the interrelationship between family life and involvement in religious activities. [Category (7)];

An ethnographic study using participant-observation where the researcher participates in the subject's activities of daily life, such as an anthropologist studying an agrarian market place by sitting in the respondent's market stall, observing interactions and sometimes selling items to help out. [Category (7)];

A participatory action research project in which middle school teachers and students use group discussions, surveys, and interviews to evaluate the school's social studies curriculum and develop recommendations for improvements. [Category (7)];

The types of research activities listed above should not automatically be considered minimal risk simply because they are presented here. The presentation of these types of research activities only indicates that a significant portion of these types of research activities will be *eligible* for review through the expedited review procedure, depending on whether the specific circumstances of the proposed research activity involve no more than minimal risk to human subjects. Decisions regarding eligibility for expedited review must be made on a case-by-case basis.

It should also be noted that some research studies may not fit any of the types of research activities presented above, and yet still fall within the categories of the Common Rule's list of research activities eligible for expedited review. The variety of topics and research designs in social and behavioral research studies is substantial, and studies whose designs are unusual in some way may still qualify for expedited review. Here again, the decision must be made on a case-by-case basis.

In summary, a research activity must meet two qualifications in order to be eligible for expedited review: First, it must involve no more than minimal risk to the subjects, which means that the potential for negative effects of participating in the research activity must be no greater than the potential for negative effects of i) routine physical examinations or tests, or ii) routine psychological examinations or tests, or iii) daily life. One of these three standards may lend itself more readily than the other two to comparison with a particular social or behavioral research activity, depending on the nature of the activity and its potential for negative effects. That potential may be influenced by the characteristics of the specific population of research subjects,

and by features of the research activity that are designed to prevent or decrease the likelihood or seriousness of possible harm or discomfort. Second, the research activity must fit into one of the categories of research involving human subjects on the list approved by the Department of Health and Human Services and the Food and Drug Administration. Categories five, six, and seven on that list are especially germane to social and behavioral research activities. Because these categories encompass a range of different kinds of research activities, the reviewer needs to examine the particular research activity carefully to determine if it falls within one of those categories.

# IV. What Factors Influence the Successful Implementation of the Expedited Review Procedure?

The goal of the expedited review procedure is to provide for appropriate reviews of relatively low-risk research projects while avoiding an excessive expenditure of effort or time. Reaching this goal is not automatic, and depends on how the institution's expedited review procedure is implemented. Institutions can design and develop mechanisms to facilitate the processing of projects eligible for expedited review, such as the following[11]:

- Determining Eligibility. Institutions can ensure that there is an efficient procedure for promptly determining whether the proposed project is in fact suitable for expedited review or whether it should be directed elsewhere. For example, an IRB administrator who is designated to review proposals to determine whether proposed activities fall under the authority of the Common Rule can also pre-screen proposals for expedited review.
- Deciding to Use Full Board Review. Institutions can identify a mechanism for ensuring that proposals that are initially assigned to the expedited review process and are later reassigned to full Board review are not unnecessarily delayed.
- Identifying Submission Requirements. Institutions can provide guidance for researchers preparing submissions for expedited review to ensure that they include all of the information needed by the reviewer(s) for applying the standard regulatory criteria for approval to proposed research activities.
- Appointing Reviewers. IRB chairs can appoint a sufficient number of experienced, qualified IRB members to perform expedited reviews. Where more than one IRB member is assigned to this task, chairs can appoint reviewers whose backgrounds and qualifications reflect the normal range of research projects eligible for expedited review that are submitted to the IRB at that institution. If the research activity involves prisoners, the IRB chair assigns a member who is a prisoner or prisoner representative to be a reviewer.
- Using Consultants. Institutions can arrange a system for making consultants available to the reviewing IRB members to facilitate the reviewers' access to useful information on an as-needed basis[12]. For example, each department at a college or university could identify an impartial expert in their discipline to serve as a consultant on projects submitted by people in that department.

---

11 These mechanisms are taken from a report of the Social and Behavioral Sciences Working Group on Human Research Protections titled "Institutional Arrangements for Reviewing Exempt, Expedited, or Other Research and Research-Related Activities" (2004), available at: *http://www.aera.net/aera.old/humansubjects/ExemptExpedited.doc*.

12 According to the regulations, "An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues which require special expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB." (45 CFR 46.107(f).

The objective of the expedited review procedure is to enable institutions to optimize the use of institutional resources in the review of research activities to protect the human subjects of research. The expedited review procedure can provide appropriate review and oversight of many social and behavioral research studies involving only minimal risk, while allowing the institution to devote more of its resources to the review and oversight of research activities involving greater risks or more difficult ethical issues. Achieving that objective depends on the successful implementation of the expedited review procedure in the institution's human research protection program.

## Social and Behavioral Research Working Group of the Human Subjects Research Subcommittee

Chair
Jeffery W. Rodamar, ABD, U.S. Department of Education

Sue Allison, U.S. Department of Justice
Howard Bradley, Social Security Administration
Ronald Barnett, Ph.D., National Institutes of Health
Patrick Clark, Ph.D., U.S. Department of Justice
Roger Cortesi, Environmental Protection Agency
Cheryl Crawford-Watson, U.S. Department of Justice
Patty Decot, U.S. Department of Defense
Diane C. DiEuliis, Ph.D., Office of Science and Technology Policy
Glen Drew, J.D., Office for Human Research Protections
John Kraemer, Office of Management and Budget
Kellina Craig- Henderson, Ph.D., National Science Foundation
Karen Y. Matsuoka, Office of Management and Budget
David Miller, Ph.D., U.S. Department of Veterans Affairs
Caroline Miner, U.S. Department of Defense
Genevieve Nowolinski, U.S. Department of Veterans Affairs
Deborah Olster, Ph.D., National Institutes of Health
Stuart Plattner, Ph.D., National Science Foundation (retired)
Joan A. Porter, Ph.D., U.S. Department of Veterans Affairs
Ivor A. Pritchard, Ph.D., Office for Human Research Protections
Susan G. Queen, Ph.D., Health Research and Services Administration
Jody Klein-Saffran, Ph.D., Bureau of Prisons
Mark L. Weiss, Ph.D., National Science Foundation
Brenda Wolff, U.S. Department of Education

## Human Subjects Research Subcommittee

Co-Chair
Dr. Ivor A. Pritchard
*Acting Director*
Office for Human Research Protections

Co-Chair
Dr. Mark Weiss
*Division Director*
National Science Foundation

## Committee on Science

Co-Chairs

Dr. Sharon Hays
*Associate Director*
Office of Science and Technology Policy

Dr. Arden Bement
*Director*
National Science Foundation

Dr. Elias Zerhouni
*Director*
National Institutes of Health