3-19-2013-PM version

Division of Behavioral and Social Sciences and Education
Board on Behavioral, Cognitive, and Sensory Sciences

Workshop on Proposed Revisions to the Common Rule in Relation to the Behavioral and Social Sciences

The National Academies Building,
2101 Constitution Avenue, NW
First Floor Lecture Room and Overflow Room NAS 125
Washington DC 20418

AGENDA

March 21-22, 2013

Overview:

The Department of Health and Human Services issued an advance notice of proposed rulemaking (ANPRM) on July 26, 2011 to solicit comments on how current regulations for protecting research participants under 45 CFR Parts 46 ("Common Rule") could be modernized and revised to be more effective. The National Research Council appointed a panel to address the proposed revisions to the Common Rule that have particular relevance to the behavioral and social sciences. The purpose of this two-day workshop is to explore the implications of the proposed revisions and of alternative approaches for protecting human participants while advancing the behavioral, social, and educational sciences. A workshop summary will be produced and the results of the workshop will provide input for a potential consensus study.

Objectives:

With regard to the following critical topics: types and levels of risks and harms, consent process and special populations, data use and sharing, multi-disciplinary and multi-site studies, and IRB purview and roles, the objectives of the workshop are:

- To examine how the proposed revisions to the Common Rule might affect different types of research studies and methods in the behavioral, social, and educational sciences.
- To identify strategies that may currently be used to protect participants and advance science, and suggest refinements or alternatives to the proposed rulemaking that will make them more workable for behavioral, social, and educational sciences as well as for biomedical sciences.
- To identify topics for research emerging from the proposed rulemaking that will assist in developing best practices for implementing the new human research protections and assessing the effectiveness of the rules and their implementation by institutional research boards (IRB) and researchers.

	DAY 1: Thursday, March 21, 2013
8:15	**Check in and Continental breakfast**
8:45	**Welcome and Introduction of Members of the Panel on Revisions to the Common Rule for the Protection of Human Subjects in Research in the Behavioral and Social Sciences** *Robert M. Hauser, National Research Council, Director of Division of Behavioral and Social Sciences and Education*
9:00	**Opening Remarks:** Introduction: This session will briefly provide the context for the workshop by explaining why the focus is on social, behavioral, and educational sciences; how research methods overlap with those used in biomedical sciences, and an introduction to the six major topics that will be addressed in the workshop. *Susan Fiske, Chair, Committee on Revisions to the Common Rule for the Protection of Human Subjects in Research in the Behavioral and Social Sciences, Princeton University*
9:15	**Session 1: Review of the Evidence** Introduction: This session will review what has been learned from previous NRC reports on the protection of human subjects, and will review the empirical evidence on the functioning of the Common Rule and IRBs. *Connie Citro, National Research Council* (review of NRC reports) *Jeffery Rodamar, Department of Education* (review of empirical evidence)
10:00	**BREAK**
10:10	**Session 2: Risks and Harms** Introduction: This session will focus on the types of risks and harm encountered in social, behavioral, and educational sciences such as: psychological, physical, and information; the levels of risk and the difference between severity of harm and probability of harm; adverse events; and benefits. [The ANPRM asked for input on calibrating levels of IRB review to levels of risk]. *Celia Fisher, Fordham University, Center for Ethics Education*
10:20	**Speaker 1:** *Richard T. Campbell, University of Illinois at Chicago, Institute for Health Research and Policy* (Discussion of the issues in the context of research on aging, health, racial, ethnic, and socioeconomic disparities; and suggestions for calibrating levels of review to levels of risk)
10:40	**Speaker 2:** *Brian Mustanski, Northwestern University Feinberg School of Medicine* (Discussion of issues in the context of sexuality and health research with LGBT youth; participants' appraisals of risk and benefits in behavioral and social science research)

11:00	**Speaker 3:** *Steven Breckler, American Psychological Association* (Discussion of the issues in the context of the broader perspective of the behavioral and psychological sciences, providing a framework for assessing risk of harm, and critiquing the ANPRM proposals for calibrating level of review to the level of risk.)
11:20	**Speaker 4:** *Charles Plott, California Institute of Technology* (Discussion of the nature of risks in relation to economic, decision, and political sciences)
11:40	**Moderated Q & A and Discussion** *Celia Fisher*
12:00	**LUNCH**
1:00	**Session 3: Special Populations and Consent Processes** Introduction: This session will focus on the consent process in general and on research involving special populations such as children, prisoners, persons with mental illness or other disabilities, persons with different languages, and research that involves complex consents such as family members and caregivers. [The ANPRM asked for input on proposed revisions to the Common Rule that would require the use of a standardized consent form, and for a new rule that would require consent to be obtained for all future uses of biospecimens, whether identifiable or not, and for re-consenting people for further use of existing research data]. *Margaret Foster Riley, University of Virginia*
1:10	**Speaker 1:** *Sally Powers, University of Massachusetts, Amherst* (Discussion of the issues in the context of research on biopsychosocial factors hypothesized to contribute to depression in family systems; particular focus on "complex consents")
1:40	**Speaker 2:** *Roxane Cohen Silver, University of California Irvine* (Discussion of the issues in the context of research on factors, effects, beliefs, and predictors of disaster and trauma; with particular focus on the process of consent, versus the form, to protect participants and advance research that can take place during or immediately after traumatic events)
2:10	**Speaker 3:** *Celia Fisher, Fordham University, Center for Ethics Education* (Discussion of the issues in the context of research with biospecimens; and addressing issues related to the various forms of consent for different types of research)
2:40	**Moderated Q & A and Discussion** *Margaret Foster Riley*
3:00	**BREAK**
3:20	**Session 4: Data Use and Sharing and Technological Advancements** Introduction: This session will examine issues related to the protection of research participants in studies that involve data use and sharing, and which take advantage of technological advancements. Issues relate to privacy and data security, third parties, future use, analysis, de-identification, re-consent, breaches through computer losses or accidents. [The ANPRM asked for input on proposed revisions to the Common Rule that would require adopting HIPAA standards for the protection of privacy and data security; and also for a new rule that would require consent to be obtained for all future uses of biospecimens, whether identifiable or not, and for re-

	consenting people for further use of existing research data]. *David Weir, University of Michigan, Survey Research Center*
3:30	**Speaker 1:** *George Alter, University of Michigan, ICPSR* (Discussion of the issues from the perspective of data archives and technological advancements in data collection and sharing)
4:00	**Speaker 2:** *Taylor Martin, University of Utah* (Discussion of the issues in the context of educational research, learning analytics, and use of varied technologies)
4:30	**Speaker 3:** *Susan Bouregy, Yale University Human Research Protection Program, (*Discussion of the issues with a special focus on HIPAA and information risk; particular focus on implications of new HIPAA regulations)
5:00	**Moderated Q & A and Discussion** *David Weir*
5:20	**Adjourn Day 1**
	DAY 2: Friday, March 22, 2013
8:15	**Continental Breakfast**
8:45	**Welcome and Overview of Day 2** *Susan Fiske, Princeton University*
9:00	**Session 5: Multi-disciplinary and Multi-site Studies** Introduction: This session will examine issues related to the protection of research participants in studies that are multi-disciplinary (SBE; biomedical/genomics), multi-site, cross-universities, cross-national, or international. [The ANPRM asked for input on proposed revisions to the Common Rule that would allow for a single IRB for multi-site studies.] *Robert Levine, Yale University, Interdisciplinary Center for Bioethics*
9:10	**Speaker 1:** *Pearl O'Rourke, Human Research Affairs, Partners Health Care System, Inc.* (Discussion of the issues from the perspective of an IRB overseeing a large multi-site NINDS study and the challenges involved)
9:40	**Speaker 2:** *Laura Stark, Vanderbilt University, Center for Medicine, Health & Society (Discussion of issues from the perspective of anthropological research with a focus on local precedents* and innovative methods for protecting participants and advancing research)
10:10	**Speaker 3:** *Thomas Coates,UCLA Program in Global Health* (Discussion of the issues in the context of international research on prevention of chronic and infectious diseases)
10:40	**BREAK**
10:50	**Moderated Q & A and Discussion** *Robert Levine*

11:10	**Session 6: Purview and Roles of Institutional Review Boards** Introduction: This session will focus on the critical role of IRBs in the context of the proposed revisions to the Common Rule. Will they help improve IRB functioning and effectiveness? [The ANPRM asked for input on a proposed revision to the Common Rule that would create a new category of "excused" research to replace the "exempt" category and possibly imposing additional regulation relating to data protection and consent on this new category.] Issues relate to IRB oversight of excused research, continuing review; plus issues such as education/guidance to IRBs, mission creep, appeals processes, asymmetrical incentives. *Yonette Thomas, Howard University, Office of the V.P. for Research and Compliance*
11:20	**Speaker 1:** *Lois Brako University of Michigan, Regulatory and Compliance Oversight* (Discussion of the issues from the perspective of an IRB that maximizes opportunities to be flexible and innovative)
11:50	**Speaker 2:** *Rena Lederman, Princeton University, Dept of Anthropology* (Discussion of IRB issues in the context of socio-cultural anthropology and ethics)
12:20	**SHORT LUNCH BREAK**
12:50	**Speaker 3:** *Cheryl Crawford Watson, National Institute of Justice* (Discussion of human subjects protection issues from the perspective of a research funder of projects that are under the purview of various IRBs; and with particular focus on how regulations are applied)
1:20	**Moderated Q & A and Discussion** *Yonette Thomas*
1:30	**Common Themes Emerging from Workshop** *Susan Fiske* - Moderator *Melissa Abraham, Harvard Medical School and Massachusetts General Hospital* *Felice Levine, American Educational Research Association* *Richard Nisbett, University of Michigan* *Charles Plott, California Institute of Technology*
2:30	**Adjourn**

NOTE FOR PUBLIC MEETINGS: This meeting is being held to gather information to help the committee conduct its study. This committee will examine the information and material obtained during this, and other public meetings, in an effort to inform its work. Although opinions may be stated and lively discussion may ensue, no conclusions are being drawn at this time; no recommendations will be made. In fact, the committee will deliberate thoroughly before writing its draft report. Moreover, once the draft report is written, it must go through a rigorous review by experts who are anonymous to the committee, and the committee then must respond to this review with appropriate revisions that adequately satisfy the Academy's Report Review Committee and the chair of the National Research Council before it is considered a National Research Council report. Therefore, observers who draw conclusions about the committee's work based on today's discussions will be doing so prematurely.

Furthermore, individual committee members often engage in discussion and questioning for the specific purpose of probing an issue and sharpening an argument. The comments of any given committee member may not necessarily reflect the position he or she may actually hold on the subject under discussion, to say nothing of that person's future position as it may evolve in the course of the project. Any inferences about an individual's position regarding findings or recommendations in the final report are therefore also premature.