

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

Workshop Agenda Book

**NAS Building – Lecture Room
March 21 – 22, 2013**



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NATIONAL RESEARCH COUNCIL
OF THE NATIONAL ACADEMIES

**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 20001

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	<p>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</p> <p><i>Robert M. Hauser, National Research Council, Director of Division of Behavioral and Social Sciences and Education</i></p>
9:00	<p>Opening Remarks:</p> <p><u>Introduction:</u> 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.</p> <p><i>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</i></p>
9:15	<p>Session 1: Review of the Evidence</p> <p><u>Introduction:</u> 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.</p> <p><i>Connie Citro, National Research Council (review of NRC reports)</i></p> <p><i>Jeffery Rodamar, Department of Education (review of empirical evidence)</i></p>
10:00	<p>Session 2: Risks and Harms</p> <p><u>Introduction:</u> 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].</p> <p><i>Celia Fisher, Fordham University, Center for Ethics Education</i></p>
10:10	<p>Speaker 1: <i>Richard T. Campbell, University of Illinois at Chicago, Institute for Health Research and Policy</i> (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)</p>
10:30	BREAK
10:40	<p>Speaker 2: <i>Brian Mustanski, Northwestern University Feinberg School of Medicine</i> (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)</p>
11:00	<p>Speaker 3: <i>Steven Breckler, American Psychological Association</i> (Discussion of the issues in the context of the broader perspective of the behavioral and psychological sciences, providing a</p>

<p>11:20</p> <p>11:40</p>	<p>framework for assessing risk of harm, and critiquing the ANPRM proposals for calibrating level of review to the level of risk.)</p> <p>Speaker 4: <i>Charles Plott, California Institute of Technology</i> (Discussion of the nature of risks in relation to economic, decision, and political sciences)</p> <p>Moderated Q & A and Discussion <i>Celia Fisher</i></p>
<p>12:00</p>	<p>LUNCH</p>
<p>1:00</p> <p>1:10</p> <p>1:40</p> <p>2:10</p> <p>2:40</p>	<p>Session 3: Consent Process and Special Populations</p> <p><u>Introduction:</u> 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].</p> <p><i>Margaret Foster Riley, University of Virginia</i></p> <p>Speaker 1: <i>Sally Powers, University of Massachusetts, Amherst</i> (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”)</p> <p>Speaker 2: <i>Roxane Cohen Silver, University of California Irvine</i> (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)</p> <p>Speaker 3: <i>Celia Fisher, Fordham University, Center for Ethics Education</i> (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)</p> <p>Moderated Q & A and Discussion <i>Margaret Foster Riley</i></p>
<p>3:00</p>	<p>BREAK</p>
<p>3:20</p>	<p>Session 4: Data Use and Sharing and Technological Advancements</p> <p><u>Introduction:</u> 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].</p>

3:30	<i>David Weir, University of Michigan, Survey Research Center</i> Speaker 1: <i>George Alter, University of Michigan, ICPSR</i> (Discussion of the issues from the perspective of data archives and technological advancements in data collection and sharing)
4:00	Speaker 2: <i>Taylor Martin, University of Utah</i> (Discussion of the issues in the context of educational research, learning analytics, and use of varied technologies)
4:30	Speaker 3: <i>Susan Bouregy, Yale University Human Research Protection Program</i> , (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 <i>David Weir</i>
5:20	Adjourn Day 1
DAY 2: Friday, March 22, 2013	
8:15	Continental Breakfast
8:45	Welcome and Overview of Day 2 <i>Susan Fiske, Princeton University</i>
9:00	Session 5: Multi-disciplinary and Multi-site Studies <u>Introduction:</u> 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.] <i>Robert Levine, Yale University, Interdisciplinary Center for Bioethics</i>
9:10	Speaker 1: <i>Pearl O'Rourke, Human Research Affairs, Partners Health Care System, Inc.</i> (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: <i>Laura Stark, Vanderbilt University, Center for Medicine, Health & Society</i> (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: <i>Thomas Coates, UCLA Program in Global Health</i> (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 <i>Robert Levine</i>
11:10	Session 6: Purview and Roles of Institutional Review Boards

	<p>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.</p> <p><i>Yonette Thomas, Howard University, Office of the V.P. for Research and Compliance</i></p>
11:20	<p>Speaker 1: <i>Lois Brako University of Michigan, Regulatory and Compliance Oversight</i> (Discussion of the issues from the perspective of an IRB that maximizes opportunities to be flexible and innovative)</p>
11:50	<p>Speaker 2: <i>Rena Lederman, Princeton University, Dept of Anthropology</i> (Discussion of IRB issues in the context of socio-cultural anthropology and ethics)</p>
12:20	<p>SHORT LUNCH BREAK</p>
12:50	<p>Speaker 3: <i>Cheryl Crawford Watson, National Institute of Justice</i> (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)</p>
1:20	<p>Moderated Q & A and Discussion <i>Yonette Thomas</i></p>
1:30	<p>Common Themes Emerging from Workshop</p> <p><i>Susan Fiske - Moderator</i></p> <p><i>Melissa Abraham, Harvard Medical School and Massachusetts General Hospital</i> <i>Felice Levine, American Educational Research Association</i> <i>Richard Nisbett, University of Michigan</i> <i>Charles Plott, California Institute of Technology</i></p>
2:30	<p>Adjourn</p>

BEHAVIORAL, COGNITIVE, AND SENSORY SCIENCES

AT THE NATIONAL RESEARCH COUNCIL
www.nationalacademies.org/bbcss

Meetings on Proposed Revisions to the Common Rule in Relation to the Behavioral and Social Sciences are sponsored by:

National Science Foundation (NSF)

American Academy of Political and Social Science (AAPSS)

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University of Michigan Institute for Social Research

Westat

**Proposed Revisions to the Common Rule for the Protection of Human Subjects in
Research in the Behavioral and Social Sciences
Phase I: Workshop**

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

Statement of Task

This project will be conducted in two phases. In Phase I, an ad hoc committee will be set up to conduct a workshop and prepare a summary report. Assuming additional funding, Phase II will pick up from where Phase I left off and produce a consensus report with conclusions and recommendations. The workshop report and possible eventual consensus report will address prospective revisions to the Common Rule for the protection of human subjects in research of particular relevance to the behavioral and social sciences. The work of the panel is intended to inform the current efforts of the federal government to update the Common Rule (45 CFR 46), last revised in 1991. The panel will consider such issues as the appropriateness of the Common Rule for different behavioral and social science research methods; the concept of information risk and its relationship to methods and mechanisms developed by the federal statistical community to protect confidentiality while providing access to research data; the concept and appropriate treatment of psychological risk for human research participants; appropriate classification of research projects by the level of scrutiny required by an institutional review board (IRB); revisions to the consent process to facilitate informed decisions by human research participants while minimizing barriers to participation; and training that can effectively instruct researchers, IRB members, and other administrators with a role in IRB processes.

The workshop and summary report will address the following content areas:

- Issues raised in the proposed rulemaking which the panel identifies as critical and feasible for the federal government to address for the protection of participants and for the advancement of the social and behavioral sciences.
- For each issue, proposed regulatory language, and/or detailed guidance for IRBs as needed to include: techniques for addressing issues, specific examples and best practice models to illustrate how the techniques would be applied to different behavioral and social sciences research procedures.
- 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 IRBs and researchers

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DIVISION OF BEHAVIORAL AND SOCIAL SCIENCES AND EDUCATION
Board on Behavioral, Cognitive, and Sensory Sciences

Biosketches of Committee on Revisions to the Common Rule for the Protection of Human
Subjects in Research in the Behavioral and Social Sciences

CHAIR

Susan T. Fiske is Eugene Higgins Professor, psychology and public affairs, Princeton University. She investigates social cognition, especially cognitive stereotypes and emotional prejudices, at cultural, interpersonal, and neural levels. She is most known for the continuum model of impression formation, her power-as-control theory, the ambivalent sexism theory, and the stereotype content model showing fundamental dimensions of social cognition. She has chaired the Princeton IRB since 2003 and served on other IRBs ever since graduate school. The U.S. Supreme Court cited her gender-bias testimony, and she testified before President Clinton's Race Initiative Advisory Board. These influenced a recent edited volume, *Beyond Common Sense: Psychological Science in the Courtroom*. Her most recently authored book is *Envy Up, Scorn Down: How Status Divides Us*. Currently an editor of the *Annual Review of Psychology*, *Psychological Review*, *Handbook of Social Psychology*, and *Science* (Board of Reviewing Editors), she wrote *Social Beings: Core Motives in Social Psychology* and *Social Cognition: From Brains to Culture*. Author of more than 300 articles and chapters, she has won a Guggenheim, as well as psychological science honors: the American Psychological Association's Distinguished Scientific Contribution Award and the Association for Psychological Science William James Award. She has been elected president of the Association for Psychological Science, president of the Foundation for the Advancement of Behavioral and Brain Sciences, president of the Federation of Associations in Behavioral and Brain Sciences (FABBS), and fellow of both the American Academy of Arts and Sciences and the American Academy of Political and Social Sciences. She is a member of the NRC Division Committee for the Behavioral and Social Sciences and Education, and a member of the NRC Board on Behavior, Cognitive, and Sensory Sciences. She has served on the NRC Committee to Study the National Needs for Biomedical, Behavioral, and Clinical Research Personnel and on the NRC Panel on Methods for Assessing Discrimination. She has a Ph.D. in Social Psychology from Harvard University and honorary doctorates from Université Catholique de Louvain-la-Neuve, Belgium and the Universiteit Leiden, Netherlands.

BEHAVIORAL AND SOCIAL SCIENCES

Celia B. Fisher is Marie Ward Doty University Chair and professor of psychology, and founding director of the Fordham University Center for Ethics Education. She is best known for research emerging from her federally funded research programs on ethical issues and well-being of vulnerable populations, including ethnic minority youth and families, active drug users, college students at risk for drinking problems, and adults with impaired consent capacity. She currently directs the NIDA funded Fordham University Training Institute on HIV Prevention Research Ethics. She is past chair of the Environmental Protection Agency's Human Studies Review

Board, a past member of the DHHS Secretary's Advisory Committee on Human Research Protections (SACHRP; and co-chair of the SACHRP Subcommittee on Children's Research) and a founding editor of the journal *Applied Developmental Science*. She chaired the American Psychological Association's Ethics Code Task Force, the Society for Research in Child Development (SRCD) Common Rule Task Force and the New York State Licensing Board for Psychology, and served on the National Institute of Mental Health Data Safety and Monitoring Board, and the Institute of Medicine's Committee on Clinical Research Involving Children. Dr. Fisher is author of *Decoding the Ethics Code: A Practical Guide for Psychologists* (3rd Edition, 2013); co-editor of eight books, including *The Handbook of Ethical Research with Ethnocultural Populations and Communities* and *Research with High-Risk Populations: Balancing Science, Ethics, and Law*; and author of over 100 theoretical and empirical publications in the areas of ethics in medical and social science research and practice and life-span development. She is the recipient of the 2010 Health improvement Institute's Lifetime Achievement Award for Excellence in Human Research Protection and fellow of the American Association for the Advancement of Science. She has a Ph.D. in experimental psychology from the New School for Social Research.

Robert M. Groves (NAS, IOM) is provost of Georgetown University. Previously he was director of the U.S. Census Bureau. He also served as professor of sociology and director of the Survey Research Center in the Institute for Social Research at the University of Michigan. He is the author of *Survey Errors and Survey Costs* and the coauthor of *Nonresponse in Household Surveys*. He is a fellow of the American Statistical Association and an elected member of the International Statistical Institute, and he has received the Innovator Award and an award for exceptionally distinguished achievement from the American Association for Public Opinion Research. He is a member of the National Academy of Sciences and the Institute of Medicine and has served on numerous NRC committees, including the Committee on National Statistics and the Panel on Institutional Review Boards, Surveys, and Social Science Research. He has a Ph.D. in sociology from the University of Michigan.

Richard E. Nisbett (NAS) is Theodore M. Newcomb distinguished university professor and co-director of the Culture and Cognition Program at the University of Michigan. Dr. Nisbett's research interests have focused primarily on how laypeople reason and make inferences about the world. His earlier work was concerned with inductive inference, causal reasoning and covariation detection. More recent work on reasoning compares East Asians with Westerners. He has also studied "cultures of honor" and the Hispanic cultural tradition of *sympatia*, and the ways in which it differs from mainstream American culture. Dr. Nisbett was elected to the National Academy of Sciences in 2002 and became a fellow of the American Academy of Arts and Sciences in 1992. He was awarded the John Simon Guggenheim Fellowship in 2002. His book *The Geography of Thought* won the American Psychological Association's William James Book Award in 2004. Dr. Nisbett has a Ph.D. in Social Psychology from Columbia University.

ECONOMICS

Charles R. Plott (NAS) is Edward S. Harkness professor of economics and political science, founder and director of the Laboratory for Experimental Economics and Political Science at the California Institute of Technology. Dr. Plott is widely acknowledged for his role as co-founder of

experimental economics, which he founded with Vernon Smith. He has also been particularly influential in applying the methodology of experimental economics to address public policy issues and challenges. These include the design and implementation of computerized market mechanisms for allocating complex items such as the markets for pollution permits in Southern California, the FCC auction of licenses for Personal Communication Systems, the auctions for electric power in California, and the allocation of landing rights at major U.S. airports. Dr Plott is a member of the National Academy of Sciences, fellow of the American Academy of Arts and Sciences, fellow of the Econometric Society, and distinguished fellow from the American Economic Association. He has a Ph.D. in economics from the University of Virginia.

David R. Weir is research professor in the Survey Research Center, Institute for Social Research (ISR) at the University of Michigan. He is the principal investigator for the Health and Retirement Study, a longitudinal survey of over 22,000 persons over age 50 in the United States, which is supported by the National Institute on Aging. Prior to joining ISR, he was a Visiting Associate Professor in the Department of Economics and Research Associate in the Harris School of Public Policy at the University of Chicago and the recipient of a Special Emphasis Research Career Award in the Economics and Demography of Aging from the National Institute on Aging. Prior to that he was an Associate Professor of Economics at Yale University, working on economic history and historical demography, primarily in Europe. His current research interests include the use of longitudinal data to study chronic disease processes, especially diabetes and dementia; health care decision-making at older ages, including Medicare Part D; how couples jointly plan for risks of old age including retirement, widowhood, and disability; the role of personality factors in lifetime economic success, and the use of biomarkers, particularly genetics, in population surveys. He serves as an advisor to international studies linked to the HRS in Europe, the UK, Ireland, Japan, Israel, China, India, and Brazil. He currently serves on the National Research Council Committee on Population and the Panel on Policy Research and Data Needs to Meet the Challenge of Aging in Asia. He also served on the Planning Committee for the Academies-wide Initiative on the Grand Challenges of an Aging Society. He has a Ph.D. in economics from Stanford University.

BIOMEDICAL SCIENCE

Thomas J. Coates (IOM) is Director of the UCLA Program in Global Health, and is the Michael and Sue Steinberg endowed professor of Global AIDS Research within the Division of Infectious Diseases at UCLA. He co-founded the Center for AIDS Prevention Studies (CAPS) at UCSF in 1986 and directed it from 1991 to 2003. He was the founding executive director of the UCSF AIDS Research Institute, leading it from 1996 to 2003. His areas of emphasis and expertise are HIV prevention, the relationship of prevention and treatment for HIV, and HIV policies. His domestic work has focused on a variety of populations, and he is currently finishing a nationwide clinical trial of an experimental HIV preventive intervention focused on high-risk men. He is also finishing domestic trials of post-exposure prophylaxis. With funding from USAID and WHO, he led a randomized controlled trial to determine the efficacy and cost-effectiveness of HIV voluntary counseling and testing for individuals and couples in Kenya, Tanzania, and Trinidad. He is now directing a 48-community randomized clinical trial in South Africa, Zimbabwe, Tanzania, and Thailand to determine the impact of strategies for destigmatizing HIV. He is also leading a prevention clinical trial in South America as part of a 5-country effort, and has a trial in China to determine the impact of prevention in the context of

care. He is co-principal investigator of the National Institute of Allergy and Infectious Diseases-funded HIV Prevention Trials Network (HPTN), and is conducting policy research domestically and internationally. He was cited in *Science* in 2002 as the 4th-highest-funded scientist in the clinical, social, and behavioral sciences and was elected to the Institute of Medicine in 2000. He has a Ph.D. in psychology from Stanford University.

ADMINISTRATION OF INSTITUTIONAL REVIEW BOARDS

Melissa E. Abraham is assistant clinical professor at Harvard Medical School and is on the staff of the Department of Psychiatry at Massachusetts General Hospital in Boston. She is a chair at the Partners Human Research Committee, the IRB for the Brigham and Women's and Massachusetts General Hospitals where she reviews a large volume of minimal risk biomedical and social and behavioral research protocols, is involved in developing guidance and policy on social science methods used in the biomedical setting, such as deception, quality improvement, internet/social media, medical education, and cognitive science. Previously she had a postdoctoral fellowship with the Mongan Institute for Health Policy and a fellowship in Medical Ethics at Harvard Medical School. She has a M.Sc. in epidemiology from the Harvard School of Public Health and a Ph.D. in clinical psychology from Northwestern University Medical School.

Yonette F. Thomas is associate vice president for research compliance at Howard University. Previously she served as the program director for the sociology epidemiology program and branch chief of the Epidemiology Research Branch at the National Institute on Drug Abuse the National Institutes of Health. She has faculty appointments in the Department of Psychiatry and Behavioral Sciences and the School of Pharmacy at Howard University as well as serving as a voluntary associate professor of epidemiology in the Department of Epidemiology and Public Health at the Miller School of Medicine, University of Miami. She is a member of the Consortium of Social Science Associations (COSSA) Advisory Committee as well as a senior research fellow with the Center for Minority Health Services Research within the College of Pharmacy, Nursing, and Allied Health Sciences at Howard University. Her primary research and publications have focused on the social epidemiology of drug abuse and HIV/AIDS and the link with geography. Specifically, she recently edited *Geography and Drug Addiction*. She has a Ph.D. in social epidemiology from Howard University.

LEGAL, ETHICAL, AND POLICY ISSUES RELATED TO HUMAN RESEARCH PROTECTIONS

Felice J. Levine is executive director of the American Educational Research Association. Previously she was executive officer of the American Sociological Association. She was also director of the Law and Social Science Program at the National Science Foundation (NSF) and senior research social scientist at the American Bar Foundation. Her work focuses on research and science policy issues, research ethics, data access and sharing, the scientific and academic workforce, and higher education. Previously she served on the National Human Research Protections Advisory Committee of the U.S. Department of Health and Human Services and on the 2000 Decennial Census Advisory Committee. She was on the National Research Council panel on *Putting People on the Map: Protecting Confidentiality with Linked Social-Spatial Data* and chaired the NRC workshop on *Protecting Student's Records and Facilitating*

Education Research. In addition, she co-authored *Education and Training in the Social, Behavioral, and Economic Sciences: A Plan of Action*, undertaken at the request of the National Science Foundation. She is an associate editor of the *Journal of Empirical Research on Human Research Ethics*. She also serves on the Executive Committee of the Consortium of Social Science Associations, is past chair of the Board of Directors of the Council of Professional Associations on Federal Statistics, and is secretary general of the newly established World Education Research Association. She is a fellow of the American Association for the Advancement of Science, the American Educational Research Association, and the Association for Psychological Science as well as an elected member of the International Statistical Institute. She holds two current NSF awards, Advancing Knowledge and Building the Research Infrastructure in Education and STEM Learning and An Assessment of Education Research Doctorate Programs. She is also a past president of the Law and Society Association. She has a Ph.D. in social psychology from the University of Chicago.

Robert J. Levine is professor of medicine and lecturer in pharmacology, senior fellow and founding co-director in the Interdisciplinary Center for Bioethics, and director of the law, policy and ethics core of the Center for Interdisciplinary Research on AIDS at Yale University. He is a fellow of The Hastings Center, the American College of Physicians, and the American Association for the Advancement of Science; a member of the American Society for Clinical Investigation and American Society for Pharmacology and Experimental Therapeutics; past-president of the American Society of Law, Medicine & Ethics (two terms); and past-chairman of the Connecticut Humanities Council. He was the chair of the Institutional Review Board at Yale-New Haven Medical Center, chief of the section of clinical pharmacology at Yale, chair of the section on medico-legal matters and R&D administration of the American Society for Clinical Pharmacology and Therapeutics, associate editor of *Biochemical Pharmacology* and editor of *Clinical Research*. He is the founding editor of *IRB: Ethics and Human Research* and chair of the Editorial Board, and has served as consultant to several federal and international agencies involved in the development of policy for the protection of human subjects. He was, for example, chair of the Council for International Organizations of Medical Sciences' Steering Committee for revision of its International Ethical Guidelines for Biomedical Research Involving Human Subjects. He is the author of numerous publications including the book, *Ethics and Regulation of Clinical Research* and coauthor of the *Belmont Report*. Most of his research, teaching, and publications have been in the field of medical ethics with particular concentration on the ethics of research involving human subjects. Additionally, he has received numerous awards for his contributions to the field of human research protection. He served on the National Research Council's Panel on Collecting, Storing, Accessing, and Protecting Biological Specimens and Biodata in Social Surveys. He has an M.D. from the George Washington University School of Medicine.

Margaret Foster Riley is professor of law at the University of Virginia School of Law where she teaches in the areas of bioethics, law and ethics of human subjects research, food and drug law, health law, animal law and public health law. She also has secondary appointments in the Department of Public Health Sciences at the University of Virginia School of Medicine and in the Batten School of Leadership and Public Policy. Her areas of interest include health institutions and reform, animal law and rights, biomedical ethics and research, food and drug

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**Proposed Revisions to the Common Rule for the Protection of Human Subjects in
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Biosketches of Speakers on Revisions to the Common Rule for the Protection of Human Subjects in Research in the Behavioral and Social Sciences

George Alter is Director of the Inter-university Consortium for Political and Social Research (ICPSR), Research Professor at the Population Studies Center, and Professor of History at the University of Michigan. ICPSR is the world's largest social science data archive with units that specialize in data on aging, childcare, criminal justice, demography, health, and substance abuse. Alter's research grows out of interests in the history of the family, demography, and economic history, and recent projects have examined the effects of early life conditions on health in old age and new ways of describing fertility transitions. He was president of the Social Science History Association in 2011. Recent publications include: Alter and Clark, "The demographic transition and human capital," in *The Cambridge Economic History of Modern Europe* (Cambridge University Press, 2010); and Alter, Dribe, and Poppel, "Widowhood, Family Size, and Post-Reproductive Mortality: A Comparative Analysis of Three Populations in Nineteenth Century Europe," *Demography* (2007). Dr. Alter holds a Ph.D. in History from the University of Pennsylvania.

Susan Bouregy is Chief HIPAA Privacy Officer and an IRB Vice-Chair at Yale University. As privacy officer, Dr. Bouregy is responsible for the HIPAA privacy program throughout the University, including both a health plan component and the healthcare providers in the faculty practice and University Health Services, a full service care provider for students, employees and their families. Concurrently, Dr. Bouregy is responsible for oversight of the social and behavioral science IRB at Yale initially as IRB Director and subsequently as Vice-Chair. This IRB is responsible for review of the broad range of social, behavioral and educational research conducted at Yale. Dr. Bouregy also served as co-director of the University's successful human research protection program accreditation project. Dr. Bouregy holds a Ph.D. in biology from Brandeis University.

Lois Brako is Assistant Vice President for Research–Regulatory and Compliance Oversight, at the University of Michigan, Ann Arbor. Her responsibilities include coordinating activities related to the development and modification of campus-wide research policies and procedures and strategic planning for regulatory compliance oversight. Dr. Brako is the Director of University of Michigan's Human Research Protections Program, which spans four IRB Offices and nine IRBs, with oversight of more than 5600 projects. Dr. Brako chairs the University of Michigan IRB Council, co-chairs the Human Pluripotent Stem Cell Research Oversight Committee, serves as a member of the Institutional Biosafety Committee, and is a consultant to the University Committee on the Use and Care of Animals. She is also a member of University of Michigan's Leadership team for electronic information system development and is currently helping to design a new system for conflict of interest review and management. Dr. Brako is co-Chair of the Federal Demonstration Partnership's Human Subjects Protections Subcommittee, a group dedicated to reducing regulatory burden for investigators, and a participating member in the Council on Governmental Relations. Dr. Brako holds a Ph.D. in biology from the City University of New York.

Steven J. Breckler is executive director of the American Psychological Association's Science Directorate, overseeing programs that promote psychological science in academic and scientific arenas, and that advocate on behalf of scientific psychology. Before joining APA, Dr. Breckler directed the National Science Foundation's Social Psychology Program. He also helped to develop and lead the NSF

Science of Learning Centers program, which supports interdisciplinary teams of scientists to advance our understanding of human and animal learning. Dr. Breckler was an associate professor of psychology at Johns Hopkins University. He is author or co-author of more than 60 published or conference papers on topics ranging from attitude development to jury functioning, some of which have earned awards from scientific societies. Dr. Breckler's research has been supported by grants from the National Science Foundation, the National Institutes of Health, and the Department of Defense. He is also the co-author of a widely-used textbook, *Social Psychology Alive!* Dr. Breckler served on the editorial boards for *Personality and Social Psychology Bulletin*, *Psychological Bulletin* and *Psychological Science in the Public Interest*. Dr. Breckler is a fellow of APA, the Association for Psychological Science (APS) and the American Association for the Advancement of Science (AAAS). Dr. Breckler holds a Ph.D. in social psychology from the Ohio State University.

Richard T. Campbell is Emeritus Professor of Biostatistics and Sociology. Prior to Dr. Campbell's UIC appointment he was a member of the Department of Sociology at Duke University. Dr. Campbell's current research involves the study of race and ethnic disparities in diagnosis and treatment of breast, colon and prostate cancer using geocoded patient data derived from electronic medical records and other sources along with data on the distribution of health care providers. His prior research, almost all of which has been based on large national data sets, has focused on various aspects of health and aging and on social stratification. With regard to human subject issues, he has served on IRBs at both Duke University, where he also chaired the Faculty Senate Committee on Human Subjects, and at UIC. Dr. Campbell has also served on several national panels and committees including the Working Group on Social Science Issues in Human Subjects Research and the National Science Foundation Subcommittee on Human Subjects Issues. Dr. Campbell holds a Ph.D. in Sociology from the University of Wisconsin – Madison.

Constance F. Citro is director of the Committee on National Statistics, a position she has held since May 2004. She previously served as acting chief of staff (December 2003-April 2004) and as senior study director (1986-2003). She began her career with CNSTAT in 1984 as study director for the panel that produced *The Bicentennial Census: New Directions for Methodology in 1990*. Prior to joining CNSTAT, she held positions as vice president of Mathematica Policy Research, Inc., and Data Use and Access Laboratories, Inc. She was an American Statistical Association/National Science Foundation/Census research fellow in 1985-1986, and is a fellow of the American Statistical Association and an elected member of the International Statistical Institute. For CNSTAT, she directed evaluations of the 2000 census, the Survey of Income and Program Participation, microsimulation models for social welfare programs, and the NSF science and engineering personnel data system, in addition to studies on institutional review boards and social science research, estimates of poverty for small geographic areas, data and methods for retirement income modeling, and a new approach for measuring poverty. She coedited the 2nd – 4th editions of *Principles and Practices for a Federal Statistical Agency*, and contributed to studies on measuring racial discrimination, expanding access to research data, the usability of estimates from the American Community Survey, the National Children's Study research plan, and the Census Bureau's 2010 census program of experiments and evaluations. Dr. Citro holds a M.A. and Ph.D. in political science from Yale University.

Roxane Cohen Silver is Professor in the Department of Psychology and Social Behavior, the Department of Medicine, and the Program in Public Health at the University of California, Irvine, where she has been

actively involved in research, teaching, mentoring and administration since 1989. An international expert in the field of stress and coping, she has spent the past three decades studying acute and long-term psychological and physical reactions to stressful life experiences, including personal traumas such as physical disability, loss, and childhood sexual victimization, as well as larger collective events such as war, firestorms, the Columbine High School shootings, the September 11, 2001 terrorist attacks, and other community disasters across the world (including the 2010 8.8 earthquake in Chile and the 2006 destructive earthquake in Yogyakarta, Indonesia). Her research has been funded by the National Science Foundation, the National Institute of Mental Health, the US Department of Homeland Security, and the US Public Health Service. Since December 2003, Dr. Silver has served on numerous senior advisory committees and task forces for the U.S. Department of Homeland Security, providing ongoing advice to DHS and its component agencies on the psychological impact of disasters and terrorism. She is also one of the founding Directors of *Psychology Beyond Borders*, an international nonprofit organization that facilitates research, intervention and policy development in the prevention, preparedness and response to terror attacks, conflict, or natural disasters across the world. Dr. Silver is a Fellow of the American Psychological Association (in 4 Divisions) and the Association for Psychological Science. In 2007 Dr. Silver received the American Psychological Association's Award for Distinguished Service to Psychological Science and in 2010 she received the Public Advocacy Award from the International Society for Traumatic Stress Studies (for “outstanding and fundamental contributions to advancing social understanding of trauma”). In 2011 she received the American Psychological Association's Award for Distinguished Contributions to Psychology in the Public Interest (Senior Career) and the Award for Outstanding Service to the Field of Trauma Psychology from the American Psychological Association's Division 56 (Trauma Psychology). Dr. Silver holds a PhD in social psychology from Northwestern University.

Rena Lederman is Professor of Anthropology at Princeton University. Dr. Lederman's research background includes early work conducted in rural Papua New Guinea regarding the politics and everyday practice of “gift” (non-market) exchange, gender relations, and historical consciousness. Dr. Lederman's current work concerns the anthropology of academic practice and involves comparative research on disciplinary knowledge and expertise in the humanities and social sciences. Intra-disciplinary talk and writing about ethical practice and cross-disciplinary evaluations of “good work” are rich sources for grasping the disciplines' partly overlapping, partly divergent epistemological assumptions. Much of Dr. Lederman's recent writing has focused on controversy over IRB regulations. She has served as both chair and member on the American Anthropological Association's Committee on Ethics, on Princeton University's IRB, and most recently, as co-author of the American Anthropological Association's commentary on the proposed overhaul of IRB regulations (45 CFR 46). Dr. Lederman has been the recipient of research grants from the National Institutes of Health, the National Sciences Foundation, the American Philosophical Society, Columbia University and Princeton University; and conference grants and sponsorship from the Wenner Gren Foundation and the National Endowment for the Humanities. Dr. Lederman holds a PhD in Anthropology from Columbia University.

Taylor Martin is Associate Professor at Utah State University. Dr. Martin has worked in research and development in curriculum and design of instructional systems on projects such as the Adventures of Jasper Woodbury and the Algebra Project. She has also worked as an elementary school teacher, particularly in the area of mathematics. She was an Associate Professor in the Department of Curriculum

and Instruction and was an affiliate faculty in Developmental Psychology and the Learning Technology Center at the University of Texas, Austin. Taylor collaborates extensively with partners in the College of Engineering, the Physics Department, and the Texas Advanced Computing Center at the University of Texas, Austin, in Computer Science and Learning Science at the University of Washington, and with the Regional Educational Laboratory Mid-Atlantic. She is currently an Associate Professor in the Department of Instructional Technology and Learning Sciences at Utah State University. Dr. Martin holds a Ph. D. in educational psychology from Stanford.

Brian Mustanski is Associate Professor of Medical Social Sciences and Psychology at Northwestern University and Director of the IMPACT LGBT Health and Development Research Program. The IMPACT Program has a mission to conduct translational research that improves the health of the LGBT community. Dr. Mustanski also has appointments in a number of centers, including the Institute for Policy Research and the Center for Community Health. A central focus of Dr. Mustanski's research has been on the relationships between mental, behavioral, and physical health, particularly as they relate to HIV/AIDS in vulnerable populations. Dr. Mustanski has been the Principal Investigator for multiple federal (NIH, CDC, NSF) and foundation research and training awards totaling over \$13 million in funding. The majority of his research focuses on the health and development of gay, lesbian, bisexual, and transgender (LGBT) youth and the application of new media and technology to sexual health promotion and HIV prevention. He is currently leading or co-leading three studies of online/text messaging based HIV prevention for adolescent men who have sex with men. Dr. Mustanski has received a number of awards for his work in this area, included being named a William T Grant Scholar and the 2011 recipient of the Award for Distinguished Scientific Contribution to LGBT Psychology from the American Psychological Association Division 44. He has published on ethical and regulatory issues in sexual health with adolescents and served on an IRB. Dr. Mustanski holds a Ph.D. in Clinical Science from Indiana University.

P. Pearl O'Rourke is Director of Human Research Affairs at Partners HealthCare Systems in Boston and an Associate Professor of Pediatrics at Harvard Medical School. Dr. O'Rourke is responsible for the systems that support the regulatory and ethical oversight of human research and human embryonic stem cell research. Her career began as a pediatric critical care physician at Children's Hospital, Boston and then Children's Hospital, University of Washington, Seattle as Director of the Pediatric Intensive Care Unit. Dr. O'Rourke did clinical research in extracorporeal membrane oxygenation (ECMO), liquid ventilation, high frequency ventilation and pediatric resuscitation. Following a Robert Wood Johnson Health Policy fellowship working for Senator Edward Kennedy, from 1997 to 2000 she was the Deputy Director of the Office of Science Policy in the Office of the Director at the NIH where she worked on issues such as privacy, gene therapy (transfer) embryonic stem cells, and genetic discrimination. Dr. O'Rourke has been actively involved with PRIM&R (Public Responsibility in Medicine and Research), as a Board member and past president of the Board. Dr. O'Rourke holds a M.D. from the University of Minnesota.

Sally I. Powers is professor of Psychology and Associate Dean of the College of Natural Sciences at the University of Massachusetts Amherst. Dr. Powers is Director of the Center for Research on Families, and a faculty member in the Neuroscience and Behavior interdisciplinary graduate program. The primary focus of her research is the study of biological and psychosocial risk factors (particularly endocrine

dysregulation, and early life and current social and behavioral stressors in family and close relationship contexts) that influence the longitudinal course of depression and anxiety in children, adolescents, and young adults. Dr. Powers research has been funded by NSF, NIMH, NICHD, and the William T. Grant Foundation, and is currently funded by NCI and NIGMS. She has previously served as a member of the IOM and NRC's *Committee on the Science of Family Research* and facilitator of the IOM and NRC's Planning Meeting on *The Science of Family Research: The Improvement of Family Measurement in Large Scale Studies*. Prior to joining the faculty at UMass Amherst, Dr. Powers served as Senior Research Associate at the Murray Research Center (now the Radcliffe Institute of Advanced Studies, Harvard University) and Director of Family Research, Laboratory of Developmental Psychology and Developmental Psychopathology, McLean Hospital and Harvard Medical School. Dr. Powers holds an Ed.D in Human Development and Psychology from Harvard.

Jeffery Rodamar is Protection of Human Subjects Coordinator with the US Department of Education. Prior to his current post, Mr. Rodamar worked in program evaluation with the Department's Planning and Evaluation Service. He has also served as senior legislative assistant for education and labor issues for a member of Congress on the Education and Labor Committee, has taught at the college level, and worked in survey research and data analysis. Mr. Rodamar is an ex-officio member of the Secretary's Advisory Committee on Human Research Protections (SACHRP), participates in the interagency Confidentiality and Data Access Committee (CDAC), was selected as a member of the American Statistical Association's Committee on Privacy and Confidentiality, and is Chair of the Social and Behavioral Research Working Group of the interagency Human Subjects Research Interest Group. He is also a board member of the *Journal of Empirical Research on Human Research Ethics (JERHRE)*. Mr. Rodamar is an ABD in political science at the University of Michigan.

Laura Stark is Assistant Professor at Vanderbilt University's Center for Medicine, Health, and Society, and affiliate of the Department of History and Center for Biomedical Ethics and Society. Dr. Stark is also Associate Editor of the journal *History & Theory*. Stark is the author of *Behind Closed Doors: IRBs and the Making of Ethical Research*, an ethnography and new history of Institutional Review Boards published in 2012 by University of Chicago Press. She is author of several book chapters on human-subjects regulation, as well as historical and contemporary studies of ethics decision-making published in journals such as *Cambridge Quarterly of Healthcare Ethics*, *Law and Society Review*, and *Journal of the History of the Behavioral Science*. Dr. Stark's current research explores research settings through the lives of "normal control" research subjects enrolled in the first clinical trials at the US National Institutes of Health after World War II. Dr. Stark holds a Ph.D. in sociology from Princeton University.

