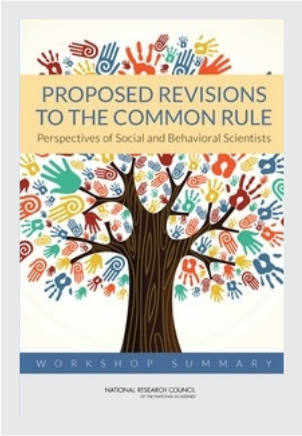

Proposed Revisions to the Common Rule: Perspectives of Social and Behavioral Scientists: Workshop Summary

DETAILS

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PROPOSED REVISIONS TO THE COMMON RULE

Perspectives of Social and Behavioral Scientists

WORKSHOP SUMMARY

Robert Pool, *Rapporteur*

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

Board on Behavioral, Cognitive, and Sensory Sciences

Division of Behavioral and Social Sciences and Education

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Acknowledgments

This workshop summary has been prepared by the workshop rapporteur as a factual summary of what occurred at the workshop. The committee's role was limited to planning and convening the workshop. The views contained in the report are those of individual workshop participants and do not necessarily represent the views of all workshop participants, the committee, or the National Research Council (NRC).

The workshop summary has been reviewed in draft form by individuals chosen for their diverse perspectives and technical expertise, in accordance with procedures approved by the Report Review Committee of the NRC. The purpose of this independent review is to provide candid and critical comments that will assist the institution in making its published report as sound as possible and to ensure that the report meets institutional standards for objectivity, evidence, and responsiveness to the charge. The review comments and draft manuscript remain confidential to protect the integrity of the process. We thank the following individuals for their review of this report: Nancy Adler, Departments of Psychiatry and Pediatrics, University of California, San Francisco; Wylie Burke, Department of Bioethics and Humanities, University of Washington; Susan Fiske, Department of Psychology, Princeton University; Richard Lempert, Eric Stein Distinguished University Professor of Law and Sociology (*Emeritus*), University of Michigan, Ann Arbor; Julia Milton, Public Affairs, Consortium of Social Science Associations, Washington, DC; Vimla L. Patel, Center for Cognitive Studies in Medicine and Public Health, The New

York Academy of Medicine; and Gerald S. Schatz, Pellegrino Center for Clinical Bioethics, Georgetown University Medical Center.

Although the reviewers listed above provided many constructive comments and suggestions, they were not asked to endorse the content of the report nor did they see the final draft of the report before its release. The review of this report was overseen by Matthew Rizzo, review coordinator, and Larry Brown, review monitor. Appointed by the NRC, they were responsible for making certain that an independent examination of this report was carried out in accordance with institutional procedures and that all review comments were carefully considered. Responsibility for the final content of this report rests entirely with the author and the institution.

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Contents

Introduction

On July 26, 2011, the U.S. Department of Health and Human Services issued an advance notice of proposed rulemaking (ANPRM) with the purpose of soliciting comments on how current regulations for protecting research participants under Title 45, Part 46 in the Code of Federal Regulations ("the Common Rule") could be modernized and revised. The rationale for revising the regulations was as follows:

> This ANPRM seeks comment on how to better protect human subjects who are involved in research, while facilitating valuable research and reducing burden, delay, and ambiguity for investigators. The current regulations governing human subjects research were developed years ago when research was predominantly conducted at universities, colleges, and medical institutions, and each study generally took place at only a single site. Although the regulations have been amended over the years, they have not kept pace with the evolving human research enterprise, the proliferation of multisite clinical trials and observational studies, the expansion of health services research, research in the social and behavioral sciences, and research involving databases, the Internet, and biological specimen repositories, and the use of advanced technologies, such as genomics. (U.S. Department of Health and Human Services, 2011, p. 44512)

More than 1,000 commentaries were submitted in response to the ANPRM (see http://www.regulations.gov/#!docketDetail;D=HHS-OPHS-2011-0005 [June 2013]). While revisions to the regulations were still under consideration, a workshop was held in Washington, DC, in March 2013 to explore the implications of the proposed revisions and alternative

approaches for protecting human participants while at the same time advancing the behavioral, social, educational, and economic sciences.[1] The workshop was planned and organized by a committee gathered by the Board on Behavioral, Cognitive, and Sensory Sciences of the National Research Council's (NRC's) Division of Behavioral and Social Sciences and Education. Eighteen presenters, mainly from academia but also from industry, government agencies, and professional societies, provided their insights into various aspects of the topic.

The workshop presenters focused on six broad topic areas (see agenda in Appendix A):

1. Evidence on the functioning of the Common Rule and of institutional review boards (IRBs), to provide context for the proposed revisions.
2. The types and levels of risks and harms encountered in social and behavioral sciences, and issues related to the severity and probability of harm, because the ANPRM asks for input on calibration of levels of review to levels of risk.
3. The consent process and special populations, because new rules have been proposed to improve informed consent (e.g., standard consent form, consent for future uses of biospecimens, and re-consenting for further use of existing research data).
4. Issues related to the protection of research participants in studies that involve use of existing data and data sharing, because the ANPRM proposed applying standards for protecting the privacy of healthcare data to research data.
5. Multidisciplinary and multisite studies, because the ANPRM proposed a revision to the regulations that would allow multisite studies to be covered by a single IRB.
6. The purview and roles of IRBs, because the ANPRM included possible revisions to categories of research that could entail changes in IRB oversight.

These topic areas were selected at a workshop planning meeting held in January 2013. The committee developed an extensive list of experts from a range of social and behavioral science disciplines and methods, including anthropology, economics, education, healthcare services, psychology, and sociology, who could address the topic areas. The final selection of speakers for each topic area was based on the experts' availability. Each speaker was asked to address the three objectives for the workshop:

[1]For convenience, this report uses the phrase "social and behavioral sciences" to refer to these disciplines.

1. 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.
2. 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.
3. To identify topics for research emerging from the proposed rulemaking that might 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 and researchers.

This report is a summary of the presentations and discussions that took place at the two-day workshop and does not offer additional comment, interpretation, or analysis. During discussion periods, speakers, committee members, and audience members commented on the presentations, and some of their comments are included in this summary. Although the perspectives of a broad range of behavioral and social scientists were provided at the workshop, some topics may not have been covered in sufficient depth. Among these are privacy issues and disclosure risks presented by advances in technology, such as data mining and tracking of individuals. The workshop also did not cover the full body of evidence on the functioning of the Common Rule and IRBs, particularly questions related to the evidence for over-regulation or under-regulation of human participants in social and behavioral sciences research. However, the workshop did provide the basis for additional study of these issues and topics by the committee.

REFERENCE

U.S. Department of Health and Human Services. (2011). Human subjects research protections: Enhancing protections for research subjects and reducing burden, delay, and ambiguity for investigators. Advance notice of proposed rulemaking. *Federal Register* 76(143):44512–44531. Available: http://www.gpo.gov/fdsys/pkg/FR-2011-07-26/pdf/2011-18792.pdf [June 2013].

Session 1

Review of the Evidence

The workshop began with two presentations designed to provide background to the issues and to situate them in the context of prior evidence. The first presentation offered an overview of previous reports published by the National Academies on the general topics of data access and human research protection; the second discussed what is known about the functioning of institutional review boards (IRBs), particularly those involved with the social and behavioral sciences.

PREVIOUS REPORTS BY THE NATIONAL ACADEMIES

Connie Citro, director of the National Research Council's (NRC's) Committee on National Statistics, offered an overview of reports published by the NRC and the Institute of Medicine (IOM) that addresses the general topic of human subjects protection. The NRC and IOM have a long history of attention to this subject, she said, and a major focus of this attention has been the area of privacy, confidentiality, and data access, which is important in social and behavioral research.

One of the earliest studies discussed (National Research Council, 1979) pertained to public opinion about privacy and confidentiality protection and how it influences individuals' responses to government surveys. Six years later, *Sharing Research Data* (National Research Council, 1985) addressed the ethical problem of researchers keeping their data to themselves and called for a new approach that emphasized sharing research data. That creates a tension, Citro noted, because "if you share

research data, what happens to confidentiality?" Numerous subsequent reports have presented ways to address that tension and find the proper balance between protecting the confidentiality of the individuals involved in studies and providing access to the studies' data, which is critical to advancing scientific research. Box S1-1 lists the NRC and IOM reports on the general topic of privacy, confidentiality, and data access.

The 2005 NRC report, *Expanding Access to Research Data: Reconciling Risks and Opportunities*, is particularly germane, Citro said. It lays out a justification for why research access to rich data is so essential for a healthy social, behavioral, and economic research enterprise. Another report, *Putting People on the Map: Protecting Confidentiality with Linked Social-Spatial Data*, discusses the challenges posed to confidentiality by data that include details about geographic location, in addition to the usual factors, such as age, sex, occupation, and health (National Research Council, 2007). Another major report that grapples with the issues of confidentiality and access to data is *Beyond the HIPAA Privacy Rule: Enhancing Privacy, Improving Health Through Research* (Institute of Medicine, 2009).

More challenges to confidentiality are likely in the future, Citro said.

BOX S1-1
National Research Council and Institute of Medicine Reports on Privacy, Confidentiality, and Data Access

1979 *Privacy and Confidentiality as Factors in Survey Response*
1985 *Sharing Research Data*
1993 *Private Lives and Public Policies: Confidentiality and Accessibility of Government Statistics*
2000 *Protecting Data Privacy in Health Services Research*
2000 *Improving Access to and Confidentiality of Research Data: Report of a Workshop*
2005 *Expanding Access to Research Data: Reconciling Risks and Opportunities*
2006 *Effect of the HIPAA Privacy Rule on Health Research: Proceedings of a Workshop*
2007 *Engaging Privacy and Technology in a Digital Age*
2007 *Putting People on the Map: Protecting Confidentiality with Linked Social-Spatial Data*
2009 *Beyond the HIPAA Privacy Rule: Enhancing Privacy, Improving Health Through Research*
2010 *Conducting Biosocial Surveys: Collecting, Storing, Accessing, and Protecting Biospecimens and Biodata*

SOURCE: Citro presentation at Workshop on Proposed Revisions to the Common Rule in Relation to the Behavioral and Social Sciences, Washington, DC, March 21, 2013.

"Big data," the term used to refer to the enormous amounts of data from the Internet and other sources that are threatening to overwhelm current capabilities for analysis, may pose one such challenge. There are already hints of the sorts of capabilities that big data will usher in, such as recent reports of use of the online social networking service Twitter to predict weekly unemployment claims. "What do data confidentiality and access mean in that context?" Citro asked.

The NRC and IOM have also done two systemwide studies on protection of human research participants, she noted *Responsible Research: A Systems Approach to Protecting Research Participants* (Institute of Medicine, 2002) and *Protecting Participants and Facilitating Social and Behavioral Sciences Research* (National Research Council, 2003). The former was focused mainly on biomedical research, while the latter dealt with the social and behavioral sciences.

A 2010 NRC report, *Conducting Biosocial Surveys: Collecting, Storing, Accessing, and Protecting Biospecimens and Biodata*, looked at the issues raised when biospecimens are included in social science surveys, Citro noted. Not only does this pose various challenges for social scientists related to the collection, storing, and accessing of the biological samples, it also adds a layer of complexity to the privacy and confidentiality issues. Finally, there have been several reports concerning studies of three special populations: children, students, and prisoners.

Big-Picture Lessons

Looking across these studies, Citro said, one can discern a number of big-picture lessons. The first is that human subjects protection is an extremely complex topic. It involves three different areas, each quite complex by itself: the biological and psychological characteristics of humans; the physical, social, economic, and technological environment; and the scientific research enterprise, with its research methods, ethical principles, and management structures. Furthermore, these three areas—the human, the environmental, and the research aspects—are constantly evolving, as is our knowledge of them, which means that human subjects protection must also constantly evolve. Citro also noted that mandating a one-size-fits-all approach is likely to have unintended consequences and might actually do harm, either to the research or the participants. The reports also point to the idea that there is often no need to reinvent the wheel, and that available models should be used. "Aristotle's 'Golden Mean' is very applicable," she added, "although it's actually hard to implement in a regulatory environment." The social and behavioral sciences, she concluded, "need to be continually vigilant and proactive to achieve useful improvements in regulations."

The Changing Environment Related to Data Access and Confidentiality Protection

To understand the evolving challenges related to data access and confidentiality, Citro said, it helps to consider how information technology has changed over the past 50 years. In the 1960s, relatively little information was available in digital form. Most was on paper, such as printed census reports, and digital information was not particularly easy to manipulate. Programming a computer, for example, required the use of a stack of paper punch cards. "So there were less data available, and that actually made it easier to protect," she said.

In the 1970s and 1980s, the growing power of computers, and the development of personal computers, led to richer datasets and a greater ability to analyze the data, but it also made the data harder to protect. "It was in this era that the government started to get agitated about [privacy and confidentiality]," Citro noted. This concern led to the 1974 Privacy Act and a great deal of discussion about the best ways to protect the privacy of human research subjects and the confidentiality of their data.

By the mid-1990s, the widespread use of the Internet "ballooned the availability of data," she explained, and made it much harder to protect the confidentiality of individuals. Since then, the availability of biosocial data, geospatial data, linked survey data, and administrative data has increased even more.

With the increasing threats to confidentiality, particularly those posed by the Internet, Citro explained, many data providers, such as statistical agencies, began tightening the rules on access. But with pressure from a variety of sources, the data providers and academia developed new ways and means of access. For example, Citro noted, there are now statistical techniques for synthesizing public-use microdata so that the probability of individuals being identified is very low. There are also a number of research data centers around the country where researchers can work with data onsite. The data are more easily protected because they never leave the center. Another approach has been to license individual researchers, allowing them to work with confidential data as long as they agree to certain strict rules about protecting confidentiality. Researchers increasingly are also using remote monitored access, where they work online with data that are maintained behind a firewall at the agency in which they are housed. Much of the work in developing these new forms of access has been done by federal statistical agencies, but a number of nonprofit data archives have also become involved, such as the Inter-university Consortium for Political and Social Research, headquartered at the University of Michigan, Ann Arbor, and NORC at the University of Chicago.

Implications for IRBs

Based on this overview, Citro offered a number of implications for proposals for revising the Common Rule.

HIPAA

First, she said, although IRBs definitely need better guidance about appropriate levels and methods of confidentiality protection, the approach taken in the Health Insurance Portability and Accountability Act (HIPAA), which has been proposed in the advance notice of proposed rulemaking (ANPRM), is not the right direction to follow. According to IOM reports and other researchers active in this area, HIPAA is outmoded even within its own domain of protecting administrative health records. It overprotects in many ways, Citro suggested, for example by not permitting geographic identification below a state level. It underprotects in other ways, for example, potential re-identification for many rich social and behavioral datasets.

For an alternative to the HIPAA approach, Citro pointed in particular to the recommendations of the 2003 report *Protecting Participants and Facilitating Social and Behavioral Sciences Research* and of the 2005 report *Expanding Access to Research Data: Reconciling Risks and Opportunities*. Both recommended exempting secondary research that uses data from established organizations whose confidentiality protection is known and can be certified to be state of the art. Some IRBs, she noted, already do have lists of organizations that can be trusted to maintain the confidentiality of data, but this approach is not yet part of the national Common Rule.

Risks and Harms

The NRC and IOM reports also address possible risks and harms in social and behavioral research. A number of reports have concluded that IRBs do not have sufficient evidence of the risks that participants actually face from participating in surveys and other kinds of research in these fields. *Protecting Participants* (National Research Council, 2003) recommends that researchers debrief the participants in their studies to learn more about what these participants understand and believe about the risks of participation. Reports have also recommended that the Office for Human Research Protections (OHRP) and other agencies fund research aimed at exploring both perceived risks and actual harms. The goal, Citro said, is to have evidence-based guidance on risk so they can "hit the Golden Mean between over- and underprotection."

Informed Consent

Even though consent forms have been revised regularly over the years, Citro said, some observers have suggested that the changes often have not improved matters and have taken up valuable time that IRBs could have devoted to other tasks. Another critique is that in many cases obtaining written informed consent is not necessary and, moreover, that insistence on written consent may be excessive and counterproductive, because it discourages participation.

The ANPRM includes proposals on obtaining re-consent (new consent for new uses of previously collected data). In Citro's opinion, the proposed new rule is not clear. "If people have already consented for research, it certainly doesn't help research, and it doesn't benefit the participants unless that original consent was very limited and specific."

However, she said, getting consent for administrative records in research is another matter. The 2003 report urged that those collecting the data should attempt to get consent from individuals for the use of their data for research purposes at the time the data are collected.

On the issue of exactly what consent forms should look like, Citro said that the typical advice has been to supply guidance instead of hard-and-fast rules. *Protecting Participants* (National Research Council, 2003) calls for agencies to supply detailed examples of consent guidance, which can help IRBs avoid both over- and underprotection. "The problem here," she continued, "is that regulatory bodies, including their legal counsel, are often uncomfortable with ambiguity. They want something clear-cut."

One problem facing those who attempt to improve the performance of IRBs is that there is little evidence on how they really function. Thus, *Protecting Participants* (National Research Council, 2003) called on OHRP to request yearly information from IRBs on their operating procedures and outcomes, including such things as the percentages of studies that are exempted, given expedited review, or subjected to a full review. A further recommendation was that federal agencies should fund in-depth research into the functioning of IRBs that could be used in the development of performance guidelines.

The 2003 report also offered a useful framework for thinking about IRBs, Citro said. It likened their reviews of research protocols to manufacturing production processes. In carrying out such processes, she said, one goal is to allow for appropriate variation while at the same time minimizing the extremes. Thinking of IRBs in these terms might help the workshop participants frame their discussions, she suggested.

Challenges for Social, Behavioral, and Educational Researchers

Citro concluded by discussing a number of challenges facing

researchers in the social and behavioral sciences. This family of disciplines has often seemed to be a stepchild in the context of human subjects protection because the focus has been on the protection of human subjects in biomedical research. In 1974, when the Department of Health, Education, and Welfare released regulations that were the precursor to the Common Rule, and again in 1979, when the proposed revisions to those regulations were released, the social and behavioral research community reacted vigorously, she explained. Many researchers saw the regulations as focused almost exclusively on the concerns of the biomedical research community and worried that they would make it much more difficult to carry out social and behavioral studies—yet without improving the protection of research subjects in those fields. Some of the responses were extreme, Citro noted—some researchers suggested that social and behavioral studies did not require any oversight—but the response did lead to the creation of categories for exempt and expedited research, even if some IRBs have been slow to use those categories. The social and behavioral community also succeeded in having a number of types of studies added to those categories in a 1998 revision of the Common Rule.

Some of the IRB-related problems facing researchers in social and behavioral fields can be traced to major issues with biomedical research, including the deaths of some participants in the late 1990s, which led to the establishment of the OHRP and strengthening of protections for human research subjects. These developments led to tightened scrutiny by IRBs, which in turn led social and behavioral researchers to become even more frustrated with what they perceived as a one-size-fits-all approach to human subjects protection, Citro explained. After the 2002 IOM report, *Responsible Research: A Systems Approach to Protecting Research Participants*, which focused on biomedical issues, the NRC produced *Protecting Participants and Facilitating Social and Behavioral Sciences Research* in 2003 so that social and behavioral issues would not get overlooked.

In Citro's opinion, the ANPRM is well intentioned with regard to social and behavioral research and offers some good ideas, but is not completely adequate. "An important lack," she said, "is that it does not reflect the hard-won knowledge we have gained in such areas as the continuing balancing act on confidentiality protection and data access, the need for guidelines for informed consent, and, in general, the role that detailed, evidence-based guidance and guidelines and effective training . . . could play instead of hard rules." Hard rules, she added, can "both underprotect and overprotect."

In conclusion, Citro observed that, "based on past experience this workshop cannot be the be-all and the end-all. You can't just have a good discussion and go away, satisfied that everything is okay. You're going to need to work hard to push and continually be vigilant in trying to

improve the Common Rule and the IRB implementation to appropriately protect participants and facilitate research."

IRBs: THE EVIDENCE

The next presenter was Jeffery Rodamar, of the Department of Education, who noted that the views presented in his talk were his own and did not necessarily reflect the official position of the department. He explained that his perspective on IRBs has been shaped by a variety of experiences throughout his career. He has been a regulator working daily with other regulators, researchers, IRBs, program staff, and study subjects; has had experience working with other agencies and dealing with interagency issues; and has been a legislative staffer for a committee dealing with education and labor issues. He has also been a social and behavioral researcher, a consumer of research, an advocate of evidence-based practice, and a long-time critic of IRBs and regulations that needlessly hinder rigorous research.

Rodamar began by listing a number of common complaints about IRBs, including that they take too long and that the delays harm studies; that they cost too much; that reviews are often flawed; and that they undermine research with burdensome requirements. Indeed, there are many strong opinions about the IRB system, Rodamar said, but unfortunately there is relatively little hard evidence about how well IRBs function and what researchers' experiences with them are really like.

Data on IRB Performance

To illustrate, Rodamar listed a number of the common criticisms about IRBs and analyzed the evidence supporting them. For example, a study by the Federal Demonstration Partnership (Decker et al., 2007; Rockwell, 2009) on the burden created by IRBs reported that principal investigators on federal grants estimated that they spent about 42 percent of their time on "administrative burden" and that of the 24 administrative tasks in the survey, researchers reported that IRB-related tasks account for the largest burden. While the study, which had 6,295 respondents, may look convincing, there are a number of reasons for caution, Rodamar said. There was only a 26 percent response rate, for example, so the results may have been skewed, with researchers unhappy with IRBs being more likely to respond. The burden score for IRBs was quite similar to the scores for other common administrative tasks, such as applying for grants and hiring and training staff. Thus, Rodamar explained, the IRB burden does not seem to be significantly different from that of many other tasks that

scientists take for granted as part of the process of carrying out funded research.

There are several studies of the costs to an institution of operating an IRB,[1] Rodamar said, although there are not many on how much IRB review costs a researcher. A 2003 study of a hypothetical cancer research project found that institutions reported that about 1.4 percent of the total time to conduct a study funded by the National Institutes of Health (NIH) would be spent on all of the activities—including IRB review—that took place prior to actually beginning the research (Emanuel et al., 2003). The figure for a similar study funded by the pharmaceutical industry (Emanuel et al., 2003) showed that about 2.9 percent of the total study time was devoted to activities that took place prior to research. The percentage of total costs devoted to activities that took place before the start of research was in line with these figures.

To explore how long it takes to get IRB approval, Rodamar combined data from two studies, one done by the Association for the Accreditation of Human Research Protection Programs (AAHRPP) (2011) and one performed by IRBNet (2011). He concluded that for an expedited review it takes an average of 14.8 days to have a protocol reviewed and an average of 27.6 days to gain approval. For a full review, it takes an average of 23.3 days for the review to be carried out and 48.1 days to gain approval. Because IRBs typically meet every 30 days, he observed, those times seem relatively prompt.

Rodamar noted, however, that there are reports of studies that have taken many months or even years to be approved. These delays might be caused by the IRBs, he observed, or by the researchers applying for approval; better data are needed to explain such delays. There are very few studies that are not eventually approved by their IRBs. AAHRPP data for 2011 showed that 60 percent of IRBs had not rejected a single study and that about another 20 percent had rejected only one study.

A variety of factors influence the length of time it takes an IRB to review a proposal, Rodamar explained. One factor is the complexity of the proposal. For instance, the University of Nebraska reported that in 2008 the average length of time to approve simpler protocols was 18 to 24 days, while the more complex protocols took an average of 63 days (University of Nebraska–Lincoln, 2013). IRBNet reports that roughly a third of the time required for IRB approvals is accounted for by researchers'

[1]Several studies have been conducted of the cost to a university or other entity of operating an IRB. For example, Jeremy Sugarman and colleagues (2005) published a survey of 121 U.S. medical schools (63 responded) that showed that those academic centers spent an average of $750,000 (ranging from $400,000 to $1.15 million). The range of costs was $400 per study review at high-volume medical centers to $600 at low-volume centers: see also Wagner et al. (2010).

omissions and errors in providing information needed for review and responding to IRB comments, he noted (IRBNet, 2011). He noted that case studies indicate that relatively small changes in IRB operations, and in training and support for researchers, can result in substantial reductions in the time required to receive IRB approval (Rosenberg, 2011; University of Nebraska–Lincoln, 2013).

Researchers' Attitudes Toward IRBs

Rodamar also discussed the attitudes of social and behavioral researchers toward IRBs. He noted that there is a widespread impression that researchers in these fields see IRBs as more a hindrance than a help, but he noted that studies of the issue do not support this perception. One study asked researchers to rate their own IRBs versus an ideal IRB on a variety of elements, such as "timely review" and "competency in distinguishing exempt from nonexempt research," using a seven-point scale. The gap between ratings for real and ideal IRBs was not particularly large, Rodamar noted, always less than one point. A 2012 survey found that the attitudes of social and behavioral researchers towards IRBs were not significantly different from the attitudes of biomedical researchers (DeVries et al., 2006; Pennell and Lepkowski, 2010).

Rodamar also explored the perception that social and behavioral research is closely regulated despite the fact that most of it poses little risk to the participants. To the contrary, he said, most such research does not require IRB review under the Common Rule for one or more of the following reasons: (1) it is not "human subjects research" as defined by the regulation, (2) it is not funded by a covered source, or (3) it falls under one or more of the exemptions. For example, Rodamar said, in 2009, review by the full IRB was required for only about 4 percent of social and behavioral studies conducted at the University of Michigan (Kim, 2009). Of the social and behavioral studies submitted to the University of Michigan IRB, 35 percent were deemed to be exempt, and another 61 percent were given expedited review.

Rodamar next discussed data on enforcement, noting that, "we hear a lot about how burdensome the feds are." A review of new compliance oversight cases initiated by OHRP between 1990 and 2011 (Borror, 2012) shows that the highest number of new cases in any one year was 91. From 2008 to the most recent year for which data are available, they never exceeded eight per year. These data cover thousands of studies in the United States and many more outside the United States, Rodamar noted. Most cases are handled through phone calls, e-mails, and letters, and most investigations center on informed consent forms, IRB meeting minutes, and other procedural issues, he added.

Perhaps because of this focus on procedural issues, little is actually known about the effectiveness of IRBs in protecting research subjects, Rodamar said. While there are few reports of problems, it is not clear whether this is because there are no problems or because the problems simply do not get reported, he noted, adding that in this area also, better data are needed.

Risks Posed by Social and Behavioral Research

As an example of the sorts of SBE research that can lead to serious harms to the participants, Rodamar mentioned the work of a sociology graduate student at the University of Chicago who studied people living in Chicago public housing (Venkatesh, 2008). Venkatesh learned how much various individuals were earning from such illegal activities as selling drugs, prostitution, and stealing cars. "In the course of his study, he disclosed some of this information to the people in the gangs," Rodamar said. "Soon you had people who provided the information being seriously beat up, and various other harms coming to them." In another example, Rodamar noted, Fulbright scholar Alexander van Schaick was asked by a U.S. embassy official to provide information on any Venezuelan or Cuban doctors or field workers that he encountered during his studies in Bolivia (Zwerling, 2011). The information requested included names, addresses, and activities. Sharing this sort of information could have put the foreign workers—or van Schaick—at risk, Rodamar said. Thus, he added, while much social and behavioral research poses minimal risks for participants, there are reasons for caution.

Rodamar also noted that the threat to the confidentiality of individuals included in large datasets is real. One study has found, for example, that using just three facts—birth date, sex, and five-digit zip code—it is possible to identify 87 percent of the U.S. population (Sweeney, 2000). Educational datasets offer particular challenges, he added, because "education research often involves small samples, with longitudinal data, of students in classrooms in schools that may be linkable to external data sources to re-identify subjects." Perhaps even more worrisome are two recent articles in *Science,* Rodamar observed, which reported that researchers were able to figure out the identities of DNA donors (Bohannon, 2013; Gymrek et al., 2013). There are a rapidly growing number of linkable datasets that can be used to re-identify genetic and other data, Rodamar noted.

These risks are important to many people, Rodamar said. Studies have shown that people are less willing to participate in studies when they are told about the risks to confidentiality (Singer, 2011). People also worry that details about their behaviors—including online behaviors—might be made available to various entities without their consent.

Over time, the response rates to surveys in the United States have been dropping steadily. "Clearly this is not all happening due to IRBs, but we have to worry about the impacts that IRBs can have in amplifying things that are going on anyway," Rodamar noted. On the other hand, he added, IRBs can play a positive role by, for example, lending credibility to studies in the eyes of the potential participants, which can benefit study recruitment, and also by helping to avoid problems with studies that can lead to greater mistrust and increased regulation of research.

Rodamar concluded with the observation that while the Common Rule is not perfect, it is arguably a notable success story. Since its adoption a quarter of a century ago, the quantity and quality of research have continued to increase and there have been few reports of serious problems or unethical research in the United States. There do remain some concerns about IRBs. Some worry that they are too influential in setting the research agenda, for example, or that they have created a certain amount of self-censorship among scientists. It has also been suggested that IRBs favor more traditional approaches over studies that introduce new research methods or that challenge existing paradigms.

To resolve uncertainties over the roles that IRBs play, Rodamar said, it will be important to collect evidence on their functioning and effects, with the ultimate goal of making decisions about them based on systematic evidence rather than on anecdotes and small-scale studies. There is movement toward monitoring the effects of regulations and on creating and modifying regulations based on evidence, he said, and it is "a wave we can ride" (Greenstone, 2009; Executive Office of the President, 2012).

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Session 2

Risks and Harms

Celia Fisher, of Fordham University, introduced the session on risks and harms. The advance notice of proposed rulemaking (ANPRM) has stimulated a dialogue on the appropriateness of the current review and evaluation of social and behavioral research. Questions under discussion, Fisher explained, include whether the current federal regulations are biased toward biomedical research and whether "some IRBs may be overestimating the magnitude and probability of reasonably foreseeable risks in [social and behavioral] research." Fisher added that because there is little evidence that certain types of social and behavioral research, such as surveys and interviews, carry significant risks, there are concerns that these disciplines may be over-regulated and that this over-regulation may mean that actual harms in other areas are being overlooked.

Another issue raised by the ANPRM is which types of research should be eligible for expedited review. In general, the only studies that can be given expedited review by an institutional review board (IRB) are those that include only research activities that pose minimal risk. When an IRB is considering whether to grant expedited review, it consults a limited list provided on the Office for Human Research Protections (OHRP) website.[1] The ANPRM proposes expanding the list of studies that can receive expedited review. It is important, Fisher said, that an expanded list include examples of the types of studies that might be eligible for expedited

[1]See definition of minimal risk and categories of expedited review at http://www.hhs.gov/ohrp/policy/expedited98.html [June 2013].

review. She also stressed the importance of ensuring that an expanded list include age-graded examples, because the Common Rule minimal risk definition and expedited category list govern IRB interpretation of the conditions under which child and adolescent research can be expedited (Fisher et al., 2013). Fisher noted that no list can adequately cover all the variations in research procedures that meet minimal risk criteria, so the expanded category list could explicitly state that IRBs would consider as posing minimal risk any procedures not specifically listed in the expedited categories, but whose risk can be determined to be equivalent or less than that of the examples (Fisher et al., 2007).

A related issue is that the ANPRM calls for separating out the issues of informational risk from minimal risk evaluations. Fisher noted that it is important to evaluate the pros and cons of this approach for social and behavioral research. For example, the ANPRM recommends that the Health Insurance Portability and Accountability Act (HIPAA) Security Rule, designed to protect patient health information, be used as a standard for collection and storage of research data. In Fisher's view, the HIPAA criteria for de-identification and processes permitting access to data for patients and their guardians is an inappropriate and potentially prohibitive standard for social and behavioral studies. In addition, data security criteria could be empirically supported by relevant research to ensure adequate participant protections and to guard against overly burdensome security protections for low-probability and low-magnitude information risks that could discourage research.

Finally, the issue of exempt research is of major importance to social and behavioral researchers. There are now six categories of studies that are exempt from IRB review. The categories are not clearly defined, Fisher said, and one of the difficulties that social and behavioral scientists, in particular, face is that it can be very difficult to understand exactly what is meant by such terms as "educational tests," "survey procedures," and "observation of public behavior." An expanded list of exempt categories needs to include examples that facilitate IRB and investigator evaluation of research that meets the requirements of the exempt category.

There is an interplay between exempt research and informational risk that will change if the proposals in the ANPRM are adopted, Fisher noted. Under the current rules, any studies in which the participants can be identified are not included in the exempt category if the disclosure can create some sort of informational risk. The proposed changes would separate the issue of informational risk from IRB review. Although every study would still have to follow the guidelines for data security protection, studies in which information risks were the only risks could be exempted from IRB reviews. The pros and cons of removing exempt and information risk decisions from the purview of IRBs require additional deliberation.

The session's four speakers were asked to explore aspects of risks and harms and, particularly, minimal risk. Richard Campbell provided an overview of the issue of minimal risk from the perspective of a researcher who studies racial and ethnic disparities in diagnosis and treatment of cancer using patient data and data on the distribution of health care providers. Brian Mustanski spoke about risks and harms in the context of studies of a special population—lesbian, gay, bisexual, and transgender (LGBT) youth. Steven Breckler discussed issues related to risk in psychology research. Charles Plott discussed whether some entire areas of social and behavioral research might be exempted from IRB review based on the topics they explore and the methods they employ. All four stressed the importance of using empirical data to support IRB risk assessments and to avoid over- or underestimations of research risk in the social and behavioral fields.

UNDERSTANDING MINIMAL RISK

Richard T. Campbell, of the University of Illinois at Chicago, began his overview of minimal risk with the general observation that although human subjects research is governed by a very specific set of federal regulations, the regulations are carried out "in the context of universities and other research organizations that are free to up the ante, as they wish, and IRBs which are free to interpret them within very broad limits." For example, he said, he recently served on an IRB with a colleague "who felt that he was free to interpret minimal risk as he wished." This situation is highly unusual, if not unique, for the operation of regulatory processes.

Minimal risk is important, Campbell said, because it provides the threshold for determining the level of review. It determines, in part, the types of research that are eligible for expedited review, and it also determines, at least implicitly, which research is exempted, or "excused," to use the terminology in the ANPRM.

Cognitive Complexity of the Term "Minimal Risk"

The natural place to begin in understanding minimal risk is with the definition provided in the Common Rule (45 CFR 46.102(i); 1991):

> 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.

A problem with this definition of minimal risk, in Campbell's view, is the fact that the term "minimal risk" is cognitively complex—that is, people must make some mental effort to comprehend it and use it appro-

priately. However, because the term is used repeatedly in the regulations, people tend to start thinking of it in simpler terms and ignore its complexities. For example, he said, it is easy to fall back into the assumption that both the magnitude of harm and the probability of it occurring could be minimal even though this is not what the definition says.

The term is complex for several reasons, Campbell said. First, he explained, probability is a "notoriously difficult concept that many people—even sophisticated academics—often do not fully understand or use consistently." Risk is an even more difficult concept, he added. In common usage it has at least three meanings. The formal definition that is used in epidemiology is the probability of a particular event occurring within some unit of time or period of exposure. Risk may also refer to a negative outcome, with or without reference to probability involved, as in the phrase "risky behaviors." Risk may also refer to general uncertainty, as in the idea of a "risky investment." In that case, the outcome might be good or bad, but the implication is that it will be bad. In discussions of minimal risk, Campbell said, any of these meanings may be implied by the speaker. Similarly, the members of IRBs often use the two terms interchangeably, leading to potential confusion.

Campbell suggested several ways that investigators and reviewers can respond to these difficulties. First, he said, it is important to keep clear the distinction between *risk* in the sense of the probability of harm, and the *magnitude* of potential harms. The goal for IRBs is to determine the worst harms that could result from participation in a study, he added, so it is important for them to ask whether there is some reasonable estimate of the probability of various possible harms. He also cited the importance of research to develop realistic probability estimates, and to study the perceptions that people have concerning the magnitude of various types of harms. It is important to know which aspects of a study the participants themselves are likely to see as most harmful or stressful, he noted.

Areas of Improvement for IRBs

Campbell discussed several issues he believes need further attention. One is how to better deal with surveys that include sensitive questions. In his experience, Campbell said, there are two main reasons that IRBs tend to be cautious about questions involving intimate behaviors, criminal activities, and the like. In such cases, reviewers worry about accidental disclosure and also about participants' psychological reactions to sensitive questions. Respondents should be told during the informed consent process that they have the right to not answer any question and that they can terminate the interview at will, he said.

Campbell also noted the distinction between absolute and relative

risk. The "daily life" standard, specifies that research participants should not be exposed to greater harm than they might expect to experience in their daily lives. The question, Campbell noted, is "whose lives are the standard?" Many populations frequently face much higher risks in their daily lives than most investigators are likely to face, he noted. "Should risk be evaluated relative to the "average person" or to the population being studied?" he asked.

Another important distinction is between voluntary and involuntary risks, Campbell said. People accept every day certain risks over which they have little or no control, such as exposure to an illness. Other risks are more voluntary—those assumed when one gets into a car and drives down the street, for instance. Similarly, study participants are asked to voluntarily accept some risks, usually with no benefit to themselves. "But," Campbell pointed out, "the daily life standard refers to risks that we accept with the expectation of some benefit." That makes the risks that study participants are being asked to accept of a different nature. "This is an ethical issue which I don't think has been thoroughly explored and could bear some discussion," Campbell observed.

Another distinction is between permanent and transitory harm. "An unstated aspect of the daily life standard is that we assume the presumed harms are of low magnitude and *short lasting*," he said. But it is possible to imagine permanent harm coming from participation in a study—a simple blood draw could lead to an infection with long-term consequences, for example. The probability of that may be extremely low, he noted, "but it is not zero. How does this fit with the daily life standard?"

There is also a difference between the probability of harm to a given person and the probability that at least one person in a study will be harmed. The larger a study is, the greater the chance of harm to at least one person, even if the probability of harm to any one person is small. "It is important to keep this distinction in mind if you want to think clearly about risk and harm," Campbell observed.

Campbell concluded with his thoughts about how the committee could help improve the current situation regarding minimal risk. "I suspect that it's unlikely that a new definition of minimal risk will appear," he said. "The concept is too deeply embedded in the fabric of human subjects regulations." However, the committee might elaborate on the concept in its report, he suggested, and with that prodding, perhaps the OHRP will issue official guidance that elaborates on the definition and suggests how it can be applied more consistently.

RISKS AND HARMS IN THE CONTEXT OF RESEARCH WITH LGBT YOUTH

Brian Mustanski, of Northwestern University Feinberg School of Medicine, discussed the types of risks and harms that may arise in research with LGBT youth.

The Benefits of Research on Risky Behaviors

Mustanski began by highlighting the benefits as well as the risks of research, noting some of the reasons there is a need for research on risky or sensitive behaviors among youth. Adolescent risk behaviors, such as substance use, conduct problems, and sexual risk-taking, are primary contributors to both direct and indirect causes of morbidity and mortality among young people in this country, he said, so studying them is an important part of addressing the health issues of adolescents (Blum, 2009; Feigelman and Gorman, 2010; Eaton et al., 2011).

Consider, he suggested, men who have sex with men. According to the Centers for Disease Control and Prevention (CDC), from 2007 to 2010 nearly 58 percent of all HIV infections in the United States occurred among men who had sex with men. Furthermore, Mustanski said, 13- to 24-year-old men who have sex with men are the only group in the country that is showing an increase in HIV infections, and they are close to being the highest-risk group in the United States. Thus, in his view, research on risky behaviors among males in this age group is critical for dealing with the ongoing HIV/AIDS epidemic.

Unfortunately, Mustanski said, there has been very little research into such behaviors. For example, the CDC has endorsed a collection of 74 evidence-based HIV-prevention programs. Of those, 17 are aimed at youth, but there is not a single such prevention program aimed at adolescent men who have sex with men, despite the fact that this is a high-risk group and the only group in the United States in which the rate of HIV infections is increasing (Centers for Disease Control and Prevention, 2012). In general, Mustanski explained, the funders of prevention programs require some evidence that a program will be effective before providing funds, and because there has been little research into the effectiveness of prevention programs among adolescent men who have sex with men, there are no prevention programs for this group.

Mustanski suggested that IRBs are partly responsible for the lack of research on this group. "I can say from my conversations with many researchers in the areas of adolescent health and HIV prevention," he observed, "that researchers shy away from doing research on adolescent [men who have sex with men] because of the belief or experience that they could not receive IRB approval to do that work." The IRBs'

hesitance to approve such studies, he said, is often motivated by "value-laden concepts" and general concerns about the psychological and other risks posed to the participants by such studies, rather than by any solid evidence about the effects that these studies—which generally ask the participants to answer questions—actually have on the participants.

The Risks of Research on Risky Behaviors

Despite these issues, quite a bit is known about the risks of social and behavioral research with these youths, Mustanski said. When the Society for Adolescent Medicine (SAM) reviewed literature on the topic, it concluded that there are three possible ways in which asking adolescents about risky behavior could itself pose risks (Santelli et al., 2003). First, asking adolescents about risky behavior could promote that same risky behavior—for example, asking questions about sexual behavior could lead adolescents to go and have sex. But, Mustanski said, the SAM review found no such relationship in the large body of research it reviewed. Another possible risk is that adolescents who answered questions about various sorts of risky behavior could see those answers made public in some way. The third possibility is that participants could have a negative psychological reaction to their participation. For instance, people who are asked questions about their drug use or about having sex with someone of the same sex could be stressed by being asked the question. These behaviors are often kept private and may, in some cases, be illegal, so being asked about them could be psychologically distressing.

Because of such concerns, Mustanski said, many IRBs have considered that these surveys pose greater than minimal risk, and they often encourage or require researchers to provide a statement to potential participants that includes such warnings as "Some of these issues could make you feel uneasy or embarrassed" or "You may be very upset by answering these questions" or even "You may need psychological services after answering these questions."

However, Mustanski said, there is evidence that the risks of such psychological stress are actually quite low, citing research on the participants in his own Project Q2 study, a long-running longitudinal study of LGBT youth, which asked questions about mental health problems, substance use, HIV, and sexual behavior. He asked the study participants how they felt about being in the study and what the psychological effects of being in the study were. In particular, he asked them how they felt answering questions about sexual behavior, drug and alcohol use, mental health, and suicide. The results, which were published in the *Archives of Sexual Behavior* in 2011, showed little stress to participants from answering such questions (Mustanski, 2011). "About 90 percent of the participants

said that they were comfortable or very comfortable answering questions about sexual behavior, drug use, and mental health," he noted.

Although there is relatively little literature on the subject, the few other studies that have asked participants how they felt about answering questions on sensitive topics have had similar findings, Mustanski said. One such study involved adult men who have sex with men who answered questions about their sexual behavior and substance use (Fendrich et al., 2007). A second examined adults participating in a mental health survey (Jacomb et al., 1999), and a third looked at adults in South Africa questioned about HIV and gender-based violence (Jewkes et al., 2012). Two others surveyed adolescents about drug use, suicidal behavior, and physical and sexual abuse (Langhinrichsen-Rohling et al., 2006) and youth about sexuality (Kuyper et al., 2012). Across these studies, Mustanski said, there is "consistent evidence of very low rates of people saying that they were very uncomfortable answering such questions."

Should Research on Risky Behaviors Be Considered Minimal Risk?

Mustanski posed the question of whether this evidence means that research on risky behaviors should no longer be considered "minimal risk" for the purpose of an IRB review, acknowledging that it is not an easy question to answer. When he asked the participants in one of his studies to compare their level of comfort answering survey questions with a typical visit to a doctor or counselor, 54 percent said it was more comfortable answering the survey questions, another 35 percent said it was about the same, and 11 percent said it was more uncomfortable answering the survey questions.

Mustanski suggested that it is not really clear what it means for research to pose more than minimal risk to participants. The regulations do not offer enough guidance even for cases about which there is more evidence than exists for risky behaviors. Indeed, it is not even clear whether being uncomfortable should be considered a risk in the first place, he added. Nevertheless, Mustanski said, questions about minimal risk are critically important because their answers can determine whether or not a particular study involving adolescents can even be carried out. For example, he said, his research with LGBT youth would not be possible without waivers of parental consent because many of these youth have not told their parents about their sexual orientation. Waivers of parental permission can only be issued when research risks are minimal or only a slight increase over minimal risk.

To illustrate how these issues can play out in practice, Mustanski described his experiences with IRB reviews for his Project Q2 study. Two IRBs were involved, one at the University of Illinois at Chicago, and one

at a community-based organization where the majority of work was being done. The community-based organization's IRB was composed of representatives from the LGBT community. He received approval from that IRB within a month, while it took six months and four rounds of review to gain approval from the university IRB. Most of the university board's questions centered on the risks of the study, and the board ultimately decided that the study posed only a slight increase over minimal risk. The IRB never specified what the risks were, but because it had found Mustanski's privacy and confidentiality protection plan to be adequate, it seems likely that their concerns centered on the potential of psychological harm to participants.

After receiving approval from the institutional IRB, Mustanski had to return to the community IRB to once again get its approval. "All in all," he said, "it took 10 months out of a 24-month grant to receive IRB approval."

Mustanski closed with a brief discussion of the benefits that participants reported from being included in the study. The Common Rule specifies that a basic element of informed consent is letting participants know of any benefits—to the participants or to others—that can reasonably be expected from the study, but "benefit" is not clearly defined. When the participants in his study were questioned about how they benefited from taking part, they said things like "It made me feel like I'm part of something important" and "It helped me to talk to somebody about my experiences" (see Table S2-1). However, Mustanski said, "We were not allowed to actually mention these benefits in our consent form because the IRB pushed back saying, 'Well, that's not a defined benefit, that's not a personal benefit.'" Mustanski observed that the participants in his study might disagree.

CALIBRATING RISK OF HARMS WITH LEVELS OF REVIEW

Steven Breckler, of the American Psychological Association, focused on the issues of calibrating level of review to the risk of harm and of defining and assessing minimal risk. He spoke first about the concept of risk. Noting that the title of the session was "Risks and Harms," he suggested that it made more sense to speak of the "risks *of* harms" because that phrasing points to the fact that there is a second, parallel issue to consider—benefits. Instead of focusing entirely on the risks of harm, he said, the goal would be to find the proper balance between the probability of harm on the one hand and the probability of benefit on the other. This idea of balance is particularly important in discussions of minimal risk, he said, "because the benefits of research participation often get set aside in our preoccupation with harm, and I think it harms us in the process by doing that."

TABLE S2-1 Benefits of Research Participation in Crew 450 Study

Benefit	Ages: 16–17 (n = 52)		Ages: 18–20 (n = 221)	
	Mean	SD	Mean	SD
It made me feel like part of something important.	1.6	0.7	1.8	0.8
It made me feel like I am helping my community.	1.8	0.7	1.7	0.8
It helped me to have someone to talk to about my experiences.	1.8	0.8	2.0	0.9
It made me feel like I am helping other young men like myself.	1.8	0.8	1.8	0.8
It gave me the opportunity to meet successful LGBT adults.	2.0	0.9	2.0	0.9
It helped to know people care about other young men like myself.	1.6	0.7	1.8	0.8
Answering the questions helped me reflect on who I am.	1.8	0.8	1.8	0.9
Participating in Crew 450 made me feel supported.	1.6	0.8	1.8	0.9
Participating in Crew 450 helped me to think about my behavior.	1.8	0.9	1.7	0.9

NOTES: Scale: 1 = strongly agree; 2 = agree; 3 = neutral; 4 = disagree; 5 = strongly disagree; SD = standard deviation.
SOURCE: Unpublished data, Mustanski (2013).

Breckler then turned to the issue of determining the appropriate level of review based on the risk of harm. "We must have a better delineation of research studies that qualify for expedited review and for those that would be considered exempt from review," he observed. In particular, he added, such delineations need to be based on evidence concerning what the risks of harm truly are.

Such evidence already exists for most of what happens in social and behavioral research, he said. Data are available on many foreseeable *sources* of harm: the methods and procedures used, the particular topics chosen, the features of the populations under study, and interactions among these factors. Data are also available on many foreseeable *types*

of harm: economic, physical, psychological, and social harm. "We can estimate the probability and magnitude of many of these reasonably foreseeable harms," he said. Furthermore, he added, in those cases where the data do not yet exist, it would be straightforward to obtain it. Thus, in his view, it makes sense to use those data to make decisions about which research studies would qualify for expedited review or be classified as exempt from review.

The ANPRM contains a proposal that the continuing review of expedited studies be eliminated. This is a change "that many of us desire," Breckler said. Exceptions could be made in certain circumstances, he said, but IRBs should treat the continuing review of expedited studies as an exception, not as the norm.

Another proposal in the ANPRM is to expand the list of studies to be considered exempt from review. Many researchers would agree that such an expansion is a good idea, Breckler said, but the determination of which studies are exempt should not be made purely on the basis of the methodologies being used because a methodology by itself does not provide a sufficient basis on which to judge the risk of harm. In reality, he added, the risk of harm is really determined by an interaction among many factors, such as the topic of study, the population being studied, the person conducting the study, and the methodology.

Minimal Risk

Breckler echoed earlier speakers in highlighting the importance of how minimal risk is defined and assessed for social and behavioral research. The existing definition as Richard Campbell had explained is rooted in the concept of the risks ordinarily encountered in daily life. Although many researchers are comfortable with this definition or some close variant of it, Breckler suggested that it is worth considering another standard for dealing with risk, the "relative standard." Under the relative standard, the probability and magnitude of harm or discomfort caused by the research are assessed in comparison with those ordinarily encountered by typical individuals *in the study population* in their daily lives. In other words, the relative standard determines minimal risk by looking at risks that the individuals enrolled in the study—rather than individuals in the general population—experience in their daily lives.

For Breckler, one of the most pressing issues—and one for which there is very little guidance for researchers and IRBs—is how to assess minimal risk in the context of a particular study. He noted that a potentially useful approach to the issue was developed at a 2005 conference sponsored by the American Psychological Association and Fordham University. To help researchers and reviewers deal with the cognitively complex task

of assessing minimal risk, participants at the conference developed a flowchart. The flowchart lays out a step-by-step process for determining whether a study is minimal risk (Fisher and Panicker, 2005).

"It gets us to focus first on whether a study involves any reasonably foreseeable sources of harm or any reasonably foreseeable types of harm," Breckler explained. "In the absence of any reasonably foreseeable sources or types of harm, we are done. We have a minimal risk study." On the other hand, he explained, if possible sources or types of harms do exist, the flowchart points to a new set of questions: What are those harms? What are their probabilities and magnitudes? Are the probabilities and magnitudes typical of the harms found in daily life? If so, then the study is of minimal risk.

A major advantage of such an approach, Breckler said, is that it forces a researcher or an IRB to focus on both probability and magnitude. These are difficult issues, he noted, and ones that IRBs very often fail to understand, but they are important. If the researcher determines that the probability and magnitude of the reasonably foreseeable harm are greater than those encountered in daily life, then the flowchart points to questions about how the protections in the study can reduce the risk to the level that would be encountered in daily life. This balance between the risk of harms and the protections included in the study is key to determining minimal risk, Breckler said. "This point is often lost on IRBs—that it's possible to mitigate reasonably foreseeable harms with protections that render those potential harms as minimal risk." That is why decision-making tools of this sort can be so valuable in determining which studies are minimal risk, he suggested.

The possibility of developing and using such decision-making tools suggests, Breckler said, "that there is hope that the Common Rule and all of the guidance that goes with it can be revised without introducing wild new interventions." Some of the problems with the system may be less about the rules and regulations themselves and more about the availability of "clear, useful, and pragmatic guidance and tools."

In closing, Breckler referred both to Citro's comment that there is no need to reinvent the wheel and to the data presented by Rodamar suggesting that researchers are not particularly dissatisfied with the current IRB system. All of this, he said, suggests "that the regulations can be improved and that they should evolve but that draconian changes may not be needed."

POSSIBLE EXTENSIONS OF THE EXEMPT AND EXCUSED CATEGORIES

Charles Plott, of the California Institute of Technology, spoke on risks and harms in economics and related areas and asked whether it might be possible to exempt all research in certain areas from IRB review. As an economist dealing with mathematical economics, experimental economics, and political science, Plott became interested in the question of whether and what types of harms might occur in the areas of economics, political science, game theory, and judgment and decision making. "I suspect that there are no risks and no harms associated with experimental research in these areas," he said. "The questions are: What are the researchers doing? How do they avoid risks and harms? Is there anything special about these particular research areas? Are there analogies with other areas that provide hints about the limitations on exposure to risk?"

Research in economics and political sciences is particularly interesting to examine in the context of risks and harms, Plott commented, because they are different than the medical sciences, and because they account for a tremendous amount of the research being carried out in the behavioral and social sciences. Economics and political science, for example, are large areas with many researchers working in them, he said, and much of what is studied in business schools can be found in these areas, including operations research, management science, economics, applied economics, and antitrust studies.

Furthermore, the research done in these areas has significant effects on society, he noted. For example, cell phone licenses are sold using a process based on many years of research regarding the best ways to carry out auctions of complex goods. The Kidney Exchange, a program that allows transplant kidneys to be "traded" so that their recipients get the best possible matches, was designed using basic science and experiments in economics. Pollution permits markets, the auctioning off of toxic assets in financial markets, and the buying of network access for such things as phones and electricity, Plott added, are additional examples from research done in these areas. "These are large, important areas in which billions of dollars' worth of decisions are made," Plott said, and they depend upon the experimental use of human subjects.

Risks and Harms Economics and Related Areas

To examine the risks and harms posed to subjects in the areas of economics, political science, game theory, and judgment and decision making, Plott surveyed major researchers and laboratories in these areas, as well as members of the Society for Judgment and Decision Making. He asked three questions: What are the potential subject risks and harms

that exist in these sciences? What are the experiences of these particular scientific communities with respect to potential harms? Are there other scientific disciplines that have similar features concerning risks and harms? He asked this last question, he explained, because there are a number of areas of science, including sociology, psychology, and social psychology that have similar features with respect to risks and harms, and it might be possible to share the lessons learned.

Plott's survey of major research groups or researchers in economics and political science had 30 respondents. Together they reported on experiments in which more than 104,000 subjects participated. Across this set of studies, there was only a single adverse event. There were no reports of harm and no reports of risk, physical, psychological, social, or informational.

Plott conducted a survey of members of the Society for Judgment and Decision Making. Eighty-five respondents reported on studies in which a total of 680,000 people participated. There were no adverse incidents reported and 73 reports of harm. Of the 73 reports of harm, 60 came from one researcher, who characterized the harm as "stress due to negative feedback about personal performance." The other 13 reports of harm in the survey were varied and very minor in their nature. For example, one person could not understand the nature of lotteries, got very frustrated, and asked to leave the experiment. Some people complained about photos they were shown and another had feelings of guilt about defecting in a study involving a prisoner's dilemma. There were complaints about equipment that did not work. "One person was irritated because he was asked about the value of life," Plott said, adding that "another . . . was upset because there was a mix-up on the addresses. That is it."

If there were true risks involved in such research, Plott said, they would show up in a study that involved this many people. As it was, the only harms reported were extremely mild, and Plott suggested that they are not what would be considered "real harms."

Part of the reason why there is no risk or harm involved in these studies, Plott said, is that the research topics are drawn from daily life. Some studies look at how markets operate, for example, and ask participants to participate in buying and selling, motivated by financial incentives. Others involve participants in voting or playing computerized games. He explained that the researchers are "studying processes and the way individuals are coordinated by complex systems of institutions. So the individual never shows up."

Another reason these sorts of studies carry no risk of harm, Plott continued, is that the methods used generally involve no risk. Research into judgment and decision making, for example, primarily relies on questionnaires. Other research uses computer and Internet games that

have no consequences for the participants, aside from the possibility that they may win money. Before they participate, the subjects know what to expect, he observed. They are trained and tested on the rules "because understanding the rules is a primary reason for doing the research to start out with," he explained. Plott added that in experimental economics there is a belief that deception should not be used in designing studies because it could affect the subjects' trust of the researchers. Finally, no confidential data are collected from the participants beyond what is needed for accounting.

One possible exception to the general rule that the methods pose no risk of harm, Plott said, is studies that use functional magnetic resonance imaging to observe people's brains as they respond to stimuli and make decisions. However, this technology is used only in a small percentage of studies in these areas.

Exempting Large Areas of Research

Plott argued that the possibility of an exemption or an excused category should be pursued. "We should ask ourselves," he commented, whether there "are there large areas that might not be part of this [IRB] process." He added that, "if no evidence of risk or harm exists, then the appropriate techniques, methods, areas, and fields of the social sciences might be identified and exempted, or excused." These considerations may hold not just for economics, political science, game theory, and judgment and decision making, he said. "I suspect that many social sciences have similar types of features and themselves should be exempt or excused, depending on what those categories are," he noted. "Understanding risk and harm means recognizing when they do not exist," Plott added. "So maybe that's one of the places we might start: Are we dealing with areas of research where risks to subjects do not exist? If so, we should identify them and move from there," he concluded.

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Session 3

The Consent Process and Special Populations

Three presenters examined the issue of informed consent through the lens of specialized populations. Each of the special types of subjects examined—groups of family members, people who have experienced disasters or other traumas, and children—present different challenges with respect to informed consent. Margaret Foster Riley, of the University of Virginia, noted in her introductory remarks that the proposed changes to the Common Rule bring up the possibility of a standardized informed consent form, but the variety of issues raised by these distinct populations makes it clear that it will be exceptionally difficult to develop a single form—or a single informed consent process—that can be applied uniformly to these disparate types of research participants.

LONGITUDINAL RESEARCH WITH BEHAVIORAL AND BIOSPECIMEN DATA FROM FAMILIES

Sally Powers, of the University of Massachusetts, Amherst, spoke about her 30 years of research on the effects of social stress on depression and the consent issues associated with such studies. Her research is longitudinal, and she follows her child, adolescent, and adult subjects over several years. Her particular research interest is the stress that arises from conflict within families and how that stress influences the emergence and course of depression. She works with multiple family members within a family. Her subjects have included newlywed couples during the first years of their marriages, new parents with infants and young children,

families with teenagers, and young adults just out of high school who are part of dating couples. To observe how the various subjects respond to stress, she asks subjects to discuss heated, unresolved conflicts in their relationships. She measures stress through observations of behavior, self-reports, and analysis of stress hormones in saliva samples taken before the conflict task, during the conflict task, and afterward.

Rich Data

Powers focused on consent issues involving *rich data*, which she defined as data that can be "recoded, reassayed, and retested to yield new information that was not proposed in the original study." She explained that she was not referring to the reanalysis of existing coded information from large survey datasets, which can produce new insights and interpretations but which usually does not produce new data. Instead, she was specifically referring to datasets that allow researchers to derive new information through new coding, assaying, or testing of the original behavioral or biospecimen data samples.

In the case of biospecimens, for example, Powers explained, there are many different types of information that can be gained through various analyses, and the original researchers are likely to have obtained only a small portion of everything that is possible. In her research, Powers said, she analyzes the biospecimens from her participants mainly for stress hormones because she is interested in stress levels. The most common biospecimen she collects is saliva, which provides an indication of stress levels around the time of the sample, but she also looks at hair samples, which gives her information on stress levels over the preceding months.

An important fact about these biospecimen samples is that over time researchers are able to get more and more information from them. When she began collecting saliva more than a dozen years ago, Powers said, the purpose was to analyze the levels of the stress hormone cortisol. Today there are dozens of endocrine molecules, neurotransmitters, immune factors, and other molecules whose levels can be detected in saliva samples, each of which provides a different set of information about the subjects. "We have hundreds of those samples frozen from many, many families," she said, so she can go back and extract a tremendous amount of information about the subjects from their samples. Furthermore, the amount and types of information that can be extracted from the biospecimens are only going to increase further in coming years.

Behavioral data can also be rich data, Powers said. In her experiments she videotapes subjects in various situations, including conflict situations, and the videotapes can be analyzed to obtain many different types of information. When she carried out her earliest studies, she was focused

on submission and dominance behaviors—how much and how often subjects were acquiescing to what other subjects wanted, for instance—and on how those behaviors might be associated with the onset of depression. Later on she became interested in what she calls "secure base behaviors" in married couples and dating couples, and she was able to go back to the videotapes from earlier work and examine them for this new type of behavior. Most recently, she said, she has begun working with computer scientists to amplify color changes in subjects' faces as a way to observe cardiovascular stress reactions to family conflict. The analysis allows her to see the color of a subject's face go from normal to flushed with the subject's pulse, making it possible to get a second-by-second reading of stress, which can be combined with measurements of stress hormones taken at the same time.

The opportunities posed by rich data do, however, come with a number of ethical and consent issues, she explained.

Consent Issues for Rich Biological Data

A major issue with rich biological data such as saliva samples, Powers said, is that the presence of so much information waiting to be unlocked by various analytical techniques means that it will become increasingly possible to identify the subjects who provided the samples. This possibility may blur the line between identified and de-identified data, and make it possible in the future to determine the identity of the people who provided the samples. Thus, it will be increasingly problematic for researchers to assure participants who provide biospecimens that their identities can be protected by such measures as keeping their names and other identifying information confidential.

Given that, she asked how the proposed changes to the Common Rule might affect her research. The current rules allow de-identified biospecimens to be used in other studies without re-consent, while for identified specimens it is necessary to obtain re-consent before carrying out new research. The proposed revision to the Common Rule would require getting prior consent whenever one obtains biospecimens and also asking for blanket consent for open-ended use, meaning that the research participants would agree to have their samples used for any type of future analysis. This consent would be requested whether or not the biospecimens were to be de-identified.

In her own research, Powers said, she has always considered the biospecimens and other data she collects to be identifiable because she is conducting longitudinal research, which by its nature requires that the researcher know which data comes from which subject in order to observe how the data change over time. Furthermore, she said, because it is

unlikely that even de-identified biospecimens will be able to remain anonymous in the face of increasingly powerful analytical tools, she always assumes that biospecimens will become identifiable in the future. Thus, she asks her subjects for prior consent for future use of their specimens, but she does not ask for blanket consent for open-ended use. Instead she asks for consent within broad categories of testing that are designed to anticipate the various future uses to which the saliva samples might be put. For example, she said, "a particular . . . study may be funded to assay cortisol, but I know that in the future I would like to also explore relations between stress hormones and immune functioning." In that case, she would ask the participants at the beginning of the study if they would be willing for their biospecimens to be used in such a future study.

The difference between such a broad prior consent and a completely open-ended prior consent might be important, she said, because some participants are very concerned about the open-ended use of their data. In particular, many of them worry that their DNA data will be identifiable. On the other hand, she noted, the vast majority of her participants do not seem to worry about it at all. It is unclear that subjects' lack of concern is based on a clear understanding of the risk of identification in the future.

Consent Issues with Rich Behavioral Data

The issues concerning consent for rich behavioral data are somewhat different, Powers said. While she feels very cautious about requiring open-ended, all-inclusive prior consent for biospecimens, she feels less cautious about the sort of videotape data that she collects. The reason is that every participant who gives informed consent on videotaped data knows that his or her face is identifiable on the videotapes. Participants have no expectation that the data can be de-identified, as biospecimens can, so any informed consent implicitly includes the acknowledgment that the subject will be identifiable in any future use of the data. Thus, she said, "I suggest that this [blanket, open-ended] standard is acceptable for video data, but not for biospecimen data."

Because the proposed changes in the Common Rule seem to be focused mainly on biospecimen data, she said, it would be useful to think carefully about those changes as they would apply to behavioral research and, particularly, videotape data. "IRBs are so variable in terms of how they assess the risk of videotaped identifiable data," she said, that it would be to everyone's advantage to pay attention to this area and to develop some guidelines for IRBs about "what is risk with videotape data and what is not."

Prior Consent for Longitudinal Follow Up

Powers also noted the issue of getting consent when doing the follow-up studies in a longitudinal series. Institutional review boards (IRBs) differ, she pointed out, on whether participants who have not already given consent to be re-contacted for future studies can be re-contacted using their contact information from the original study. One particularly tricky situation arises when a researcher wishes to do a follow-up study with subjects who were adolescents in an earlier study and who are now adults. Because they were adolescents at the time of the previous study, they could not have given informed consent for future contact. To address the issue, Powers said, she always asks participants in her studies for permission to re-contact them later. "We ask them to give us contact information; we even ask them if they would give us names of friends who may know where they've moved."

Consent for Interdependent Data

Because her data involve multiple subjects who interact—a videotape with a mother and daughter arguing, for example—Powers must deal with consent issues involving interdependent data. She illustrated with an example of a woman who had taken part in an earlier wave of the study as an adolescent and is now a mother with her own teenager. Following up on this subject could provide insights into, for instance, how her interactions with her own mother have affected the way she interacts with her own child. This sort of research requires analyzing not only new videotapes of the subject with her daughter but reanalyzing videotapes from the earlier study showing the subject at a younger age with her mother. It is clearly necessary to get new informed consent from the woman who was an adolescent in the previous study, Powers noted, but what about re-consent from this woman's mother? "There is no way to [separate] her data out from her mother's data."

Powers argued that it is not necessary to re-contact the mother because the mother's original permission to use that tape would cover the later use. The one exception, she said, would be if she were to ask the study participants to view their own videotapes in order to get their reactions and their judgments about what was going on in various interactions. That would require re-consent from the mother because her data would be viewed by someone other than members of the research staff (in this case, by her daughter).

CONSENT IN DISASTER AND TRAUMATIC STRESS RESEARCH

Roxane Cohen Silver, of the University of California, Irvine, discussed the issue of obtaining informed consent from people who have experienced traumatic events, such as the death of a child, a terror attack, or a natural disaster. Silver began with a description of the sorts of research studies she carries out. She has studied the sudden unexpected death of an infant, California neighborhoods devastated by firestorms, and the aftermath of the Columbine High School shootings. The events she studies are random, unpredictable, and uncontrollable, she said, which makes the events particularly interesting to psychologists but also makes them particularly difficult to study and raises ethical issues.

One difficulty is that, to be most useful, the research on such an event needs to start almost immediately after the event's onset. Immediate data are necessary to identify early predictors of long-term difficulties, Silver said, and early identification of at-risk individuals allows mental health professionals to target interventions to those who are most vulnerable. Early data allow educational and intervention efforts to be better planned, more sensitive, and more cost-effective. Furthermore, research shows that people cannot accurately reconstruct emotional experiences long after a traumatic event, so it is important to study people as soon after the event as possible. However, the need to move quickly after a disaster or traumatic event raises a number of ethical issues, Silver said. "First, is it ethical to conduct research immediately after a tragedy?" she asked, "can or should we intrude on individuals during a potentially vulnerable period?" A second issue is whether individuals can provide true informed consent while they are experiencing a life crisis. A related procedural issue is whether participants must provide written consent, especially when the research is seeking representative, population-based samples and needs to move quickly.

Silver described a national study she conducted following the September 11, 2001, terrorist attacks. The study was done in collaboration with Knowledge Networks, a research survey firm that retained the participants' identities to make longitudinal data collection possible while ensuring that all the data were de-identified. On behalf of Silver's collaborators, Knowledge Networks also went back to a random subsample of original participants and collected biospecimens—saliva samples—two years after the project ended, which were ultimately linked to the earlier data respondents had provided. The people who gave the samples were re-consented, Silver noted.

To maintain anonymity of participants, Silver got a waiver of written informed consent. The online data collection process provided contact information participants could use to ask questions or express concerns, as well as reminders that the participants could skip questions or quit the

survey at any time. Participants conveyed their consent by clicking on an embedded web link. Silver noted that the study, which covered seven waves of data collection, and more than 10,000 survey completions among a nationally representative panel, had very low dropout rates. There were no complaints from the participants about procedures, the survey questions, or anything else.

How IRBs Can Facilitate Disaster Research

Silver has had generally positive interactions with her IRB, she said. Of the four large disaster studies she discussed, all were either exempted from review or given expedited review. Reflecting on her experiences with IRBs, she offered several ways that the review boards can facilitate this sort of post-disaster survey research.

Most important, she said, is that the IRB needs to be willing to approve the research very quickly. "After the Columbine High School shootings, my IRB convened over e-mail the weekend after the shooting, and I was able to pick up my signed IRB approval on Monday morning." Because her research team had driven to Littleton, Colorado, over the weekend following the shootings, the team was able to get started within a week of the incident. The IRB must be willing to issue a waiver of written consent in certain cases, particularly for fast-moving research. She has also found it very valuable to have the IRB preapprove a generic proposal that can be activated immediately after a disaster. She has an approved generic disaster trauma protocol at her university that describes the background and rationale of the research, proposed methods, proposed risks and benefits, who the research team is, and sample questionnaires and interview questions. This generic protocol was reviewed and received expedited approval by her IRB.

Furthermore, she said, she has a "contract" with her IRB that it will review and decide on proposals within 24 to 48 hours of submission once she provides them with the specific purpose or event to be studied, the specific research methodology, the specific sample and sample size, and any deviations from the generic proposal in the research team, methods, compensation, or other elements. She has not yet used this generic proposal, but her relationship with the IRB is such that after a national event has occurred, the IRB has called her to see if she is going to study it.

At this point, Silver said, she is proposing a project that will begin even earlier. Working with meteorologists and wind engineers, she will focus on communities being targeted by a hurricane and will identify participants 36 to 48 hours before landfall. The goal is to link pre- and during-storm emotions, risk assessments, and behaviors to post-storm adjustment. Participants will be recruited orally as the storm approaches, and they will

be given Internet-enabled tablets that will be used to collect data before, during, and after the storm. One goal will be to accumulate data that illuminates who evacuates and why, because at this point no such data exist (only anecdotal information has been collected). Speed is essential for this project, Silver said. "We need to recruit 750 individuals within 18 hours, so we will be requesting a waiver of written consent." The project will also require flexibility of methods, she said, in order to protect both the participants and the research personnel.

The Special Case of Intervention Research

A related type of research that Silver considers even more challenging is intervention research—studies of psychological treatments or procedures that are carried out after a disaster. Examples of such treatments include the psychological debriefing sessions offered to all New York City police officers and fire fighters after the September 11 terrorist attacks, and the counseling offered in classrooms when students and teachers return after there has been a school shooting. These interventions are well intentioned, Silver explained, but are not based on evidence that they are actually helpful. Indeed, there is growing evidence that they may be unhelpful or even harmful because they may disrupt the natural course of social support and recovery. Thus, she said, it is important to evaluate the effectiveness of such post-trauma interventions.

Silver described one such intervention study she carried out in Yogyakarta, Indonesia, of a rural community that is subject to repeated natural disasters, such as earthquakes, volcanoes, tsunamis, and floods. She recruited 500 families with children in six different elementary schools. The parents consented for themselves and their children, and the children provided assent. Silver's Indonesian collaborators had told her that because of cultural norms the participants would be unwilling to sign their names to documents, so Silver received a waiver of written informed consent from the IRB. The study was explained to the participants orally, research assistants were available to answer questions, and participants were told they could skip questions or terminate their participation without penalty. There was no coercion or pressure to complete questions, and remaining in the room as the surveys were about to be distributed implied consent to participate.

Both parents and children completed surveys before the intervention, and a subsample provided saliva samples for future cortisol and genetic analysis. The parents were randomly assigned, by school, to either a skills-based psychosocial intervention or a waiting list control group. Parents and children completed surveys after the intervention, and the intervention was subsequently provided to the waiting list control group.

Finally, Silver noted that there are several ways IRBs can facilitate disaster and trauma research. They should review and decide on proposals quickly. They should also allow subjects to be randomly assigned to different conditions—an intervention group versus a waiting list or a no-treatment control group, for instance. And they should allow flexible informed consent procedures. The Indonesian project went through a full-committee IRB review, Silver said, and it was successful "because of IRB acceptance of my proposed methodology."

To obtain representative samples of participants in trauma and disaster research, she said, researchers find that "flexibility in consenting procedures is crucial, including the opportunity to maintain anonymity [for participants]." Such flexibility might mean allowing a waiver of written consent, or allowing a delay in consent for the future use of biospecimens, particularly in the early aftermath of a disaster or a tragedy. "Requirements in the revisions to the Common Rule that prohibit flexibility will impede this kind of research," Silver observed. Defining or evaluating trauma and disaster research as necessarily "emotionally charged," and therefore disqualified from being considered exempt or excused, will impede scientific progress, she added. Finally, eliminating the waiting period before exempt or excused data collection can commence would facilitate trauma or disaster research, whereas requiring even a brief waiting period—as little as one week—could impede the research.

INFORMED CONSENT WITH CHILDREN AND VULNERABLE POPULATIONS

Celia Fisher, of the Center for Ethics Education at Fordham University, spoke about a variety of issues that arise in studies involving children and other special populations (see also Fisher et al., 2013). One of the first recommendations made in the advance notice of proposed rulemaking (ANPRM) concerns the length, content, and documentation of consent for informed consent forms. The proposal to shorten the length of informed consents is timely, Fisher said, commenting that many researchers seem to agree with this recommendation. However, she said, the proposal to standardize forms poses problems. It could lead to confusion and misinformation, she observed. "We need the flexibility in format and language to ensure that any informed consent is crafted so it is age appropriate, it is language appropriate, and it is appropriate to the educational level and familiarity with research of the population," she explained. Informed consent forms should also be flexible enough to take cultural understanding into account, she added. For example, when doing research with American Indian tribal nations, it is very important to obtain the consent of the tribal leader or tribal groups before seeking the consent of individuals.

The issue of oral consent is equally important, she said. Informed consent is a process, not a standardized document, and its goal is to ensure that decisions to participate are informed, rational, and voluntary. Thus, oral consent may be more appropriate than written consent for certain populations. With children, for example, oral consent can be less coercive because of children's more limited reading skills, their deference to authority, and their lack of experience in signing forms. Furthermore, written consent can jeopardize participant safety in war zones; in research in which partner violence is an issue; and in studies looking at stigmatized or illegal behavior, such as drug use, HIV status, or homosexual activity. Thus, Fisher said, it would be useful to have population-specific guidelines to help IRBs and investigators craft appropriate oral consent.

Other issues raised by the ANPRM concern flexibility and accuracy in the informed consent process. It would certainly be useful to have the flexibility to waive irrelevant informed consent components, she said. With respect to Brian Mustanski's comments about IRBs requiring participants to be warned about the possible harmful effects of stressful questions, she commented that such statements are often not accurate because there is no evidence that such harm may occur. "We are actually communicating untruths to our participants." Such unsubstantiated statements should be removed from informed consent forms, she said.

Fisher suggested that the following default statement could be included in forms to describe minimal risk research: "This research presents minimal risks no greater than those of daily life or routine medical, dental, psychological, or educational examinations or tests" (Fisher et al., 2013). Such a statement would not only truthfully describe the risks but would also serve an educational purpose because it is based on the IRB's evaluation of the risks.

Research Risk Versus Institutional Liability

Fisher also addressed the issue of distinguishing research risk from institutional liability. One reason informed consent forms are so long, she said, is because the institutional liability information is attached to them. However, in Fisher's view, such institutional liability statements do not belong on an informed consent form, because they refer to risks outside of the research procedures themselves, such as falling in the research facility. "In fact," she said, "Section 46.116 says that no informed consent 'may include any exculpatory language through which the subject or representative is made to waive or appear to waive any of the subject's legal rights or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.'"

Furthermore, she said, including this liability language within an

informed consent form is unfair to children or other vulnerable populations, who may not be familiar with what their legal rights are or have access to legal advice. "In some of the research I have done with populations where I ask them about ethical issues, some of them believe that they are signing their rights away when they sign an informed consent or a legal liability form, and I think we have to be very careful about that," Fisher observed. In her view, it is important to separate institutional liability from the informed consent document. If institutions wish to notify prospective participants or their guardians about limits to the institution's legal liability, they should do so in a separate document, she added.

Waiver of Guardian Permission

An issue specific to minors is the waiver of guardian participation, Fisher noted. *Emancipated minors* are adolescents who are supporting themselves and who are, under the laws of their state, considered adults; they may themselves be parents. *Mature minors* are those adolescents who by state law can independently and without parental permission gain access to health or mental health services. Under federal regulations, both emancipated and mature minors are considered to be adults. However, Fisher said, most states do not include language specific to research participants in their emancipated and mature minor laws, and "this has been incredibly confusing to IRBs because they don't know whether or not they should require parental permission."

As a result, she said, IRBs often needlessly require guardian permission for minors' involvement in research related to treatment and procedures for which they've already obtained a legal right to adult status. For example, an adolescent who can go to a clinic and get sexual health treatment or prescriptions independently under the mature minor rule may still be required by an IRB to get parental permission to participate in a survey that asks about his or her experiences. This requirement could deprive adolescents of their rights and of the potential benefits of research participation, Fisher said.

Waiver of guardian permission is also relevant to Section 46.116 of the Common Rule, which discusses procedures to ensure that "waiver or alteration will not adversely affect the rights and welfare of the subjects." When studies involve children and adolescents—and some other vulnerable populations—IRBs often overreact when considering what the participants actually understand, Fisher said. However, there is a considerable body of developmental research that can be used to determine whether subjects can give an independent consent, so IRBs should use "evidence-based literature to evaluate whether or not an age group has an understanding of their rights and research procedures."

A provision in Section 46.116c stating that components of informed consent may be waived if "the research could not practicably be carried out without the waiver or alteration" also poses an issue, Fisher noted. The Secretary's Advisory Committee on Human Research Protections has recommended that guardian permission should never be waived for the convenience of the investigator, or solely for reasons of cost or speed or other expedient measures, if doing so will weaken the protection of subjects' rights and welfare. This body has also stated that parents' reluctance to permit their children to participate in research is not a legitimate reason to waive this protection. Researchers who work with marginalized communities often encounter parents who do not want to give permission, perhaps because they don't trust the research or perhaps because of other concerns. "Their reluctance is legitimate," Fisher said, and parental permission should not be waived simply because the researcher thinks that the research is important.

There is also plenty of research on how to enhance consent for children and for adults with impaired cognitive capacity, Fisher said. That knowledge should be used, she suggested, to develop enhancement procedures for use in the informed consent process to help members of these groups autonomously consent to research, and to make sure that the language used is age- and participant-appropriate.

Informed Consent for Future Use of Data

Fisher also discussed informed consent for the future use of biospecimens and archived socially sensitive data, focusing on permission granted by guardians for future research on data collected from children. It is important to ask under what circumstances permission granted by a guardian will be sufficient for future data use even after the participant reaches adulthood, she noted. In her view, it is appropriate not to require re-consent if several conditions are met: (1) appropriate security protections are in place and are updated to reflect evolving information technologies and federal standards; (2) the level of harm associated with the informational risk has not increased with changes in societal attitudes, health coverage, or other policies; and (3) the original informed consent informed the guardians—and minors old enough to understand—that their consent represented a default permission for continuing to use the data after the child reached the age of maturity.

Another important question, Fisher noted, is when it is acceptable to expand the original informed consent commitment to de-identified data for socially sensitive research. Emerging technologies may make obsolete the original de-identification data security protections to which guardians, minors, or vulnerable adult populations originally consented. One

way to address this, Fisher said, is to have the initial informed consent indicate that all investigators who will have access to data in the future will be bound by the best practices in data and confidentiality protections at the time of the data collection as well as any new protections that emerge. Federal regulations should ensure that future investigators honor this commitment. This approach is consistent with proposals in the ANPRM to establish regulatory procedures for the continuous updating of data security procedures.

A final question, Fisher said, pertains to when informed consent is necessary for linking identifiable archival data to the collection of new data. Whenever an original investigator or a new investigator wants to link archival identifiable data with collection of new data, she explained, it is necessary to get re-consent from the original participants, Fisher said. The original informed consent should indicate that any investigators interested in linking new data collection with the archival dataset will be given access to the participants' contact information in order to request additional permission for its use. In the case when archival data was collected during childhood, once a participant reaches adulthood consent for linking new data to the archival set should be obtained from the original participant, not the guardian.

Summing up, Fisher said that informed consent procedures should be age- and population-sensitive; should be based on the substantial evidence base concerning consent capacities; and should include, where appropriate, consent-enhancing procedures. Any decisions regarding the waiver of informed consent components should provide adequate protections against misunderstanding by and exploitation of participants and such waivers should also ensure that children and vulnerable populations have equal access to the potential benefits of research.

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Session 4

Data Use and Sharing and Technological Advancements

David Weir, of the University of Michigan, Ann Arbor, introduced a session on the state of the art in technologies for data sharing and in the rules and regulations that govern data sharing. In every area of research, he noted, the goal should be to find the proper balance and trade-offs among risk, consent, and procedures for protecting data and making them available to researchers. This balance determines the amount of protection that is accorded to the human subjects who provide the data.

ARCHIVING AND SHARING CONFIDENTIAL DATA IN THE SOCIAL SCIENCES

George Alter discussed issues that arise in the storing and sharing of confidential data, citing his experiences as director of the Inter-university Consortium for Political and Social Research (ICPSR) at the University of Michigan. ICPSR is a collaboration of more than 700 member universities around the world that contribute to the archiving of social science data that is shared among the member institutions. The consortium also provides sponsored archives for about 20 different agencies, including institutes at the National Institutes of Health and agencies in the Department of Justice. "For those sponsors we set up web portals to preserve and make available the data that they or their grantees are collecting," he explained.

Disclosure Risks in Social Science Data

Alter briefly noted some of the factors that are increasing the risks of disclosure in social science data and, in particular, in data from which direct identifiers have been removed so that the data seem to be anonymous. As other speakers had noted, even with de-identified data it can be possible to identify individuals from the information that remains in the dataset, and several trends are increasing concerns about re-identification. One is that more and more research is being done with geocoded data, he noted. Another is increasing use of longitudinal datasets, such as the Health and Retirement Survey, "where the accumulation of information about each individual makes them identifiable," he said. Finally, many datasets have multiple levels—data on student, teacher, school, and school district, for example, or on patient, clinic, and community—which can make it possible to identify individuals by working down from the higher levels.

Protecting Confidential Data

With respect to protecting confidential data, Alter said, it is useful to think in terms of a framework that considers protecting confidentiality with four different but complementary approaches: safe data, safe places, safe people, and safe outputs. "You can approach making data safe in all of these different ways," he said, "and in general we try to do some of each."

Safe Data

It is possible to take steps to make data safer both before and after they are collected. Before data are collected, one can design studies in such a way that disclosure risks are reduced. Researchers can, for example, carry out their studies at multiple sites because "a study that is designed in one location, especially when that location is known, is much more difficult to protect from disclosure risk than a national survey or a survey in multiple sites." Researchers can also work to keep the sampling locations secret, releasing characteristics of the contexts without providing locations.

After the data are collected, there are many procedures that researchers can use to make the data more anonymous. They can group values, for instance, or aggregate over geographical areas. They can suppress unique cases or swap values, and there are a variety of more intrusive approaches, such as adding noise to the data or replacing real data with synthetic data that preserve the statistical relationships in the original data.

Safe Places

The second approach is to provide the data in places that are safe, Alter said, and there are three levels to this type of safety. The first is providing the data to a researcher under a data protection plan and making the researcher responsible for the data protection. Alter said that the consortium has been working on improving data protection plans. Because the technology for handling data is changing so quickly, ICPSR is trying to develop data protection plans that focus not on the technology but rather on the risks and on how a researcher plans to deal with them.

The second level of safety is using remote submission and execution. In this approach, the data are held in a data center and the researcher submits program code that is executed at the data center, with the results returned to the researcher. A virtual data enclave is an easier-to-use version of remote execution, Alter noted. Researchers gain access to and manipulate the data remotely from their own computers, but the data and the manipulations remain on the data center's computers. Results are sent to the researcher after being reviewed. However, the researcher can still see confidential data on his or her screen so there must be a data use agreement as well.

The third level is the use of a physical enclave, to which the researcher must go in person to gain access to the data. "We have a room in our basement that is locked up, and we frisk people when they come in, and we go through their pockets when they come out to make sure that they are not taking anything that they should not," Alter said. The physical enclave provides the most control over the data, but it is the most intrusive for the researchers because they must travel to get to the data.

Safe People

There are two main ways to create safer people, Alter said. The first is to use data use agreements. The University of Michigan, ICPSR's parent institution, signs data use agreements with both the researchers who produce the data and the researchers who use the data. For data producers, there is a data dissemination agreement that specifies how ICPSR will manage and preserve the data. Researchers who receive data sign an agreement describing how they will protect the confidentiality of research subjects.

ICPSR requires researchers to provide a research plan, IRB approval, a data protection plan, behavior rules, and also an institutional signature. In the institutional agreement, the member institution must agree that if the consortium alleges a violation or breach of the agreement by the researcher, the institution will treat that as research misconduct and pursue that individual under its own research misconduct policies. "I

consider this one of the strongest things that we do," Alter said, "because we are saying it is not just the individual's responsibility, it is really the institution's responsibility to assure compliance with the agreement."

The second approach is training. Until recently, Alter said, ICPSR has not done a particularly good job in training researchers about disclosure protection, but it is now developing an online training course that researchers will need to complete before they get access to the consortium's data. It is designed to teach researchers about disclosure risk, about how they can use information technology to protect the data, and how they can make sure that their research is not published in ways that will reveal identities.

Safe Outputs

Making sure that the outputs from data analysis do not threaten confidentiality is done in the context of safe places. For example, remote submission and execution allows individuals at the data center to control what is returned to the researcher and to make sure that nothing in the results threatens confidentiality.

ICPSR has been developing ways of releasing data in which they adjust the requirements of release to the characteristics of the data, Alter said. For example, he explained, in the case of a national survey such as an opinion poll, which has very few identifying questions, "we certify the data as having very low risk of re-identification or harm" and provide it under a simple terms-of-use agreement, in which the user agrees not to re-identify anyone in the sample. For more complex data that have greater risks, ICPSR imposes a stronger user agreement and such technology as the virtual data enclave. "And for the stuff that is really radioactive," he said, "we put it in our basement in the enclosed data center." In this way, ICPSR is able to control outputs from the data and make sure that nothing threatens the confidentiality of the individuals whose sensitive information appears in the dataset.

Who Should Be Responsible?

Alter also addressed the question of who should be responsible for making sure that the confidentiality of shared data is protected. In general, he said, it is usually the IRBs of the data producers and the data producers themselves who think most deeply about the issues of risk and harm, because they are most closely associated with the research subjects. Thus, he said, "we usually rely on the data producer to tell us the terms of dissemination."

On the other hand, many IRBs do not have expertise in disclosure

risk, which can get very technical. Furthermore, the data in a data center may persist longer than the IRB itself, or at least longer than the membership of the IRB. So it is important, Alter said, that there be centers of expertise in disclosure risk that can advise IRBs of what to do, and that there also be a system that provides for an IRB to take over supervision of a dataset if the original IRB is unable or unwilling to continue. Data repositories can play a role here, he said.

Ultimately, though, it is the institutions that receive data that are responsible for its security, Alter said. Ideally, the IRBs of the data recipients should defer to the protocols established by the original IRBs. The recipients' institution, having signed an institutional agreement, is responsible for compliance with the data use agreement and for investigating any alleged violations. The recipient institution is also responsible for making sure that data users understand disclosure risks and that they behave safely.

Finally, there is the question of who is responsible for paying the costs of sharing confidential data. Often the institutions that pay for the data are willing to assume the cost of distribution, Alter said, "but I think for many things we are going to be moving to a situation where the data user, because using confidential data has special costs associated with it, is going to have to pay user fees for access to confidential data."

DATA-BASED DECISION MAKING FOR EDUCATION

Taylor Martin, of Utah State University, described her research in mathematics education and discussed what the proposed changes to the Common Rule could mean for education research. Martin studies how people learn mathematics and how mathematics education can be improved. The recent explosion in computer learning methods, such as online courses or online games designed to teach math skills, offers a "new microscope," she noted, that can be used to study how people learn and then apply those insights to helping them learn better. For example, she explained, by analyzing how children interact with a game that teaches them about fractions, she was able to identify several patterns of learning. Some approached the game haphazardly, she explained, trying different things in a seemingly random way. Others carried out a more careful exploration, trying things in a very structured way. Still others thought carefully before each step, trying to zero in on the answer as efficiently as possible. Having identified these different patterns, Martin said, it becomes possible to see how the patterns relate to the effect of learning the game on students' test scores, to explore which teaching strategies work best for different types of students, and see ways to modify the

game to encourage children playing it to try different approaches to maximize their learning.

The data derived from such observations can be combined with various other types of data, Martin said, such as neural activation patterns recorded during learning sessions, to provide more insights into learning. The lessons learned from such learning games can be used to develop general learning principles that can be applied to other games.

Martin characterized her approach to improving mathematics education as "big vision, big data." The "big vision" includes four components: (1) personalized learning, (2) connected learning, (3) anytime/anywhere learning, and (4) increasing opportunity for all children in science, technology, engineering, and mathematics (STEM) education. There is a major push by education businesses to develop personalized learning, which involves watching how children interact with their learning environment—what kinds of resources they use, what lessons they learn and how they learned them, and so on—and then personalize the environment to reflect individual children's learning styles. Keeping track of a student's progress, and providing feedback to students, parents, and teachers, is an important component of this approach.

Connected learning, Martin explained, refers to creating connections between the various places where children learn. Children spend a relatively small percentage of their lives in school classrooms, and they learn in many other settings—in such places as the Exploratorium, the science learning center in San Francisco, and in online sites where they may learn to program, talk to their friends about programming, share their programs, and do other programming-related activities.[1] Ideally, these learning settings should be connected. Anytime/anywhere learning refers to the possibilities offered by online learning, including massive open online courses (MOOCs). MOOCs and related approaches to online learning allow students to listen to lectures, do practice problems, and take tests anywhere, at any time.

The "big vision" Martin described calls for using personalized learning, connected learning, and anytime/anywhere learning to help interest kids in and teach them about STEM topics, giving all children the opportunity to learn about math and science. Achieving that vision will be helped along by the growing presence of "big data." Martin characterized the present state of affairs as a "biggish data" world rather than a big data world, but believes that a world characterized not only by tremendously large amounts of data but also by rich data streams that provide a great

[1]See, for example, the Scratch Program available at: http://scratch.mit.edu/about [June 2013].

detail of data on any one individual, by connected data streams, and by shared data, is fast approaching.

The Effect of the Proposed Changes on Education Research

Martin spoke about the effects that the proposed changes to the Common Rule would have on her research and on education research in general. She shares with other speakers the goal of having more readable and understandable consent forms and agrees that continuing review should not be "one size fits all." She believes IRB forms should be simplified, and that multisite studies should have a single IRB.

Focusing on the issue of information risk and educational data, Martin noted that she has been running education studies for 25 years and has kept her data stored in a locked filing cabinet. Nothing she has done in those studies has put a child a risk, she noted. However, she pointed out that massive datasets and powerful computers will increase the potential for exposure of information and introduce a new type of risk. IRBs have not been trained traditionally to assess this new type of risk, she added, so it will be important to develop standards to guide them.

Meanwhile, educational technology companies are collecting a lot of data, and they are not subject to the restrictions of the Common Rule. These companies' analyses are often what schools, school districts, and states are basing their educational decisions on. In her view, partnerships with these companies, which have extensive product development and broad national scope, would be beneficial for many academic research groups. However, standards for data privacy for these situations would need to be clarified if this were done, she noted, because they would not be subject to the Common Rule.

Potential Information Risk Solutions

Martin suggested a few solutions to the information risks she had raised. First, she advocated that standards be set for risk in the "real universe." Continuing work on what "de-identified" means will be needed as the possibilities for re-identifying de-identified data grow, she noted. Funding agencies should support the establishment of safe data repositories that follow standard guidelines, she added. For her, the most useful step would be to provide templates for institutional IRBs that instruct them on how to set up data management and safety plans. This would help not only her university IRB but also school district IRBs, many of which are struggling with these information risk issues.

TOWARD UNIFIED DATA SECURITY REQUIREMENTS FOR HUMAN RESEARCH

Susan Bouregy, of the Yale University Human Research Protection Program, discussed some of the ways in which the proposed revisions to the Common Rule would lead toward unified data security requirements for human research and what some of the consequences of that might be. One of Yale University's five IRBs, she explained, is devoted exclusively to reviewing social and behavioral research, she said, and it handles a very diverse range of research, from cognitive development in children to video ethnographies of marginalized communities. Although Yale's healthcare clinic, faculty medical practice, and self-insured health plan are covered by the Health Insurance Portability and Accountability Act (HIPAA), research carried out by faculty, staff, and students outside these areas is governed by HIPAA only when it makes use of information from those health-related entities. Thus, most social and behavioral research that takes place at Yale is not covered by HIPAA at this time.

Bouregy's presentation focused on the potential effects of Section 5 of the ANPRM, which deals with strengthening data protections. She identified three areas: (1) harmonizing the concept of "individually identifiable" information, (2) requiring data security protections to be indexed to identifiability, and (3) using HIPAA security and breach notification standards as the model for data protection schemes.

Harmonizing the Concept of Individually Identifiable Information

One of the key proposed revisions related to data protection in the ANPRM is that the Common Rule should adopt HIPAA standards regarding what constitutes individually identifiable information, a limited dataset, and de-identified information. Adopting the HIPAA definition of individually identifiable information would not be a major change, Bouregy said, because the current Common Rule definition is very similar. The major difference is that under the Common Rule identifiability is largely determined based on whether the investigator can identify the participants, whereas HIPAA is much broader.

The two regulations differ more sharply with respect to the question of how data are de-identified, she noted. The Common Rule leaves it to the IRB and the investigator to decide what needs to be done to data for it to be considered de-identified, while HIPAA is much more specific about what must be done. It lists 18 identifiers that must be removed from the data for it to be de-identified. Alternatively, a statistician can perform a documented risk assessment to show that there is very little risk that the data can be re-identified.

The practical effect of modifying the Common Rule to meet the HIPAA standard, she said, would be that a great deal of data that would generally be considered by an IRB to be de-identified will no longer meet the criteria. For example, ethnographic interviews that include a zip code or some other geographic information would now be considered identified. This is important because the issue of whether data have been de-identified will affect the data security requirements and the level of review for a study. In particular, a study whose data are not considered to be de-identified cannot be exempted from review.

On the other hand, Bouregy said, this change would address the problem that there is no single, generally accepted term in the literature that is used to convey the concept of "de-identified" or "anonymous" or "unlinked." There are dozens of different terms used to convey this idea, and "it would be really nice to have a unified term," she noted. The adoption of a clear definition of "de-identified" could also help clear up confusion on the part of IRBs and investigators regarding what constitutes de-identified data, she said.

Indexing Data Security Protection to the Level of Identifiability

For identifiable data, under the proposed changes, the Common Rule would mandate a minimum level of data security that is indexed to the identifiability of the data. In particular, the proposal would use HIPAA data security standards as the model. This would change how researchers and institutions deal with data in several important ways. First, the standards require encryption of data at rest (in desktops, laptops, thumb drives, smart phones, etc.), which comes into conflict with export control issues. It is illegal, for example, to take an encrypted laptop to certain countries. Second, HIPAA requires secure transmission of data, and the necessary e-mail encryption is difficult to use. Strong physical security is required, which can be a problem for researchers working in a remote location. Access control and logging is another HIPAA requirement that can be difficult to adhere to in the field.

Several issues would arise if the HIPAA requirements were adopted, Bouregy said. First, in her view, IRBs are not necessarily the best place for determining appropriate data security plans, but the proposed rule would require IRBs to become even more involved in data security plans than they are now. Under the proposed rule, even excused research would be subject to these data security standards, she added. Second, she noted that not all identified data are risky, and not all studies promise confidentiality. "We have plenty of studies where there is no risk to the participants by having their name associated [with the data], and so there is no need to

go through this process," she said. Also, the proposed rules would greatly increase the cost of reviews, because IRBs would have to review more studies and go into greater detail regarding their data security plans.

Bouregy described several types of studies that were performed by members of the political science department and noted that the risks associated with identification of subjects ranged from great to essentially nonexistent. For example, some studies of efforts to promote voting in the United States have included data on who voted in local elections, which is publically available information. These data do not require a stringent security plan, she observed, but added that a similar study that was carried out in an emerging democracy could put some participants in the study at risk. "So it is not necessarily the identifiability of the data but the sensitivity of the data in context that needs to be taken into account," she said.

Thus instead of a minimum level of required data security protection, she said, she would prefer to see some sort of detailed guidance for IRBs and researchers that evolves over time. The IRB is best suited to determining the risk of harm, and the principal investigator is best suited to determining what is manageable in the field. In her view, the best approach would be to provide them with guidance concerning the appropriate data security plan for low-, medium-, and high-risk data.

Incorporating the HIPAA Breach Notification Requirement

Bouregy also discussed using HIPAA security and breach notification standards as the model for data protection schemes. A breach, she noted, is unauthorized acquisition of or access to data. According to the HIPAA regulations, any access, use, or disclosure of personal information in a manner not in compliance with the rule is a breach, and is presumed to be a breach unless there is a risk assessment demonstrating that there is a low probability the data have been compromised. "That is pretty stringent," she observed.

By contrast, under the Common Rule, a data breach is treated as an adverse event or unanticipated problem that must be reported to the IRB. The IRB can then consider notifying participants as part of a risk-mitigation strategy. In making that decision, Bouregy said, IRBs generally take into account such factors as the possible extent of the harm, whether anything can be done to further mitigate the problem by notifying the participants, and whether the subjects would want to know that their data were compromised, given the nature of the data and any confidentiality promises that were made. The HIPAA approach would not allow so much flexibility and adopting it for the Common Rule would likely lead

to increased costs. According to estimates, she said, it costs about $200 per record to do an investigation and notify participants of a breach incident.

The most relevant difference for social and behavioral researchers, however, may be that under the HIPAA approach the IRB would not have the ability to consider the context of a breach, which will influence both its significance and the value of providing notice of the breach. For example, if a researcher conducting a study in another country lost the data after returning to the United States, the risk to the subjects would likely be quite low. "The idea of going back and notifying that population back in the little village in some other country gets a little absurd," Bouregy said, and it would not really be of much value to the subjects.

Session 5

Multisite and Multidisciplinary Studies

Studies that involve multiple sites or multiple disciplines, or both, present particular problems for institutional review boards (IRBs), Robert Levine, of the Center for Bioethics Yale University, noted in his introductory remarks. A study that involves multiple sites has historically been overseen by multiple IRBs, one for each site, which raises issues of consistency and coordination. The advance notice of proposed rulemaking (ANPRM) proposes requiring a single IRB for multisite studies. And a study with multiple disciplines requires IRBs to deal not only with the issues that relate to each of the individual disciplines involved but also with those issues that relate to the interactions among the disciplines. In this session, Pearl O'Rourke described her experiences serving on the central IRB of a multisite collaboration. Laura Stark discussed the way IRBs function in practice and why different IRBs sometimes come to different conclusions about identical studies. Thomas Coates described his experiences leading a long-running study that is both multisite and multinational. Levine noted that each offered unique insights into the problems that multisite and multidisciplinary studies pose to IRBs and into how these problems might be addressed.

A SINGLE IRB FOR MULTISITE RESEARCH

Pearl O'Rourke, of the Partners HealthCare System in Boston and Harvard Medical School, discussed the benefits and challenges of using a single IRB for multisite research and described her experience with such a

central IRB. She began with a brief description of the possible benefits of having a single IRB handle multisite studies. These include a more efficient IRB review process, with multiple sites being approved more quickly, and continuing review and amendments being handled more effectively; less duplication of reviews; and a more consistent review because a single IRB will be seeing all of the adverse events. Together, these benefits may help studies get under way more quickly, which may allow researchers to enroll participants more easily and increase their chances of completing their studies successfully.

However, O'Rourke said, having a single IRB for a multisite study simplifies only part of the process. In addition to IRB review, there are also ancillary committee reviews, such as those for conflict of interest, radiation safety, and biosafety; grants and contracts reviews; and institutional sign-off and responsibility for the local conduct of the research. Thus, there will remain a great deal of institutional involvement at each site even with a single IRB.

Types of Central IRBs

Among central, or single IRBs, there are two types: a share model and a nonshare model. In the nonshare model the central IRB fulfills all the IRB review requirements. It is responsible for the initial review, the continuing review, amendments, adverse event reporting, and so forth. In the share model, the central IRB and the local IRBs share some review responsibilities, most frequently regarding amendments and adverse events. O'Rourke suggested thinking of them as falling on a spectrum, with nonshare, central IRBs at one end of the spectrum and the situation in which there are only local IRBs at the other end. Commercial IRBs and IRBs in the Veterans Administration system tend to fall at the nonshare end of the spectrum, she noted. The status quo for most academic multisite studies is at the other end, with each site having its own IRB. The original National Cancer Institute IRB falls somewhere in the middle, she added, because the central IRB would do the initial review, but local IRBs reviewed local site amendments and local adverse events that were not too severe. In another type of share model, the IRBshare, there is "a sharing of documentation and review of what happened at the initial review, but basically everything reverts back to the local IRB once the protocol is up and running," she explained.

IRB Versus Institutional Responsibilities

O'Rourke also noted that there are institutional responsibilities relating to research that are not handled by IRBs. Institutions are respon-

sible, for example, for a number of the terms of the federalwide assurance for the protection of human subjects. Furthermore, IRB offices often end up with responsibilities beyond reviewing research protocols.

In the nonshare model of a central IRB, the central IRB would be responsible for all IRB review tasks, including the initial review, continuing review, amendments, and so on, and might also be responsible for the Health Insurance Portability and Accountability Act (HIPAA) issues. Meanwhile, the local institutions will be responsible for a large number of other tasks, such as ancillary reviews, HIPAA implementation, oversight of the conduct of the research itself, and required federal reporting (which is not an IRB requirement).

Thus even if a central IRB is put in place, the institution finds itself left with a number of responsibilities. For example, it has to have some way to determine whether a particular protocol is eligible for central IRB review. It must also have some internal process for following the research that is being carried out onsite. It must decide how to deal with such onsite issues as noncompliance. Similarly, the investigator is responsible for knowing the local requirements for using a central IRB and understanding the processes for completing ancillary committee reviews and completing sponsored research office sign-off.

This situation leaves a number of challenges for the institution. The institution may need, for example, to integrate different information technology systems. In many cases, O'Rourke said, the IRB serves as "the center of the wheel," connecting the various entities involved in overseeing research. Institutions will also have to train their researchers in how to use central IRBs, and the initial negotiations involved in setting up the central IRB require a great deal of time and effort.

The relationship between a central IRB and a local site is set up with a reliance agreement, a formal document that sets forth the details of who is responsible for regulatory reviews and of how the legal, regulatory, and contractual responsibilities are assigned. It is important that the reliance agreement be very detailed, O'Rourke said. "We feel it's very worthwhile in that if something happens, you have something to go back to and say, 'This is what we agreed to,'" she explained.

The reliance agreements can be quite complicated, O'Rourke said, because the institutions involved tend to be very complicated. "Very few of us are single entities," she noted. For example, there may be a primary site with three affiliates. It is important to know where the research will take place. Will it take place just at the primary site or at some of the affiliates as well? And what is the relationship among them? Do they share an IRB, or does each have its own?

Experience with NeuroNEXT Model

O'Rourke described her institution's experience with NeuroNEXT, a network of about 25 academic medical centers funded by the National Institute of Neurological Disorders and Stroke to do Phase II research in rare neurologic diseases. It uses a central IRB located at the same site as the clinical coordinating centers, which was at Massachusetts General Hospital. NeuroNEXT uses a nonshare model, with the central IRB conducting all IRB reviews. Before any protocol, each network site had to sign a reliance agreement with the central IRB, which sets forth the process of the central IRB review and assigns legal, regulatory, and contractual responsibilities. The reliance agreement covers all NeuroNEXT studies, so when a new study begins, the agreement is already in place.

O'Rourke described the process by which the central IRB approves a research protocol. It begins with researchers submitting a protocol through the clinical coordinating center. Two IRB chairs make an initial assessment to determine whether the protocol is ready to go to a full panel. Once it is ready, they send it to the sites that have been selected for the research. These sites identify any substantive or local issues that concern them and communicate those to the central IRB, which may send the protocol back to the principal investigator for resolution. Next, the full committee of the central IRB reviews the protocol. If it is approved, it is sent back to the participating sites, which can then choose to proceed under that protocol or, if their concerns were not addressed, to drop out.

Most of the protocol and informed consent forms are fixed, but there are a few locally customizable items. Different institutions have different injury language and local contacts, for example, which must be accounted for.

Challenges

O'Rourke closed with a number of challenges that must be addressed in using single IRBs for multisite studies. One is to differentiate between the tasks to be carried out by the IRB and those to be carried out by the various institutions, such as understanding and addressing the local context, dealing with the logistics of communication, and developing trust. That challenge is not surprising, but some challenges may not be expected, she said. The complexity of member sites, which had multiple subsites at which research would be conducted and myriad organizational structures, may add a challenge. "Although there are 25 member sites, we have 57 reliance agreements," she said of her own project, adding that there was also confusion about authority. "Although everyone signed off that we would be the IRB of record for any regulatory decisions, once our first protocol went through we still had people saying, 'It has to have

our IRB stamp on it,'" she explained. There were also diverse views on some basic issues, such as different approaches to regulations, she noted.

The member sites had their own challenges, O'Rourke said, such as if and how to provide institutional review. Questions included who should be involved? The local IRB? And what should the review include? Another challenge for the relying sites was determining the appropriate ongoing institutional oversight of the research. The institution has responsibilities for protecting the research participants, but its role once the study is under way is not clear, O'Rourke observed. There was also confusion for those institutions that were involved in a number of multisite, single IRB studies, she added. If those studies use different single IRB models, it can be difficult for the institution to keep track of the varying systems.

In closing, O'Rourke said that mandating a single IRB for all multisite research would be "unconscionable." The ANPRM does not provide details about how the single-IRB approach would be carried out, she said, nor does it adequately suggest the complexities involved and the resources required both for being the central IRB and for relying on a central IRB. Those who play the role of a central IRB in a multisite study should not underestimate the time required for development, the start-up and long-term costs of the central IRB infrastructure, the confusion that can result from differences in the ways institutions allocate responsibilities to the institution and the IRB, and the critical role that trust and familiarity play in the development and negotiation of IRB reliance relationships.

O'Rourke does believe that single IRB review can improve the efficiency and perhaps the quality of multisite research, she commented, depending on the quality of the central IRB. But developing and using a central IRB is not easy, she added. It requires a different way of approaching the issue of research review and oversight.

MANAGING LOCAL PRECEDENTS—THREE MODELS

When a number of local IRBs review the same protocol, they may come to very different conclusions about the level of review required for the protocol, Laura Stark, of Vanderbilt University, observed. She suggested that this is one reason for the push to have single IRBs handle multisite research. She noted that local precedent may be one reason why IRBs often reach different conclusions about the same study.

Stark, who studies IRB decision making, described three approaches institutions are using to reduce the problems associated with local precedents. Stark began by describing survey research showing that when different IRBs are presented with the same standard protocol to review, they often arrive at different judgments about how the protocol needs

to be changed before it can be approved. The survey research tends to conclude that the variable decisions are the product of uneven resources across boards, Stark said, so that with larger staffs, more time, and better training, boards would be more likely to arrive at more consistent decisions about protocols.

She believes that there is a second factor at play. Her own research has shown that IRB members rarely deliberated about specific protocols by applying broad rules, such as the Common Rule. "Instead, they made decisions about a protocol by comparing it to previous cases they had decided," she explained. The previous exemplar cases upon which the IRBs based their decisions are what Stark refers to as local precedents, and they vary from one IRB to another (Stark, 2012). There is nothing inherently wrong with using precedents, Stark said, but in practice their use can lead to a variety of problems, such as when local IRBs use site-specific precedents to evaluate multisite studies or when IRBs use inappropriate precedents in evaluating novel areas of research or new methodologies.

Stark has studied how precedents shape IRB decision making, and she suggested that it is unlikely that any improvements will come from trying to scrub IRB judgment and discretion from the review process. However, she said, it is possible to harness local precedents and turn them into a beneficial phenomenon. "Several institutions are developing models that hold on to the advantages of local precedents while minimizing the many problems that they cause," she noted.

Models for Addressing the Problem of Local Precedents

Stark described three models. One, the study network approach, is directly relevant to issues raised in the ANPRM. The other two—collegial review and decision repositories—are strategies that can be developed within the framework of existing regulations to address the problem of local precedents. They are practices that can improve review for social science research and research participants even if the proposed changes to the Common Rule are not carried out.

Study Networks

In the study network approach, large, well-funded organizations review all of the studies that are attached to common research initiatives. Examples include the NeuroNEXT collaboration that Pearl O'Rourke described, as well as networks supported by the National Institutes of Health, such as central IRBs for cancer studies, and health maintenance organization research network mechanisms. In a study network, Stark said, "hundreds of investigators who are working in one broad area and

toward one general goal but who are doing so at multiple institutions get reviewed within the same system." Because one central meta-board makes decisions for all institutions and investigators, a study network limits the problem of local precedents. Ideally, a single set of local precedents—that of the study network—will be used in the review process for investigators conducting similar studies at different sites.

Two limitations affect study networks, Stark noted: liability and money. To reap the benefits of a network study, such as reduced administrative load and more consistent decisions, local boards must largely defer to the decisions made by study networks. (This approach is similar to the nonshare model that O'Rourke described, Stark noted.) But local boards' liability concerns can undermine these benefits. These concerns are often grounded in the need to take local community attitudes into account in order to comply with federal regulations. Because local institutions remain legally accountable for the research their investigators conduct, she said, many are inclined to interpret those requirements strictly, dismantling many of the advantages of networked studies.

Study networks also require substantial funding. Thus it is generally only those institutions and research programs that can most easily secure funding that can afford access to study networks. There are independent study networks, which are unattached to research sponsors or research sites, Stark said, and these may remedy some of the problems of inequitable access. However, she said, review boards are more likely to be independent of financial considerations if the boards are not operated for profit. Commercial IRBs have received mixed reviews, she said, because they are paid by the very organizations—namely, study sponsors—that have an interest in seeing research move ahead quickly. In Stark's view, not-for-profit, centrally administered review boards offer the greatest potential for addressing the contradictions between local precedents without undermining the reviewers' freedom from financial conflicts of interest.

Collegial Review

The second model, collegial review, is designed to minimize the application of inappropriate precedents by assigning reviewers who are from the same research tradition as the investigator(s). At universities, Stark said, collegial review is most commonly used for student projects and involves a local review by members of the student-researcher's discipline. This model can be extended beyond student research if a system of review organized around institutions, departments, or offices is developed. Doing so would move protocol evaluation closer to the people who have expertise in the field in which the investigator is working. Reviewers

who know the implications of the proposed methodologies for the populations under study would conduct the evaluations. Some university IRBs already use department-level subcommittees to complete expedited reviews for the department's own investigators, Stark said.

One downside of this approach, she noted, is that it could make it more likely that personal politics could influence the decision-making process. To avoid such conflicts, she said, institutions could use external collegial review mechanisms for human subjects review, sending protocols to researchers at other institutions for review.

Decision Repositories

The third approach, decision repositories, is designed to make it possible for IRB members and researchers to learn about decisions made by various institutions regarding studies similar to a particular study of interest to them. One way to do this is to create an online repository of approved protocols that have been appropriately de-identified. Such a decision repository might be more feasible than other models, Stark said, because it would not require institutions or the federal government to fundamentally restructure the review process.

This approach would require the generosity of a few institutions and agencies, she noted. "Repositories require funding, server space, time, and, importantly, the donation of protocols," she explained. Researchers are often hesitant to share their current research protocols because of concerns about protecting their intellectual property, she said, so it might make more sense to collect records from completed projects, even though these would become outdated more quickly.

Stark pointed to two existing decision repositories to illustrate this approach. The Sunnybrook Health Sciences Centre in Toronto has created a bank of decisions with the aim of making more consistent decisions, but it is accessible only within the institution. In New Zealand, there is a publicly available digital archive of decisions called the Ethics Application Repository housed at the University of Otago.

Such repositories should help remedy the problem of local precedents, Stark said. Today, decision makers who wish to apply precedents must rely on individual memory, so IRBs with a low turnover rate in membership are likely to develop inertia in their decisions and also to narrow the set of problems they tend to identify with protocols. In contrast, IRBs with a high turnover rate are likely to make inconsistent decisions about similar protocols over time. Decision repositories can help widen the horizon of IRBs with low turnover rates and help remind IRBs with high turnover rates of what decisions have been made in the past. Publicly accessible decision repositories would also help researchers interact more

effectively with their IRBs, Stark said. "Researchers are in a position, in other words, to teach their IRBs how studies should be evaluated, to signal to their boards that a research community exists even if the topic or method is new to reviewers, and to assure IRBs that they wouldn't be alone in approving a new methodology or new topic," she observed.

INTERNATIONAL MULTISITE AND MULTIDISCIPLINARY STUDIES

Thomas Coates, of the University of California, Los Angeles, discussed issues that arise in international multisite research. He had recently completed a 10-year clinical trial of the effectiveness of various interventions to prevent HIV infection, which took place at five international sites and involved 14 IRBs in six different countries. The study received informed consent from approximately 200,000 people, using various forms of consent. Although international research is not addressed in the proposed changes to the Common Rule, Coates noted, the implications of these issues are vast, and they are in some ways similar to those of other issues addressed by the workshop speakers.

Issues

Coates described a number of issues that researchers face when running an international multisite study. An overarching issue is the incredible disparity in resources between the United States and many of the countries that may be involved in an international study. Potential study participants in other countries may lack access to many basic medical services, for example, and may not even be able to talk with somebody about filling out a questionnaire. The disparities are also evident in the value that participating in such a study has for local scientists and scientific organizations, who can get access to resources that otherwise would be out of reach. "This inequality is part of what needs to be acknowledged when we think about how best to structure international studies," Coates said.

Many countries, particularly those in the less-developed parts of the world, also have less stringent regulations governing human subjects research. There may be less emphasis on informed consent, and researchers from the United States must make sure that the subjects in the studies actually are freely providing informed consent. U.S. researchers may also notice a lack of strict ethical oversight in some international research projects, in comparison with U.S. customs, as well as less concern about confidentiality and privacy among those working on a study.

Coates illustrated his point with an experience he had in a low-income

neighborhood outside a city in Peru, where a health center had been established. He discovered that the staff of the health center had developed a complete house-by-house map of the neighborhood that specified health-related problems that had been observed in each, including such health problems as diabetes or cardiovascular disease, as well as behavior-related problems such as alcoholism, depression, and partner violence.

Though most of his examples concerned biomedical research, Coates noted that many studies now blend behavioral, social, and biomedical research. The proposed changes in the Common Rule seem to be based on the assumption that the social and behavioral studies are completely separate from biomedical studies. To the contrary, he said, in many cases a combination of disciplines is essential to understanding how things work. For example, if his research group finds that a new treatment is not working in the field as well as expected, they will need to examine the reason from various angles. They will need to ask, "Is that because the agent isn't any good? Is that because . . . people don't use it the way it was intended to be used or because of health systems or other social issues?" he explained.

This blending of various areas of science raises questions about what standards will apply to a study, he said. "If it is a combined study, do the proposed changes in the Common Rule apply to the social and behavioral pieces? Do the biomedical pieces get judged by a different standard?" he asked.

Another issue is how to what extent U.S. standards and regulations should be imposed on foreign countries taking part in international studies funded by U.S. institutions. For example, Coates noted, it is not clear whether foreign regulatory bodies should be required to have a federalwide assurance in place, or whether an equivalent can be accepted. It is also not clear whether the proposed changes have the same implications in a foreign country that they do in the United States, or whether minimal risk is the same in other countries as it is in the United States. It is also important to note that the level of ethical oversight typical in the United States is very costly, and it is not clear which entities involved in multinational studies should bear the additional costs, he added.

Coates suggested that it might be necessary to develop ways to strengthen local oversight in other countries if the proposed changes to the Common Rule are enacted. "If we in the United States are interested in doing research in collaboration with local investigators in foreign countries, we also need to address the kinds of capacity building that might be necessary to ensure that the standards are adhered to," he suggested. This would mean providing training for investigators and IRB staff and members, particularly in response to the changing expectations for oversight, he added.

Changes and Proposed Alternatives

Coates offered some suggestions for altering the proposed changes to the Common Rule to better suit international multisite studies. If it is useful to apply the proposed changes to all studies funded by federal agencies and clinical studies that seek Food and Drug Administration approval, he suggested, it might also make sense to apply the new regulations to studies that are funded entirely by other countries, multilateral agencies, or philanthropic organizations, such as the Bill & Melinda Gates Foundation, which funds much of the research in his own area. He suggested that adverse event reporting systems, even for social and behavioral studies, should be designed to address issues arising in international studies and should be multinational. He also said that enhanced and simplified consent procedures would be useful and important, particularly for written consent. In many countries, he said, "a waiver of signed informed consent is not only useful but essential." In some parts of the world signing documents carries great significance, he explained, but there are many cases where subjects are not capable of signing their own names even if they wish to.

More thought needs to be given to the issue of minimal risk when a study spans multiple countries, he said, because the definition of minimal risk may vary from country to country. Reporting that one is homosexual is much more dangerous in a country where homosexuality is illegal than it is in the United States, for example. More thought also needs to be given to the issue of IRBs for multicountry studies, he added, to answer such questions as whether it would make sense to have a central IRB based in the United States or to have local IRBs involved. It is probably important that any study done in a foreign country have the approval of local regulatory bodies, he said, but that raises the question of how local IRBs can be held to standards of efficiency and timeliness of approval. Furthermore, it is not clear whether the U.S. IRB or the local one would make decisions about such issues as minimal risk and expedited status.

One other issue is how—or whether—U.S. guidance should be harmonized with international guidance and regulations. The U.S. Department of Health and Human Services could work with the World Health Organization or other agencies, Coates noted, but there are questions about how and to what extent the U.S. guidelines could be harmonized with local guidelines. One thing that should be carefully avoided, Coates said, is having studies funded within the United States that take advantage of lax regulations in other countries to carry out research that would not be acceptable in this country.

REFERENCE

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Session 6

Purview and Roles of Institutional Review Boards

Yonette Thomas, of Howard University, introduced the final session of the workshop that provided a look at the role of institutional review boards (IRBs) from three very different perspectives, that of a university official overseeing human research participants protection, a sociocultural anthropologist who must deal with IRBs in her work, and a research funder.

PERSPECTIVE OF A HUMAN RESEARCH PROTECTIONS PROGRAM THAT MAXIMIZES OPPORTUNITIES TO BE FLEXIBLE AND INNOVATIVE

Lois Brako, of the University of Michigan, Ann Arbor, offered some observations and suggestions about the proposed changes to the Common Rule, based on her experiences with regulatory and compliance oversight at the University of Michigan. She described the university's human research protections program as one that seeks to maximize its opportunities to be flexible and innovative, and noted ways the university works to take full advantage of the flexibility in the regulations concerning human subjects protection. The university limits the scope of the federalwide assurance by applying it only to federally funded projects. "It's really important on a campus like ours with so many student projects," she said. "This allows us to do some local review if we want. . . . Again, our school has tried to take full advantage of this," she noted.

The university also regulates only research that meets the defini-

tion of human research. In 2012, 172 of the 1,024 new submissions to the university's health sciences and behavioral sciences institutional review board (IRB-HSBS) were classified as not regulated.[1] "We don't want to over-regulate," she said. A large percentage of the protocols submitted to the IRB-HSBS—more than 40 percent in 2011 and 2012—are exemptions by IRB staff reviewers. Exemptions do not have to be granted by the IRB itself, she noted; the process can be carried out by educated staff members. The IRB-HSBS is also constantly using and streamlining its expedited review process; in 2012 nearly 40 percent of the new submissions were given expedited review. She added that the IRB-HSBS regularly uses waivers or alteration of informed consent and waivers of documentation of informed consent, particularly for the social sciences, and it has established cooperative research arrangements to avoid duplicate review.

As a result, even though the IRB-HSBS has about 1,200 projects ongoing, the workload of the full committee has been reduced, and the time it takes the committee to make decisions has been significantly decreased, Brako said. For example, the median turnaround time for an exempt determination went from five to six days in the first part of 2011 to one or two days by the end of 2012.[2] The median turnaround time for expedited approvals also has dropped, she said, and was at about 14 to 15 days in the second half of 2012.[3]

The university's IRB-HSBS has also conducted demonstration projects on minimal risk research. The projects cannot be federally funded or regulated by the Food and Drug Administration, and they must not hold certificates of confidentiality. One demonstration allows two-year approvals, and another created a new exemption category for secondary data analysis with identifiers. "In the first two years of our projects," Brako said, "we saved ourselves about 1,000 project reviews. . . . We also audited, and we found no problems."

Comments on ANPRM Proposals

Brako offered several comments about the proposed changes to the Common Rule. The advance notice of proposed rulemaking (ANPRM), she noted, proposed to create a category of "excluded" research that would require only a one-page application and no review before research began; there would be a data security check and a random audit later (Emanuel and Menikoff, 2011). This is similar, Brako said, to a current University

[1]For details, see http://www.hrpp.umich.edu/Indicators_Report_January_2013_Final.pdf [March 2013].

[2]Ibid.

[3]Ibid.

of Michigan IRB-HSBS process with a short application reviewed by an IRB staff specialist. "So we're already in a very streamlined mode, with a one- to two-day turnaround time."

Brako suggested that "registered" might be a better term than "excluded" because "as an institution we're responsible for connecting up to federally funded projects. We really want to see these projects registered." She also supported the idea of allowing investigators to determine their own exemption status using standardized tools such as decisions trees or exemption wizards. She said there is some advantage to maintaining institutional screening processes to validate these exemptions but believes it would be preferable to validate them before the initiation of the research. Finally, she said, IRBs should continue to review ethical concerns related to the protection of privacy and confidentiality, but they should be able to rely on institutional resources, such as information technology experts, for the evaluation of data security.

Brako said she sees great advantage to expanding the exemption categories, and she made several suggestions for new exemption categories. These included social networking, the human testing of technology, the analysis of secondary data with identifiers, minimal risk deception research, the collection of data from videos and other recordings, and group characteristics from surveys and interview.

In Brako's view, new categories should be created for expedited review. An expert panel composed of social scientists and other researchers, IRB members and chairs, IRB administrators, and nonscientific IRB members should be formed to determine what the new categories should be, she added, and the panel should update the list regularly. The list from the Council on Governmental Relations comments on the ANPRM, which suggested new expedited categories for studies of Internet behavior, functional magnetic resonance imaging at standard exposure levels, the establishment of registries for future research purposes, and occupational health activities, such as walking, deep breathing, and mild exercise, could provide a starting point for this work, she noted.[4] Brako also suggested letting IRBs use expedited procedures for any other activities they determine to be of minimal risk.

On the subject of the elimination of continuing review (Emanuel and Menikoff, 2011), she said she strongly supports this for qualifying minimal risk studies, but she added that the change should be accompanied by clear guidance and examples of what IRBs would no longer be required to do.

On the issue of a single IRB for multisite research, Brako said that she

[4]The list is available at http://www.regulations.gov/#!documentDetail;D=HHS-OPHS-2011-0005-0656 [March 2013].

supports a movement to reduce duplicate reviews by multiple IRBs, but that it should not be mandated for all cases. There are reasons to have the flexibility to use more than one IRB, she said.

Brako said she generally agrees with the idea of clarifying and harmonizing regulatory requirements and agency guidance across the agencies. Inconsistencies in guidance from various agencies—she mentioned the Food and Drug Administration, Department of Defense, Department of Justice, Department of Education, Environmental Protection Agency, and the National Science Foundation in particular—weaken human subjects protection by distracting researchers and IRBs from more important considerations. They impede research by slowing the review process and by confusing and intimidating researchers. However, she cautioned against harmonizing by creating a "one-size-fits-all" approach to different types of research, which often results in unfavorable cost–benefit ratios. Instead, she would like to see a single, multiagency regulatory standard that calibrates its provisions to the nature and magnitude of risk that it addresses.

Brako offered comments on the proposed changes to informed consent. "I think just about anyone would agree, that the process of informed consent could be improved," she said. Specifically, consent documents can be greatly simplified if they focus on descriptions of the research activities, the risks imposed by the experimental component, the potential benefits of the research, and the burdens (e.g., financial, time commitments, alterations in medical care) imposed by participation in the project. Mainly, she said, what is needed for the social and behavioral sciences is flexibility.

Proposed Changes That Would Increase Burden

Some of the proposed changes in the ANPRM are likely to increase the burden for institutions, and Brako identified several that would likely prove particularly burdensome at the University of Michigan. Requiring federal oversight of all human subjects research at an institution that receives federal funding would be overly burdensome, she said. This change would cause her institution to lose a lot of the flexibility that it has taken advantage of in dealing with human subjects protection. Similarly, mandating institutional data security and information protections whenever data are collected, generated, stored, or used would also be burdensome. "I think there are many ways that we can deal with this data issue in a different way," Brako said.

Expanding the meaning of "human subject" to include biospecimens without identifiers within the ANPRM provisions related to informed risk and requiring written consent for the research use of de-identified specimens would also increase the burden, Brako added. The proposal to require records of adverse events and unanticipated problems to be

submitted and stored in a central database is premature, she said. There is much to learn and understand before such a requirement is instituted, in her view.

In summary, Brako said that while she supports several proposed changes in the ANPRM that clearly reduce burden, she also believes that in some cases clear and concise guidance could accomplish more than changing the regulations in terms of assisting investigators, institutions, and IRBs to better protect research participants. She said that she is particularly concerned that some of the proposed changes seem to shift, rather than reduce, the burden.

EFFECTS OF PROPOSED CHANGES ON SOCIOCULTURAL ANTHROPOLOGY

Rena Lederman, of Princeton University, discussed how the proposed changes to the Common Rule—and, in particular, the creation of an "excused" category of research that has only informational risks—would be likely to affect anthropologists and other ethnographers. Lederman described the distinctive features of participant observation, which she described as "my discipline's way of understanding human experience." This approach to research is quite different from the approach in other areas of science, she explained, which makes it a poor fit for the Common Rule in many ways.

To carry out their fieldwork, Lederman explained, anthropologists immerse themselves in the lives of the people they study, communicating in their language and staying for long stretches of time. The settings are not controlled and thus not particularly suitable for systematic hypothesis testing. "Our goal," she said, "has generally been to put ourselves in social situations controlled by the people whose circumstances we're interested in understanding, who are not therefore our subjects, but more accurately our hosts, our interlocutors, our instructors, our consultants, and increasingly our collaborators." Unlike researchers in most of the social and behavioral sciences, who do not form close relationships with their subjects, ethnographers form relatively "thick" relationships with their research participants. She explained that the researchers are being observed by the participants at the same time that the participants are observing them. These full and complex interactions with research participants are a major source of the understanding that ethnographers derive from their research.

At the same time, these investigator–participant interactions do not lend themselves to the sort of informed consent envisioned by the Common Rule, Lederman said. A consent agreement works like a contract, she said, spelling out the relationship between investigator and

participant "in terms of a socially thin set of expectations and agreements." Such an agreement is not attuned to the relationship-thick ethical demands of ethnographical fieldwork, she observed.

Problems with Proposed Data Privacy Protections

One of the key changes proposed in the ANPRM would be to allow projects that pose only "informational" risks to be excused from undergoing prior IRB reviews of their research plans, as long as special data privacy protections are instituted before the data analysis is begun, Lederman noted. The ANPRM also proposes to classify the risks posed by most anthropological research as informational. Consequently, Lederman said, it might appear that the new "excused" category would be a boon for anthropologists. Because the new rules place most anthropological research in the informational risk category, she explained, anthropologists would no longer have to submit study designs to IRBs. However, in her view, the current Common Rule's demand for scientifically rigorous project designs—which, by the nature of ethnographical work, are essentially impossible to specify—undermines the training of students. This provision "encourages the rest of us to offer misleadingly formalized accounts of our prospective work," Lederman said.

However, she continued, the special data privacy protections envisioned by the ANPRM, based on the Health Insurance Portability and Accountability Act privacy standards, would be equally ill-suited for ethnographical fieldwork. Although anthropologists do traditionally shield the identities of their research participants through the use of pseudonyms, useful ethnographic descriptions require a significant amount of contextual specificity. "De-identifying or anonymizing ethnographic data would render them unusable," she said.

Furthermore, she added, while data anonymization may be feasible for such relationship-thin research as surveys and experiments, it is theoretically impossible for fieldwork if genuine anonymization means that the investigators themselves are unable to re-identify research participants. The value of ethnographical research lies in the details amassed by researchers in their long-term interactions with the research participants. By the very nature of the work, researchers know the identities of the participants, she explained. Thus de-identifying data before beginning post-fieldwork analysis, as proposed in the ANPRM, would be unworkable for sociocultural anthropologists and other ethnographers.

The effective ethical oversight of sociocultural anthropology, ethnographic sociology, and many other areas of the social and behavioral sciences requires an approach that is not so narrowly grounded in the ethical issues that arise in the biomedical sciences. One useful start, she observed,

would be to tighten up the definition of what is being regulated so as to refocus IRB review more explicitly on biomedical and physical risk. Doing so would enable IRBs to give potentially higher-risk projects the attention they deserve, she suggested. Then alternative approaches could be developed to more adequately address the actual ethical dilemmas of sociocultural anthropology fieldwork and related forms of scholarship: approaches that promote rather than undermine these sciences.

Lederman suggested forming a national commission to develop a rationale and framework for promoting ethical conduct in those areas of scholarship poorly served by or newly excused from the Common Rule. Such a commission might be made up of experts in fields inadequately served by the existing system of oversight, together with legal scholars and philosophers knowledgeable about those fields. To avoid reinventing the wheel, she explained, the commission should be instructed to draw together and build on existing knowledge.

HUMAN SUBJECTS PROTECTION IN RESEARCH FUNDED BY THE DEPARTMENT OF JUSTICE

Cheryl Crawford Watson, of the National Institute of Justice, described human subjects protection in research funded by the Department of Justice (DOJ). Because of the sensitive nature of much of that research, which often focuses on criminals and illegal activities, research is subject to additional regulations protecting confidentiality, above and beyond the Common Rule. This creates additional issues for the IRBs reviewing the research, Watson observed.

Any research funded by the DOJ, Watson explained, is governed by a confidentiality statute that not only forbids the release of identifiable information by federal employees and those receiving federal funds, but that also states that such information is immune from legal processes and shall not, without the consent of the person who provided the evidence, be used in any judicial, legislative, or administrative proceedings. Researchers who receive funding from the DOJ who collect personally identifiable information must submit a privacy certificate that describes the research, promises that the researcher will comply with the confidentiality requirements, and describes in detail the procedures the research will use for protecting the confidentiality of the identifiably information collected as part of that research. The procedures for protecting the confidentiality of the information address, for example, the administrative and physical security that will be used to protect the data, who will be allowed access to the data, the information transfer agreements that will be used, and details about the final disposition of the data, including how and in what form it will be archived.

The privacy certificate also includes details about what the research participants will be told during informed consent discussions. Watson added. They must be told that the information they provide will be used only for research and statistical purposes, that the study is voluntary and they can quit at any time, what the study's risks and benefits are, how the data will be securely maintained, and how the data will be archived or disposed of after the study.

Confidentiality can only be broken with the subject's consent, and the identifiable data collected for the study can only be used for research purposes with the subject's consent. "We are a law enforcement agency," Watson explained. "Few would participate in DOJ-funded research without strong protections on that identifiable data." The one exception is that the regulations do not apply to information collected regarding future criminal intentions.

This exception can bring a researcher into conflict with state mandatory disclosure laws, she noted. Whereas the certificate of confidentiality required by many other federal agencies allows a researcher to disclose matters, such as child abuse, reportable communicable diseases, or a subject threatening to harm someone, the privacy certificate required by DOJ does not, she noted. Thus, when mandatory disclosure laws are an issue, the researcher must get two different consent forms signed by the participants—a consent to participate and a consent to allow reporting.

IRB Interactions with the DOJ

Because of these DOJ-specific regulations, researchers go through a somewhat different process with DOJ than they would if their research were funded by, for example, the Department of Health and Human Services, Watson explained. IRBs play the same role with DOJ-funded research as they do with research funded by other federal agencies. Extramural research—that is, research funded by DOJ but performed outside the department—is reviewed by the grantee's own IRB or by a commercial IRB. Intramural research is reviewed by the Office of Justice Programs' IRB at DOJ.

DOJ research is governed by several federal laws and regulations, including 42 USG § 3789g, which provides for confidentiality of information. DOJ adopted the Common Rule but not its subparts, Watson noted. However, if an IRB or a grantee organization has promised or, in its federalwide assurance has said, that it would follow the subparts, the DOJ requests that it do so.

Researchers who receive DOJ funding need to understand that there are withholding conditions on those funds, Watson said. For the funds to be released, the DOJ must receive both the privacy certificate and the

Human Subjects Protection Form, which provides the grantee's Federal-wide Assurance number and IRB number and indicates whether the IRB review has already taken place or whether it will take place at some point in the future.

One of the main areas that cause concern is attempts by principal investigators to self-exempt, she said. In some cases, the research truly should be exempt; but in other cases, the research is greater than minimal risk and the researcher has, for unknown reasons, decided that it fits within the exemption criteria.

Another common issue is that IRBs are unaware of DOJ regulations, particularly the confidentiality statute. Watson said she sees many consent forms that specify that the investigator will report child abuse, suicidal ideation, threat of harm to others, and so on. The DOJ will not accept such forms. In other cases, the IRBs are simply confused by the regulations, she added, as they are somewhat different from what IRBs usually encounter. In at least two cases, researchers have decided not to take DOJ funding—in one case after it had already been awarded—because the DOJ will not accept informed consent forms that include mandatory disclosure statements. To address these issues, the DOJ has an effort under way to compile an information packet it will send to IRBs and principal investigators.

REFERENCE

Emanuel, E.J., and J. Menikoff. (2011). Reforming the regulations governing research with human subjects. *New England Journal of Medicine* 365:1145–1150.

Appendix A

Workshop Agenda

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

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 (NRC) 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,

multidisciplinary and multisite studies, and institutional review board (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; and
- 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 IRBs and researchers.

DAY 1: THURSDAY, MARCH 21, 2013

8:15 am **Check in and Continental breakfast**

8:45 **Welcome and Introduction of Members of the Committee 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, Executive Director, 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 pm	**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, Ann Arbor, Survey Research Center*
3:30	**Speaker 1:** *George Alter, University of Michigan, Ann Arbor, 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 am	**Continental Breakfast**
8:45	**Welcome and Overview of Day 2** *Susan Fiske, Princeton University*
9:00	**Session 5: Multidisciplinary and Multisite Studies** *Introduction:* This session will examine issues related to the protection of research participants in studies that are multidisciplinary (SBE; biomedical/genomics), multisite, 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 multisite 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 multisite NINDS study and the challenges involved.)
9:40	**Speaker 2:** *Laura Stark, Vanderbilt University, Center for Medicine, Health, and 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, University of California, Los Angeles, 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, Ann Arbor, 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, Department of Anthropology* (Discussion of IRB issues in the context of sociocultural anthropology and ethics.)
12:20 pm	**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, Ann Arbor
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 National Research Council'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.

Appendix B

Biographical Sketches of Speakers

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, Ann Arbor. 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. Recent publications include "The Demographic Transition and Human Capital," a chapter in *The Cambridge Economic History of Modern Europe* (Cambridge University Press, 2010); and "Widowhood, Family Size, and Post-Reproductive Mortality: A Comparative Analysis of Three Populations in Nineteenth Century Europe," a 2007 article in *Demography*. He is past president of the Social Science History Association. He holds a Ph.D. in history from the University of Pennsylvania.

Susan Bouregy is chief Health Insurance Portability and Accountability Act (HIPAA) privacy officer and an institutional review board (IRB) vice-chair at Yale University. As privacy officer, Dr. Bouregy is responsible for the HIPAA privacy program throughout the university, which covers the health plan; the healthcare providers in the faculty practice; and University Health Services, a full-service care provider for students, employees, and their families. Dr. Bouregy has been responsible for oversight of

the social and behavioral science IRB at Yale. This IRB is responsible for review of the broad range of social, behavioral, and educational research conducted at the university. Dr. Bouregy also served as codirector of the university's 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 campuswide research policies and procedures and strategic planning for regulatory compliance oversight. Dr. Brako is the director of the University of Michigan's Human Research Protections Program, which spans four IRB offices and nine IRBs, with oversight of more than 5,600 projects. Dr. Brako chairs the University of Michigan IRB Council, cochairs 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 the 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 cochair 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 (APA'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 (NSF'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 understanding of human and animal learning. Dr. Breckler was an associate professor of psychology at Johns Hopkins University. He is author or coauthor of more than 60 papers on topics ranging from attitude development to jury functioning. Dr. Breckler's research has been supported by grants from the NSF, the National Institutes of Health, and the Department of Defense. He is also the coauthor 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*. He is a fellow of the APA, the Association for Psychological Science, and the American Association

for the Advancement of Science. Dr. Breckler holds a Ph.D. in social psychology from the Ohio State University.

Richard T. Campbell is an emeritus professor of biostatistics and sociology at the University of Illinois, Chicago. 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 healthcare providers. His prior research, almost all of which has been based on large national datasets, has focused on aspects of health and aging and on social stratification. He has served on IRBs at both Duke University, where he also chaired the Faculty Senate Committee on Human Subjects, and at the University of Illinois, Chicago. 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 (CNSTAT), a position she has held since 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 second–fifth 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 M.A. and Ph.D. degrees in political science from Yale University.

Thomas J. Coates is director of the University of California, Los Angeles (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. In 1986, he cofounded the Center for AIDS Prevention Studies at the University of California, San Francisco (UCSF), 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 and 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 the World Health Organization, 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, Tanzania, Thailand, and Zimbabwe, to determine the impact of strategies for destigmatizing HIV. He is also leading a prevention clinical trial in South America as part of a five-country effort and has a trial in China to determine the impact of prevention in the context of care. He is coprincipal investigator of the National Institute of Allergy and Infectious Diseases–funded HIV Prevention Trials Network and is conducting policy research domestically and internationally. He was cited in *Science* in 2002 as the fourth-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.

Roxane Cohen Silver is a 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. 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 earthquake in Chile and the 2006 earthquake in Yogyakarta, Indonesia). Her research has been funded by the National Institute of Mental Health, the National Science Foundation, the U.S. Department of Homeland Security, and the U.S. 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 the department

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 of, preparedness for, and response to terror attacks, conflict, or natural disasters across the world. Dr. Silver is a fellow of the American Psychological Association (in four 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 Ph.D. in social psychology from Northwestern University.

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 National Institute on Drug Abuse–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 Department of Health and Human Services Secretary's Advisory Committee on Human Research Protections (SACHRP; and cochair 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 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); coeditor 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 more than 100 theoretical and empirical publications

in the areas of ethics in medical and social science research and practice and lifespan 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.

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" (nonmarket) exchange, gender relations, and historical consciousness, which resulted in a Cambridge University Press book, several book chapters, and articles in *Annual Review of Anthropology* and other scholarly journals. 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. Dr. Lederman's recent publications in *American Ethnologist*, *PoLAR: Political and Legal Anthropology Review*, and elsewhere have focused on the impacts on ethnography and related research styles of IRB regulations. She was an invited plenary speaker at Public Responsibility in Medicine and Research; served as both chair and member on the American Anthropological Association's Committee on Ethics and as a member of Princeton University's IRB; and was coauthor of the American Anthropological Association's 2011 commentary on the proposed overhaul of IRB regulations (45 CFR 46). Dr. Lederman has been the recipient of research grants from the American Philosophical Society, Columbia University, the National Institutes of Health, the National Science Foundation, and Princeton University; and conference grants and sponsorship from the Wenner Gren Foundation and the National Endowment for the Humanities. Dr. Lederman holds a Ph.D. in anthropology from Columbia University.

Taylor Martin is an associate professor of instructional technology and learning sciences at Utah State University. Dr. Martin has worked in research and development on curriculum and design of instructional systems on such projects as the Adventures of Jasper Woodbury and the Algebra Project. She has also worked as an elementary mathematics teacher. She was an associate professor in the Department of Curriculum and Instruction and was an affiliate faculty member in the Department of 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

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Brian Mustanski is an 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 conducts translational research that improves the health of the lesbian, gay, bisexual, and transgender (LGBT) community. Dr. Mustanski also has appointments at the Institute for Policy Research and the Center for Community Health. Dr. Mustanski's research has focused 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 (Centers for Disease Control and Prevention, National Institutes of Health, National Science Foundation) and foundation research and training awards totaling more than $13 million in funding. Dr. Mustanski has also studied the health and development of LGBT youth and the application of new media and technology to sexual health promotion and HIV prevention. He is currently leading or coleading three studies of online/text messaging based HIV prevention for adolescent men who have sex with men. He has published on ethical and regulatory issues in sexual health with adolescents and served on an institutional review board. Dr. Mustanski has received a number of awards for his work in this area, including 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 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. She has served as a pediatric critical care physician at Children's Hospital, Boston, and at 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, liquid ventilation, high frequency ventilation, and pediatric resuscitation. She has served as the deputy director of the Office of Science Policy in the Office of the Director at the National Institutes of Health, where she worked on such issues as privacy, gene therapy (transfer) embryonic stem cells, and genetic discrimination. Dr. O'Rourke has been

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Jeffery Rodamar is protection of human subjects coordinator with the U.S. Department of Education. Prior to assuming his current post, Mr. Rodamar worked in program evaluation with the Department's Planning and Evaluation Service. Mr. Rodamar is an ex-officio member of the Secretary's Advisory Committee on Human Research Protections, participates in the interagency Confidentiality and Data Access Committee, 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.*

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. She is the 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 National Institutes of Health after World War II. Dr. Stark holds a Ph.D. in sociology from Princeton University.