

## PANEL DESCRIPTORS

### ***A Great Debate: Be It Resolved that Consent Forms are an Obstacle to Informed Consent and Should be Abolished***

Obtaining informed consent from subjects is an essential condition for performing ethical research. Discussions of informed consent often draw distinctions between the informed consent *process* and informed consent *forms*, and there are often complaints about the forms, e.g. they are too long, too complicated, not truly useful to potential subjects, etc. Despite widespread efforts to improve the written consent form, most research professionals would agree the problems with consent forms continue. This debate will present a point-counter-point discussion on the utility of consent forms and whether it is time to consider a new approach.

### ***Panel I: Pushing the Envelope: Examining Campus-Based Research***

The purpose of this panel is to highlight controversial and/or sensitive campus-based research that has the potential to generate significant benefit, but which presents risks of litigation and/or negative publicity to institutions. (For example, although no one would argue that learning more about the etiology and prevention of violent and/or self-destructive behaviors on college campuses is extremely important, university administrators (and sometimes IRBs) can be hesitant to support such research based on the potential risks.) This session will feature panelists representing institutions engaged in such controversial issues. The presenters will stress the importance of conducting this type of research, discuss the relevant ethical issues within the current regulatory framework, and will help those who attend better understand the ways in which IRBs approach and handle such projects.

### ***Panel II: Global Standards for Research Ethics: Is Uniformity Possible... Or Desirable?***

The earliest statements regarding the ethics of research with human subjects – the so-called *Nuremberg Code* (1947) and the *Declaration of Helsinki* (1964) – were promulgated as globally applicable standards. Yet, over the succeeding decades, as research has spread to all corners of the world, tensions have arisen between national standards and practices and evolving global expectations, as well as between the rules of different jurisdictions. To what extent do global norms now exist, especially regarding the most contentious issues (such as the use of placebo controls in drug trials, or the post-trial obligations of sponsors and investigators to the populations among whom trials are conducted)? This panel will address the a range of issues in international research, including the tension between the “ethical relativism” that comes from modifying global standards to account for local customs and beliefs and the “ethical imperialism” that comes from not doing so; whether U.S. rules serve as de facto standards for research around the world; why no other system has been recognized as providing “equivalent protection”; and whether the embrace by the FDA of the ICH-GCP standards, in place of the current *Declaration of Helsinki*, manifests an intention to make the ICH standards the global norm.

### ***Panel III: When Research Includes the Most Vulnerable Subjects: Key Considerations in IRB Review of Research with Adults Who Cannot Consent for Themselves***

The discussion of research protections for adults who lack consent capacity too often limits the focus to the assessment of capacity alone. This panel will focus instead on the broader set of considerations in IRB review necessary to safeguard the rights and welfare of subjects who cannot protect themselves during the course of research participation. Lessons learned from a history in which captive and incompetent individuals were exploited helped drive modern approaches to research protections. But, while regulatory subparts were developed for children, prisoners, and pregnant woman and fetuses, the regulations and regulatory guidance remain all but silent with regard to those most vulnerable to “coercion or undue influence.” Speakers will examine seminal events in the history of research with

incompetent adults, the forces that influenced these events, and the many failed efforts to develop a regulatory framework to address the problem. Moral and ethical implications of research with those who cannot consent and may not benefit from participation, as well as modern approaches to risk identification and minimization, will be presented. A discussion of this most challenging aspect of research protections serves as a reminder of the fundamental tensions between individual and societal interests and the role of the IRB in safeguarding individual welfare.

**Panel IV: Making Sense of Community Responses to Tissue Research**

This panel will explore the ethical issues related to conducting research on the community of individuals from whom biological specimens are obtained. Because the results of research may impact members of the community besides the individuals who participate directly in the research, and because biological specimens are often used in secondary research studies that are unrelated to the original clinical or research purpose for which they were obtained, results may affect people who had no say in the research. In the wake of broad public discussion about Henrietta Lacks and the derivation of HeLa cells, this panel will consider the ethical issues related to tissue research in light of lessons to be learned from previous research in selected high-profile cases (including specifically the Havasupai case), as well as how such issues are now being addressed in tissue research in selected communities.

**Panel V: Research in Complex Humanitarian Disaster Settings and War Zones**

During this panel, the speakers will examine the various ethical issues that arise when studying the social, psychological, and economic consequences of complex humanitarian situations including war, genocide, hurricanes, and environmental calamities. Such projects are significantly different from those that arise when studying the same populations under normal circumstances. While the impact of data gathering on the lives of research subjects is a central concern in *all* research, it raises more complex questions in disaster research, such as: What additional responsibilities do researchers have when interviewing people who may have lost their livelihood and/or their family members? Should researchers avoid asking certain questions that may be especially difficult for the subject to answer? Should researchers perform emergency-related tasks in disaster areas? How can and should researchers respond to findings of human rights abuses and violations? How do researchers in disaster areas avoid engaging in so called “helicopter research?” These and other questions will be addressed.

**Panel VI: Hot Off the Presses: Selected Abstracts on Innovative HRPP Programs and Research on Research Ethics**

We’ve got data, strategies, great ideas, and more, or at least our presenters do! During this session, research professionals will present empirical research on research ethics and will provide audience members with concrete tools and strategies designed to improve the effectiveness of their IRB/HRPPs.

**Panel VII: Going Global or Staying Local? Research Ethics in a Culturally Diverse World**

Both globalization and the changing demographics within the U.S. impact research ethics in new and challenging ways. Historically, sensitivities to cultural differences were a relevant concern only for research conducted outside our national boundaries (with the exception of research with Native American and First Nation populations). But now, with increasing immigrant populations and communities within the U.S., researchers need to be more attuned to such differences. By the same token, globalization and advances in communication technologies have made international research more common. When conducting research in populations having cultural norms different from those of the researchers, whether in this country or in another, the mere translation or adaptation of consent forms and survey instruments may not be ethically or legally sufficient. Researchers must take into consideration a number of issues including the relevance of the research objectives to the particular population, the cultural norms, the regulatory requirements, and the potential societal impact of the research on both the individual and the group. This panel will feature researchers working in international and domestic arenas where occidental views on research ethics collide with local cultural values and ethics. The presentations will illustrate how researchers and IRBs deal with these ethical and regulatory issues.

### **Panel VIII: Biological Specimens, Biobanking, and Informed Consent Issues**

Research involving the use of biospecimens is booming. Biospecimen research includes obtaining specimens for specific research studies, banking specimens for as yet unknown research studies, and the secondary use of specimens that were originally collected for clinical reasons or for unrelated research purposes. Is informed consent necessary for any or all of such research studies? Does it matter if the specimens have been or will be anonymized? This panel will explore the practical, regulatory, and ethical dimensions of these questions, including recently developed recommendations in this area from the Secretary's Advisory Committee on Human Research Protections.

### **Living Room Conversation: In Their Own Voices: A Discussion with Research Subjects Who Also Work in the Field of Subject Protections**

The experiences of individual research subjects will be explored during this session. The unique and exciting twist on this year's *In Their Own Voices* panel is that the research subjects who will be participating are also working in the IRB/HRPP field. Through the experiences of these individuals, attendees will gain insight into whether the IRB profession and those dedicated to research ethics are focusing on the right topics when reviewing protocols, considering risk assessment, discussing subject selection, consent, etc. The discussants will explore and compare what IRB professionals think is important versus what is *actually* important to those participating in research.

### **Panel IX: How Do We Measure Quality? Identifying New Metrics for Evaluating HRPPs and IRBs**

Presenters will discuss how the work of IRBs/HRPPs has been traditionally, and is currently, measured or evaluated. They will also discuss how such activities can be measured using principles and methodologies from other disciplines. Recognizing that the current benchmarks for quality are based on the documented performance of an IRB/HRPP against an established set of standards and/or regulatory requirements, the panelists will consider whether additional and/or alternative metrics exist to assess performance, the quality of the IRB's determinations, and the extent to which the IRB contributes to the protection of research subjects. Because IRB review is "people-driven" and thus highly subjective, outside-the-box thinking is necessary to address the problem of identifying and measuring those factors that are most important to the function of the IRB.

### **Panel X: Research that Seeks to Build Community Involvement**

Owing to a number of factors, including the U.S. National Institutes of Health Roadmap and the focus on translational and public health research, researchers have become increasingly aware of the importance of the community-based participatory research (CBPR) model in learning about health disparities and the social and physical determinants of health. Researchers are learning that tailoring research projects to the concerns and cultures of the participants involved, and that involving participants in an active rather than passive role in the development and implementation of studies, is a more effective means of finding solutions to public health problems. Among the topics to be covered during this panel are ways in which researchers can involve members of the community in study design and implementation; how researchers can apply the ethical principles to CBPR, including the Belmont principles of respect for persons, beneficence, and justice; whether additional ethical principles are at stake in CBPR; and whether the federal regulations apply to CBPR.

### **A Great Debate: Be It Resolved There Is an Obligation to Participate in Research**

Research ethics typically focuses on the obligations of researchers, rather than on the obligations of prospective participants. Do healthy volunteers or patients have an obligation to participate in clinical research? From the standard view, perhaps best articulated by Hans Jonas, participation is supererogatory; it is above and beyond the call of duty. From the obligation view, participation is obligatory; it is wrong not to participate in research. In addition, this debate will consider what might be said for and against both views, and what is implied by both views. For example, why might people have an obligation to participate? Does the fact that the current generation benefits from the participation of past subjects create an obligation for the present generation to future patients? What is implied by such an obligation? Would it follow that consent is not necessary or that subjects do not have a right to withdraw? These and other questions will be explored in this debate.

**Panel XI: Protecting “Vulnerable” Participants in Research: The Tension Between Justice and Respect for Persons**

Over the years, the concept of vulnerability in research has been extended beyond the traditional populations covered by the regulations (45 CFR 46 Subparts B, C, and D) to encompass other broad groups such as immigrants, women, minorities, persons living with disabilities, those suffering from an illness, etc. This broadening of the definition has diluted its meaning and leads to over-defining many groups as “vulnerable.” In addition, broadening the definition of vulnerability may lead to increased paternalism in the protection of research participants, which, in turn, may compromise individual autonomy. Paternalism is inherent in research regulation, and its expansion warrants examination. When, for example, are heightened protections justified? Efforts to ensure the fair distribution of research burdens may violate another basic tenet of research ethics: respect for persons. This is especially problematic in social, behavioral, and educational research when the risks of harm are minimal, or less than minimal, and the potential benefits to the population are significant. The speakers will explore the ethical issues that arise from labeling a group/population as “vulnerable” within the framework of current regulations.

**Panel XII: Distinguishing Between Biomedical and Non-Biomedical Research in a Trans-Disciplinary World: An Increasingly False Dichotomy?**

Why do some in the research community maintain a dichotomy between biomedical research and non-biomedical research (a term that encompasses the social, behavioral, and educational sciences)? Few would argue there are not elements of behavioral and social science in almost every biomedical protocol, and, on the other hand, much non-biomedical research avails itself of the fruits of the genetic/genomic revolution and advances in imaging technologies, traditionally seen as belonging to the biomedical realm. Furthermore, the trend toward trans-disciplinary research and team science is blurring the boundary between biomedical and non-biomedical research. Yet, many institutions persist in maintaining separate biomedical and non-biomedical IRBs. As a result, behavioral or social scientists often submit protocols to biomedical IRBs that might not be well-equipped to review such research, and may be prone to incorrectly assessing risks of harm. Similarly, non-biomedical IRBs may lack the necessary experience to deal with incidental findings and returning research results to subjects. Through this panel, the presenters will consider the advantages and disadvantages of this bifurcated oversight responsibility. Researchers working in an assortment of settings and studying topics that include both biomedical and non-biomedical elements will discuss the pragmatics, as well as the ethical and regulatory issues that arise in trans-disciplinary studies.

**Panel XIII: Research on Pregnancy: A Necessary Risk?**

Research involving pregnant women (rather than, more broadly, on research with women of childbearing potential) will be addressed during this panel. Very little is known about drug metabolism during pregnancy, and research is therefore needed to guide policy on the inclusion of pregnant women in research. “Second Wave” scholars identify the dual problem of over-caution regarding interventions for the benefit of the pregnant woman, and overzealousness regarding interventions for the benefit of the fetus. Both would benefit from more research and from a modification of the traditional “maternal-fetal conflict” view that is exemplified in Subpart B. This panel will include a federal representative, a “Second Wave” scholar, and an individual who will provide examples of research involving pregnant women and who will frame some of the practical ethical and policy issues using a case study.