

Panel I: What Kinds of Research Should Fall under IRB Review? Do the Rules Work for All Types of Research?

After almost thirty years of working hard to find optimal ways to review research, it may now be time to step back and take a critical look at an overarching question, **“If there were no federal regulations, no FDA, and no OHRP what should be regulated and why?”**

This panel will therefore *not* focus on either current or future OHRP and/or FDA (or other federal) regulations or guidances. Instead, it will look at IRBs and the review process from an *ethics* perspective, exploring questions relating to the appropriate sphere of IRB oversight, among them:

- Is it really value added for IRBs to address privacy matters in the research context, when privacy is already protected in so many other ways? Isn't such review therefore redundant?
- Are there parts of social science research (e.g., oral history, interviews, surveys, etc.) that should not be regulated? Whatever the “risks” might be of such research, wouldn't they be apparent to the subjects who could decide to answer or not answer questions as they are asked?
- Are there other methods of conducting social/behavioral science research, like Milgram's and Zimbardo's work, that should be subject to more oversight than survey research?
- Should research on new surgical techniques be regulated?

This panel will engage in a critical evaluation of procedures that many of us take for granted. We hope that this “foundation-shaking” opening session will help all of us better understand how we can best fulfill the HRPP's mission and most effectively protect human subjects.

Panel II: What Ethical Duties of Care and Caring do Researchers Owe to their Subjects

Investigators' responsibilities include 1) conducting those procedures that are specified in the research protocol and consent forms, and 2) complying with applicable laws, regulations, guidelines and institutional policies. However, sometimes circumstances arise that fall outside the scope of the above requirements. For instance, in the course of doing research an investigator may encounter incidental findings potentially relevant to a participant's health but beyond the aims of the study. Incidental findings raise the issue of researchers' ancillary-care obligations: When, if ever, are researchers obliged to provide participants care not required by the protocol or by study safety? How we think investigators should handle these circumstances is rooted in how we understand the nature and limits of the investigator-subject relationship itself. Starting from the problems of incidental findings and ancillary care, we will seek to articulate a framework for the investigator-subject relationship.

Among the implied and/or explicit duties to be discussed during this panel are questions such as:

- What are investigators' responsibilities when incidental findings arise?
- How far do investigators' responsibilities to provide ancillary care extend?
- What is the nature of the investigator-subject relationship?
- How does one's view of the nature of the relationship guide one's approach to the problems of incidental findings and ancillary care.

These and other issues will be explored in an effort to clarify what duties a researcher “owes” her subjects, and what exactly the source of those duties is.

Panel III: When Social Psychology and Neuroscience Research Merge: Challenges for the Social Science IRB in the 21st Century

What happens when psychologists begin doing more research in the burgeoning field of social cognitive neuroscience, an area that is blurring the lines between biomedical and non-biomedical research -- at least as those lines have been traditionally drawn. A whole new world is created by the merging of the two disciplines which creates many issues for IRBs and ethicists.

While some individuals and IRBs might think of this as biomedical research, it is not necessarily so in cases where researchers are looking at the neural bases of behavior. Most proposed interventions that employ methodologies involving social cognitive neuroscience are behavioral in nature and not biomedical. This type of research is usually reviewed by SBER IRBs, not biomedical ones.

Confusion arises in this area because it was formerly the province of biomedical researchers. Now psychologists use neuroimaging techniques which may be unfamiliar to SBER IRBs. HRPPs are just beginning to understand the ethical challenges and policy-related issues that arise in social cognitive neuroscience.

Panel IV: In Our Own Voices: Pediatric and Adolescent Research Subjects Share their Stories

Clinical research relies on human subjects, but how much do we know about their individual and collective reactions to their research participation? This panel is designed to help attendees improve their understanding and treatment of adolescent subjects by learning from their stories and those of their families. Among the questions to be posed to panelists will be:

- Why did the subjects decide to participate in research?
- What factors did the subjects consider before deciding to participate in a given research protocol, particularly in more than minimal risk studies?
- What was the incentive to participate and how did the subjects evaluate the stated risks?
- What did the children/adolescent research subjects understand about the research in which they were considering participation?
- How did the assent process work and how did it impact family decision making?
- Did children and adolescents feel their voices were heard and respected during both the recruitment and the research phases?
- How did the adolescents and their families feel about the manner in which they were treated during and after the trial?
- What was the role and responsibility of the parents and/or other family members during the trial?

Pediatric and adolescent research subjects and a parent will discuss these questions as well as their general experiences as research subjects.

Panel V: Desperately Seeking Experimental Therapies: Compassionate Use and Expanded Access

What “rights” do patients have to experimental agents, and how does the resolution of that question affect other issues, such as the principle that “research is research,” not therapy, and that investigators’ duties run to science above all else?

Two high profile cases were prominently featured in the research ethics headlines this past year, the Abigail Alliance and the “Penelope” case, both focused on subjects/patients who wanted a drug that was not readily available to them. A lawsuit between the University of Kentucky and Amgen reviewed the roles and responsibilities of institutions, researchers, sponsors, the FDA, and patients/subjects in connection with access to experimental drugs.

Using these three cases, the panel will examine whether drugs or other therapies constitute consumer “goods” that can be had on demand, and, if not, in what cases *should* compassionate use be invoked?

Panel VI - The Great Debate - The Tension Between IRB Review and Academic Freedom/the First Amendment

Have you heard of “mission creep” with respect to your IRB/HRPP? Have you heard about, and/or read, the many articles that discuss the allegation that the biomedical model of research review has been unreasonably imposed on non-biomedical research? Do you think such an alleged “imposition” violates longstanding principles of academic freedom? If so, come to the Great Debate!

Two knowledgeable, experienced, and opinionated debaters will frame their arguments so as to demonstrate the real implications of the intellectual issues referred to above. Always a crowd favorite, and PRIM&R’s closest approximation to the Fourth of July, the debate promises to get you thinking, and, maybe even debating these issues further with your colleagues back home.

Panel VII – Autonomy and Voluntariness - Current Controversies Regarding Informed Consent in Research

Two foundational ethical elements underlying human subjects protections are autonomy and voluntariness. However, both concepts are at times misunderstood and misapplied. Are autonomy and paternalism mutually exclusive? Do we “accord” subjects autonomy, or do we “mandate” it? What do these principles mean for IRB review?

Among the topics to be discussed are:

- The impact of family pressures on subject decision-making;
- The meaning of voluntariness when involving captive populations, including those who do not have insurance or money for treatment, and who thus might be impelled to join a clinical trial in order to obtain treatment;
- The impact of undue influence and/or coercion on autonomy and voluntariness;
- The ethical difference between affirmative and passive choices (e.g. organ donor programs).

Panel VIII: Beyond the Subparts: The Impact of an Expanded View of Vulnerable Populations on Social, Behavioral, and Educational Research

What do we mean by “vulnerable populations?” The focus of this panel is to explore the concept of “vulnerability” in research, including (1) the way it is used within the current regulatory framework, (2) the ethical implications of its usage, and (3) its impact on SBE research. The

session is expected to look closely at those populations considered “special” or “vulnerable,” but that are not covered by the present sub-parts.

Problems arising from the lack of a uniform definition of “vulnerability” will be addressed. The term often conflates one or more of the following subject characteristics, i.e., (1) susceptibility to coercion or undue influence, (2) lack of capacity to make autonomous decisions, and/or (3) susceptibility to potential harms.

Applying the concept of vulnerability so loosely raises serious ethical issues – among them the possibility of violating the Belmont Principles. For example, the exclusion of vulnerable subjects from certain types of research implicates the Justice Principle. Similarly, the appointment of an authorized representative in certain cases might implicate the principle of Respect for Persons by infringing on the individual’s right to choose

There is no consensus on whether the concept of vulnerability should be applied to entire populations or whether it should be defined within the specific context of each protocol. While the former application makes regulatory control possible (Subparts B, C, and D), the latter would rely on the professional judgment of the researcher. There is also a need to identify the different categories of vulnerabilities, e.g., “state,” “situational,” “chronic,” etc. so that the concept can be applied appropriately within the research context.

The regulations (subparts) identify three specific populations as “vulnerable,” and call for additional protections (e.g., full review, prohibition of waivers of informed consent) for research with these populations. The IRB Guidebook refers to other “special classes of subjects” – commonly translated as other “vulnerable” populations, including the cognitively impaired, students, employees, pregnant women, traumatized & comatose patients, terminally ill patients, and minorities, with no guidance on how and when the term applies to these populations.

The characterization of certain populations as “vulnerable” under existing regulations has a potentially significant impact on research. For example, if victims of post traumatic stress disorder (PTSD) are considered “vulnerable,” it may be impossible to conduct a study evaluating the efficacy of telephone therapy for PTSD patients in rural areas, as the study would require a waiver of documentation of consent.

Other questions to be addressed by this panel include:

- What issues arise when using the same manipulations or interventions with "vulnerable" and "non-vulnerable" populations?
- How do vulnerability and level of risk intersect?
- What does it mean to label a person or group in this way?
- What does vulnerability mean when the research involves only minimal risk?
- If would be the impact of a subpart E? What exactly IS sub-part E?
- HOW did we get into this situation of not knowing what to do with this population?

Panel IX: What Do We Know about How IRBS Work?

This plenary session will present and utilize insights from empirical research studies as a basis for exploring the manner in which research is reviewed and approved by IRBs. The panel’s major goal is to identify and demonstrate where at least a few opportunities for improvement might lie. The overarching questions to be discussed are: What do we know about how IRBs do their jobs? What are the outcome measures for knowing whether or not an IRB is effective? What are the

available measures which can help ‘prove’ that an IRB ‘did something that *did not* make something else happen?’

The session will examine the IRB review and approval process, ways in which IRBs relate to other components of an HRPP program, and, perhaps most importantly, the role of leadership in all of these concentric and overlapping circles.

Other questions to be raised include:

- What defines and/or constitutes an HRPP and how is one created within an institution?
- Is it a formal program, or just a group of people who fill certain roles?
- What would an HRPP look like in a community hospital?
- How does an institution avoid “IRB-centric” HRPPs?
- How well do HRPPs protect human subjects?
- How can institutions surmount the multiple challenges they face when developing and maintaining strong HRPPs?

Panel X: Social Behavioral Research In and With the Community

There are several ethical issues involved in the review and conduct of research in and with the community. This panel will consider the value and risks involved in community research, and propose strategies for avoiding conflict and misunderstanding among researchers, community members and IRBs.

Speakers who conduct research in various areas, such as violence prevention with adolescents, will share their methods for doing research in and with communities, including practical strategies for intervening with at-risk and vulnerable populations. Discussing these kinds of recurrent challenges will help reduce instances in which the community and the researchers want the research to move forward and the IRB does not.

Panel XI: Intercultural Review from Multi-National Perspectives

Intercultural research is complex and expanding. There is cultural and ethnic diversity even within a given city or country. This panel will focus on the ethical review of research conducted in domestic and international groups which are ethnically or culturally diverse.

Much can be learned from representatives of sponsoring and developing countries who share their challenges as well as the strategies they use in overcoming the barriers that often attach when reviewing intercultural research at both the domestic and international levels.

Topics that may be explored include:

- Multicultural studies within and across countries;
- How to communicate appropriately and fairly amongst cultures and countries;
- Issues of appropriate use and enrollment of subjects;
- Research that cuts across cultures (without focusing on cultural differences).

Panel XII: Law and Order: The IRB and Criminal Justice Research

This session will present talks by three experts in prisoner research. The perspectives of both principal investigators and National Institute of Justice human subjects protection compliance experts will be offered. Particular emphasis will be placed on juvenile/youth offender populations and the associated ethical challenges inherent in research involving such populations. Practical issues such as gaining, when appropriate, parental consent and child assent; data security; and risks to subjects, will be highlighted. Individual presentations will be followed by a question/answer period.

Panel XIII: Introducing our Abstracts Plenary Sessions

In this session PRIM&R introduces its first Symposium of Refereed Abstracts. Five abstracts were selected for presentation as mini-panels on topics chosen by the authors.

Panelists and Topics:

1. **Ethical Issues With Human Embryonic Stem Cell Research: Beyond the Moral Status of the Embryo** - Sandra Alfano , Insoo Hyun
2. **Behavioral Trials: Understanding the Safety Risks** - Peter Kaufmann, Robert Lindblad
3. **The Challenges of Integrating Research Oversight Programs of the Army, Navy, Air Force Medical Centers and Uniformed Services University in the National Capital Area** - Deborah J. Kenny, Charles McQueen
4. **Is a Comprehensive Adverse Event Reporting System in Human Subject Research a Realistic Possibility?** - Joan M. Caron, Gustavo Fernandez
5. **Eliminating Disparities in Clinical Trials: An Ethical, Economic, and Scientific Imperative** – Dan Bustillos, James Powell

Panel XIV: Hot Topics in SBE Research

Subject pools, international student research, and military research will each be the subject of a presentation during this panel:

- The topic of subject pools raises issues ranging from autonomy and coercion to the adequacy of informed consent.
- The conduct of non-biomedical research by students in developing countries raises questions as to the most appropriate way to gain IRB approval for such studies.
- The Department of Defense, as well as others, are doing more social and behavioral science research with military personnel who are potentially "multiply vulnerable" participants in that they are at risk of emotional disturbance such as PTSD, sensitivity to certain topics and research methods, and coercion as a result of their status as military personnel.

Describing how to walk through this “mine field,” will prove helpful to those involved with one or two, or all three of these areas of vulnerability when studying military personnel.