

PRIMR Advancing Ethical Research Conference
2012 Guided by Principles in an Era of Change
December 4-6 | San Diego, CA | Pre-Conference Programs December 3

Monday, December 3

Pre-Conference Programs*

7:00 AM Lobby 20
Registration Opens

7:00-8:30 AM Ballroom 20AB
Continental Breakfast

8:30 AM-4:00 PM
• *Research Involving Children: Framing and Applying Additional Protections* 33C

8:30 AM-4:15 PM
• *Institutional Review Board (IRB) 101sm* 29BC
• *Quality Assurance/Quality Improvement (QA/QI) 101: Fundamentals and Application* 27AB

8:30 AM-4:30 PM
• *Advanced Research Ethics* 33AB
• *Centralized IRB Review* 32B
• *Consent: Processes, Criteria, and Considerations for Obtaining Informed Consent* 32A
• *Hot Topics for Institutional Officials (IOs)* 23C
• *IRB 201: An In-Depth Analysis of the Criteria for Review* 26AB

8:30 AM-4:45 PM
• **SOLD OUT!** *IRB 301: Review and Application of the Regulatory Criteria for Approval* 29D

8:30 AM-5:00 PM
• *ABCs of Tissue Banking* 24ABC
• *Regulatory, Ethical, and Technical Challenges in Internet Research* 23AB

4:00-6:00 PM 28ABCD
Pre-Conference Program Networking Reception

All those registered to attend a pre-conference program are welcome to join us for a networking reception immediately following the conclusion of their program. Light refreshments will be served.

4:00-6:00 PM 28ABCD
Affinity Group Pre-Conference Networking Reception

Affinity Group members who are going to be in San Diego the evening of December 3 are welcome to join us for this chance to meet and greet their fellow group members. Interested in learning more about PRIMR's affinity groups? Please visit our [website](#).

*All pre-conference programs with the exception of *Quality Assurance/Quality Improvement (QA/QI) 101: Fundamentals and Application*, *Consent: Processes, Criteria, and Considerations for Obtaining Informed Consent*, and *Institutional Review Board (IRB) 101sm* qualify for CIP Continuing Education credit.

PRIM&R Advancing Ethical Research Conference 2012 Guided by Principles in an Era of Change

December 4-6 | San Diego, CA | Pre-Conference Programs December 3

Tuesday, December 4

7:00 AM Lobby 20
Registration Opens

7:00-8:00 AM Sails Pavilion
Continental Breakfast

7:00-8:00 AM 28ABCD
Continental Breakfast to Welcome our First-Time Attendees 
All first-time conference attendees are welcome! Join us for this continental breakfast to connect and network with colleagues and hear from the PRIM&R staff. *Please select this option during registration or [email us](#) if you're interested, and we'll be sure to save you a seat!*

7:00-8:00 AM 25B
Affinity Group Networking Breakfast 
Those who signed up for an [affinity group](#) are invited to join us for this continental breakfast where they can connect and network with their fellow group members. *Please select this option during registration or [email us](#) if you're interested, and we'll be sure to save you a seat!*

8:00-8:30 AM Exhibit Hall D
Welcome and Conference Overview 

8:30-9:15 AM Exhibit Hall D
Keynote Address   
John P. A. Ioannidis, MD, PhD
C.F. Rehnberg Professor in Disease Prevention and Director, Stanford Prevention Research Center
Professor of Medicine and Health Research and Policy, Stanford University School of Medicine

9:15-10:00 AM Exhibit Hall D
Plenary Address   
Robert H. Bartlett, MD
Professor of Surgery, Emeritus, University of Michigan

10:00-10:30 AM
Break

Icon Key:

-  didactic session
-  interactive workshop
-  recorded session
-  qualifies for CME credit
-  pre-registration required
-  chosen session
-  double session
-  qualifies for CIP CE credit

Tuesday, December 4 (continued)

10:30–11:45 AM:

Didactic Sessions and Workshops Series A

A1

A Dialogue with the National Institutes of Health (NIH)

A Dialogue with the Feds I Track

Faculty: Jacquelyn Goldberg, Valery Gordon, Dina Paltoo, Maria Stagnitto

Attendees are encouraged to come with questions. This session will provide attendees with an opportunity to:

- Hear from representatives of the NIH Office of Science Policy, the NIH Office of Extramural Research, and the National Cancer Institute about activities that are pertinent to clinical research policy and the protection of human subjects in research
- Participate in an open discussion about topics relevant to NIH stakeholders.
- Ask questions about new and ongoing initiatives at the NIH

25A



A2

A Dialogue with the Office for Human Research Protections (OHRP)

A Dialogue with the Feds II Track

Faculty: Kristina Borrer, Julie Kaneshiro, Irene Stith-Coleman, Elyse Summers

Attendees are encouraged to come with questions that will be of interest to all. This session will provide attendees with an opportunity to:

- Hear from OHRP representatives about evolving initiatives, issues, and guidance.
- Participate in an open discussion about topics relevant to OHRP stakeholders.
- Ask questions of OHRP representatives.

30D



A3

Preparing for a Successful AAHRPP Site Visit

Accreditation of HRPPs Track

Faculty: Anastasia Doherty, Sujatha Sridhar

This session will provide attendees with an opportunity to:

- Consider the process of organization-wide education in preparation for a site visit.
- Share experiences of and develop strategies for preparing for a site visit.
- Discuss practical tips for organizing the visit.
- Examine common problems found during site visits.

29A



A4

Comparative Effectiveness Research: What Bioethicists Need to Know

Activities Along the Boundaries Between Research and Practice Track

Faculty: Newell McElwee, Walter Straus, Steven Teutsch, Hugh Tilson

Comparative Effectiveness Research (CER) incorporates a multidisciplinary approach, drawing upon both biomedical and social scientific disciplines. The purpose of CER is to provide information on the safety and effectiveness of different approaches to addressing health care issues and inform health care decision making. CER can involve reviewing existing data (observational research), as well as conducting innovative prospective research to compare, drugs, diagnostics and medical devices, surgical interventions, or behavioral methods and other approaches. In this session, faculty will:

- Familiarize attendees with CER so that they are equipped to assess CER proposals.
- Explore the increasing attention to this field, given the recent designation of \$1 billion in federal funds addressing high-priority issues via CER.
- Discuss the importance of CER to the bioethics community, given the expectation that non-conventional research proposals will need to be reviewed.

30C



Icon Key:



Tuesday, December 4 (continued)

10:30–11:45 AM: Didactic Sessions and Workshops Series A

A5 Advanced

30AB



Perfection is the Enemy of the Good: How IRBs Can Harm a Study by Trying to Make it Better

Advanced Forum for IRB Professionals Track

Faculty: Susan Fish, Lindsay McNair

IRBs may require changes to research protocols under review for the benefit of subjects in that study. However, when those changes are implemented, the resultant research question may become irrelevant, the results may become less generalizable, or the study may become unfeasible to conduct. This session will provide attendees with an opportunity to:

- Use real cases to discuss the reasons IRBs might require protocol changes, as well as the scientific impact of those changes on the study and its results.
- Identify unintended consequences of IRB-required changes to research protocols.
- Discuss how improving subject benefits can result in irrelevant study questions.
- Learn how to work with investigators in order to maximize the subject benefit and scientific merit of studies.

A6

24A



The PI's Responsibility: The Rubber-Meets-the-Road Relationship

Clinical Research Professionals Track

Faculty: Charlotte Coley, Karena Cooper, Bruce Gordon

In this session, faculty will:

- Review the nine statements investigators commit to when signing Form FDA 1572.
- Explore the implications of signing the form and how doing so affects the conduct of research and FDA inspections and audits.
- Analyze the implications of FDA warning letters to investigators.

A7

33B



Ethical Issues Involving Third Parties and Secondary Subjects in Research

Ethical Issues Track

Faculty: Sara Goldkind, Robert Levine, Mitchell Parrish

In this session, faculty will:

- Identify when pregnant partners, caregivers, and other third parties are research subjects under DHHS and FDA regulations and guidelines.
- Understand how the IRB interprets protocol and consent form language considerations that implicate third parties or secondary subjects.
- Identify confidentiality, Health Insurance Portability and Accountability Act (HIPAA), and informed consent considerations for third parties.

A8 Advanced

31C



Nontraditional Access to Investigational Drugs and Devices: Single-Patient Investigational New Drugs (INDs), Expanded Access, and Humanitarian Uses

FDA Regulations Track

Faculty: Lynn Henley, Richard Klein, Joanne Less

In this session, faculty will:

- Review the FDA requirements related to nontraditional uses of FDA-regulated test articles.
- Discuss the similarities and differences in the expanded access provisions for investigational drugs, biologics, and medical devices.
- Explore Humanitarian Device Exemptions (HDEs) and Humanitarian Use Devices (HUDs) and the IRB's role in their review.

Icon Key:



Tuesday, December 4 (continued)

10:30–11:45 AM: Didactic Sessions and Workshops Series A

A9 Advanced

31B

To Waive or not to Waive? *That Is the Question*



Informed Consent Track

Faculty: Jeffrey Cooper

In this session, faculty will:

- Discuss the appropriate use of waivers.
- Review the regulatory applicability of waivers.
- Explore a variety of cases in which a waiver would add more protections and help facilitate research.

A10 Basic

23C

Supporting Your Institutional Official (IO), Protecting Your Organization, and Enhancing Human Subjects Protections



Institutional Officials Track

Faculty: Scott Lipkin, Ivor Pritchard, David Wynes

IOs must assure that human subjects research is conducted in accordance with the Office of Human Research Protections (OHRP) Terms of Assurance, regulatory requirements, and institutional policy. In this session, faculty will:

- Help attendees understand the responsibilities of the IO.
- Discuss ways that administrators educate IOs and keep them informed about organizational issues.
- Explore ways to maintain open channels of communication between administrators and IOs.

A11 Advanced

32B

Issues When Conducting Research in the Midst of Social Injustice



International Research Track

Faculty: Liza Dawson, Jeanita Richardson, Jerome Singh

In this session, faculty will

- Discuss the ethical issues presented when research is proposed in settings where there is social injustice.
- Explore whether the conduct of research in such settings can be perceived as an endorsement of the injustice.
- Explain how research can be designed to anticipate and address such ethical challenges.
- Review considerations of additional protections for research participants who are also the target of the injustice in areas such as informed consent, privacy, and confidentiality.

A12 Basic

33A

Essential Documentation: IRB Membership, Record Keeping, Meeting Minutes, and More



IRB Bootcamp Track

Faculty: Julia Gorey, Cheryl Savini, Jean Toth-Allen

In this session, faculty will:

- Outline the basic federal requirements for IRB documents.
- Discuss federal requirements for maintenance of accurate, complete, and timely IRB records.
- Identify the components of a complete record of IRB meeting activities as reported in IRB meeting minutes.

Icon Key:



Tuesday, December 4 (continued)

10:30–11:45 AM: Didactic Sessions and Workshops Series A

A13

Practical Tools for Dealing with Conflict: Helping IRB Staff Communicate More Effectively with Investigators

IRB Operations and Toolkit Track

Faculty: Suzanne Rivera

This interactive session will use studies, concrete examples, and role-playing exercises to provide attendees with an opportunity to:

- Learn techniques for delivering bad news to investigators clearly and with grace.
- Acquire specific strategies for using the medium of email more effectively for transmitting IRB findings and stipulations.
- Practice skills for diffusing anger and resolving conflicts in a professional manner.

24C



A14 Advanced

Private Sector Concerns Regarding Biorepositories and Tissue Banking

Issues for Pharma/Biotech Track

Faculty: Amelia Warner

Pharmaceutical companies consider specimens collected for future biomedical research to be critical resources for understanding patient variability to drug response. In this session, faculty will:

- Reveal how discussions of issues such as tiered consent, return of results to subjects, sharing of coded genomic data sets, and scope of research differ between the academic setting and commercial companies, given that the latter do not maintain ongoing relationships with patients participating in clinical trial specimen collection and storage.
- Review how changes in global regulations are driving discussions about how commercial companies will structure specimen collection procedures in the future.

28E



A15 Advanced

New HITECH/HIPAA Developments and Strategies for Success

Legal Track

Faculty: Susan McAndrew, Susan Stayn

In this session, faculty will:

- Review regulatory requirements, OCR's new enforcement tools (such as breach and audit), and practical compliance strategies in the research environment.
- Discuss research-related aspects of the new rules and guidance under the Health Information Technology for Economic and Clinical Health (HITECH) Act and the Health Insurance Portability and Accountability Act (HIPAA).

31A



A16

"Front-Door" Consent for Biospecimens: Making It Work

Out-of-Body Experiences: Research Involving Tissue and Data Track

Faculty: Marianna Bledsoe, Ty Hoover, Paula Kim, Michele Russell-Einhorn, Nicole Sieffert

The explosion of new technology and the need for high-quality research specimens has led to increasing interest in obtaining "front-door" consent for specimens obtained during the course of routine care. In this session, faculty will:

- Discuss when such mechanisms are feasible and what makes "front-door" consent work.
- Review the practical implementation challenges and benefits of an institution-wide biospecimen banking initiative.
- Address the ethical and regulatory responsibilities of the institution using "front-door" consent and of its researchers.

30E



Icon Key:



Tuesday, December 4 (continued)

10:30–11:45 AM: Didactic Sessions and Workshops Series A

- Provide attendees with a practical approach to evaluating barriers, risks, and benefits for implementing “front door” consent at their own institutions. Participant perspectives, as expressed by a patient advocate, will also be presented.

A17 Advanced

Protection and Inclusion: Considerations for Participants with Disabilities



23A

Populations Requiring Additional Protections Track

Faculty: Jeremy Block, Jenny Kiratli

Studying populations that include disabled participants requires additional considerations. What does “disability” mean in the legal sense and to the participant? What protections are provided under law and what protections are ethically mandated? How do we ensure inclusion of this group as participants? This session will provide attendees with an opportunity to:

- Examine this topic from the perspectives of the IRB member, researcher, and participant.
- Learn to distinguish when the research is studying a disabled population, and how to identify what types of additional protections might be necessary.
- Develop an understanding of the different models of disability and how they contribute to our understanding of participation in research by individuals with disabilities.
- Learn about the various laws, rules, and policies at all levels (institutional, state, federal, international) pertaining to individuals with disabilities, and how these laws, rules, and policies interact with the human subjects research enterprise.

A18 NEW SESSION!

Rewriting the National Cancer Institute (NCI) Informed Consent Template



23B

Potpourri Track

Faculty: Jeanne Adler

The NCI has recently completed a two-year effort to revise the NCI Informed Consent Template to result in shorter and more concise informed consent documents. In this session, faculty will:

- Present the finalized template with the hope of obtaining an evaluation as well as comments for incorporation into the next version.
- Discuss the concerns which prompted the NCI to revise the template.
- Explore the benefits and beneficiaries of the revisions of the template.
- Describe the federal regulations pertaining to the informed consent form and how the NCI Informed Consent Template achieves compliance for each.

A19

Nuts and Bolts of Not-for-Cause Study Reviews



33C

QA/QI and Post-Approval Monitoring Track

Faculty: Kelly Dornin-Koss, Sarah White

In this session, faculty will:

- Review points to consider when developing a QA/QI program
- Review basic auditing concepts
- Discuss how to determine a sample size for audits
- Discuss advantages of standard observations.

Icon Key:



Tuesday, December 4 (continued)

10:30–11:45 AM: Didactic Sessions and Workshops Series A

A20 Basic

24B

Finding Flexibilities in the Federal Regulations: Basic Considerations and Applications



Regulatory Balance Track

Faculty: Lois Brako, Laura Odwazny, Cindy Shindledecker

In this session, faculty will:

- Provide attendees with a basic overview of the multiple opportunities to find flexibility in the regulations.
- Help attendees discover the pros and cons of “unchecking the box.”
- Discuss basic ways to utilize regulatory flexibility throughout the HRPP.
- Help attendees learn about applying the criteria for exemptions and expedited review.

A21 Basic

29B

Internet Research with Minors



Research Involving the Internet and Social Networking Track

Faculty: John Santelli

In this session, faculty will:

- Review the basic ethical and regulatory elements of research with minors.
- Discuss unique issues in internet research involving minors, including specific online research procedures and age verification.
- Provide suggestions to researchers and IRBs for preparing and executing informed consent and assent with minors in internet settings.

A22

29C

Building Best Practices in Clinical Research



Responsible Conduct of Research Track

Faculty: George Gasparis

Building best practices in clinical research requires focus by both researchers and institutions. In this session, faculty will:

- Review what can go wrong in clinical research that could compromise results.
- Discuss what can be learned from cases of clinical research misconduct to prevent it in the future.
- Explore how a university can become more involved in promoting high-quality clinical research, and what researchers can do to prevent errors.
- Discuss areas of clinical trials that are most likely to experience problems, and answer the question of whether all research should be subject to audits.

A23 Basic

29D

The What, Why, When, and How of Informed Consent



SBER I Track

Faculty: Pierre Deschamps, Michelle Feige, Ada Sue Selwitz

In this session, faculty will:

- Explore the concept of informed consent and underlying ethical principles.
- Review when informed consent is mandatory and when it can be altered or waived.
- Discuss how to implement an alteration or a waiver of documentation of consent.
- Examine the challenging issues of “passive consent,” minor assent, and short forms.

Icon Key:



Tuesday, December 4 (continued)

10:30–11:45 AM: Didactic Sessions and Workshops Series A

A24 Advanced

International Social, Behavioral, and Educational Research (SBER)

SBER II Track

Faculty: Edward Bartlett, David Borasky, Kathleen MacQueen

In this session faculty will:

- Discuss a framework for reviewing international SBER.
- Review guidance and best practices when such international SBER is conducted by students.
- Raise awareness about issues that may be specific to different cultures, countries, and populations.

32A



A25

Networking: A Necessity for Those Working at Institutions with Small Research Programs

Small Research Programs Track

Faculty: Eric Allen, Erica Tauriello

This session will start with a 15-minute didactic presentation on tools to develop your network with others in the field. The remainder of the session will take the shape of “speed networking,” in which attendees will interact with everyone in the session at least once. This session is intended for individuals from institutions with small research programs. Please bring business cards. This session will provide attendees with an opportunity to:

- Learn new skills related to developing a professional network.
- Use these skills to begin to develop a professional network among attendees from institutions with small research programs.

27A



A26

The Roles and Responsibilities of the Unaffiliated and Non-Scientist Member of the IRB

Unaffiliated and Non-Scientist IRB Members Track

Faculty: Argelis Ortiz, Susan Rose, Elizabeth White

As key members of the IRB, unaffiliated/non-scientist members join with the other IRB members in shaping the culture and conduct of research within their institutions. In this session, faculty will:

- Review the relevant regulatory provisions governing IRB membership and recent academic articles about the perceptions of the role of the unaffiliated/non-scientist member.
- Examine the ethical and regulatory responsibilities of the unaffiliated/non-scientist IRB member.
- Discuss the responsibilities and challenges of lay review in a variety of IRB scenarios.

27B



12:00-1:00 PM

Lunch with Plenary Speaker Robert Bartlett, MD

Join us for a luncheon with plenary speaker Robert Bartlett. This event will provide attendees the opportunity to talk with and ask questions of this distinguished researcher and medical pioneer in an intimate and informal environment. *Please note that this event is sold out and you will not be able to sign up for it when registering. Please [email us](#) if you are still interested in attending and we will add you to the waiting list!*

25B



12:00-1:00 PM

Lunch with Keynote Speaker John P. A. Ioannidis, MD, PhD

Join us for a luncheon with Keynote Speaker John Ioannidis. This event will provide attendees the opportunity to talk with and ask questions of this distinguished and provocative researcher in an intimate and informal environment. *Please note that this event is sold out and you will not be able to sign up for it when registering. Please [email us](#) if you are still interested in attending and we will add you to the waiting list!*

26AB



Icon Key:



Tuesday, December 4 (continued)

12:00-1:00 PM

28ABCD

Research Ethics Book Group Lunch with Jonathan Haidt, PhD



Participate in a vibrant discussion of *The Righteous Mind: Why Good People Are Divided by Politics and Religion*, the newest title from **2011 AER Conference** keynote speaker Jonathan Haidt. Attendees will have the opportunity to discuss the book with their peers and with the author, who will be joining the discussion via live video feed. Copies of Dr. Haidt's book are available at the onsite Bookstore. *Please select this option during registration or [email us](#) if you're interested, and we'll be sure to save you a seat!*

12:00-1:00 PM

Sails Pavilion

Common Ground Networking Lunch

Time to connect... over lunch! The tables will be divided by affinity groups and professional affiliations so that you can find and meet your peers for conversation and networking. Tables will also be available for those for those wishing to "just lunch." *The Conference Connection* will be open during this time, and the posters will be available for viewing.

1:00-1:45 PM

Sails Pavilion

Meet and Greet with the Conference Supporters, Exhibitors, and Poster Presenters

Network in *The Conference Connection* during or after lunch!

1:15-1:45 PM

Sails Pavilion

Demonstration of PRIM&R's Online Course and Knowledge Center

Join us in the PRIM&R Booth for a demonstration of two of our interactive online resources—*The Ethical Oversight of Human Subjects Research Course (Online Course)* and PRIM&R's Knowledge Center. A 15 minute presentation on each resource will provide you with an introduction to utilizing these tools to strengthen your understanding of human subjects protections.

2:00-3:15 PM

Exhibit Hall D

Plenary: Panel I – “The Common Rule:” How Did We Get Here, and Where Should We Go?

Moderator: *Alexander Capron*

Panelists: *Barbara Bierer, Ivor Pritchard, Jeremy Sugarman*

This panel will discuss what kinds of changes to the Common Rule are needed, and which of those changes might realistically be achieved, given the historical, political, and cultural forces that drive such development. The panel will begin by looking at the trends of the last two decades, from the highly sensationalized research-related events of the late 1990s, which resulted in a new focus on compliance and inadequacies in the IRB system; increased funding of IRBs, and the growth of the IRB professional community; to the more recent backlash against IRBs and the ensuing call for reform from an empowered scientific community more aligned with the regulators than ever before. The panel will then discuss proposed changes to the regulations, as well as where those changes should originate, who should be involved, and how success should be measured.

Icon Key:



Tuesday, December 4 (continued)

2:00-3:15 PM

Ballroom 20AB

Plenary: Panel II – An Introduction to Flexible Adaptive Clinical Trial Designs: Implications for IRB Review and Informed Consent



Moderator: Michele Russell-Einhorn

Panelists: Donald Berry, Roger Lewis, William Meurer

The Critical Path Initiative was launched by the FDA in 2004 in recognition of the need for more flexibility in scientific design and enhanced collaboration and cooperation to drive innovation in scientific processes. One of the central innovations the Critical Path Initiative encourages is the use of adaptive trial designs. This panel will review different types of adaptive trial designs and consider such issues as: why and how adaptive designs differ from standard designs and the regulatory implications of those differences; whether adaptive trial design can make research more ethical; how subject safety may be improved by these flexible designs; and obstacles to the implementation of adaptive designs. The goals of the Critical Path Initiative, as implemented by encouragement of adaptive trial designs, include: (a) improved efficiency of the trial design; (b) improved drug efficacy; (c) improved effectiveness of the trial; (d) reduction in the time of drug development; and (e) reduction of all the associated costs.

2:00-3:15 PM

Ballroom 20CD

Plenary: Living Room Conversation – Whose Ethics Matter? Conducting Responsible Research in the Global Arena



Moderator: David Borasky

Panelists: Albert J. Allen, Anant Bhan, Cassandra Kennedy, Linda Nielsen

A recent *Dateline NBC* story reported flaws in the oversight of US pharmaceutical industry-sponsored clinical research that is increasingly being outsourced to locations such as India, China, and Eastern Europe. This story has served to reinforce the public perception that the pharmaceutical industry is more likely than other research funders to take advantage of certain global realities, including favorable regulatory environments and the ready availability of willing study subjects. This session will use the *Dateline* report as a jumping off point to explore the roles that *all* stakeholders in the global research enterprise, from CROs and the pharmaceutical industry to public health agencies and research ethics committees, play in fostering and conducting ethically responsible international research.

3:15-3:45 PM

Break

3:45-5:00 PM

Didactic Sessions and Workshops Series B

B1

A Dialogue with the Food and Drug Administration (FDA)

31B



A Dialogue with the Feds I Track

Faculty: Karena Cooper, Joanne Less, Diane Maloney, Kevin Prohaska, James Saviola

Attendees are encouraged to come with questions. This session will provide attendees with an opportunity to:

- Hear from representatives of the FDA about new and evolving issues, initiatives, regulations, and guidance.
- Participate in an open discussion about topics relevant to FDA stakeholders.
- Ask questions about evolving issues at the FDA.

B2 CANCELLED!

A Dialogue with the Department of Defense (DOD): Updates for DOD-Funded Researchers

If you would like to change your session registration, please [email](#) us.

Icon Key:



Tuesday, December 4 (continued)

3:45–5:00 PM: Didactic Sessions and Workshops Series B

B3

29A

Collecting and Analyzing Metrics for Quality Improvement



Accreditation of HRPPs Track

Faculty: Gary Cseko, David Forster

In this session faculty will:

- Discuss how to use 2011 metrics, collected and posted by AAHRPP, to inform your HRPP quality improvement program.
- Provide examples of benchmarking metrics and illustrate how data has been measured and analyzed across multiple organizations.
- Offer suggestions for selecting categories and measuring HRPP performance data at attendees' home institutions.

B4

33A

Community Engagement and Participation in Research



Activities Along the Boundaries Between Research and Practice Track

Faculty: James Edwards, Harry McGee, Meredith Minkler

In this session, faculty will:

- Discuss the ethical tensions inherent in community-based participatory research (CBPR).
- Explain the purpose and process of specific projects relating to CBPR.
- Explore the role the IRB played in these projects in assuring compliance with federal regulations and adherence to high ethical standards for human subjects research.

B5

30C

VOICE: The Valid Optimized Informed Consent Education Program



Advanced Forum for IRB Professionals Track

Faculty: Elizabeth Bankert, Dianne Ferris

While commonly recognized that review of the consent form is necessary, little attention has been paid to the conduct of the consent process. In addition, FDA audits have identified “obtaining informed consent” as an investigator responsibility that is often inappropriately delegated. The VOICE project team at Dartmouth focuses on the “teach back” method in an educational program developed for individuals obtaining consent. This session will provide attendees with an opportunity to:

- Discuss the pilot project that was used to develop the educational program
 - Receive a description of the educational program.
 - Learn how to implement the program at their home institutions.

B6

23C

Ensuring Study Data Integrity:



Standards, Chain of Custody Documentation, Transfer of Data Agreements, and Audit Trails

Clinical Research Professionals Track

Faculty: Michelle Stickler

In this session, faculty will:

- Present the standards for the proper securing and handling of study data.
- Address chain of custody documentation and audit trails.
- Discuss transfer of data agreements regarding data and specimen repositories.

Icon Key:



Tuesday, December 4 (continued)

3:45–5:00 PM: Didactic Sessions and Workshops Series B

B7

33B

Looking Beyond Responsible Conduct of Research: Ethical Research From Design to Data Collection to Dissemination of Results



Ethical Issues Track

Faculty: Philip Alberti, Heather Pierce

In this session, faculty will help attendees to:

- Learn how a clinical trial conducted entirely within the RCR guidelines with review, approval, and oversight from an IRB might *still* fall short of our ethical responsibilities in the broader social contract of research.
- Understand how the conduct of research fits into a continuum from concept and funding through the dissemination of results, and what other entities bear responsibility for ensuring that the results of research reach those populations that could benefit most.
- Understand the ethical imperatives of understanding health disparities and the populations affected by the conditions being studied throughout the full scope of research, from basic science through implementation research.

B8

23B

Introduction to the FDA's Center for Tobacco Products (CTP) and Ensuring Human Subjects Protections in Clinical Tobacco Trials



FDA Regulations Track

Faculty: Lester Jao Lacorte, Susan Rudy

In this session, faculty will:

- Describe CTP's mission and role in regulating tobacco products.
- Explain the Family Smoking Prevention Tobacco Control Act (TCA) and the public health standard for evaluating the risk of tobacco products in both users and non-users.
- Describe the ethical and regulatory considerations in the review of different pathways of tobacco products to market.
- Discuss how CTP's regulations impact IRB review of tobacco product research.
- Explore considerations for IRBs in evaluating tobacco product clinical trials to ensure adequate human subjects protections.

B9 Basic

29C

Regulatory Requirements and Ethical Considerations Regarding Pediatric Assent in Research



Informed Consent Track

Faculty: Steven Joffe

In this session, faculty will:

- Review the regulatory requirements for child assent and waivers of assent.
- Discuss developmental issues, with an emphasis on determining when a child acquires the capacity to provide assent and consent.
- Explore ethical issues, including how to proceed when there is disagreement between children and their parents or legal guardians about research participation.

Icon Key:



Tuesday, December 4 (continued)

3:45–5:00 PM: Didactic Sessions and Workshops Series B

B10 Advanced

29D

Centers for Medicare and Medicaid Services (CMS)'s Proposed "Sunshine" Regulations: Implications for Research and Human Subjects Protections



Institutional Officials Track

Faculty: Mark Barnes, Robyn Shapiro

In this session, faculty will:

- Provide background information about the Patient Protection and Affordable Care Act (PPACA), commonly referred to as the Physician Payment Sunshine Act.
- Provide an update on the status of the new rule.
- Discuss ways for institutions to ensure they comply with PPACA requirements.

B11

24B

It Takes a Village... Models for Working with the Community in International Research



International Research Track

Faculty: Steven Wakefield

In this session, faculty will:

- Review models for community engagement in international settings.
- Discuss mechanisms for training community members on research and research ethics.
- Present considerations for the ongoing maintenance of a community advisory group.

B12 Basic

30D

Is it Human Research? Is it Exempt?



Determining When an Activity Must Undergo IRB Review

IRB Bootcamp Track

Faculty: Jeffrey Cooper, Julie Kaneshiro, Ada Sue Selwitz

This session will provide attendees with an opportunity to:

- Become familiar with the two distinct definitions of human subjects research found in the DHHS and FDA regulations.
- Review the federally mandated exemption categories
- Discuss the differences between DHHS and FDA regulations regarding exempt research categories

B13

30E

How to Develop Effective IRB Forms to Keep You in Compliance and Keep Investigators Happy



IRB Operations and Toolkit Track

Faculty: Kelley O'Donoghue, James Riddle

In this session, faculty will:

- Review practical strategies for using IRB forms to help ensure IRB compliance, auditability, and ease of IRB member review, including options for adjusting form layout or question sequences
- Describe how researchers view IRB forms and how to use that perspective to the greatest advantage.
- Identify practical and accessible techniques for helping researchers select the right form, complete their forms accurately, and ensure they attach all the right supporting materials.
- Discuss strategies for transitioning from a paper-based form to an online submission system and for improving the use of an online submission system once implemented.
- Share case studies from two institutions showing how they improved the effectiveness of their forms.
- Facilitate the sharing of ideas about best practices.

Icon Key:



Tuesday, December 4 (continued)

3:45–5:00 PM: Didactic Sessions and Workshops Series B

B14

24C

Globalization of Clinical Research: Emerging Issues for Pharmaceutical and Biotechnology Companies, Contract Research Organizations (CROs), and IRBs



Issues for Pharma/Biotech Track

Faculty: Nicholas Slack, Cassandra Kennedy

Clinical research funded in North America is increasingly being conducted abroad, and in particular in emerging economies. The offshoring of clinical trials, and the fact that many of these trials are being conducted by CROs, and not pharmaceutical and biotechnology companies, raises important ethical questions. This session will provide attendees with an opportunity to:

- Discuss IRBs' levels of awareness about the extent to which CROs are responsible for such research, and whether IRBs are equipped to ask the right questions.
- Explore the ability and commitment of CROs to conduct research ethically and appropriately.
- Discuss issues of jurisdiction, including the level of oversight CROs receive, who is responsible for that oversight, and the role of centralized review.
- Discuss strategies that pharmaceutical or biotechnology companies and CROs can use to a) gather data about the practical implications that ethical considerations have on pharmaceutical research done abroad, b) assess the quality of that data, and c) ensure the presence of infrastructure needed to conduct trials ethically.

B15 Basic

32B

Genetic Privacy:

How to Keep Up with the Expansion of Federal and State Legal Requirements



Legal Track

Faculty: Susan McAndrew, Susan Stayn

In this session, faculty will:

- Review the laws and rules that an IRB may need to consider in research involving genetic information.
- Discuss federal requirements such as HIPAA and the Genetic Information Non-Discrimination Act (GINA).
- Explore the proliferation of state laws and proposed legislation with broad reach.

B16

31C

Genome-Wide Association Studies (GWAS):

The Impact of NIH's Data Sharing Policy on the IRB's Role in Reviewing Genetic Research



Out-of-Body Experiences: Research Involving Tissue and Data Track

Faculty: Laura Lyman Rodriguez, Pearl O'Rourke

In this session, faculty will:

- Explore the ethical and regulatory issues raised by NIH's data sharing policy.
- Help attendees gain an understanding of the IRB's role in the review of GWAS.
- Define best practices and standards for review of GWAS.

Icon Key:



Tuesday, December 4 (continued)

3:45–5:00 PM: Didactic Sessions and Workshops Series B

B17 Advanced

33C

The Nexus of Vulnerability and Minimization of Risk

Populations Requiring Additional Protections Track

Faculty: Andre Ivanoff, Alan Wertheimer

In this session, faculty will:

- Review the definition and taxonomy of vulnerability.
- Discuss general approaches to minimizing risk, with an emphasis on particular at-risk populations.
- Explore the tension between justice and beneficence, and the consequences of over-protection.
- Discuss groups and populations as vulnerable subjects, and discuss concepts relating to group harm and examples of such.



B18 Advanced

25A

Ethical Guidelines for Information and Communication Technology Research:

The Menlo Report

Potpourri Track

Faculty: David Dittrich, Erin Kenneally, Wendy Visscher

This session will review novel ethical challenges in information and communication technology research (ICTR), through a discussion of the Department of Homeland Security's recent "Menlo Report: Ethical Principles Guiding Information and Communication Technology Research." In this session, faculty will:

- Explain the purpose of and motivations for the Menlo Report and how IRBs can use it to evaluate ICTR.
- Explore the risks and benefits of ICTR and discuss when it is important to focus on whether research is potentially "human harming," rather than whether a "human subject" is involved.
- Review risks of ICTR beyond privacy, and discuss why the Menlo Report can help identify and analyze these risks.



B19

23A

Delivering Bad News: Play and Practice

QA/QI and Post-Approval Monitoring Track

Faculty: Bertha deLanda, Terry VandenBosch

Bring a sense of humor! This session will provide attendees with an opportunity to:

- Use a scenario involving "bad news" audit observations to role-play ways to provide constructive, supportive, and effective feedback to a principal investigator (PI).
- Share ideas and observations with fellow attendees and faculty.



B20 Advanced

30AB

Finding Flexibilities in the Federal Regulations: Advanced Considerations and Applications

Regulatory Balance Track

Faculty: Lois Brako, Moira Keane, Irene Stith-Coleman

This advanced session, designed for experienced IRB staff, administrators, and chairs, will explore implemented procedures that incorporate flexibility within the regulations while providing equivalent protections to participants. In this session, faculty will help attendees to:

- Discover ways to utilize flexibility in IRB authorization agreements.
- Learn about applying the criteria for exemptions and expedited review.
- Discover ways to utilize flexibility when applying subparts B, C, and D.
- Explore ways to customize informed consent to fit a study.



Icon Key:



Tuesday, December 4 (continued)

3:45–5:00 PM: Didactic Sessions and Workshops Series B

B21 Advanced

31A

Privacy in the Information Age:

The Ethical and Regulatory Implications of Data Mining on Social Networking Sites

Research Involving the Internet and Social Networking Track

Faculty: Lauren Solberg, Latanya Sweeney

In this session, faculty will:

- Define and describe data mining on social networking sites as a method of data collection for research.
- Analyze whether data mined from social networking sites is private information as defined in the regulations governing human subjects research at 45 CFR 46.
- Use this privacy analysis to evaluate the ethical and regulatory implications of data mining on social networking sites under 45 CFR 46; issues to be considered include whether research involving data mining on social networking sites is considered research with human subjects.



B22

27A

Train the Trainer: When Can We Stop Teaching About Research Misconduct?

Responsible Conduct of Research Track

Faculty: Mike Kalichman

This session will provide attendees with an opportunity to:

- Discuss at least three reasons why a focus on research misconduct is a sub-optimal strategy for teaching research ethics.
- Examine at least three examples of responsible conduct that are likely to have failed if research misconduct occurred.
- Explore the idea that effectively teaching about responsible conduct of research will create an environment in which it is necessarily more difficult for research misconduct to occur.



B23 Basic

29B

What You Need to Know about Privacy and Confidentiality

SBER I Track

Faculty: Sharon Freitag, Joseph Konstan

In this session, faculty will:

- Discuss the question of public vs. private behavior, including what counts as a reasonable expectation of privacy.
- Review identifiable vs. anonymous participation and data.
- Discuss the tension between public recognition of research participation and de-identification of results to ensure participants are not individually identifiable.
- Examine the adequacy of confidentiality protections and procedures designed to avoid or minimize privacy invasion.



B24 Advanced

32A

Reviewing Qualitative Research

SBER II Track

Faculty: Cynthia Gómez

This session will address ethical and regulatory issues that arise in qualitative research, and will provide attendees with an opportunity to:

- Discuss potential harms associated with oral history, ethnography, and other qualitative methodologies.
- Review qualitative data collection methods such as PhotoVoice.
- Share best practices for reviewing such research.



Icon Key:



Tuesday, December 4 (continued)

3:45–5:00 PM: Didactic Sessions and Workshops Series B

B25 Basic

24A

Developing and Implementing an Education Program at an Institution With a Small Research Program



Small Research Programs Track

Faculty: Eric Allen, Michelle Feige

In this session, faculty will:

- Focus on how to develop and implement an education program for a small biomedical or social behavioral institution with no staff members that are specifically designated for education.
- Discuss various methods for providing education.
- Review tips for how to leverage current staff time to get the most out of your education program.
- Examine options for funding an education program.

B26 Basic

27B

Scientific Aspects of Clinical Study Design: A Primer for Non-Scientists



Unaffiliated and Non-Scientist IRB Members Track

Faculty: Susan Fish, Lindsay McNair

In this session faculty will:

- discuss how to identify the components of a research question
- review the main types of observational and interventional study designs
- explain the basic concepts of bias and confounding, and the most common ways these issues are addressed in study designs

5:00-6:30 PM

Sails Pavilion

2012 AER Conference Welcome Reception

Join us in The Conference Connection to kick off the **2012 AER Conference**, meet and greet with our supporters and exhibitors, view this year's poster presentations, and receive a complimentary mini-massage! Light refreshments will be served.

Icon Key:



Wednesday, December 5

7:00 AM **Lobby 20**
Registration Opens

7:00-8:00 AM **Sails Pavilion**
Continental Breakfast

7:00-8:00 AM **28ABCD**
CIP® Breakfast

Interested in earning your Certified IRB Professional (CIP) credential? Want to connect with other "CIPers?" Attend this continental breakfast to learn more about the credential, meet representatives of the Council for Certification of IRB Professionals, network with fellow CIPs, and ask questions of those already certified. *Please select this option during registration or [email us](#) if you're interested, and we'll be sure to save you a seat!*

8:00-8:30 AM **Exhibit Hall D**
Welcome and award presentation
Presentation of the PRIM&R ARENA Legacy Award (ALA) to Susan Delano

8:30-9:15 AM **Exhibit Hall D**
Keynote Address  
James R. Gavin III, MD, PhD
Executive Vice President and Chief Medical Officer, Healing Our Village
Clinical Professor of Medicine, Emory University School of Medicine

9:15-9:30 AM
Break

9:30-10:45 AM **Ballroom 20AB**
Plenary: Panel III – Hot Off the Presses: Selected Posters on Innovative Programs and Research on Research Ethics  

During this panel, 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 HRPPs/IRBs.

Moderators: *Susan Fish, David Borasky*

Topics:

1. Can we facilitate research by maximizing data and biosample utility while complying with subject's consent?
Panelist: *Maria Adela Grando*
2. Incentivized Corrected Feedback: A combined remedial and motivational approach for improving recall of consent information
Panelist: *David Festinger*
3. "No Man is an Island": Cancer patients' experience of autonomy related to their decision-making process about clinical trial participation
Panelist: *Jennifer Bell*
4. Strategies for Helping Researchers Do the Unthinkable: Destroy Their Data
Panelist: *Teresa Doksum*

Icon Key:

- | | | | |
|---|--|--|---|
|  didactic session |  interactive workshop |  recorded session |  qualifies for CME credit |
|  pre-registration required |  chosen session |  double session |  qualifies for CIP CE credit |

Wednesday, December 5

9:30-10:45 AM

Ballroom 20CD

Plenary: Panel IV – Do Investigators Have Ethical Responsibilities to Their Subjects Outside the Scope of Research, and If So, What are They?



Moderator: *Ivor Pritchard*

Panelists: *Henry Richardson, Jeanita Richardson*

Investigators conducting research may find themselves in a position to help their subjects in ways that go beyond obligations deriving from the ethical requirements of the research itself. Are investigators just like any other person in such a position, or does the investigator-subject relationship create special ethical obligations? If investigators know at the outset that subjects are in need of particular assistance, should they plan to provide it? Does this lend support to the claim that researchers should return incidental findings? If the provision of assistance will compromise the research itself, should the investigator ignore the opportunity to intervene? This panel will explore these and other questions.

9:30-10:45 AM

Exhibit Hall D

Plenary: Panel V – Ethical Implications of Novel Methodologies and Technologies in Social and Behavioral Research



Moderator: *Dean Gallant*

Panelists: *Richard Gilbert, Ian Kerr, Meredith Minkler*

We are currently seeing an explosion in the use of sophisticated, electronically based methodologies and technologies as tools for data collection, storage, and sharing. This panel will look at a sampling of these developments in social and behavioral research—including PhotoVoice, the use of wearable devices for data tracking, and digital anthropology/ethnography in virtual worlds such as Second Life—and discuss their implications for human subjects protections.

10:45-11:15 AM

Break

11:15 AM-12:30 PM

Didactic Sessions and Workshops Series C

C1

A Dialogue with the Department of Veterans Affairs (VA) Program for Research Integrity Development & Education (PRIDE) and Office for Research Oversight (ORO)



A Dialogue with the Feds I Track

Faculty: Robert Brooks, Lynn Cates

[Please note this is a double session and will end at 1:45 PM. Please pick up your boxed lunch before proceeding to the session room. Pre-registration is required to attend and a lunch ticket will be included on your name badge.]

Attendees are encouraged to come with questions. This session will provide attendees with an opportunity to:

- Hear from and ask questions of PRIDE staff about the VA's human subjects protections policy.
- Hear ORO representatives discuss compliance oversight activities of the VA.
- Participate in an open discussion about issues relevant to VA stakeholders.

Icon Key:



Wednesday, December 5 (continued)

11:15 AM-12:30 PM: Didactic Sessions and Workshops Series C

C2 NEW SESSION!

32B

Staff Update from the Presidential Commission for the Study of Bioethical Issues (PCSBI): Creating Instructional Materials for Ethics Education



A Dialogue with the Feds II Track

Faculty: Paul Lombardo

In October 2012, PCSBI is releasing *A Study Guide to "Ethically Impossible": STD Research in Guatemala from 1946 to 1948*, based on its investigation into the unethical U.S. Public Health Service STD experiments conducted in Guatemala in the 1940s. This ethics study guide will be freely available for downloading and printing on www.bioethics.gov, and is designed for university students and all other interested members of the public.

This session will provide attendees an opportunity to:

- Understand why the Guatemala STD studies are a critical element in research ethics education.
- Hear from a Commission representative about the development of the Study Guide, including the decision to base the Study Guide on accessible case studies from the research in Guatemala and thereby promote guided ethics discussion based on real world examples.
- Discuss with Commission staff the tension between the need for more ethics education and the fact that not all institutions have ethics department or access to ethics curricula, and explore how the development of pedagogical materials to accompany Commission reports, in particular, can enrich contemporary ethics education.

C3

29B

The Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP)'s Top 10 Findings in Step One Applications and Draft Site Visit Reports



Accreditation of HRPPs Track

Faculty: Sarah Kiskaddon

In this session, faculty will:

- Discuss common findings in step one application reviews.
- Present common site visitor observations and areas of concern.
- Review the evaluation instrument and draft site visit report findings.
- Explore strategies for avoiding common pitfalls.
- Share concrete examples and solutions to common problems encountered during the accreditation process

C4

31B

Models for Ethics Review of Public Health Projects: Experiences From Canada and the United States



Activities Along the Boundaries Between Research and Practice Track

Faculty: Melody Lin, Nancy Ondrusek, Raphael Saginur, Donald Willison

[Please note this is a double session and will end at 1:45 PM. Please pick up your boxed lunch before proceeding to the session room. Pre-registration is required to attend and a lunch ticket will be included on your name badge.]

This session will bring together representatives from Canada and the United States to identify common interests and challenges around governance of public health research activities, with a view toward building long-term relationships and collaborations. In this session, faculty and attendees will:

- Explore challenges surrounding ethics review of public health projects and strategies for addressing those challenges.
- Discuss development of tools at Public Health Ontario for streamlining ethics review and encouraging investigators to engage in ethical reflection during project planning.
- Consider issues and potential solutions for ethics review of research during public health emergencies.
- Provide the OHRP perspective on how proposed changes to the common rule will impact the review of public health projects.

Icon Key:



Wednesday, December 5 (continued)

11:15 AM-12:30 PM: Didactic Sessions and Workshops Series C

- Reflect on developments and discuss other challenges and approaches with attendees and the panel of presenters.

C5 Advanced

Using Metrics to Monitor, Manage, and Improve IRB Operations

Advanced Forum for IRB Professionals Track

Faculty: Gary Cseko, Dan Nelson

[Please note this is a double session and will end at 1:45 PM. Please pick up your boxed lunch before proceeding to the session room. Pre-registration is required to attend and a lunch ticket will be included on your name badge.]

In this session, faculty and attendees will:

- Explore how metrics and monitoring can be used to assess the workload, staffing, and performance of IRB operations.
- Discuss how to apply elements of a quality management system to support continuous IRB operations improvement.
- Review how to identify and manage unexpected and nonconforming events in the IRB process and use them for quality improvement.

30AB



C6

Train the Trainer: One Way to Get Good Clinical Practice (GCP)

Training to Your Principal Investigator

Clinical Research Professionals Track

Faculty: Shirley Roach

In this session, faculty will:

- Define GCP.
- Share their experiences developing a GCP education program.
- Outline the features of a successful interactive program geared toward adult learners.
- Present an example “train-the-trainer” program on GCP for investigators.

27A



C7 Advanced

Assessing the Prospect of Direct Benefit in Pediatric Studies and Component Analysis

Ethical Issues Track

Robert Nelson, Susan Kornetsky

[Please note this is a double session and will end at 1:45 PM. Please pick up your boxed lunch before proceeding to the session room. Pre-registration is required to attend and a lunch ticket will be included on your name badge.]

In this session, faculty and attendees will:

- Examine the process for reviewing research interventions that offer the prospect of direct benefit to a pediatric population.
- Discuss the application of component analysis in the IRB's review of pediatric studies.
- Outline the expectations for documenting the prospect of direct benefit and component analysis in review of pediatric studies.

24A



Icon Key:



Wednesday, December 5 (continued)

11:15 AM-12:30 PM: Didactic Sessions and Workshops Series C

C8 Basic

30E

The End of Your Search for Information on FDA's Investigational New Drug (IND) and Investigational Device Exemption (IDE) Regulations



FDA Regulations Track

Faculty: Christine Drabick, Owen Faris

[Please note this is a double session and will end at 1:45 PM. Please pick up your boxed lunch before proceeding to the session room. Pre-registration is required to attend and a lunch ticket will be included on your name badge.]

In this session, faculty and attendees will:

- Examine the federal regulations for INDs (21 CFR 312) and IDEs (21 CFR 812).
- Discuss FDA guidance on INDs and IDEs that may further IRBs' understanding of the regulatory platform for the studies they review.
- Review example scenarios and discuss the application of IND and IDE regulations.

C9

30D

Informed Consent: Elevating the Process and Improving the Form



Informed Consent Track

Faculty: Marc Teitelbaum

Most PIs, funders, regulators, and IRB members would probably say that informed consent is the process most closely associated with the IRB, and the "stamped" informed consent form (ICF) is the most visible evidence of the IRB's labors. Yet, despite the best of intentions and evidence that reform is necessary, ICFs continue to grow in size, and unnecessarily challenge subject comprehension and readability. Investigators, coordinators, and study sponsors, afraid to run afoul of the IRB, put in information they don't need, and leave out information they need, but can't comfortably explain in lay terms. In this session, faculty and attendees will explore several novel approaches and models to informed consent that attempt to address these well known problems. Specifically, this session will present attendees with an opportunity to:

- Explore background issues such as: What is the state of health literacy? What works best for patients and subjects? What does research literature on informed consent tell us?
- Discuss general strategies to adjust for reading level, translation, and overall readability.
- Review an innovative sample set of recommendations for the development and formatting of easy-to-read and easy-to-comprehend ICFs and examine a novel informed consent template that incorporates these recommendations as a generalizable ICF model.
- Learn a second novel approach to reading, writing, and editing informed consent language that is rooted in thinking about popular fiction. By identifying what a good book and a good consent form have in common, and by interactively learning to apply the rules of good fiction to the serious rules and mission of informed consent, participants will take home a skill that will not only make consent writing more pleasant and less stressful, but will also decrease unnecessary words, improve reading level, and enhance understanding, without sacrificing regulatory compliance and relevance
- Learn how to resolve informed consent battles by adapting an agreed-upon rule set.

C10

33B

Understanding the Elements of a Strong Compliance Program



Institutional Officials Track

Faculty: Lisa Murtha, Ernest Prentice

In this session, faculty will:

- Identify the key components and characteristics of a strong compliance program.
- Discuss the challenges of day-to-day operations.
- Outline performance metrics.

Icon Key:



Wednesday, December 5 (continued)

11:15 AM-12:30 PM: Didactic Sessions and Workshops Series C

C11 Advanced

29A

Clearing Customs: Addressing Cultural Competency in International Research



International Research Track

Faculty: Kathleen MacQueen

When conducting research outside the researcher's cultural experience, whether international or domestic, merely translating or adapting consent forms and survey instruments is not sufficient. Researchers need to take into consideration a number of issues including the relevance of constructs being studied to that particular population and learn to navigate different cultural norms, regulatory requirements, and social issues outside of research, e.g. the impact of research participation not just on individuals but the group as well. In this session, faculty will:

- Discuss the use of interpreter services.
- Explore the factors important for recruitment and retention, such as involving family and/or community members.
- Discuss the challenges around cultural immersion.
- Review administrative and organizational accommodations.

C12 Basic

24C

The Basics and Beyond:

Research with Children, Pregnant Women and Fetuses, and Prisoners



IRB Bootcamp Track

Faculty: Julia Gorey, Robert Levine

In this session, faculty will:

- Review the DHHS regulations governing research with children, pregnant women and fetuses, and prisoners, i.e. 45 CFR 46 subparts B, C, and D).
- Present FDA regulations governing human subjects research at 21 CFR 50 and 56, and how they apply to children, pregnant women and fetuses, and prisoners
- Outline best practices for research with these populations and discuss other relevant guidance.

C13 Advanced

29C

Protocol Rage and Meeting Fatigue: Therapeutic Options for IRB Chairs



IRB Operations and Toolkit Track

Faculty: Melissa Abraham, Elizabeth Hohmann

In this session, faculty will:

- Review common problems with protocols submitted for IRB review.
- Share strategies for working with difficult investigators.
- Explore best practices for managing the challenges and stressors that come with being an IRB chair from two long-serving chairs.

Icon Key:



Wednesday, December 5 (continued)

11:15 AM-12:30 PM: Didactic Sessions and Workshops Series C

C14

28E

Informed Consent: Enhancing the Industry Approach with Subjects in Mind



Issues for Pharma/Biotech Track

Faculty: Amelia Warner, Ellen Kelso, Anita Nelsen

This session will provide attendees with an opportunity to:

- Explore new industry approaches to the consent process, including steps to enhance patient involvement and the information provided to potential clinical trial participants.
- Hear faculty members from across industry share their experiences of introducing patient-friendly models of consent. Examples will be used to illustrate the changes that have been introduced and how these have been received.
- Engage in an open dialogue with members of industry about best practices and ongoing challenges around informed consent.

C15 Basic

23B

Challenges in Securing Coverage for Research-Related Injury



Legal Track

Faculty: Marc Francis, Karen Moe

Research sites and pharmaceutical and biotechnology companies often negotiate heavily over consent and contract language covering research-related injury. In this session, faculty will:

- Address the challenges arising from this language, including practical difficulties in terms of when an injury is, in fact, covered under the language; when a participant's own insurance must be billed first; and how a research site can reach some resolution expeditiously to help protect the injured participant.
- Suggest strategies for handling these challenges.

C16

30C

Tissue Issues:



Ethical, Regulatory, and Practical Issues in Banking Biological Specimens for Research

Out of Body Experiences: Research Involving Tissue and Data Track

Faculty: Marianna Bledsoe, Julie Kaneshiro, Nicole Sieffert

[Please note this is a double session and will end at 1:45 PM. Please pick up your boxed lunch before proceeding to the session room. Pre-registration is required to attend and a lunch ticket will be included on your name badge.]

In this session, faculty and attendees will:

- Identify the ethical and regulatory principles that guide biobanking for research purposes.
- Outline how different types of biobanks operate.
- Explore practical challenges biobankers face in implementing regulations and policies related to biobanking.
- Discuss research use of tissue collected for routine purposes.
- Review informed consent and waivers for the use of tissue for research purposes.

C17 Basic

25A

Research with Cognitively Impaired Subjects



Populations Requiring Additional Protections Track

Faculty: Elizabeth LeQuesne, David Strauss

This session will provide attendees with an opportunity to:

- Discuss regulatory requirements when a subject is considered cognitively impaired.
- Review federal regulations related to legally authorized representatives and explore examples of state rules.
- Identify the ethical issues around consent, permission, and assent.
- Explore the concept of substituted judgment of risk.

Icon Key:



Wednesday, December 5 (continued)

11:15 AM-12:30 PM: Didactic Sessions and Workshops Series C

C18 Advanced

Recommendations of the National Cancer Institute (NCI) Think Tank on Identifiability of Biospecimens and Genomic Data

Potpourri Track

Faculty: Nicole Lockhart, Carol Weil

This session will provide attendees with an opportunity to:

- Review the regulatory and ethical issues surrounding the identifiability of DNA and genomic data with respect to the twin but conflicting goals of optimizing data security for research participants and maximizing data sharing among researchers.
- Explore various legislative, regulatory, and institutional policy alternatives for protecting privacy and promoting genomic research.
- Identify recommendations developed by the NCI Think Tank on Identifiability of Biospecimens and Genomic Research on June 11-12, 2012.

29D



C19

Auditing International Studies

QA/QI and Post-Approval Monitoring Track

Faculty: Stanley Estime

In this session, faculty will:

- Describe human research compliance risks and issues arising from rapidly increasing globalization in clinical research.
- Examine methods to select higher-risk international studies for auditing.
- Outline audit processes for centralized remote monitoring and practical issues in conducting audits at the international site.

23A



C20 Advanced

You'll Know it When you See It:

Defining "Human Subjects Research" under the DHHS Regulations

Regulatory Balance Track

Faculty: Ivor Pritchard, Nancy Olson

In this session, faculty will:

- Review the definitions for human subjects research and clinical investigation found in the DHHS and FDA regulations, respectively.
- Outline a process and set of criteria for determining whether an activity is research involving human subjects.
- Describe how and when to apply the definitions of "research" and "human subject."

32A



Icon Key:



Wednesday, December 5 (continued)

11:15 AM-12:30 PM: Didactic Sessions and Workshops Series C

C21

33A

Informed Consent in Internet Research: Realities and Possibilities



Research Involving the Internet and Social Networking Track

Faculty: Emily Anderson, Elizabeth Buchanan, Laura Odwazny

[Please note this is a double session and will end at 1:45 PM. Please pick up your boxed lunch before proceeding to the session room. Pre-registration is required to attend and a lunch ticket will be included on your name badge.]

In this session, faculty and attendees will:

- Identify the unique settings and conditions for consent in internet research.
- Discuss how to apply the federal regulatory requirements for informed consent to internet research.
- Highlight regulatory flexibilities that are applicable to consent in internet research.
- Discuss parental consent and child assent in internet research involving minors.
- Share sample language on data security and confidentiality of research-related information for informed consent documents for internet research.

C22

33C

Understanding and Responding to Wrongdoing in Research



Responsible Conduct of Research Track

Faculty: James DuBois

[Please note this is a double session and will end at 1:45 PM. Please pick up your boxed lunch before proceeding to the session room. Pre-registration is required to attend and a lunch ticket will be included on your name badge.]

In this session, faculty and attendees will:

- Explore and understand the frequency, variety, and hypothesized causes of wrongdoing in research.
- Identify when a researcher's wrongdoing can be addressed adequately using traditional means, and when more specialized interventions are required.
- Outline the kinds of interventions that research data indicates may be most effective in reducing recidivism rates.

C23 Basic

23C

Speed it Up: Exempt... Expedite... Relax!



SBER / Track

Faculty: Dean Gallant, Lorna Hicks, Irene Stith-Coleman

[Please note this is a double session and will end at 1:45 PM. Please pick up your boxed lunch before proceeding to the session room. Pre-registration is required to attend and a lunch ticket will be included on your name badge.]

In this session, faculty and attendees will:

- Use case-based scenarios to explore regulatory flexibilities while assuring that research is conducted ethically.
- Discuss the process for determining when behavioral, educational, and social research must undergo review by the full IRB, when it qualifies for expedited review, when it is exempt, and when it does not constitute research involving human subjects.

Icon Key:



Wednesday, December 5 (continued)

11:15 AM-12:30 PM: Didactic Sessions and Workshops Series C

C24

50 Shades of Risqué Research

SBER II Track

Faculty: Susan Miller, Patricia MacCubbin

Often, IRBs are confronted with reviewing a proposal to study a socially or politically sensitive issue. Even if the proposed study has the potential to generate valuable information, pressures from inside and outside the institution might make the review and approval of such studies difficult. Through the use of case studies, this session will provide attendees with an opportunity to:

- Evaluate issues that could potentially hinder approval of a research proposal.
- Develop regulatory rationales in support of the sample proposals that will equip attendees with tools to use when reviewing sensitive research.

31C
  

C25

Developing a Human Research Protections Program (HRPP) at an Institution with a Small Research Portfolio

Small Research Programs Track

Faculty: Wilma Acosta, Ofer Amit

This session will focus on the challenges of developing and maintaining an effective HRPP at a small institution. The interactive format will help attendees explore structural and operational aspects common in small HRPPs and identify solutions that can work effectively in the unique small HRPP environment. Faculty and attendees will:

- Discuss and explore together what makes small HRPPs unique: What are the minimal requirements? What should you do first? Who else should be involved and how can you gain their support? (You may be a one-person IRB office, but there is no such thing as a one-person HRPP!)
- Outline how to establish and maintain a small HRPP: How do you maintain organizational support? When, where, and how can you receive outside help? What is the best way to look for and find a other HRPPs colleagues?

27B
 

C26 Basic

PRIM&R's Primer for the "Newbie" Reviewer

Unaffiliated and Non-Scientist IRB Members Track

Faculty: Janet Donnelly, Robert Ferguson, Gigi McMillan

[Please note this is a double session and will end at 1:45 PM. Please pick up your boxed lunch before proceeding to the session room. Pre-registration is required to attend and a lunch ticket will be included on your name badge.]

In this session, faculty and attendees will:

- Review the basics of phase I, II, and III trials.
- Discuss ethical and regulatory concepts including coercion, therapeutic misconception, minimal risk, assent, conflicts of interest, and recruitment standards.
- Share a glossary of common terms and acronyms used in the human subjects protections field.

24B
 

Icon Key:



Wednesday, December 5 (continued)

C27 NEW SESSION!

Ballroom 20AB

Film Screening and Discussion: *How to Survive a Plague*

Faculty: A. Cornelius Baker

[Please note this is a double session and will end at 1:45 PM. Please pick up your boxed lunch before proceeding to the session room. Pre-registration is required to attend and a lunch ticket will be included on your name badge.]

This session will comprise a screening followed by a facilitated discussion of the critically acclaimed, feature-length documentary [How to Survive a Plague](#), a powerful look at the role of early AIDS activists in expediting the development of HIV/AIDS drugs. From the film's website: "*How to Survive a Plague* is a story about two coalitions—ACT UP and TAG (Treatment Action Group)—whose activism and innovation turned AIDS from a death sentence into a manageable condition. Despite having no scientific training, these self-made activists infiltrated the pharmaceutical industry and helped identify promising new drugs, moving them from experimental trials to patients in record time. With unfettered access to a treasure trove of never-before-seen archival footage from the 1980s and '90s, filmmaker David France puts the viewer smack in the middle of the controversial actions, the heated meetings, the heartbreaking failures, and the exultant breakthroughs of heroes in the making."



12:45-1:15 PM

Sails Pavilion

Demonstration of PRIM&R's Online Course and Knowledge Center

Join us in the PRIM&R Booth for a demonstration of two of our interactive online resources—*The Ethical Oversight of Human Subjects Research Course (Online Course)* and PRIM&R's Knowledge Center. A fifteen minute presentation on each resource will provide you with an introduction to utilizing these tools to strengthen your understanding of human subjects protections.

12:45-2:00 PM

Sails Pavilion

Lunch

12:45-2:00 PM

26A

Lunch with Keynote Speaker James R. Gavin III, MD, PhD

This event will provide attendees the opportunity to talk with and ask questions of this distinguished leader of the nation's efforts to address health disparities and research inequalities in an intimate and informal environment. *Please note that this event is sold out and you will not be able to sign up for it when registering. Please email us if you are still interested in attending and we will add you to the waiting list!*



12:45-2:00 PM

26B

Lunch and Book Signing with Panelist Henry S. Richardson, JD, PhD

Join us for this informal luncheon with Panel IV speaker Henry Richardson and participate in a timely discussion of ancillary-care obligations in research. This event will provide attendees an opportunity to talk with and ask questions of this distinguished ethicist and author of the new book, [Moral Entanglements: The Ancillary-Care Obligations of Medical Researchers](#). Professor Richardson's book will be available in hardcover on [amazon.com](#) on October 2, 2012. Copies may also be purchased onsite at the Bookstore. Professor Richardson will be available to sign books during this lunch. *Please note that this event is sold out and you will not be able to sign up for it when registering. Please email us if you are still interested in attending and we will add you to the waiting list!*



Icon Key:

- | | | | |
|--|--|--|---|
|  didactic session |  interactive workshop |  recorded session |  qualifies for CME credit |
|  pre-registration required |  chosen session |  double session |  qualifies for CIP CE credit |

Wednesday, December 5 (continued)

12:45-2:00 PM

28ABCD

Research Ethics Book Group Lunch and Book Signing with Laura Stark, PhD

Participate in a vibrant discussion of [Behind Closed Doors: IRBs and the Making of Ethical Research](#), by Laura Stark. Attendees will have the opportunity to discuss the book with their peers and the author. Copies of Dr. Stark's book are available at the onsite Bookstore, and she will be available to sign books during this lunch. *Please select this option during registration or [email us](#) if you're interested, and we'll be sure to save you a seat!*

2:15-3:30 PM

Exhibit Hall D

Plenary: A Great Debate – Be it Resolved That Large-Scale Genomic Research Poses Special Privacy Risks to Research Subjects

Moderator: Susan Kornetsky

Panelists: Jeffrey Botkin, Latanya Sweeney

This debate will explore the ethical issues and privacy concerns related to genetic information learned through research such as large-scale genome sequence data. Some take the position that people need to protect themselves from the risks to their privacy inherent in the use of genetic databases and genomic research more broadly. Many on this side argue that genetic material cannot be de-identified and can be very dangerous in the wrong hands. Others take the position that genetic data is only useful if there is a reference that can be used to identify a sample or piece of data, and researchers typically do not have access to the reference. In fact, provisions can be made so that researchers do not obtain reference material information about subjects. In addition, this side argues, our society is moving toward the increased use of genetic information in personalized medicine. It will therefore become as useful as other medical information and should be protected in a similar manner. The controversy about just how risky, and how threatening to our welfare, large-scale genomic research is has implications for one of the core sections of the recent Department of Health and Human Services' Advance Notice of Proposed Rulemaking (ANPRM) on the protection of human subjects.

2:15-3:30 PM

Ballroom 20 AB

Plenary: Panel VI – Should Society Treat Research Differently From Other Risky Activities?

Moderator/Panelist: Alan Wertheimer

Panelists: Alexander Capron, Holly Fernandez Lynch

The purpose of this panel is to examine what is sometimes referred to as “research exceptionalism.” The regulation of research is both more stringent and more lenient than the approach that we take toward many other activities that also involve risk and consent, e.g. employment. On the one hand, many activities expose individuals to risks for the benefit of others, yet are not subject to extensive regulation or oversight and do not require comprehensive disclosure of information and elaborate procedures for obtaining consent. On the other hand, research participants are not regularly afforded some protections that are afforded to workers, such as compensation for injury. This panel will seek to clarify whether we should treat research participants in much the same way as we treat workers.

Icon Key:



Wednesday, December 5 (continued)

2:15-3:30 PM

Didactic Sessions and Workshops Series D

D1

A Dialogue with the National Science Foundation (NSF)

A Dialogue with the Feds I Track

Faculty: Kellina Craig-Henderson

Attendees are encouraged to come with questions. This session will provide attendees with an opportunity to:

- Hear from NSF representatives about evolving issues at NSF.
- Participate in an open discussion of topics relevant to NSF stakeholders.
- Ask questions about new and ongoing initiatives at NSF.

24A



D2

A Dialogue with the Department of Energy (DOE)

A Dialogue with the Feds II Track

Faculty: Betsy Ellis, Lindsay Motz, John Ordaz, Elizabeth White

Attendees are encouraged to come with questions. This session will provide attendees with an opportunity to:

- Learn about DOE's Human Subjects Research Database.
- Participate in an open discussion of issues relevant to DOE stakeholders.

24B



D3

Getting Smaller HRPPs Accredited: Resources and Other Challenges

Accreditation of HRPPs Track

Faculty: Francis DiMario, Scott Lipkin

This session will provide attendees with an opportunity to:

- Discuss the special challenges faced by smaller organizations in preparing for accreditation.
- Examine strategies that are especially effective in small organizations.
- Explore the primary issues relevant to the decision to begin accreditation.
- Review the process of accreditation and provide strategies for achieving each step.
- Receive guidance from faculty who have experience with the accreditation process and serving as site visitors.

29D



D4

Defining the Status of the Research Subject in Resuscitation Research

Activities Along the Boundaries Between Research and Practice Track

Faculty: Sara Goldkind, Korin Hudson, Ryan Spellecy, Jeremy Sugarman

Cardiac arrest resuscitation research necessarily involves dead people, raising unique regulatory and ethical issues. In this session, faculty will:

- Address questions such as: What regulations apply in such cases? What should the IRB do in reviewing this type of research? How should researchers plan to approach informed consent?
- Explore how IRBs, investigators, and research sponsors have approached this challenging topic.

23B



Icon Key:



Wednesday, December 5 (continued)

2:15-3:30 PM: Didactic Sessions and Workshops Series D

D5 Advanced

25A

Making Subpart Determinations when Reviewing Research Involving Vulnerable Populations: Case Studies



Advanced Forum for IRB Professionals Track

Faculty: Jeremy Block, Bruce Gordon

This session will provide attendees with an opportunity to:

- Use case studies to examine research protections for vulnerable populations in clinical and behavioral studies.
- Examine the protections that must be in place in order to include vulnerable population groups in research.
- Review the ethical and regulatory guidelines for including these groups in research.

D6

33B

Data Safety Monitoring Plans and Data and Safety Monitoring Boards: What Does an IRB Need to Know?



Clinical Research Professionals Track

Faculty: Adrianna Brigatti, Susan Ellenberg

In this session, faculty will:

- Compare various approaches to ensuring subject safety and meeting regulatory requirements when monitoring the data collected.
- Outline a model for developing standard operating procedures for data safety monitoring.
- Share policies, procedures, training and educational materials, as well as logistical and communications support strategies around data safety monitoring.

D7 Advanced

33A

Risk Tolerance and Risk Recalibration: Are You Overdoing It?



Ethical Issues Track

Faculty: Moira Keane

This session will provide attendees with an opportunity to:

- Learn how to measure risk tolerance in IRB administration and review.
- Discuss options for recalibrating risk and evaluating how to make changes in practice.
- Explore ways to introduce flexibility in practice while maintaining regulatory compliance.

D8 Basic

30C

FDA Expectations of IRBs When Making the Significant and Non-Significant Risk Determination in Device Investigations



FDA Regulations Track

Faculty: Erica Heath, James Saviola

In this session, faculty will:

- Examine the regulatory requirements for risk determination of medical devices.
- Discuss the FDA guidance on making risk determinations for device studies.
- Explore a practical approach to evaluating medical device risk determination and discuss expectations for written procedures.

Icon Key:



Wednesday, December 5 (continued)

2:15-3:30 PM: Didactic Sessions and Workshops Series D

D9

32B

Laying the Foundation for Better Consent: Guidelines, Templates, and an Online Tool Called Consent Builder



Informed Consent Track

Faculty: Rebecca Armstrong

This session will provide attendees with an opportunity to:

- Discuss the informed consent process from the perspective of research subjects.
- Learn specific strategies for improving informed consent forms using a web-based tool called Consent Builder.
- Understand the importance of gaining support from the institution and from researchers to develop such resources and use them appropriately.

D10

24C

Identifying, Reducing, and Managing Conflicts of Interest



Institutional Officials Track

Faculty: Mark Barnes, Heather Pierce

In this session, faculty will:

- Discuss how to create and maintain an organizational culture that understands, acknowledges, and addresses potential conflicts of interest.
- Review how to handle institutional conflicts of interest, including when institutional officials don't follow HRPP/IRB policies.

D11

23A

Telling It Like It Is: Challenges in Informed Consent in International Settings



International Research Track

Faculty: Terry Elliott, Kathleen MacQueen

In this session, faculty will:

- Review the international standards for informed consent and documentation of consent.
- Describe practical challenges, such as varying degrees of literacy, translation issues, and differences in cultural norms.
- Review measures taken to adapt the Western informed consent model to international settings.

D12 Basic

30AB

How to Grow Your IRB Career: Professional Development and Networking



IRB Bootcamp Track

Faculty: Charlotte Coley, Karen Hansen, Yvonne Higgins

In this session, faculty will:

- Offer practical advice about education and mentoring opportunities for IRB professionals.
- Discuss creative solutions for developing a network of trusted advisors within the IRB community.
- Discuss the important role of the IRB professional in serving the HRPP community on a local, regional, and national level.

Icon Key:



Wednesday, December 5 (continued)

2:15-3:30 PM: Didactic Sessions and Workshops Series D

D13 Basic

Writing Stellar Standard Operating Procedures (SOPs)

IRB Operations and Toolkit Track

Faculty: Karen Hale, Elyse Summers

This session will provide attendees with an opportunity to:

- Discuss the components of comprehensive and effective HRPP/IRB SOPs.
- Understand the resources, input, and/or approvals needed to develop specific SOPs.
- Draft a new or revise an existing template for HRPP/IRB SOPs.

30D



D14 Advanced

Pharma/Biotech Responsibilities in Unanticipated Problems and Adverse Event Reporting

Issues for Pharma/Biotech Track

Faculty: Albert J. Allen, Kevin Prohaska, Glenn Veit

In this session, faculty will:

- Review existing guidance governing pharmaceutical and biotechnology companies' responsibilities for adverse event and unanticipated problem reporting.
- Outline the March 2011 FDA regulations on adverse event reporting.
- Discuss and clarify the responsibilities of investigational new drug (IND) sponsors, as laid out in the FDA regulations, with respect to the reporting and analysis of serious, unexpected events suspected to be caused by the study drug.

31A



D15 Basic

Securing Data in Research: Legal Requirements, Consequences, and Best Practices

Legal Track

Faculty: Elizabeth Hohmann, Susan McAndrew

This session will provide attendees with an opportunity to:

- Review legal requirements for ensuring data security in research.
- Discuss best practices, including the respective roles of the IRB, compliance, and privacy or security offices in oversight efforts.
- Explore challenging domains such as multi-institutional studies and waiver studies.
- Evaluate case studies of data security breaches.

32A



D16 Advanced

Regulatory and Ethical Issues Surrounding the Consent of Pediatric Donors of Biological Specimens Who have Reached the Age of Majority

Out-of-Body Experiences: Research Involving Tissue and Data Track

Faculty: Irene Stith-Coleman, Carol Weil

In this session, faculty will:

- Explore the specific regulatory and ethical issues that surround this group.
- Discuss a framework for assessing whether consent should be sought in these instances.

30E



Icon Key:



Wednesday, December 5 (continued)

2:15-3:30 PM: Didactic Sessions and Workshops Series D

D17 Advanced

31B

Populations on the Edge: The Homeless, Substance Abusers, and More



Populations Requiring Additional Protections Track

Faculty: Jeffrey Cohen, Susan Delano

This session will address populations not explicitly addressed in federal regulations, but who are nonetheless vulnerable because of homelessness, substance abuse, or other circumstances. This session will provide attendees with an opportunity to:

- Review the special considerations to be addressed by study teams when designing a study with these populations.
- Examine the special considerations for IRBs when they are reviewing these studies, such as payment and undue influence.
- Discuss how to ensure confidentiality and balance criminal liability with the need for individual assistance and protection from harm.
- Explore how to recruit and maintain contact with subjects during the study.

D18

29A

The Certified IRB Professional (CIP®) Credential: What's it all About?



Potpourri Track

Faculty: Jaime Arango, Gregorio Lim, Kelley O'Donoghue

This session will provide attendees with an opportunity to:

- Discuss the CIP credential and the steps involved in pursuing it.
- Review eligibility and recertification requirements.
- Discuss the types of questions on the CIP exam.
- Share exam preparation strategies.

D19

28E

Post IRB Approval Auditing: Department of Veterans Affairs (VA) Standards and Metrics



QA/QI and Post-Approval Monitoring Track

Faculty: David Rickaby

In this session, faculty will:

- Discuss the national VA not-for-cause auditing standards and processes.
- Explore a compilation of audit observations and metrics across the VA system.

D20 Advanced

27A

Roadmap for Change: You, Too, Can Implement a Demonstration Project



Regulatory Balance Track

Faculty: Judith Birk, Susan Rose

In this session, faculty will:

- Discuss how to create and implement a federal demonstration project.
- Examine issues specific to non-federally funded research, such as the lengthened continuing review period of two years.

Icon Key:



Wednesday, December 5 (continued)

2:15-3:30 PM: Didactic Sessions and Workshops Series D

D21 Basic

31C

IRBs and Internet-Based Research:



Navigating the Realities of Human Subjects Protections in the Digital Age

Research Involving the Internet and Social Networking Track

Faculty: Diana Holt, Laura Odwazny, Adrienne Tanner

This session will provide attendees with an opportunity to:

- Identify additional IRB review challenges pertaining to internet-based research, such as public vs. private domain, subject selection and recruitment, privacy and confidentiality, and informed consent.
- Learn about tips, tools, and resources for enhancing the dialogue on these topics within the IRB.
- Develop internet-based research guidance documents and training approaches that are designed to elicit more complete and accurate IRB applications, as well as lead to increased IRB review efficiency.

D22

23C

Navigating the Overlapping Roles of Human Subjects Protection and Research Misconduct: Issues for IRBs and Research Integrity Officers (RIOs)



Responsible Conduct of Research Track

Faculty: Kristina Borrer, David Wright

In this session, faculty will:

- Help attendees to develop more awareness regarding areas of joint responsibilities between IRB chairs and research integrity officers (RIOs) and how they need to work together and determine priorities.
- Understand and be sensitized to identify how clinical data can have both human subjects violations and possible research misconduct.
- Address attendees' questions to representatives from the Office of Human Research Protections (OHRP) and the Office of Research Integrity (ORI).

D23 Basic

29B

School Rules! Conducting Research in Elementary and Secondary Public Schools



SBER I Track

Faculty: Claire Dunne, Jeffery Rodamar

This session will provide attendees with an opportunity to:

- Discuss consent, assent, and parental permission.
- Explore the problem of undue influence, specifically in the classroom setting.
- Use case studies to examine when the 'Common Rule,' Family Educational Rights and Privacy Act (FERPA), and Protection of Pupil Rights Amendment (PPRA) regulations apply to particular research studies conducted in a public school setting.

Icon Key:



Wednesday, December 5 (continued)

2:15-3:30 PM: Didactic Sessions and Workshops Series D

D24 Advanced

33C

Incomplete Disclosures and Outright Deceptions



SBER II Track

Faculty: Greg Manship, Michael Tai, Jacqueline Wall

This session will explore complications that arise during research involving deception. Using case studies, this session will provide attendees with an opportunity to:

- Discuss how to approach research in which subjects are intentionally misled about the nature of the research.
- Review how to approach research in which the researchers do not disclose to the subjects that they are conducting research.
- Discuss whether research subjects should be allowed to withdraw data about themselves when they are debriefed.

D25

27B

Comparing the Contract With the Protocol and Consent Forms When You Have Limited Access to a Contract Officer and/or a General Counsel Office



Small Research Programs Track

Faculty: Robert Bienkowski, Lynn Smith

In this session, faculty will use examples to:

- Describe the common components of a clinical trial agreement (CTA), emphasizing those parts that bear on human subjects research.
- Poll participants about who in their institution gives the final approval for a CTA, and who negotiates the CTA/consent document language.
- Review the CTA items that should concern a local IRB, and what a central IRB expects when a protocol is reviewed.
- Discuss how to develop education programs for hospital offices that are not familiar with clinical research.

D26

29C

Statistics Without Tears



Unaffiliated and Non-Scientist IRB Members Track

Faculty: Susan Fish

In this session, faculty will:

- Explain the most intimidating statistical words and their usages.
- Describe the basic concepts of testing.
- Explore the concept of statistical power.
- Discuss the relationship between statistics and ethics.
- Review circumstances in which it is important to consult a statistician.

Icon Key:



Wednesday, December 5 (continued)

3:30-5:30 PM

Sails Pavilion

Meet and Greet the Supporters and Exhibitors

Network with this year's conference supporters and exhibitors in The Conference Connection! Light refreshments will be served.

3:45-5:00 PM

Sails Pavilion

Moderated Poster Discussions

Join us for an informal opportunity to learn about how your colleagues are supporting the advancement of ethical research. Attend one of four discussions with the authors of select posters. Each discussion promises to provide important and original ideas in a relaxed and interactive environment. Light refreshments will be served.

3:45-5:00 PM

Sails Pavilion

Speed Mentoring

Gather with your colleagues for a one-on-one networking event where you can connect with HRPP professionals, the Feds, ethicists, and other experts to receive personalized answers to your regulatory, ethical, and/or operational questions. Light refreshments will be served. *Please note that this event is sold out and you will not be able to sign up for it when registering. Please [email us](#) if you are still interested in attending and we will add you to the waiting list!*

Icon Key:

- | | | | |
|---|--|--|---|
|  didactic session |  interactive workshop |  recorded session |  qualifies for CME credit |
|  pre-registration required |  chosen session |  double session |  qualifies for CIP CE credit |

Thursday, December 6

7:00 AM

Registration Opens

Lobby 20

7:00-8:00 AM

Continental Breakfast

Sails Pavilion

7:00-8:00 AM

PRIM&R Online Connections & Resources Continental Breakfast

28ABCD



Interested in learning more about PRIM&R's array of online communities and resources? From our **Ethical Oversight of Human Subjects Research Course** and our new Knowledge Center to the IRB Forum and our groups on Facebook and LinkedIn, PRIM&R has many ways for you to connect, learn, and grow professionally from the convenience of your home and office. Attend this breakfast to learn more about PRIM&R's offerings and to speak with/ask questions of the PRIM&R staff. *Please select this option during registration or [email us](#) if you're interested, and we'll be sure to save you a seat!*

8:00-8:30 AM

Welcome and Recognition of Melinda Hurst, Pioneering "Community Member"

Exhibit Hall D

Please join us in recognizing the exemplary contributions of Melinda Hurst, a woman who has volunteered as a unaffiliated, non-scientific IRB member for over 30 years. As an advocate for research subjects, Ms. Hurst embodies the values, ethics, and commitment to protection that human subjects who participate in research deserve, and PRIM&R is thus proud to honor her at this year's Conference.

8:30-9:15 AM

Pillars of PRIM&R Lecture:

My Journey Through Madness: Schizophrenia and Research Ethics

Elyn R. Saks, JD, PhD

Orrin B. Evans Professor of Law, Psychology, and Psychiatry and the Behavioral Sciences, University of Southern California Gould School of Law

Exhibit Hall D



9:15-9:30 AM

Break

9:30-10:45 AM

Plenary: Panel VII – IRB Review of Research on Mental Illness:

Are Additional Protections Always Appropriate Protections?

Moderator/Panelist: *David Strauss*

Panelists: *Michael Caligiuri, Lisa Dixon, Anne Donahue*

"Mental Illness" encompasses a diverse group of highly prevalent disorders that are often poorly understood by practitioners outside the mental health community and by the public at large. Sound IRB review of research involving mental disorders requires an appreciation of the characteristics of mental illness as they relate to a range of research methodologies and the regulatory notions of vulnerability and susceptibility to risk. This panel will consider, from a range of perspectives, when subjects with mental illness require additional protections and when additional protections hinder research or have an inappropriate impact on autonomy or access to care.

Ballroom 20AB



Icon Key:



Thursday, December 6 (continued)

9:30-10:45 AM

Ballroom 20CD

Plenary: Panel VIII – Ethical Design and Conduct of Cluster Randomized Trials



Moderator/Panelist: *Charles Weijer*

Panelists: *James Feldman, Catarina Kiefe*

Cluster randomized trials (CRTs) are an increasingly important design for the evaluation of interventions across the spectrum of health research. In CRTs, groups or “clusters” of individuals—rather than the constituent individuals themselves—are randomly allocated to study arms (e.g. medical practices, hospital wards, schools, or communities). Study interventions in CRTs may be delivered at the cluster level (e.g. a community-wide advertising campaign to promote smoking cessation), or at the individual level (e.g. vitamin supplements or leaflets distributed to patients); interventions may also be delivered to health professionals or other individuals at the head of a cluster with the aim to improve patient care or service delivery. CRTs raise complex ethical and methodological challenges to researchers and IRBs reviewing these trials. For example, in a single CRT, the units of randomization (e.g. medical practices), experimentation (e.g. health professionals), and observation (e.g. patients) may differ. Absence of specific ethics guidelines has led to considerable variation and uncertainty as to what practices are permissible in CRTs. This panel will explore the ethical, practical, and methodological issues around the design, conduct, and ethical review of CRTs.

9:30-10:45 AM

Exhibit Hall D

Plenary: Panel IX – To Return or Not To Return: Individual Research Results and the Role of Biobanks



Moderator: *Pearl O'Rourke*

Panelists: *Laura Beskow, Edward Quigley, Susan Wolf*

There has been much discussion in recent years about returning research results to individual participants from single stand-alone studies; yet, given the many complexities around genetics and genomics research, reaching a consensus has been difficult. The discussion of returning individual results has now expanded in scope to include return of results from studies using data and samples in biobanks. A recently published proposal suggests that responsibilities for the return of research results should be shared among the players in a biobank research system, including the primary research or collection site, the biobank itself and secondary researchers accessing the data and samples. This panel will explore the ethical justification for, as well as the logistical, regulatory, and ethical challenges of this proposal for biobanks, researchers, and IRBs.

10:45-11:15 AM

Break

10:45-11:15 AM

Lobby 20

Book Signing with Author and Keynote Speaker Elyn Saks, JD, PhD

Join us in the Registration Area after the morning plenary sessions for a book signing with keynote speaker Elyn Saks, JD, PhD. Copies of the books are available [online](#), as well as at the onsite Bookstore.

Icon Key:



Thursday, December 6 (continued)

11:15 AM-12:30 PM

Didactic Sessions and Workshops Series E

E1 NEW SESSION!

SACHRP Considerations on Internet Research

31A
  

A Dialogue with the Feds I Track

Faculty: Barbara Bierer, Elizabeth Buchanan, Dean Gallant

Formal guidance around IRB review of internet research has not been issued, and many IRBs and researchers are asking complex questions about all aspects of Internet research, from what is exempt to what is public information to how we ensure informed consent. This session will provide attendees with an opportunity to:

- Review with representatives of SACHRP its work to date around IRB review of Internet research.
- Discuss and explore current examples and best practices currently under consideration by SACHRP.
- Ask questions of and discuss Internet research issues with faculty members and other attendees.

E2

A Dialogue with the Department of Education

32B
 

A Dialogue with the Feds II Track

Faculty: Jeffery Rodamar

Attendees are encouraged to come with questions. This session will provide attendees with an opportunity to:

- Hear from Department of Education representatives about evolving issues at the Department of Education.
- Identify new initiatives related to ongoing research by the Department of Education.
- Participate in an open discussion about topics relevant to Department of Education stakeholders.

E3

Breaking Down the Rumors About Accreditation Standards

27A
 

Accreditation of HRPPs Track

Faculty: Gary Chadwick, Moira Keane

In this session, faculty will:

- Present rumors that have circulated about AAHRPP accreditation, and separate the mythical components from the truth.
- Discuss and explore speculations that attendees may have heard.

E4 Advanced

QA/QI/Program Evaluation: Is it or is it Not “Research?”

30AB
  

Activities Along the Boundaries Between Research and Practice Track

Faculty: George Gasparis, Ivor Pritchard

This session will use case studies to highlight distinctions between QA/QI/program evaluation and research. This session will provide attendees with an opportunity to:

- Address the question of whether an activity is human subjects research, including a discussion about generalizability.
- Discuss an investigator's involvement in another institution's QA/QI research.
- Explore whether the home institution is engaged in research, for instance, if investigators from a graduate school of education are recruited to evaluate a program conducted at another school.

Icon Key:



Thursday, December 6 (continued)

11:15 AM-12:30 PM: Didactic Sessions and Workshops Series E

E5 Advanced

29C

HRPPs and IRBs in Tough Economic Times



Advanced Forum for IRB Professionals Track

Faculty: Jan Hewett, Michele Russell-Einhorn

The downturn in the overall economy and shrinking budgets for research will have an effect on all components of an HRPP. IRBs, researchers, and administrators may be asked to maintain or exceed their productivity with fewer people and smaller budgets. In this session, faculty will:

- Discuss the implications of turning to industry as a primary source of support for the research enterprise.
- Explore the vulnerability of the research infrastructure, including IRBs, given the promised cuts in federal research funding.
- Address how HRPPs can plan for a coming economic hit.

E6

30E

What Investigators and IRBs Need to Know About Investigational Device Exemptions (IDEs) and Investigational New Drugs (INDs)



Clinical Research Professionals Track

Faculty: Christine Drabick, Amanda Hammond, David Wallach

In this session, faculty will:

- Examine institutional and investigator responsibilities and liabilities around IDEs and INDs.
- Outline what safeguards, such as education, oversight, and monitoring, the IRB should require.

E7

30C

The Ethics of Paying Research Subjects



Ethical Issues Track

Faculty: Alan Wertheimer

In this session, faculty will:

- Evaluate concerns and address justifications surrounding the topic of payment to research subjects.
- Demonstrate IRB members' trepidations about payment.
- Offer some guidance as to which worries merit the attention of IRB members and which do not.

E8 Advanced

29D

In Vitro Diagnostic (IVD) Devices Used as Integral Parts of Therapeutic Clinical Trials and Companion Devices: IRB Issues and Significant Risk Determinations



FDA Regulations Track

Faculty: J. Milburn Jessup, Elizabeth Mansfield, Mya Thomae

In this session, faculty will:

- Examine issues that IRBs should consider related to IVD devices used as an integral part of therapeutic clinical trials.
- Discuss draft guidance on IVD devices related to IRB review and oversight, and discuss some initiatives developed by the National Cancer Institute (NCI) and the FDA to manage use of investigational tests in clinical investigations of drugs.
- Discuss considerations for distinguishing significant risk from non-significant risk IVD investigations.

Icon Key:



Thursday, December 6 (continued)

11:15 AM-12:30 PM: Didactic Sessions and Workshops Series E

E9 Advanced

23A

How to Translate a Protocol into an Informed Consent Form (ICF)



Informed Consent Track

Faculty: Joy Jurnack, Jody Power

This session will provide attendees with an opportunity to:

- Evaluate a protocol to determine the topics that will need to be included in the ICF.
- Learn how to take information from a protocol and translate it to an appropriate reading level for the ICF.

E10 Advanced

24A

Operationalizing the New Public Health Service (PHS)



Financial Conflicts of Interest (FCOI) Rule

Institutional Officials Track

Faculty: Jeffrey Botkin, Lisa Murtha

In this session, faculty will:

- Review the changes to the new PHS FCOI rule.
- Discuss ways in which universities and hospitals have implemented the new requirements, including disclosure and training.
- Address difficulties that institutions have had with implementing the new requirements.

E11 Basic

29B

The (Research Ethics) World is Flat: Identifying and Working with Local IRBs in International Research



International Research Track

Faculty: David Borasky, Yali Cong

In this session, faculty will:

- Review US regulatory requirements and their applicability to international research.
- Describe mechanisms for identifying local IRBs and ethics consultants and engaging in a useful dialogue.
- Discuss the limitations of some local ethics committees in low-resource settings.

E12 Basic

31C

What Happens After the Protocol is Approved: Amendments, Continuing Review, Modifications, Incident Reports, Unanticipated Problems, and Adverse Events



IRB Bootcamp Track

Faculty: Julia Gorey, Karen Hale, Kevin Prohaska

In this session, faculty will:

- Describe the respective responsibilities and obligations of researchers and IRBs in the post-approval phase of research.
- Discuss how modifications are made through protocol amendments.
- Review expectations for managing and reporting of adverse events, unanticipated problems involving risks to subjects, and other deviations from the original protocol.
- Outline the steps in the approval process of FDA investigational applications.

Icon Key:



Thursday, December 6 (continued)

11:15 AM-12:30 PM: Didactic Sessions and Workshops Series E

E13 Basic

30D

Evaluating and Improving IRB Operations



IRB Operations and Toolkit Track

Faculty: Jeffrey Cohen, Melissa Epstein

This session will provide attendees with an opportunity to:

- Familiarize themselves with techniques such as evaluating the “life” of a protocol, identifying bottlenecks and inefficiencies, conducting desk audits, analyzing IRB metrics, evaluating staff morale and workload, evaluating resources, and obtaining feedback from investigators.
- Learn ways to improve operations and streamline processes, including using a computer-based recordkeeping system, maximizing staff efficiency, using flexibilities in the regulations, and adopting written standard operating procedures.
- Bring and share solutions that have worked at their respective institutions.

E14 Basic

24B

Ethical and Regulatory Issues in Clinical Trials' Websites and Social Media



Issues for Pharma/Biotech Track

Faculty: Kristina Borrer, J. Michael Warner

In this session, faculty will:

- Discuss the growing use of subject-driven social media sites (such as PatientsLikeMe) during pre-enrollment to enhance recruitment by matching volunteers with clinical trials.
- Learn about the growing importance of and uses for clinical trial registration and results reporting, in the context of advancing ethical research.
- Discuss the increasing use of social media sites for post-enrollment communication among study subjects, in order to, for instance, compare side effects and determine who is taking the active drug and who is taking the placebo.
- Explore perspectives on evolving second-generation issues in trial registration and results reporting.

E15 Basic

23B

Cooks in the Kitchen: The Roles of Various Entities in Human Subjects Research



Legal Track

Faculty: Lisa Leiden, Monica Neuman

Different elements of research involving human subjects are overseen by IRBs, DSMBs, tumor boards, conflict of interest committees, and hospital compliance departments, among others. This session will provide attendees with an opportunity to:

- Address the overall approach to research ethics and compliance within an organization.
- Understand the roles of each to ensure that there is clear and transparent communication so that nothing is overlooked.

Icon Key:



Thursday, December 6 (continued)

11:15 AM-12:30 PM: Didactic Sessions and Workshops Series E

E16

33A

Emerging Issues in Whole Genome Sequencing: Informed Consent and Beyond



Out-of-Body Experiences: Research Involving Tissue and Data Track

Faculty: Sharron Docherty, Laura Lyman Rodriguez

In this session, faculty will:

- Discuss the most up-to-date set of issues IRBs should consider when reviewing whole genome sequencing proposals.
- Share resources and best practices regarding informed consent and other protocol considerations for whole genome sequencing.
- Facilitate an open discussion with representatives from the National Human Genome Research Institute (NHGRI) to determine IRB-relevant needs as they pertain to whole genome sequencing.

E17 Advanced

24C

Challenges of Research with Adolescent Populations



Populations Requiring Additional Protections Track

Faculty: Mary Ott, John Santelli

This session will provide attendees with an opportunity to:

- Familiarize themselves with best practice guidelines for research with adolescents from the Society for Adolescent Health and Medicine (SAHM).
- Consider ways in which adolescents are vulnerable, and how research can address those vulnerabilities.

E18 *NEW SESSION!*

28E

Suicidality in Research: Asking Questions About Suicidal Thoughts, Enrolling Suicidal Individuals, and Other Ethical Issues



Potpourri Track

Faculty: Elizabeth Small, Barbara Stanley

In this session, faculty will:

- Address ethical concerns around screening for suicidality in both general and vulnerable populations.
- Delineate ethical issues regarding enrolling suicidal individuals in trials and basic research.
- Discuss when it is appropriate to enroll suicidal individuals in research.
- Describe procedures that enhance safety and decrease risk when enrolling suicidal individuals in trials.

E19

25A

Study Reviews Before Anything Goes Wrong



QA/QI and Post-Approval Monitoring Track

Faculty: Cynthia Kern, Eunice Newbert

This session will provide attendees with an opportunity to:

- Learn how to do preventive study reviews.
- Discover how to review and become educated about study materials before the first subject is enrolled.

E20 Advanced

31B

Collaborative Multi-site IRB Agreements: Lessons Learned and Best Practices



Regulatory Balance Track

Faculty: Valerie Bonham, Melissa Frumin

In this session, faculty will:

- Review the regulatory requirements of collaborative IRB agreements.

Icon Key:



Thursday, December 6 (continued)

11:15 AM-12:30 PM: Didactic Sessions and Workshops Series E

- Discuss the respective responsibilities of the institution and the IRB.
- Describe best practices and lessons learned.

E21

Not Lost in Translation: Transforming Data Security Requirements Into Language Understandable to IRBs and Researchers

Research Involving the Internet and Social Networking Track

Faculty: Teresa Doksum, Carter Epstein, Sean Owen

In this session, faculty will:

- Help attendees understand basic security procedures based on regulations such as the Health Insurance Portability and Accountability Act (HIPAA), the Family Educational Rights and Privacy Act (FERPA), and the Federal Information Security Management Act (FISMA), which researchers need to follow in order to protect confidentiality and minimize risk of a security incident.
- Use an analysis of over 200 agreements for data governed by HIPAA, FERPA, and other federal and state laws to help attendees understand common requirements found in data agreements and strategies for ensuring researchers adhere to these requirements.
- Explore the shared responsibility of IRBs, researchers, data analysts, and data archivists in minimizing the risk of disclosure around de-identified datasets, and provide a preliminary set of recommendations.



32A

E22

A "Premiere" Showing of *The Clinic* – The Successor to the Office of Research Integrity (ORI)'s Popular Interactive Video, *The Lab*

Responsible Conduct of Research Track

Faculty: Elyse Summers, Sandra Titus

In *The Clinic*, the watcher becomes the lead character in an interactive movie and must make decisions about human subject protection and research integrity that can have long-term consequences. The simulation addresses responsible conduct of research topics such as avoiding research misconduct, management of data to ensure integrity, interacting with the IRB, and fully informing subjects when obtaining consent.



33C

E23 Basic

Lay Down Your Burden! Streamlining the Process of Reviewing Student Research

SBER I Track

Faculty: Eric Allen

In this session, faculty will:

- Review the instances when student research should be reviewed by the IRB.
- Discuss how the review of student research can be improved both in terms of efficiency and effectiveness.
- Explore alternative models of review for student research.
- Examine the role of institutional culture in approaches to reviewing student research.
- Discuss ways to improve communication and build better relations with faculty who teach research courses.



33B

Icon Key:



Thursday, December 6 (continued)

11:15 AM-12:30 PM: Didactic Sessions and Workshops Series E

E24 Advanced

29A

Tribal Participatory Research:

Unique Aspects of Working in American Indian and Alaska Native Contexts

SBER II Track

Faculty: William Freeman, Deborah Morton

In this session, faculty will:

- Explore lessons from the native context about community consent, secondary use of data, data sharing agreements, and the role of translation and dissemination.
- Discuss how insights gleaned from tribal participatory research methods can offer general ethical lessons for the field and inform the development of ethical research policy more broadly.



E25 Advanced

23C

Managing a Small Research Operation in a Large, Growing, Multi-Component Healthcare System

Small Research Programs Track

Faculty: Robert Bienkowski

In this session, faculty will use examples to:

- Discuss developing and enforcing conflict of interest policies for employed and non-employed physicians.
- Describe strategies for explaining and enforcing compliance with physician-investigators and getting their support.
- Provide guidance for developing comprehensive, uniform policies and procedures for IRB oversight education, review, and communication standards.
- Illustrate how to establish a research culture using research compliance as a tool for integration.
- Evaluate different ways to develop and implement a financial interest reporting system that complies with new NIH regulations in an institution with limited NIH funding.



E26 Basic

27B

Review a Protocol! Regulatory Considerations in the Approval Process

Unaffiliated and Non-Scientist IRB Members Track

Faculty: Michelle Feige, Susie Hoffman

This session will provide attendees with an opportunity to:

- Review the federal regulatory criteria for approval.
- Discuss strategies and tools used to facilitate protocol review.
- Systematically review sample protocols.



12:45-1:45 PM

Sails Pavilion

Lunch

12:45-1:45 PM

25B

Lunch with Melinda Hurst, Pioneering “Community Member”

Please join us to recognize the exemplary contributions of Melinda Hurst, a woman who has volunteered as a unaffiliated, non-scientific IRB member for over 30 years. As an advocate for research subjects, Ms. Hurst embodies the values, ethics, and commitment to protection that human subjects who participate in research deserve, and PRIM&R is thus proud to honor her at this year's conference. *Please select this option during registration or [email us](#) if you're interested, and we'll be sure to save you a seat!*



Icon Key:



Thursday, December 6 (continued)

12:45-1:45 PM

26AB

Lunch and Book Signing with Author and Keynote Speaker Elyn Saks, JD, PhD

Join us for a luncheon with keynote speaker Elyn Saks, author of [The Center Cannot Hold: My Journey Through Madness](#). This event will provide attendees the opportunity to talk with and ask questions of this distinguished author and professor in an informal environment. Copies of Dr. Saks' book are available at the onsite Bookstore, and she will be available to sign books during this lunch. *Please note that this event is sold out and you will not be able to sign up for it when registering. Please [email us](#) if you are still interested in attending and we will add you to the waiting list!*

12:45-1:45 PM

28ABCD

What's New at the CITI Program? Lunch

Staff members from CITI will demonstrate new features that will help participants get the most from their use of the CITI Program, including site navigation, refresher modules, and non-English language capabilities. *Please select this option during registration or [email us](#) if you're interested, and we'll be sure to save you a seat!*

1:15-1:45 PM

Sails Pavilion

Demonstration of PRIM&R's Online Course and Knowledge Center

Join us in the PRIM&R Booth for a demonstration of two of our interactive online resources—**The Ethical Oversight of Human Subjects Research Course (Online Course)** and PRIM&R's Knowledge Center. A fifteen minute presentation on each resource will provide you with an introduction to utilizing these tools to strengthen your understanding of human subjects protections.

1:45-2:00 PM

Break

2:00-3:15 PM

Ballroom 20AB

Plenary: Panel X – Protecting Privacy and Confidentiality: Exploring Persistent Limitations, Novel Challenges, and Whether it is Time for a New Approach

Moderator: *Cynthia Gómez*

Panelists: *Nancy Kass, Lauren Solberg*

This panel will discuss the ongoing challenge of protecting research subjects' privacy and confidentiality and the special concerns raised by new online technologies. Issues to be discussed include the differences between confidentiality and privacy; current technical approaches to data privacy and their limitations; the actuality of privacy risks in the biomedical and the social behavioral settings; and whether IRBs can meaningfully contribute to protecting subjects from these risks. The panel will close by exploring whether, given the apparent limitations of our current regulatory and technical approaches to protecting privacy and information, we need a new framework, and what such a framework might look like.

Icon Key:



Thursday, December 6 (continued)

2:00-3:15 PM

Exhibit Hall D

**Plenary: Panel XI – The Single IRB of Record Proposal:
Appraising the Balance of Risks and Benefits**



Moderator/Panelist: *Robert Levine*

Panelists: *Albert J. Allen, Gary Chadwick, Pearl O'Rourke*

In recent years support has been growing for having multi-site research reviewed by a single IRB of record, culminating with a proposed requirement in the recent Department of Health and Human Services' Advance Notice of Proposed Rulemaking (ANPRM). This panel will explore the advantages and concerns surrounding such a system. The moderator is an academic bioethicist who will give a brief description of the single IRB model including comments on its efficiencies as compared with review by multiple IRBs, the current prevailing custom. A pharmaceutical corporation representative will discuss advantages from a study sponsor's perspective of using a single IRB and then address the oft-heard concern that companies would press for single IRBs that produce rapid, pro forma reviews. An academic who stands at the intersection of academia and the pharmaceutical industry will speak about how his academic institution has changed its paradigm of ethics and regulatory review by successfully integrating university medical center research activities with a freestanding IRB, and will also address the concern that independent, commercial IRBs would attempt to corner the market for single IRBs of record. Finally, a university HRP leader will discuss disadvantages of immediate implementation of the single IRB model without first having taken into account the facts that IRBs are just one component of larger human research protections programs (HRPPs), and that oversight and protection policies vary substantially from one institution to another. Attendees will leave the panel much better informed about the issues in the controversy even if they are not yet sure whether it would be wise to adopt a policy mandating single IRBs of record.

2:00-3:15 PM

Ballroom 20CD

**Plenary: Panel XII – Compensation for Research-Related Injury:
Is it Finally Time for a Nationalized System?**



Moderator: *Daniel Nelson*

Panelists: *Karen Moe, Efthimios Parasidis, Elizabeth Pike*

For 30 years, national bioethics commissions have been calling for those who conduct research to provide treatment for subjects who may be harmed through participation, arguing that we have an ethical obligation to care for those who bear the risk. Most recently, the Presidential Commission for the Study of Bioethical Issues recommended that this issue be studied anew, and that the federal government should explain publicly why the status quo of having no nationalized system or federal requirements for compensation should be maintained or changed. Many developed countries have instituted policies that require treatment or compensation for research-related injuries, and some US agencies and institutions have independently established self-insurance programs. This panel will explore the current landscape, including the calls for a nationalized system that would mandate compensation or treatment for research-related injury.

3:15-3:30 PM

Break

Icon Key:



Thursday, December 6 (continued)

3:30-4:45 PM: Grand Finale Sessions

3:30-4:45 PM

Grand Finale Sessions

GF1

30ABCD

Ask the Experts! Everything You Wanted to Know, But Were Afraid to Ask

Faculty: Charlotte Coley, Yvonne Higgins, Julie Kaneshiro, Irene Stith-Coleman, Jean Toth-Allen

Are you new to the field of research ethics? Still have a nagging question regarding HRPPs and IRBs?

Join us for this session where experienced veterans of the field and seasoned PRIM&R pros will be available to answer all the questions you've been afraid to ask! Come with ideas, questions, and concerns to share with the group and be prepared to participate in an open, interactive and lively discussion with faculty and your peers.

GF2

33ABC

Connecting Through PRIM&R:

Mentoring, Regional Connections, Volunteer Opportunities, and More

Faculty: Megan Frame, Kimberly Hensle Lowrance

In addition to the knowledge members gain from attending PRIM&R conferences and regional programs, a major benefit is networking, which allows newcomers and those with years of experience to share common problems and solutions. PRIM&R has a number of initiatives that foster such connections, including a mentoring program, a range of volunteer opportunities, social media groups, the IRB Forum, and a long-standing Regional Connections program that provides support to members to hold a local networking and/or educational events. Come and learn tips on how to find a mentor or mentee, start planning a Regional Connections program, and more.

GF3

Affinity Groups

You've spent three days getting to know your colleagues. So where do you go from here? Come to this wrap-up session to connect with your fellow affinity group members one last time. Participate in a facilitated brainstorming session with your group leaders to determine how you would like to stay in touch after the conference, what topics you would like to see at the next AER conference, and what other activities your Affinity Group might want to undertake. Each Affinity Group will have its own session:

- **Global Research (gold)** **28E**
- **Institutional Officials (IOs) (black)** **27A**
- **IRB Chairs (teal)** **27B**
- **Quality Assurance/Quality Improvement (QA/QI) (navy)** **23A**
- **Small Institutions (neon green)** **23B**
- **Social, Behavioral, and Educational Research (SBER) (violet)** **23C**
- **Unaffiliated/Community Members (peach)** **24A**

Icon Key:

 didactic session	 interactive workshop	 recorded session	 qualifies for CME credit
 pre-registration required	 chosen session	 double session	 qualifies for CIP CE credit

Thursday, December 6 (continued)

3:30-4:45 PM: Grand Finale Sessions

GF4 NEW SESSION!

Ballroom 20AB

Film Screening: *How to Survive a Plague*

(Please note that in order to show the film in its entirety, this Grand Finale session will run from 3:30 to 5:30 PM)

Join us for a screening of the critically acclaimed, feature-length documentary *How to Survive a Plague*, a powerful look at the role of early AIDS activists in expediting the development of HIV/AIDS drugs.

“How to Survive a Plague is a story about two coalitions—AIDS Coalition to Unleash Power (ACT UP) and Treatment Action Group (TAG)—whose activism and innovation turned AIDS from a death sentence into a manageable condition. Despite having no scientific training, these self-made activists infiltrated the pharmaceutical industry and helped identify promising new drugs, moving them from experimental trials to patients in record time. With unfettered access to a treasure trove of never-before-seen archival footage from the 1980s and '90s, filmmaker David France puts the viewer smack in the middle of the controversial actions, the heated meetings, the heartbreaking failures, and the exultant breakthroughs of heroes in the making.”

- from www.surviveaplague.com

GF5

29ABC

Human Subjects Protections Jeopardy!

Faculty: Elyse Summers

You've learned so much at the conference, let's put it to use! Take part in this fun and interactive Jeopardy game to test what you've learned, show off for your friends, and enjoy your last hours at the PRIM&R conference! Answer: HSP Jeopardy. Question: What is a guaranteed good time for all!?

GF6

32A

The Evolution of Research Ethics: Bring Your Story!

Faculty: Gigi McMillan, Joan Rachlin

Celebrate the rich texture of PRIM&R's history as members of the community share meaningful tales describing their journeys in the world of ethical research. In this Grand Finale session, learn about the tradition of oral history and strategies for capturing vibrant, educational accounts. PRIM&R will describe its latest endeavor: the development of an interactive multi-media project that captures and organizes meaningful stories related to research ethics. This website, *People & Perspectives*, will present multiple topics in a variety of formats; listeners can contribute their own stories, download their favorites and link to similar speakers or subjects. The last half of this Grand Finale session will be an “open mic” format with pre-booked orators as well as opportunities for the audience to take the podium. This casual, fun, and friendly session will be videotaped for inclusion in *People & Perspectives*. Be one of the first to contribute to this ground-up body of knowledge and become part of the *People & Perspectives* oral history collection!

Icon Key:



GF7

31AB

The Uncomfortable Conversation: Talking about Diversity



Faculty: Melissa Epstein, Eric Mah

The issue of diversity is not directly addressed in the federal regulations governing human subjects research, although it is referenced in the *Belmont Report*. Nevertheless, IRB professionals have opportunities to consider issues of diversity during the protocol review process, development of policies and procedures, investigator training, and the like. In this session, members of PRIM&R's Diversity Advisory Group will pose and address questions such as: How can you, as IRB professionals, ensure the issue of diversity is adequately addressed during protocol review? How can you develop policies and procedures that support diversity when there are no clearly defined federal regulations? How do you encourage investigators to recruit diverse subject populations when resources are short? What arguments should you use, and how are those arguments based in ethics, regulations, science, and research history? Come be part of this important conversation.

4:45-5:45 PM

28 ABCD

Closing reception

Join us to wish each other a fond farewell and to make plans for the **2013 AER Conference!** Light refreshments will be served.

Boston University School of Medicine
Continuing Medical Education (CME) Accreditation Statement



This activity has been planned and implemented in accordance with the Essential Areas and Policies of the Accreditation Council for Continuing Medical Education (ACCME) through the joint sponsorship of Boston University School of Medicine and PRIM&R. Boston University School of Medicine is accredited by the ACCME to provide CME for physicians.

Boston University School of Medicine designates this live activity for a maximum of *16.75 AMA PRA Category 1 Credits™*. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

This program meets the criteria of the Massachusetts Board of Registration in Medicine for 16.75 hours of risk management study.

Course director: Leonard Glantz, JD, Associate Dean Emeritus, Academic Affairs; Professor, Health Law, Bioethics, and Human Rights

Target audience: The target audience of this activity includes Human Research Protection Program/ Institutional Review Board (HRPP/IRB) chairs, members, and administrators; researchers and research staff; institutional officials; regulatory officials; compliance officers; those charged with overseeing "responsible conduct of research" programs; hospital/university attorneys; patient advocates; representatives of voluntary health organizations; industry and biotechnology representatives; and those involved with science policy.

Educational objectives: Upon completion of this activity, participants should be able to: (1) Explain the principles listed in the various research ethics reports (Belmont Report, Nuremberg Report, Declaration of Helsinki) and apply them in their day to day work; (2) Identify the core federal regulations governing human subjects research, and recognize which aspects of their work put those regulations into practice; (3) Develop strategies for managing successful HRPPs/IRBs; (4) Assess how their HRPP/IRB policies and procedures compare with the best practices in the field; (5) Communicate effectively with those involved in various aspects of the research enterprise to ensure adherence to federal regulations and that human subjects are properly protected before, during, and after a research study; and (6) Define a "vulnerable population" and demonstrate how ethical principles and federal regulations apply to these groups during research.

Needs addressed statement: In order to successfully implement HRPPs, professionals involved with IRBs need access to current and accurate information on the laws, regulations, policies, and guidance documents governing human subject research ethics and compliance. How this information and policies are implemented varies. Past participants have rated highly the opportunity to discuss these principles with experts in the field and their peers. This conference enables participants to exchange best practices and other creative strategies that institutions around the country are employing to maximize protection of research participants, while at the same time streamlining administrative procedures influence the implementation of policies.

Faculty disclosure statement: Boston University School of Medicine asks all individuals involved in the development and presentation of CME activities to disclose all relationships with commercial interests. This information is disclosed to CME activity participants. Boston University School of Medicine has procedures to resolve any apparent conflicts of interest. In addition, faculty members are asked to disclose when any unapproved use of pharmaceuticals and devices is being discussed. A detailed copy of the disclosure statement will be available in the *Conference Guide*, and also at the CME table located onsite the San Diego Convention Center.

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