

## Thursday, November 12: 2015 SBER Conference

7:00 AM

**Registration Opens**

Breakfast on your own.

8:00-8:15 AM

**Welcome from the 2015 SBER Conference Co-Chairs**

*Elizabeth A. Buchanan, PhD, Endowed Chair in Ethics; Director, Center for Applied Ethics, University of Wisconsin Stout*

*Jeffrey M. Cohen, PhD, Chief Executive Officer, HRP Consulting Group, Inc.*

Ballroom B



8:15-9:00 AM

**Keynote Address: Regulating Behavioral Research Behavior: Back to the Future?**

[Ivor A. Pritchard, PhD](#), Senior Advisor to the Director, Office for Human Research Protections

Ballroom B



9:00-9:15 AM

**Break**

### Didactic Sessions and Workshops Series A, 9:15-10:30 AM

A1

**Strategies to Assess and Mitigate SBER Risk: Collaborative Learning Through Case Studies**

*(Advanced Track) Jennifer H. Campbell, Cynthia J. Monahan*

Through a collection of SBER case studies, attendees will identify, examine, and explore IRB strategies to address and mitigate SBER risk based on IRB review criteria such as: study procedures, population, risk/benefit, harm, confidentiality, etc. The cases raise important and difficult ethical issues connected with planning, reviewing, or conducting SBER. During this session, faculty will:

- Review how research that does not necessarily pose risk of physical harm can pose other harms (e.g., psycho-social, legal, psychological, data protection) and how this can challenge researchers and IRBs with respect to how they identify and assess risk
- Identify and examine the ethical and practical issues surrounding risk to subjects when designing and implementing SBER protocols
- Explore IRB and researcher strategies to identify, assess, mitigate, and manage SBER risks

Room 304



A2

**Changing Concepts of Anonymity, Confidentiality, and Privacy in SBER** *(Advanced Track)* Scott

*Bradner, Dean R. Gallant*

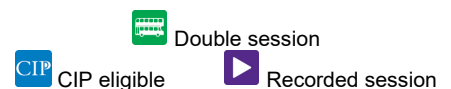
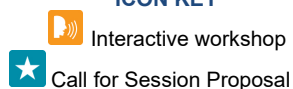
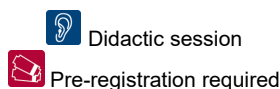
Can we still promise our research participants anonymity? What are the limits of confidentiality? Is privacy still a fundamental concept for human subjects research? Do individuals have an accurate perception of where their privacy rights end and begin, and does the public have an accurate perception of what privacy is for them? This session will explore the rapidly evolving landscape around these concepts. During this session, faculty and attendees will:

- Discuss the definitions of anonymity, confidentiality, and privacy from the regulatory, philosophical, and research perspectives
- Share examples of de- and re-identification in SBER
- Clarify the distinct and overlapping roles that Information Technology, the IRB, and researchers share in the common enterprise of data security
- Review research and IRB best practices for ensuring anonymity, confidentiality, and privacy in SBER

Room 312



**ICON KEY**



# Thursday, November 12: 2015 SBER Conference

Didactic Sessions and Workshops Series A, 9:15-10:30 AM

A3

## You'll Know it When You See it: Defining "Human Subjects Research" Under the DHHS Regulations (Basic Track) Julie Kaneshiro, Ada Sue Selwitz, Elizabeth A. Bankert

Room 302



Evaluating whether an investigator is conducting research involving human subjects has many important ramifications for both the institution and the investigator in terms of cost, time, and requirements for the activity. Since interpretation of key definitions in the regulations - including "systematic," "generalizable," and "human subjects" can be tricky, thorough consideration is needed to ensure appropriate application of the regulations. During this session, faculty and attendees will :

- Define a process and a set of criteria for determining whether an activity is research according to the current federal regulations
- Explore key decision points for determining whether or not a research study involves human subjects according to the current federal regulations
- Discuss proposed changes to the Common Rule's definitions for "research" and "human subjects."

A4

## What You Need to Know About Privacy and Confidentiality (Basic Track)

Brenda Curtis, Andrew Hedrick

Room 313



During this session, faculty and attendees will:

- Explore the question of public vs. private behavior, including what counts as a reasonable expectation of privacy
- Outline 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
- Review how to create and implement a data security plan

A5

## What Did We Learn from the Facebook Emotional Contagion Study? (Innovations Track)

Elizabeth A. Buchanan, Jeffrey T. Hancock

Room 306



This session will provide an in-depth discussion of the Facebook Emotional Contagion study, including study design, methodological and ethical considerations, and the role of the IRB. The complexities of the case and a discussion of the backlash will be shared. During this session, faculty will:

- Describe the methods and procedures used in the Facebook Emotional Contagion study
- Explore the complexities of academic-industry research from the IRB perspective
- Offer strategies for innovative IRB review of social media research

A6

## Flexibility and Innovations in SBER IRB Review Procedures (Innovations Track)

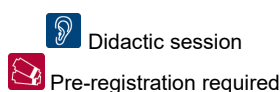
Jeffrey M. Cohen, Susan L. Rose

Room 311



This session will describe the ways in which "unchecking the box" provides optimal flexibilities for researchers while still protecting research participants. It will explore such issues as multi-year approvals and expanded exemption categories for non-federally funded, minimal risk research. During this session, faculty will:

- Define what it means to "uncheck the box"
- Review how to implement flexibilities once the box is "unchecked"
- Offer guidance for SBER researchers and IRBs on using the flexibilities



Didactic session



Pre-registration required

### ICON KEY



Interactive workshop



Call for Session Proposal



Double session



CIP eligible



Recorded session

A7

### **“Innocents Abroad?”: SBER in International Settings** (Potpourri Track)

David A. Borasky, Matthew D. Stafford

Conducting research outside the borders of the US can present a variety of issues for researchers. This session will address what IRBs should consider with respect to some of these issues, including differing cultural norms, community authorizations to conduct research, community consultation, contextual risks, and creating an IRB where there isn't one. During this session, faculty will:

- Compare regulations and cultural norms in different countries, and identify general and local resources on regulations and cultural considerations in research
- Outline US regulations for waivers of consent and assent and documentation thereof
- Discuss the cultural need for non-participant authorization to conduct research
- Review culturally sensitive/specific risk assessments, including dangerous situations (e.g., drug lords, blood diamonds)
- Share about the challenges of students conducting research abroad

Room 310



A8

### **Action/Practitioner/Teacher Research: Issues for IRBs** (Potpourri Track) Matthew J. Welch

What is action/practitioner/teacher research and why does it present issues for some IRBs? In this session, participants will learn about the factors that create misunderstandings and challenges for IRBs and action researchers during the review process of such studies. These include, but are not limited to, deciding whether the activity is research, the vagaries of conducting research in natural settings, the potential for role conflict presented to practitioners, informed consent, and assessing risk. During this session, faculty and attendees will:

- Review the fundamentals of action/practitioner/teacher research
- Explore whether the proposed action/practitioner/teacher research requires IRB review
- Discuss the ethical challenges action/practitioner/teacher research projects present for IRBs and practitioners

Room 309



10:30-11:00 AM

### **Break**

Join us for coffee.

## Didactic Sessions and Workshops Series B, 11:00 AM-12:15 PM

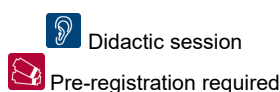
B1

### **SBER and Vulnerable Populations** (Advanced Track) Ashley D. Hicks, Lara Sloboda

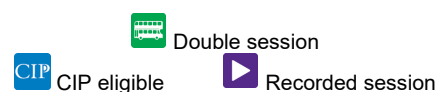
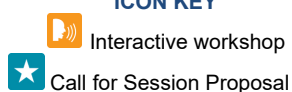
This session will explore the concept of “vulnerability” in research. The regulations (subparts) identify three specific populations as “vulnerable,” and call for additional protections (e.g., full review, prohibition of waivers of informed consent) for research with these populations. The *IRB Guidebook* refers to other “special classes of subjects” – commonly translated as other “vulnerable” populations, including the cognitively impaired, students, employees, pregnant women, traumatized and comatose patients, terminally ill patients, and minorities, with no guidance on how and when the term applies to these populations. The characterization of certain populations as potentially “vulnerable” has a significant impact on research. Thus, this session will focus on those populations that are considered “special” or “vulnerable,” but are not covered by the present subparts including: (1) the way it is used within the current regulatory framework; (2) the ethical implications of its usage; and (3) its impact on SBER. During this session, faculty will:

- Review what it means to label a person or group vulnerable
- Discuss the issues that arise when using the same manipulations or interventions with “vulnerable” and “non-vulnerable” populations
- Address how vulnerability and level of risk intersect
- Outline what vulnerability means when the research involves only minimal risk

Room 302



#### ICON KEY



# Thursday, November 12

Didactic Sessions and Workshops Series B, 11:00 AM-12:15 PM

B2

**Speed it Up: Exempt, Expedite, Relax!** (Basic Track) Kristina Borrer, Jeffrey M. Cohen, Dean R. Gallant

Room 304



During this session, faculty and attendees will:

- Discuss the procedural sequence process for review of SBER
- Use case vignettes to test the review process and classification system
- Identify flexibility in the regulations consistent with ethical research
- Share strategies for how to make this decision

Please note this is a double session and will end at 1:45 PM. Pre-registration for this session is required.

Please [register online](#) or [email us](#). Please use the ticket included on your name badge to get your boxed lunch in Ballroom A before the session.

B3

**Essential Documentation for SBER IRBs: IRB Membership, Recordkeeping, Meeting Minutes, and More** (Basic Track) Janet C. Donnelly, Michelle Feige, Julia Gayle Gorey, Ada Sue Selwitz

Room 306



Federal regulations define the requirements for IRB membership and for documenting IRB discussions, decisions, findings, and communication of IRB decisions. This session will focus on the basic regulatory requirements for documenting IRB activities. During this session, faculty will:

- Review the basic regulatory requirements for documenting IRB activities
- Discuss the 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
- Hear how the proposed changes in the NPRM could possibly affect IRB membership, recordkeeping and documentation requirements

B4

**Certificates of Confidentiality (CoCs)** (Basic Track) Ann Hardy, Julia Hesse, Leslie Wolf

Room 313



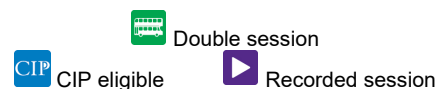
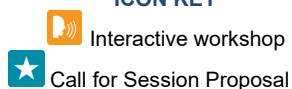
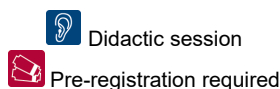
A CoC is often an area of confusion and consternation for investigators and IRBs. Determining when a study warrants one and what the process is for obtaining one are only the first steps. Confusion and misinformation also exist as to the scope of protection this document offers. During this session, faculty and attendees will:

- Review the scope of legal protection and privilege afforded to researchers under a CoC, including a review of the applicable regulations and federal guidance
- Discuss the considerations around when it would be prudent to obtain a CoC and how to avoid potential pitfalls when applying for and implementing one
- Address the implications for informed consent and how a CoC interfaces with other protective laws and possible disclosures
- Outline how a CoC interfaces with state mandatory reporting laws
- Discuss National Institute of Justice Privacy Certificates and how they differ from CoCs, especially with regard to reporting of abuse
- Share strategies for defending a CoC if challenged and alternatives to CoCs

Please note this is a double session and will end at 1:45 PM. Pre-registration for this session is required.

Please [register online](#) or [email us](#). Please use the ticket included on your name badge to get your boxed lunch in Ballroom A before the session.

## ICON KEY



# Thursday, November 12

Didactic Sessions and Workshops Series B, 11:00 AM-12:15 PM

**B5**

## **Informed Consent in Field Studies** (*Innovations Track*)

*Rebecca D. Armstrong, Jeremy Johnson, Cynthia S. Shindledecker*

The use of field experiments in social science has rapidly expanded in fields that traditionally were not heavily involved in human subjects research on a large scale, including political science and economics. Difficult issues related to consent and deception often arise in carrying out these field experiments. Field experiment sample sizes can be in the thousands of people, sometimes in the millions. Is consent feasible in field experiments and, if deception is used, when is debriefing feasible? What types of research interventions are appropriate in sensitive situations such as election campaigns or situations where individuals are making decisions about how to invest money? During this session, faculty will:

- Share strategies for obtaining consent in field experiments, including potentially involving entire communities in consideration of research before it is undertaken
- Discuss when a waiver of consent and the use of deception are appropriate for field experiments, and when is debriefing feasible
- Explore appropriate types of research interventions that can be used in particularly sensitive settings, such as elections or studies of investment decisions

Room 310



**B6**

## **Conducting Research on Campus** (*Innovations Track*)

*Andrea Rossing McDowell, Jeffery W. Rodamar, Julie F. Simpson*

There is a lot of research that takes place on university/college campuses where students are the subjects. Further, many institutions have established research pools of introductory-level students to participate in research studies and other projects for credit. This session will review applicable regulatory and ethical standards, as well as the specific issues that are raised when reviewing research in which college students on campuses are the subjects, and where they may serve as investigators or study staff. During this session, faculty and attendees will:

- Distinguish research from common non-research projects that take place on university/college campuses
- Review and discuss the operation and use of subject pools in research, especially data security and selection bias
- Identify and discuss ethical issues that such studies raise, including mandatory reporting, instructors conducting research using students enrolled in their classes, and use of extra credit as an incentive
- Discuss ethical and regulatory justifications for waiver of parental permission for minor-aged college students, including jurisdictions where majority age is not 18
- Outline the roles and accountability of students as principal investigators (especially undergraduates) and as research personnel

Room 312



**B7**

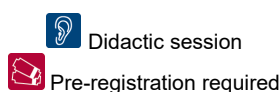
## **SBER IRBs at Biomedical Institutions** (*Potpourri Track*)

*Scott B. Cantor, Sara L. Harnish, Mary A. O'Connor*

This session will address the issues and challenges of working on an SBER IRB at a biomedical institution. During this session, faculty will:

- Outline the issues and challenges that IRBs at biomedical institutions face when reviewing SBER studies
- Provide insight on the knowledge and expertise needed to handle issues and challenges posed by SBER research
- Share strategies for addressing ethical and regulatory issues specific to various kinds of SBER projects and suggestions for managing them

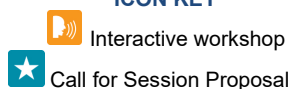
Room 309



Didactic session

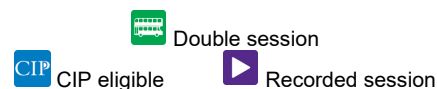
Pre-registration required

### ICON KEY



Interactive workshop

Call for Session Proposal



Double session

CIP eligible

Recorded session

# Thursday, November 12

## Didactic Sessions and Workshops Series B, 11:00 AM-12:15 PM

B8

### A Dialogue with OHRP on SBER Issues (Potpourri Track) Julie Kaneshiro, Ivor A. Pritchard

This session will be led by a representative from OHRP. Attendees are encouraged to come with questions of interest related to SBER IRB work. During this session, attendees will:

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

Room 311



12:30-1:45 PM

### Networking Lunch

Ballroom A

12:30-1:45 PM

### Lunch Session: It's Here! A Review of the NPRM

John R. Baumann, PhD, Kate Gallin Heffernan, JD, Andrew Rusczek, JD,

A NPRM has been released, and it is important for researchers, institutions, IRBs, and other stakeholders involved in research to have an awareness of the proposed changes and their potential implications for the field. During this session, faculty will:

- Review the history of human subjects protections regulations in the US leading up to the NPRM
- Outline key proposals from the NPRM
- Provide commentary on the implications of those proposals if adopted
- Address how to review and submit comments on the NPRM

Pre-registration for this session is required. Please [register online](#) or [email us](#).

Room 312



2:00-3:30 PM

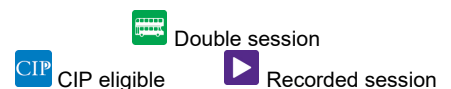
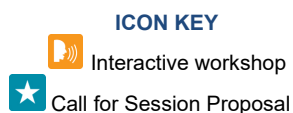
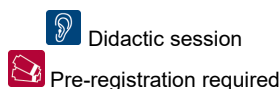
### Plenary Session: Emerging Areas in SBER

Moderator: Camille Nebeker

Panelists: Solon Barocas, Jeffrey T. Hancock, Stephen S. Intille, TBD

It's been a remarkable year for SBER – from the Facebook Emotional Contagion study to the Montana Voter study and fabricated gay marriage opinion study, there is no shortage of research ethics issues on the front pages. There's an increase in public awareness and concern around SBER and the issues that accompany these forms of research. Social media, mobile health (mHealth), big data, and ubiquitous computing are changing the ways in which the public, academic and research institutions, IRBs, and researchers think about research in general and their roles in research. SBER is also flourishing from the blurring of disciplinary boundaries and methodologies. With this, we see changes to privacy, consent, jurisdiction, and other critical areas of the research domain. This session will begin with a conceptual discussion on privacy in research and the audience will then hear from those working within the fields of social media, mHealth, and neuroscience. In these discussions, panelists will explore how SBER IRBs are dealing with these new domains and methods of research, while exploring the mashing of ethical issues that were typical of one area (e.g., deception in social psychology) with emerging areas (e.g., potential physical risks in using what was/is considered biomedical procedures).

Ballroom B



3:30-3:45 PM

## Break

Join us for coffee and cold beverages.

## Didactic Sessions and Workshops Series C, 3:45-5:00 PM

C1

### To Exempt or Not to Exempt (Advanced Track) Jeffrey M. Cohen, Cheryl A. Savini

The regulations regarding the exemptions only state that research in the attached list of categories is exempt. They do not provide guidance on how to do that determination. OHRP has provided some guidance on making exemption determinations, but institutions still face many decisions when developing policies and procedures for exemption determinations. This session will focus on the issues involved in making exemption determinations rather than on the exempt categories of research. During this session, faculty will:

- Define who should make exemption determinations
- Review how to document exemption determinations
- Provide a discussion on continuing review of exemption determinations
- Outline other ethical issues to be considered in making exemption determinations

Room 302



C2

### Mandatory Reporting (Advanced Track) Katie M. Edwards, Sharyn J. Potter, Andrew P. Rusczek

Mandatory reporting requirements (federal, state, local/institutional) may present methodological and ethical issues for IRBs and researchers. During this session, faculty will:

- Identify the legal aspects of mandatory reporting, such as who is and is not required to report, implications of not reporting (e.g., duty of a citizen), and the legal definitions of "reporter" (e.g., all psychologists or only clinicians)
- Review common federal mandatory reporting requirements that researchers face, as well as survey state requirements
- Discuss the intersection of mandatory reporting laws with Certificates of Confidentiality and National Institute of Justice Privacy Certificates
- Discuss how mandatory reporting applies to research done outside the state/country of the researcher's institution
- Explore how mandatory reporting may impact study design
- Outline mandatory reporting considerations for informed consent

Room 306



C3

### The What, Why, When, and How of Informed Consent (Basic Track)

Elizabeth A. Buchanan, Irene E. Stith-Coleman

In this session, faculty will:

- Explore the regulatory requirements for obtaining informed consent
- Review the various waivers and alterations of consent available under the regulations
- Discuss challenging issues related to use of "opt-out" procedure, minor assent, and short forms
- Address challenges related to consent with various vulnerable populations, including situations where individuals may lack the capacity to consent

Room 309



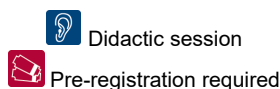
C4

### Fundamental Issues in Qualitative Research (Basic Track) Julie F. Simpson, Matthew D. Stafford

During this session, faculty and attendees will:

- Review the types of research methods used in qualitative research
- Discuss strategies for assessing scientific merit and generalizability in qualitative research
- Outline challenges to obtaining informed consent in qualitative research
- Identify risks to subjects and affected populations in qualitative research

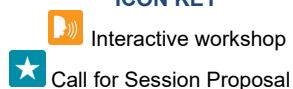
Room 311



Didactic session

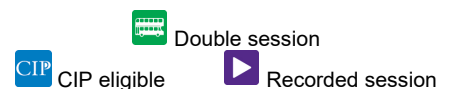
Pre-registration required

#### ICON KEY



Interactive workshop

Call for Session Proposal



Double session

CIP eligible

Recorded session

C5

### School Rules! Conducting Research in Elementary and Secondary Public Schools (Basic Track) Eric

Allen, Fanny Ennever Jeffery Rodamar, Shannon Sowards

This session will cover the regulatory requirements for protecting confidentiality of students' academic records and identify areas of flexibility to enable research on students and records, especially in challenging populations, venues, and districts with historically low parental involvement. During this session, faculty and attendees will:

- Review the Family Educational Rights and Privacy Act and the Protection of Pupil Rights Amendment, including what is required, permitted, prohibited, and waivable
- Learn about who has "school authority" to release information
- Discuss waivers and alterations of assent/consent/permission standards as they apply in schools with low parent involvement
- Explore opt out parental permission as an alteration of the consent process in non-exempt research, and analyze how opt out research methodology may or may not meet the four criteria for waiver/alteration of the consent process
- Share strategies for developing relationships with local school districts for ongoing research activity presence
- Outline considerations for regulatory oversight of distance learning beyond exemption category 1

Room 310



C6

### Panel Follow-Up: What Do We Need to Do With This? Reviewing SBER Studies that Involve Emerging Methods and Technologies (Innovations Track)

Solon Barocas, Stephen S. Intille, Katherine Lerner, Camille Nebeker

This session will explore SBER review of studies involving emerging methods and technologies, and the ethical issues that emerge in such multidisciplinary research. For example, psychology studies are increasingly using fMRIs, EKGs, EEGs, eye tracking technology, biospecimens, smart phones, etc. These innovations pose challenges for SBER IRBs that may not be accustomed to evaluating these methods and technologies, including dealing with sensitive data, incidental findings, and timely review and reporting. During this session, attendees will:

- Understand the challenges that use of traditional and emerging technologies in research studies present for SBER IRBs
- Review FDA regulations with which SBER IRBs may need to become familiar with in reviewing these studies
- Discuss guidelines and considerations for studies that include a genetics component
- Identify best practices for SBER IRBs when reviewing such studies

Room 304



C7

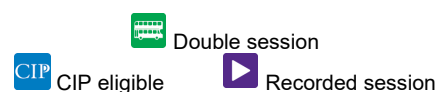
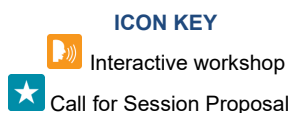
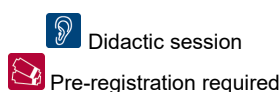
### The Internet and the IRB: A Review of Human Subjects Issues in Technology-Based Research

(Innovations Track) Brenda Curtis, Abby Rudolph

Human subjects research that uses technology-based interventions (TBIs) have been increasing steadily. TBIs constitute research delivered via computer, internet, or mobile devices, and many of these interventions involve social networking sites either at the recruitment or intervention delivery phase of research. In addition, researchers are developing their own smartphone "apps" that include location-based technologies (e.g., GPS). This session will update participants on recent forms of TBI research and the attitudes and perspectives of research participants with regard to technology. Discussion will focus on IRB review of three major areas of ethics concern: privacy and confidentiality, informed consent, and validity of data collected in general, and in research on socially and legally sensitive areas. Participants will discuss specific case examples of TBIs. During this session, faculty and attendees will:

- Review human subjects research that uses TBIs and the specific challenges this presents for privacy and confidentiality, informed consent, and validity of data collected

Room 312





- Share guidelines and strategies for protecting privacy and confidentiality, providing adequate consent information, and validating the nature of data collected
- Explore how to develop IRB decisional strategies for reviewing research utilizing TBIs

## Thursday, November 12

Didactic Sessions and Workshops Series C, 3:45-5:00 PM

C8

### Research on the Edge (Potpourri Track) Kip Kantelo, Alison S. Orkin

Imagine your IRB is presented a study that involves risky, sensitive, controversial, politically-unpopular, and/or confrontational research. Even if the proposed study has the potential to generate valuable new knowledge, the resultant public relations could be harmful to the institution. This session will look at the issues IRBs must consider when reviewing an application for the use of human subjects, as well as other considerations or institutional pressures that research “on the edge” may present. During this session, faculty will:

- Review the criteria for approving research projects involving human subjects
- Identify issues that could potentially present concerns when reviewing studies, and evaluate them vis-a-vis the regulatory framework
- Explore ways to address the issues these types of studies raise
- Discuss how the IRB fits into the institutional context of “research on the edge”

Room 313



5:00-6:00 PM

### 2015 SBER Conference Networking Reception

Join us to celebrate the 2015 SBER Conference and your involvement in this event and to network with your colleagues. Light refreshments will be served.

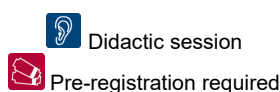
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Floor 3

5:30-6:00 PM

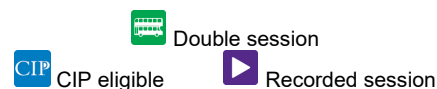
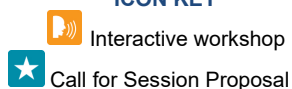
### Demonstration of PRIM&R's Knowledge Center

Join us for a demonstration of our online resource for members, the Knowledge Center, and its new annotated regulations feature. During this brief overview, you will see how you can use resources found in the Knowledge Center as continuing education tools at your institution. If you are unable to join us for this presentation, but would like to learn more about the Knowledge Center email Maeve Luthin, professional development manager, to set-up a one-on-one demonstration of this resource.

Room 305



#### ICON KEY



CIP eligible