

Critical Topics SBER

Manchester Grand Hyatt San Diego

November 14, 2018

Critical Topics in SBER is a full-day program examining issues of concern to IRBs that review SBER protocols. Intermediate/general-level didactic presentations will alternate with case discussion, focusing on the practical (and realistic) application of ethical and regulatory concepts and principles. We will discuss the revised Common Rule and its impact on SBER, including educational research, benign behavioral interventions, observational studies, and internet and social media research. We will explore strategies for balancing flexibility and oversight, addressing “grey areas” that may or may not meet the definition of human subjects research, and implementing best practices for data security. There will be ample opportunity for discussion and sharing of best practices.

Agenda

7:30–8:30 AM	<i>On-Site Check-In (breakfast on your own)</i>
8:30–10:30 AM	Welcome and Introduction The Revised Common Rule Meets SBER Case discussion
10:30–10:45 AM	<i>Break</i>
10:45 AM–12:30 PM	Balancing Flexibility and Oversight: Institutional Policy, Continuing Review (or Not), and Post-Approval Monitoring Case discussion
12:30–1:30 PM	<i>Lunch (provided)</i>
1:30–2:45 PM	Data Security, GDPR, and Other 21st Century Worries Case discussion
2:45–3:00 PM	<i>Break</i>
3:00–4:30 PM	Late-Breaking Issues Questions, Answers, and Discussion
4:30 PM	<i>Adjournment</i>