

Single IRBs: From Idea to Implementation

Manchester Grand Hyatt San Diego

November 14, 2018

This intermediate- to advanced-level educational program will provide an update on the responsibilities of reviewing single IRBs and relying on single IRBs. We'll focus on what goes into reliance agreements and the use of SMART IRB, a national master IRB reliance agreement. There will be an open discussion of difficult and problematic areas. This course is ideal for individuals working as HRPP/IRB administrators, institutional officials, IRB chairs, and anyone responsible for the implementation of central IRBs.

AGENDA

7:30–8:30 AM	<i>On-Site Check-In (breakfast on your own)</i>
8:30–9:30 AM	Welcome and Introduction The Landscape of Single IRBs <ul style="list-style-type: none">▪ The growing demand<ul style="list-style-type: none">○ NIH and Common Rule mandates▪ Different models of reliance▪ Regulatory and non-regulatory reviews▪ IRB versus institutional HRPP tasks
9:30–10:15 AM	Navigating the Reliance Agreement <ul style="list-style-type: none">▪ What needs to be in a reliance agreement▪ Nuts and bolts
10:15–10:30 AM	<i>Break</i>
10:30–11:15 PM	The SMART IRB Initiative <ul style="list-style-type: none">▪ What it is and the terms of the agreement▪ Considerations when using a master agreement Panel: Additional Challenges and Q&A <ul style="list-style-type: none">▪ Does social and behavioral research raise any specific issues?▪ Relying on an independent IRB: is this any different than relying on an academic center IRB<ul style="list-style-type: none">○ Can SMART IRB be use?▪ The issue of daisy-chaining▪ Keeping track of different reliance agreements
11:15 AM–12:00 PM	
12:00–1:00 PM	<i>Lunch (provided)</i>
1:00–2:00 PM	Implementing Single IRB Arrangements: IRB Administration <ul style="list-style-type: none">▪ How to handle ancillary reviews▪ Staffing▪ Electronic systems

Please note this agenda is subject to change

2:00–3:00 PM

Billing and Charging Models

- Approaches to determining costs
- How to provide a budget for your researchers
- What happens when the budget is exceeded
- Working with requirements for recharge centers

3:00–3:15 PM

Break

3:15–4:00 PM

Panel: Things That Go Bump in the Night

- What happens when different IRBs take advantage of different flexibilities?
 - E.g., broad consent
- Consent form differences
- How to help investigators understand their responsibilities when using a single IRB
- Noncompliance

4:00–4:30 PM

Q&A

4:30 PM

Adjournment