Single IRB Review: Lessons from the Real World

Westin Long Beach Hotel
333 East Ocean Boulevard
Long Beach, CA 90802

June 3, 2019

**Single IRB Review: Lessons from the Real World** is a scenario-based workshop covering the challenges and opportunities related to research participant protections in the era of Single IRB review. The workshop will leverage real-world experiences to highlight the important ethical considerations for any organization involved in a reliant IRB review process. The workshop will address both the relying organization and reviewing IRB perspectives, and highlight strategies for addressing the inherent challenges of protecting human subjects within a single IRB review process.

**Learning Objectives:**
- Review the roles and responsibilities of organizations and IRBs in protecting human subjects in research.
- Identify key challenges in human subjects protections when the IRB role is placed outside of the organization.
- Discuss real-world solutions to maintain the ethical conduct of research and appropriate protections for human subjects using a single IRB model of review.
- Identify initiatives and strategies to translate ethical oversight and protections into day-to-day operations of both relying organizations and reviewing IRBs.

**AGENDA**

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
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<tbody>
<tr>
<td>7:30-8:30 AM</td>
<td>On-site check-in (continental breakfast provided)</td>
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<tr>
<td>8:30-8:45 AM</td>
<td>Welcome and Introduction</td>
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<td>8:45-9:45 AM</td>
<td>HRPP Time to Redesign</td>
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<td>Gaps in the Human Research Protection Program (HRPP): What Has Happened to Our HRPP? Can it Survive?</td>
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<td>9:45-10:00 AM</td>
<td>Questions/Discussion</td>
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<td>10:00-10:15 AM</td>
<td>Break</td>
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<td>10:15-11:45 AM</td>
<td>Panel Discussion</td>
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<td>Lessons From the Real World: What Are We Holding Onto? What Should We Let Go?</td>
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Agenda is subject to change.
11:45 AM-12:30 PM  
*Case 1:*

Case Presentation and Discussion

12:30-2:00 PM  
**Lunch groups: Analyze Two Cases**

*Lunch provided*

2:00-2:15 PM  
*Break*

2:15-3:15 PM  
*Case 2:*

Analysis, Discussion, and Practical Steps

3:15-4:15 PM  
*Case 3:*

Analysis, Discussion, and Practical Steps

4:15-4:30 PM  
Wrap up – Continuing the Discussion:

PRIM&R’s Knowledge Center, Resources, and Advancing Ethical Research Conference

4:30 PM  
*Adjournment*