Unraveling the mystery of IRB review

A mock convened IRB meeting

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Objectives

• The purpose of this role play is to provide an overview of the elements of the initial review of a human subjects research protocol submitted to an Institutional Review Board (IRB). At the end of this session the audience will:

  – 1. Appreciate the IRB Review Process and IRB determinations for human subjects research protocols
  – 2. Understand the criteria for approval as defined by 45 CFR 46.11
  – 3. Acknowledge the role of local, state or Tribal Laws in review of research
## Mock IRB Participants

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<thead>
<tr>
<th>IRB Member Chair</th>
<th>Alternate IRB Member Scientist, Public Health</th>
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<tr>
<td>![Image](156x0 to 735x444)</td>
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<tr>
<td>IRB Coordinator Alternate IRB member</td>
<td>IRB Member Scientist, Epidemiologist</td>
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<tr>
<td>IRB Member Scientist, Fetal and Infant Health Research</td>
<td>IRB Member Lawyer</td>
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<tr>
<td>IRB Member Non-affiliated or Community Member</td>
<td>Research Investigator</td>
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Convened IRB Review Process

Conflict of Interest
- IRB Checks for IRB member conflict of Interest prior to research review
- Reviewed for all research protocols on the agenda

Quorum
- Ensures quorum is present for each research protocol

Overview of Research
- Primary reviewer or IRB Chair provides overview of research protocol

Discussion and documentation
- IRB discusses protocol; outlines questions for investigator
- IRB documents how controversial issues are resolved

Criteria for approval of research
- IRB reviews Criteria for approval

Voting
- IRB Votes - documents votes 'for', 'against' and 'abstained'

Document IRB Determination
- Documents IRB determination and proceeds to next item on the agenda