

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

 <p>IRB Member Chair</p>	 <p>Alternate IRB Member Scientist, Public Health</p>
 <p>IRB Coordinator Alternate IRB member</p>	 <p>IRB Member Scientist, Epidemiologist</p>
 <p>IRB Member Scientist, Fetal and Infant Health Research</p>	 <p>IRB Member Lawyer</p>
 <p>IRB Member Non-affiliated or Community Member</p>	 <p>Research Investigator</p>



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

