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Clinical Research Management Training Program
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What is the purpose of the IRB?

Select one:

a) To burden investigators with needless rules and requirements.

b) To slow the progress of research by creating delays in the approval process.

c) To require wordy and complex consent forms.

d) To ensure that the research is scientifically sound and ethical, and to protect the rights and welfare of research participants.
Human Research Protection Program (HRPP) Components

- Organizational Plan
- Education Programs
- Conflict of Interest
- Investigational Drug Services
- Contracts and Grants
- Office for the Protection of Human Subjects
- Institutional Review Board
- Communications System
- Compliance Oversight
- Investigators and Research Staff
Institutional Review Boards (IRBs)

- Established by the National Research Act (1974) for the independent review, approval, and oversight of human research
- Regulated by the Office of Human Research Protection (OHRP)
- 45 CFR 46 -- IRB membership, functions, operations, requirements
The IRB Committee

• At least 5 members
• Qualified through experience and expertise
• Diverse in race, gender, and cultural background
• At least 1 scientific member and 1 nonscientist
• At least 1 unaffiliated member
Children’s National IRB

- 2 standard committees meet monthly
- 1 ad hoc “rapid response” committee
- Most industry-sponsored clinical trials are externally reviewed by Western IRB
Office for the Protection of Human Subjects (OPHS)

- Liaison between investigators and IRB
- Regulatory & administrative arm of the IRB
- Manages protocol review process, including pre-review
- Provides education
- Reports to regulatory agencies on behalf of IRB
- Conducts QA/QI activities
IRB Functions

• Review research protocols to ensure compliance with federal regulations

• Approve, require modifications, or disapprove research activities

• Confirm that there is no exposure to unreasonable risks
IRB

• Conduct continuing review at least once a year. *If approval expires, research activities must STOP!!*

• Monitor unanticipated problems, adverse events, interim findings, and relevant literature

• Assess protocol and/or institutional violations, misconduct, and complaints from research participants
Types of IRB Review

• Studies that present “greater than minimal risk” must be reviewed at a convened meeting for full board review

• Some “minimal risk” studies are eligible for expedited review by a single member

• Some research activities are exempt from IRB review (but exemption must be determined by the IRB office)
Protocol Submissions

Institutional Review Board Electronic Application Review System
IRBear

http:www.irbear.org
IRBear SmartForms

Study Identification Information
This is the first step in your Human Research Application. You will automatically be guided to the appropriate forms needed to complete your submissions.

1.0  Study Number:

2.0  Previous Study Number:

3.0  * Study Title:

4.0  * Abstract:

5.0  * Principal Investigator:

[None]  Select...
What is the purpose of the IRB?

Correct answer:

a) To burden investigators with needless rules and requirements.

b) To slow the progress of research by creating delays in the approval process.

c) To require wordy and complex consent forms.

d) To ensure that the research is scientifically sound and ethical, and to protect the rights and welfare of research participants.
OPHS Staff

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