UPSTATE
MEDICAL UNIVERSITY

Upstate IRB Overview

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Presentation Overview

IRB

- Purpose
- Definitions
- Levels of Review
- Examples of Research

FDA

sIRB

IRB Submission Requirements & Process

Post Approval Reporting

Institutional Review Board (IRB)

Purpose…to ***review research*** to determine if the ***rights and welfare*** of human subjects involved in research are adequately protected.

Federal Definition of Human Subject Research

Research is defined as:

Systematic investigation

AND

Intent is generalizable knowledge

Human subject is defined as a living individual:

Obtains, uses, studies, analyzes, and/or generates identifiable private information or identifiable biospecimens

- Interaction
- Intervention
- Secondary use

Minimal Risk = probability and magnitude of harm/discomfort are not greater than those ordinarily encountered in ***daily life*** or routine medical, dental, psychological care (45 CFR 46.102)

Minimal Risk is NOT

- Measured based upon the amount of incremental risk over usual care posed by the study procedure
  - "but I am already taking two biopsies; what's one more…"
- Measured based upon the daily experience of the population under study
  - "but this population normally receives CTs what's one more for research…"

Levels of IRB Review

Not Research

Non-Human Subjects Research

Exempt

- Minimal Risk research meeting certain categories & criteria
- Reviewed upon submission

Expedited

- Minimal Risk research meeting certain categories & criteria
- Reviewed upon submission

Full Board

- Greater than minimal risk
- Review & approval at a convened IRB meeting
- Meeting frequency is once/month

Not Research

- Not a systematic investigation
- Not contributing to generalizable knowledge…will not be published or disseminated

Examples:

- Case Study
  - A case study involving a rare reaction to a vaccine that occurred in 1 or 2 patients. Not generalizable and not a systematic investigation.
- Quality Improvement (QI) projects
  - Project to reduce patient wait times that will only be used internally. No intent to publish or generalize findings.
- Program Evaluation
  - Internal assessments not intended for generalizable knowledge. Often used to improve departmental functions. No intent to publish or generalize findings.

Not Human Subjects Research

Research that does not involve human subjects, either directly or indirectly.

Examples:

- Research on Deceased Individuals
  - Analysis of census data from the 1918 pandemic. Subjects are deceased, so not considered human subjects.
- Anonymous Data Analysis
  - Use of datasets from a source **external** to Upstate with no identifiers or ability to re-identify individuals

Human Subjects Research

Research that involves human subjects

- Either directly or indirectly

IRB Review Pathways:

- Exempt Determination
- Expedited Review
- Full Board Review

Example:

- Investigational Drug Trial
- Epic and/or TriNetX dataset
  - Coded data from Upstate medical records
- Upstate Biobank
  - Coded biospecimens and data

1 - Research on educational practices

2 - Survey/interview/ observation/focus groups (adults)

3 - Benign Behavioral Interventions

4 - Secondary use of pre-existing data/specimens

5 - Examine public benefit or service programs (e.g., Medicare)

6 - Taste and/or food quality evaluation

7 – Storage /maintenance of identifiable biospecimens with Broad Consent

8 - Use of identifiable data/biospecimens obtained with Broad Consent

Exempt Research Categories

(45 CFR 46.104)

Expedited Review Categories (*45 CFR 46.110*)

1 - Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

2 - Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture

3 - Prospective collection of biological specimens for research purposes by noninvasive means.

4 - Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves.

5 - Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch.

6 - Collection of data from voice, video, digital, or image recordings made for research purposes.

7 - Research on individual or group characteristics or behavior or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

8 - **Continuing review** of research previously approved by the convened IRB under certain conditions

9 - **Continuing review** of research that the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

Full Board IRB Review

- Greater than minimal risk
  - Invasive procedures
  - Drugs
  - Devices
  - Sensitive, identifiable data (e.g. illegal activity)
  - Significant amounts of blood drawn
    - Adults
    - Children
  - Any amount of radiation

Reliance on a Single IRB (sIRB)

- A Reliance agreement = a document that provides a mechanism for an institution to delegate IRB review to another IRB, such as an independent IRB, or another institution's IRB.
- Requirement to use sIRB for many multi-site studies
  - ✓ NIH funded research
  - ✓ revised Common Rule (rCR) cooperative research provision
  - ✓ Industry sponsor - *typically*
  - ✓ FDA regulated research – *anticipated harmonization soon*
- Investigator must comply with external IRB and internal institutional policies and requirements, as well as applicable Regulations

Process for IRB Review & Approval

- ✓ Registration as User on IRBNet
- ✓ Required Training – CITI
- ✓ Submit Application IRBNet
  - Protocol = the plan for everything!
  - Measures, Questionnaires, Interview Guides
  - Letters of Support, Cooperation (off-site)
  - Recruitment Materials
  - Consent Documents
  - Investigational Drug and Device brochures
- Scientific & IRB Review
- Correspondence *(changes or clarifications)* between Study Team and IRB
- ✔ Confirmation of approval

Templates & IRB Information

- IRBNet.org – IRB electronic submission system
  - Forms & Templates – Select Library for Researchers
    - Standard Operating Procedures (SOPs)
    - Instructions
    - Forms
    - Templates

- Upstate Research Compliance
  - Human Subjects (IRB)
    - Case Reports
    - Emergency Use
    - Required Training
    - Contact Information
  - Institutional Biosafety (IBC)
  - Stem Cell Research Committee (SCRO)

Post IRB Approval Reporting Responsibilities

- Amendments
- Progress Reports – Continuing Reviews
- Safety Reporting
  - Adverse Events
- Premature Termination/suspension
  - Notify Subjects, IRBs, Sponsors, etc.
- Final Report


THANK YOU