Harrisburg University
of Science and Technology

Institutional Review Board Overview

Smallpox Vaccination (1796)

Session Objectives

Explain the history of Institutional Review Boards (IRBs)

Define “Research” and “Minimal Risk”

Describe the IRB review categories and regulatory criteria for approval

Discuss the IRB application process

Discuss tips for success

Offer a few suggestions about grant funding

History of Human Research Protection

- Nuremberg Code (1947)

  - Created the first principles of:

    - Informed Consent
    - Proper formulated scientific experimentation
    - Beneficence towards participants

History of Human Research Protection (cont.)

- Declaration of Helsinki (1964)
  - Created by the World Medical Association
  - Further focus on clinical research
  - Considered the cornerstone document of human research ethics

History of Human Research Protection (cont.)

- Belmont Report (1978)
  - Established three fundamental ethical principles:
    - Respect for Persons
    - Beneficence
    - Justice

Institutional Review Board (IRB)

- Approve/modify/disapprove research protocols involving human subjects
- Protect rights and welfare of human subjects
- Promulgate human research education and training
- Perform administration and record-keeping for institutional research

The Common Rule

- 45 CFR 46 (Public Welfare)

Research

FDA Definition:
Clinical Investigation: An experiment involving a test article and control when the results must meet requirements for prior submission to the FDA or are intended to be later submitted to or held for inspection by the FDA

Office of Human Research Protections Definition:
Research: A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

What is a Human Subject?

- A living individual about whom an investigator (*professional or student*) conducting research obtains:
  - ❖ data through intervention or interaction with the individual,

    or

  - ❖ identifiable private information.

45 CFR 46.102(f)

You are “engaged” in human subject research when:

Human subject research involves:

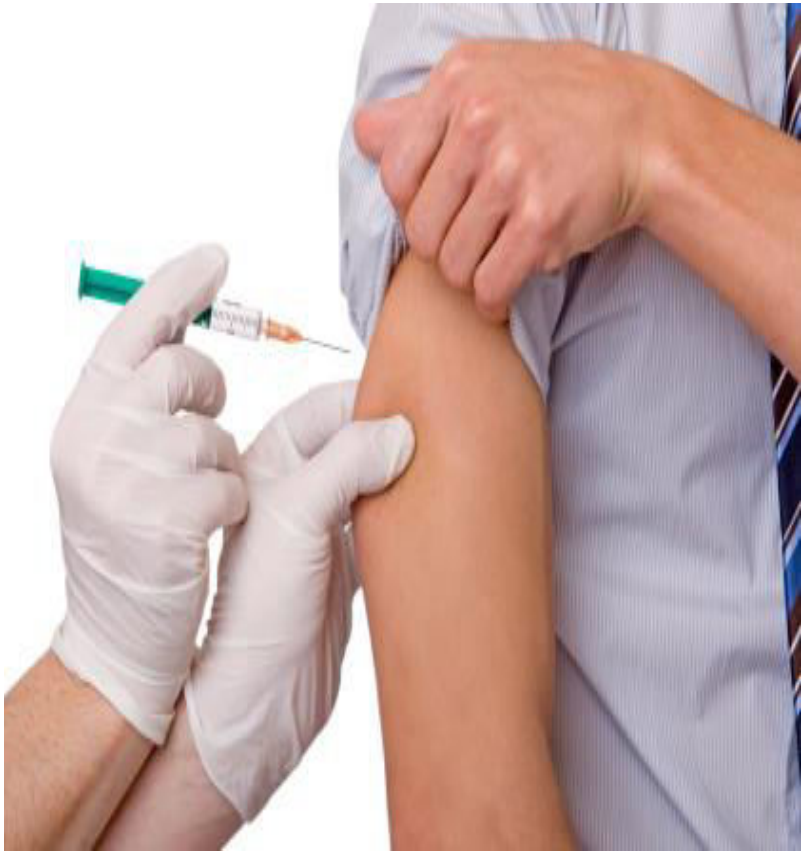
(a) Data about subjects through intervention or interaction;

(b) Identifiable private information

(c) Informed consent from a research subject

Definition of Minimal Risk (45 CFR 46.102(i))

Risk encountered in your daily life……



Types of IRB Review

- Determinations not requiring IRB review
- Exempt
- Expedited Review
- Full Board Review

Studies NOT Requiring IRB review

- Must NOT use data obtained from living human beings
- This category applies only to studies NOT involving any data about living human beings.
- Most commonly, this involves business case studies, computer science projects, and other technical studies.
- This category does NOT include studies using publicly available databases containing data obtained form human beings. These studies require exempt category applications and approvals.

Exempt Review

- Must be no or minimal risk (physical or psychological) research
- Fits one of 5 categories ➔
- Review is typically conducted by a designated IRB member

Exempt Review Categories

1. Research conducted in established or commonly accepted educational settings, involving **normal educational practices**.

2. Research involving the use of **educational tests** (cognitive, diagnostic, aptitude, achievement), **survey** procedures, **interview** procedures or observation of **public** behavior.

3. Research involving the collection or study of **existing data** that subjects cannot be identified, directly or through identifiers linked to the subjects.

And much more uncommonly:

4. Research and demonstration projects which are conducted by or subject to the **approval of Dept. or Agency heads**.

5. Taste and **food quality evaluation** and consumer acceptance studies.

Expedited Review

- Must be minimal risk (physically or psychologically)
- Rigor same as full committee review, but only one IRB member reviews the project
- Fits one or more of nine categories ➔

Expedited Review Categories

1. Collection of data via **audio/visual recordings** made for research purposes
2. Research employing **survey, interview, oral history**, focus group, program evaluation, human factors evaluation, or quality assurance methodologies that collect potentially identifiable data on subjects
3. Research involving human **materials** already collected for any purpose
4. Clinical studies where an **IND or IDE is not required**
5. **Blood** Collection
6. Prospective collection of biological specimens for research purposes by **noninvasive means**
7. Collection of data through noninvasive procedures routinely employed in **clinical practice**
8. Continuing review of a **study previously reviewed** by a convened IRB and meets three categories.
9. **Continuing review** of research, where categories (2) through (8) do not apply but the IRB has determined and documented at a convened meeting that the **research involves no greater than Minimal Risk**.

Full Committee Review

- Any study which does not meet the Exemption or Expedited Criteria
- A full quorum is assembled
- Decision is rendered by a majority of the assembled quorum
- No member with a conflict of interest can participate in the decision
- All members participate in the discussion and comments

Criteria for Approval of Research

1. **Risks to subjects are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk.**

2. **Risks to subjects are minimized by using procedures already being performed on the subjects for other purposes.**

3. **Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.**

4. **Selection of subjects is equitable.**

5. **The research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.**

   - ➔

Criteria for Approval of Research (cont.)

6. **There are adequate provisions to protect the privacy of subjects.**

7. **There are adequate provisions to maintain the confidentiality of data.**

8. **Additional safeguards have been included in the study to protect the rights and welfare of subjects vulnerable to coercion or undue influence. ("N/A" if no vulnerable subjects)**

9. **The informed consent process is adequate.**

10. **The documentation of informed consent is adequate.**

How Do Researchers Meet These Regulations?

IRB Documents (on the IRB Website)

- Human Research Protection Program slides
- IRB Policy and Procedure Manual
- CITI training program for grad students and faculty
- Forms
  - Initial Applications(exempt/expedited and full)
  - Informed Consent Documents
  - Modification Form (change in protocol or PI)
  - Continuation Form (more than one year study)
  - Unanticipated Event Form
  - Subject Withdrawal Form

Basic Elements of Informed Consent

(45 CFR 46.116(a))

- The 8 Necessities for a Full Application

1. Research Description
2. Risks
3. Benefits
4. Alternatives
5. Confidentiality
6. Compensation
7. Contacts
8. Voluntary participation and withdrawal

Alteration/Waiver of Informed Consent (45 CFR 46.116 (d))

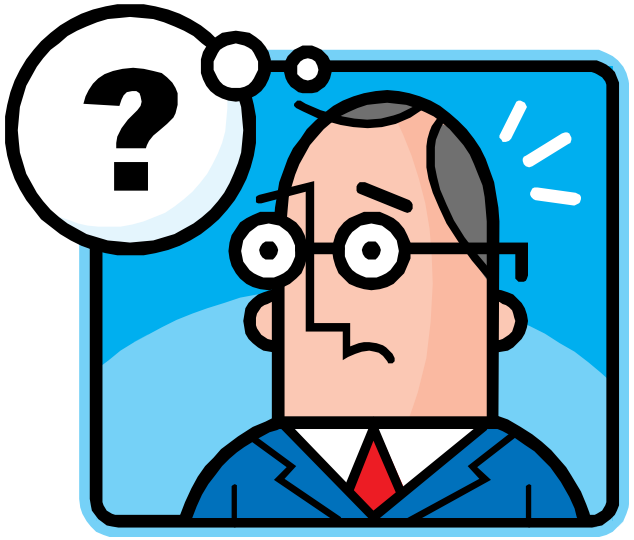
- What criteria need to be met?

1. The research involves no more than minimal risk to the subjects;
2. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
3. The research could not practicably be carried out without the waiver or alteration; and
4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Consent Form Common Mistakes

- Information in the Consent Form is not consistent with the Protocol
- Utilization of medical jargon
- Not fully identifying risks
- Consent Form is not a HIPAA Authorization form

My protocol is ready, what do I do now?

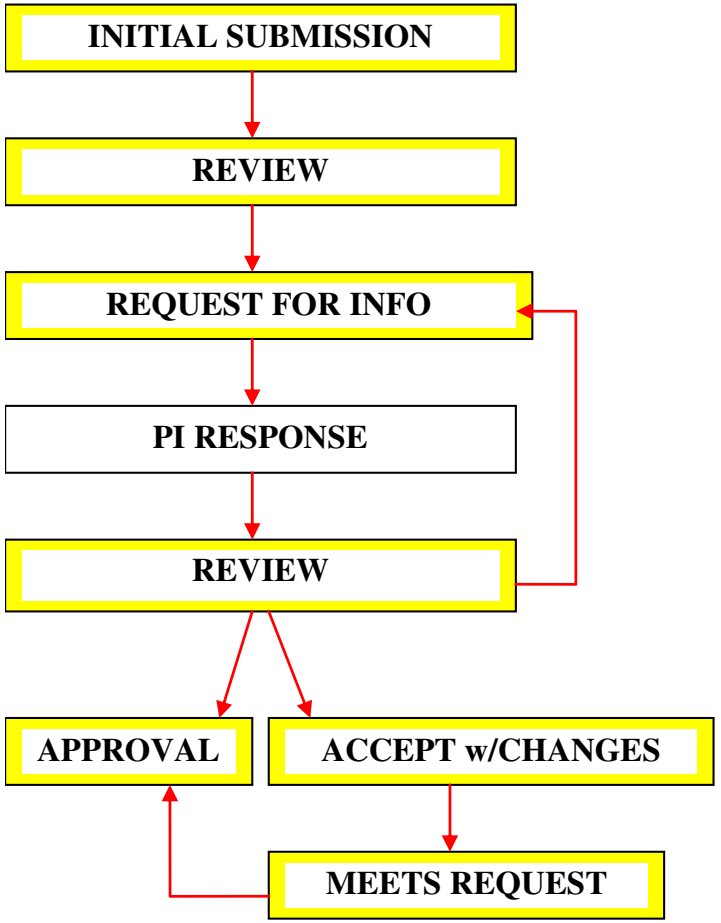


Submit the Protocol

- IRB Submission Forms

- Application for Initial Review

- Administrative Approvals



Investigator Responsibilities after Approval

- Protect human subjects.
- Ensure all personnel comply with protocol requirements and determinations of IRB.
- Avoid undue influence in enrolling subjects.
- Ensure that informed consent is adequate and understandable to subjects.
- Report new information.
- Submit changes in research to IRB for approval prior to implementation.
- Store collected data according to current policies

References

- Regulatory Agencies

  www.hhs.gov/ohrp

  www.fda.gov

- Belmont Report

  www.hhs.gov/ohrp/humansubjects/guidance/belmont.html

- ✓Download applications and forms from our website to ensure you have the latest version.
- ✓Gather all signatures prior to submission.
- ✓Place version dates on your documents at initial submission and only change them when updating the document.
- ✓Utilize and follow the Fillable Template instructions when creating your application and forms.

- ✓Attach all relevant documentation. If it is listed on the form and applicable to your research, submit it.

- ✓Have your research staff (including grad student investigators) complete their human subject research certification (CITI training) prior to submission.

- ✓Respond to the IRB in a timely manner.

- ✓When in doubt, contact the IRB!
  - ✓IRB@HarrisburgU.edu