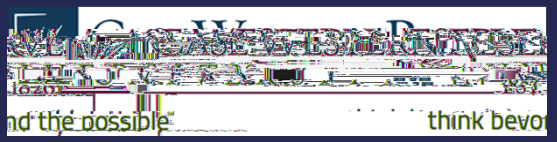
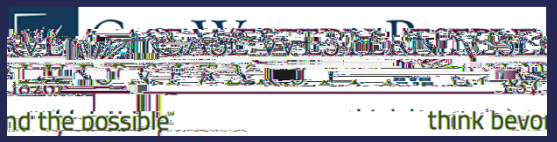
Overview:

- The IRB and Regulatory Oversight
- Protocol submission to the CWRU IRB
- SpartaIRB system
- Available Resources



Institutional Review Board (IRB)

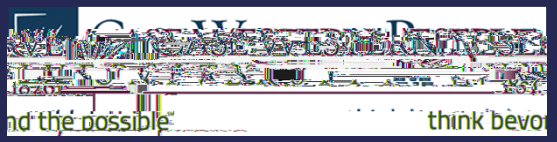
- An independent group that is charged with reviewing research to ensure that human subjects' rights and welfare are adequately protected.
- Consists of:
  - Scientists
  - Non-scientists
  - Community or non-affiliated representative
  - Men/Women
  - Ethnic/Cultural diversity
  - Prisoner representative



History of Research Abuses

- Nazi Experiments (WWII)
- Tuskegee Syphilis Study (1932-1972)
- Thalidomide Tragedy (1960)
- The Milgram Study (1963)
- Willowbrook Study (1963)

- Common Thread: The participant did not freely and knowingly volunteer for the research because pertinent information was withheld that, if known, would have compelled a refusal to participate in the study.



Ethical

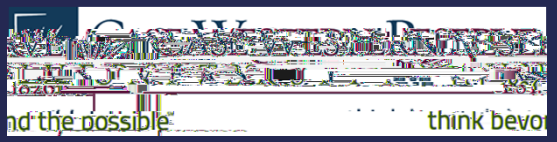
Code of Federal Regulations

The Belmont Report Codified

Federal policy for the Protection of Human Subjects - "The Common Rule" (45 CFR 46)

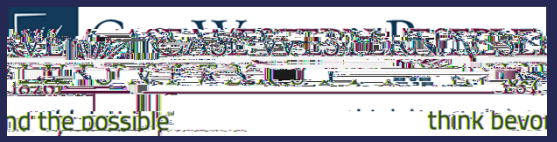
Office of Human Research Protections (OHRP)

- Establishment of Institutional Review Boards (IRBs)
- Institutional assurance of compliance
- Informed Consent Requirements



Criteria for IRB Approval

- Risks minimized
- Risk-benefit ratio reasonable
- Equitable selection of subjects
- Informed consent sought and documented
- Privacy/confidentiality of data
- Additional protections for vulnerable populations



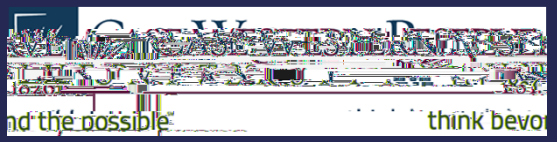
Other Federal Regulations

HIPAA

- The Health Insurance Portability & Accountability Act (HIPAA) is a Federal law that helps to protect the privacy of health information.
- Protected Health Information (PHI):
  - any individually identifiable health information transmitted or maintained in a medical record paper or electronic,
  - designated data set that was created, disclosed, or used in the course of providing a health care service such as diagnosis, payment or treatment.
  - 18 Identifiers considered PHI under HIPAA (http://case.edu/research/resources/forms-policies/)

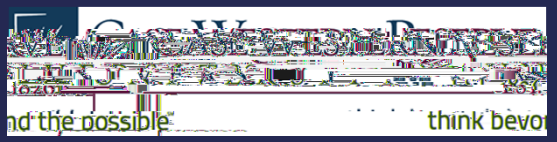
FDA

Drugs and Devices



Types of IRB Review

- Exempt
  - Determination made by the IRB Office
  - Not the same as Not Human Subjects Research
  - Not exempt from oversight, just from federal regulations
- Expedited
  - Not greater than minimal risk.
  - Review by one IRB member; does not go to a meeting
- Full Board
  - Anything that doesn't fit the above
  - Must go to a meeting



Protocol Submission

Protocol should be completely thought out before submitting.

- Be specific: recruitment, consent, study procedures, data security
- Download the most current version of the protocol template
- Don't rush the submission, review documents for typos and grammar. The information must be understandable by someone outside of your field.
- All documents must have consistent information

COVID-19

Exempt Review

Category 2: Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

- (i) the information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; or
- (ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation

- IRB will determine if data collected is identifiable and if the information is sensitive

Exempt Category 2

Survey Procedures

- Points to Consider if information being asked/provided is “sensitive” in nature:
  - If using a platform such as REDCap or

Informed Consent Process

Begins with recruitment

- Advertisements must be approved
- May need letters of cooperation

Informed Consent Process

Consent Document

- Template in SpartaIRB Library
- Be sure to:
  - Delete sections that do not apply
  - Remove instructional language

Informed Consent Process

Protocol Document

- If a waiver of consent or a waiver of documentation of consent is being requested, appropriate justification must be provided

Data Security

- Collection
  - Remote: recommend Qualtrics, REDCap, Zoom
  - If additional data will be collected
- Transfer/Sharing
  - Import and export of data
- Storage
  - PHI and identifiable data
- Destruction

Data: Terminology

- Anonymous
  - Data that cannot be identified, and never could be
  - Not the same as a file from which you removed identifiers. If you have access to identifiers at any point, it is not anonymous.
- De-identified
  - A dataset that had elements removed so it is no longer identifiable.
  - If you have a file that is linked to identifiers with a key you have access to, your study data *is not de-identified*.
- Identifiable
  - A data set that contains identifiers, can easily be re-identified, or is linked to identifiers with a key
  - Includes coded data

Expedited Review

Category 5: Research involving materials (data, documents ore specimens)

Other Protocol Considerations

HIPAA authorization

- Health Insurance Portability and Accountability Act
- Protected ¼ 4

SpartaIRB System

spartairb.case.edu

- Individuals do not automatically have an account
- Help Center and Library
- Help/Information bubbles

What else can help your IRB process?

- If you receive request for clarifications:
  - Do not send back to the IRB until all changes are made
  - If you aren't

Available Resources:

- IRB general email cwru-irb@case.edu
- CWRU