Institutional Review Board Process

Office of Research Integrity
Susan Vogtner, CIP
Jamie Zaikov, CIP

4/6/2021
Objectives

• Define Research, Human Subjects, and Institutional Review Board
• Discuss the Required Training (CITI)
• Describe the Informed Consent Process
• Navigate the Human Subjects Website
• Create an IRB application and be familiar with the IRB process
• Discuss Common IRB issues
Institutional Review Board

- Defined

Any board, committee, or other group formally designated by an institution to review, to approve the initiation of, and to conduct periodic review of research involving human subjects

45 CFR 46
Research

• Defined

a systematic investigation, including research development, testing and evaluation designed to develop or contribute to generalizable knowledge

45 CFR 46
Human Subject

- Defined

- A living individual about whom an investigator (whether professional or student) conducting research:
  Obtains information or biospecimen through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimen;
  or
  Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimen

45 CFR 46
What requires Review

• Any GSU research that uses humans, human tissue, surveys of human subjects or human subject’s records requires IRB Review, regardless of sponsorship.
Examples of Human Subjects Research

- Dissertations or thesis with human subjects
- Publications, poster presentations, conference proceedings
- Human Subjects Data – medical records, school records, past research
- Interaction with humans – online surveys, interviews, observations, classroom research, focus groups, asking opinions, interventions
Regulations

- Historical precedence – Nuremberg, Helsinki, and Belmont Report
- Code of Federal Regulations
- State and federal laws and regulations
- Ethical guidelines
Designations of Not Human Subjects Research

- If using secondary analysis of publicly available or de-identified data
- If you believe your study does not constitute human subjects research
- Application available in iRIS
- For examples: data (e.g. past studies, census data) that have no identifiers or codes linking to people, studies only for quality assurance that will not be published or presented, studies that only gather data that is not about humans (e.g. company statistics)
Institutional Review Board

• Primary function is to . . . . .
  
  A) Make your lives miserable
  B) Drive you to a premature grave
  C) Increase the demand for hair coloring products
  D) Ensure your graduation
Institutional Review Board

• Primary Function . . . .

to protect the rights, welfare, and safety of human subjects participating in research under the auspices of the institution with which it is affiliated
**GSU’s IRBs**

- Expedited Board and Full Board
- Faculty members from colleges that submit research with broad range of expertise
- Qualitative and quantitative experience
- Community representative, Non-scientific members, and Prisoner representative
Type of Review

- Review is based on the degree of risk
- Exempt, Expedited, Full
- Complete categories available on the website
Exempt

- Normal education practices in normal education settings
- Educational tests or surveys of adults
- Interviews of adults
- Public observation
- Benign behavioral interventions of adults
- Secondary review publicly available data or data recorded in a way that it is not identifiable
Expedited

- Collection of biological specimens
- Clinical procedures
- Surveys, interviews, interventions with children
Full Board

- More than minimal risk
- Prisoners
- Investigational devices
IRB Review

Exempt Review
- Low risk
- Should hear back in about 5 days

Expedited Review
- No more than minimal risk
- Pre-review
- Should receive first communication in about 3 days, then it must go for review with a board member

Full Board
- Greater than minimal risk
- Convened board meeting once a month

IRB has final determination
**Human Subjects Education**

- Citiprogram.org – widely used by many universities
- All members with interaction with human subjects or access to data must complete the training
- Self registration process – select your own username and password; then select GSU as your institution
- Be sure to complete the social and behavioral basic course or the biomedical basic course – the RCR and COI courses are not an IRB requirement
- Series of modules with text and test questions at the end of each module
- Takes about 2 – 6 hours, but you can log-out and log-in as necessary
Informed Consent

- Model informed consent form available on the website
- Full/expedited and exempt templates
- Remove Instructions and make it one color
- Must fit your study
- Use headings or justify not using them in the application
- Reading level
- Upload as a document (.doc)
**Expedited/Full Informed Consent Types**

- Signed consent
  - Signature on a piece of paper
- Waiver of documentation of consent
  - All the elements of consent but no signature
  - Online studies or simple surveys
  - If risky, no record linking the subjects to the research
- Waiver of consent
  - No consent
  - Removing any required element of consent – deception and concealment
Visit our website

- www.gsu.edu/irb
Electronic Submission

www.gsu.edu/irb

- iRIS
  - Protocol.gsu.edu
  - Chrome or Firefox
  - GSU Campus ID and the associated password
- Help Menu
  - Training Documents
- If no ‘Study Assistant’ Tab
  - Contact the Help desk at irb@gsu.edu
Application Issues

• Completion of CITI Training
• Not enough information – lay summary, recruitment, subjects data, informed consent
• Only answer the question being asked
• Inconsistencies
• Personnel
• Routing – through PI and department head/chair (or designee)
• All documents not uploaded
Common Problems

- Conducting human subjects research without IRB approval
- Not following the approved protocol – including overenrolling
  
  *No research can begin without IRB Approval*
Approval is not the end of the process

• Amendment or personnel amendment if any changes needed
• Continuing review or Status check at the appropriate time
• Study closure form when no longer enrolling or analyzing identifiable data
• Unanticipated Problem form if something goes wrong
• Protocol deviation if you accidently do something that was not approved
Closing Remarks

• Rules and regulations governing the conduct of human subject’s research can seem overwhelming.

• It is not expected that individuals participating in research that involves human subjects become regulatory experts.