Introduction to Human Subjects Research Protections at UIW

Ana Hagendorf, PhD, CRA wandless@uiwtx.edu
Office of Research and Graduate Studies

Overview

- What is human subjects research?
- Who and what needs IRB approval?
- Types of IRB reviews
- IRB application elements
- Issues and tips in preparing protocols for IRB review
- Consent documents

Key information:
https://www.uiw.edu/orgs/research/compliance/irb.html

Defining Human Subjects Research

- What is (regulated) research?
- What are human subjects?
- When are investigators considered to be engaged in human subjects research?

Federal Definition of Research

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

Source: https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/#46.102

What's a systematic investigation?

An inquiry that is characterized by a predetermined and organized method of data collection and analysis to study a specific topic, answer a specific question, test a hypothesis, or develop a theory.

What's generalizable knowledge?

Includes one or more of the following:

- Information that will expand the knowledge base of a scientific discipline or other scholarly field of study;
- Knowledge from which conclusions may be drawn that can be applied to a larger population beyond the site of data collection or the population studied;
- Results can be replicated in other settings

What's a human subject?

A living individual **about whom** an investigator (whether professional or student) conducting research obtains data through intervention **or** interaction with an individual **or** with his or her identifiable private information.

- Intervention: Includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subjects' environment that are performed for research purposes.
- Interaction: Includes communication or interpersonal contact with a subject or his or her private identifiable information.
- Private information: Includes information about behavior that occurs in a setting in which an individual can reasonably expect that no observation or recording is taking place. It includes information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (such as a medical record). Private information must be individually identifiable in order to be considered information to constitute research involving human subjects. This may include identifiable private information obtained from a primary subject about a third party.

Source: https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/#46.102

What's engagement?

An institution is considered **engaged** in human subjects research when its agents for the purpose of research obtain:

(1) data about the subjects of research through intervention or interaction with them;

(2) identifiable private information about the subjects of research; or

(3) the informed consent of the human subjects of research

IRB Purpose

Key points:

- IRB = Institutional Review Board
- Human subjects research projects conducted by UIW agents must be approved by the IRB before the conduct of research begins
- IRB Includes Reps from all UIW Schools & Colleges
- UIW has to have an IRB because it accepts federal funding, but it's also the right thing to do
- Main Intent: To protect human subjects and assign appropriate risk levels including serial monitoring of protocol to ensure continued protection.

Quality Improvement or Program Evaluation vs. Research

QI/QA or Program Evaluation

- Designed to assess or improve a process, program, or system in a specific, limited setting

Research

- Designed to ask and answer questions in order to create new, generalizable knowledge that can be applied to other contexts or settings

Class Projects vs. Research

Class Project

- Designed to practice the methods, tools and techniques of the profession
- Intended to enrich the student's learning experience
- Not intended to create new, generalizable knowledge

Research

- Designed to ask and answer questions in order to create new, generalizable knowledge

When do I apply for approval?

- **Before** the initiation of research
  - Including the recruitment of subjects.
- How do I know if I really need to?
  - Consult the IRB Manual and/or the Human Subjects Research Determination Questionnaire
  - When in doubt, just call or email the IRB office.
- But can't I just get approval later?
  - Nope.
- But it takes so long!
  - Length of time to approval depends on many factors
  - This depends a lot on you – focus on complete, succinct, high-quality applications

What do I need to do before I apply for approval?

1. Review the UIW IRB Manual: https://www.uiw.edu/orgs/research/compliance/irb.html
2. Complete the online CITI human subjects training course: http://www.uiw.edu/orgs/research/compliance/citi-training.html
3. Create a New User Account in the online IRB application system: https://uiw.forms.ethicalreviewmanager.com/

Types of IRB Review

- Exempt – administrative review by the IRB office
  - Involves little or no personal risk of physical, psychological, or social harm
- Expedited – review by a subset of the IRB
  - Involves no more than minimal risk
- Full Board – review by the full IRB
  - Involves more than minimal risk

Minimal risk: The probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

IRB Application Elements

- UIW IRB Application Form
- Research Protocol
- Attachments:
  - Recruitment tools
  - Consent documents
  - Instruments used for data collection
- Faculty Supervisor Agreement & Signature

https://www.uiw.edu/orgs/research/compliance/irb.html

Research Protocol

- Purpose of the Research Protocol
  - Communicate the essential elements of the proposed study
  - Discuss how human subjects will be protected
- Protocol is organized in a specific manner to enable prompt review of the proposed study and assist IRB members

If we can't find it, we can't review it!

Protocol sections

- ✓ Section 1: Purpose
- ✓ Section 2: Background and Significance
- ✓ Section 3: Location, Facility and Equipment to Be Used
- ✓ Section 4: Subjects and Informed Consent
- ✓ Section 5: Subject Compensation
- ✓ Section 6: Duration
- ✓ Section 7: Research Design (Description of the Research Design, methods for data collection and analysis)
- ✓ Section 8: Risk Analysis
- ✓ Section 9: Confidentiality
- ✓ Section 10: Literature Cited

Attachments

- Provide the remaining supporting documents for the protocol
  - Recruitment materials-flyers, invitations, recruitment scripts, etc.
  - Consent documents
  - Data collection Instruments

Issues, tips, and reminders

- Follow the UIW protocol format and be concise
- Provide information in each section of the protocol; Keep it focused on the essentials
- Use clear simple language, minimizing the disciplinary jargon
- Cite the literature in appropriate sections
- Give as much info as possible about subjects/participants, research sites, access, etc.
- Explain how you will manage the data, store it, who has access, for how long
- Describe data analysis, rather than say, e.g., "data will be analyzed using software”
- Proofread, check grammar and citations
- Make sure the faculty supervisor reads through the protocol before he/she signs it
- Write for IRB, not your committee

Informed Consent – Key Points

- Goal is to obtain voluntary agreement from subject or the subject's legally authorized representative
- Informed consent is an ongoing process – does not begin and end with the signing of a consent document
- Give the person enough time to think about the research
- Give the person the opportunity to ask questions
- Remember: subjects may withdraw at any time – always give contact info
- Verify the subject's continued interest in participating in the study
- Use language that is understandable

What can't you say?

- No informed consent, whether oral or written, may include any exculpatory language
- What does this mean?
  - You cannot ask or force the subject to waive or appear to waive any legal rights, or release or appear to release the investigator, the sponsor, the institution, or its agents from liability for negligence.
- Advertising cannot be coercive or make false promises or claims.
  - Bad flyer example
  - Good flyer example

Consent Guidance

https://uiw.forms.ethicalreviewmanager.com

- Consent form templates for biomedical and social/behavioral research
- Sample email invitation and consent to take part in online survey
- Sample minor assent form

Application Support

- UIW IRB Webpage
  - https://www.uiw.edu/orgs/research/compliance/irb.html
- IRB Rep & IRB Chair
- Research Compliance Coordinator
  - Mary Jo Bilicek bilicek@uiwtx.edu (210) 805-3565
- Faculty Supervisor

Questions?

Contact:

Ana Hagendorf, PhD, CRA

Associate Provost for Research and Graduate Education

wandless@uiwtx.edu

(210) 805-3036