Introduction to the UIW IRB

Dr. Ana Hagendorf, CPRA wandless@uiwtx.edu
Research Officer, Office of Research Development

Overview

- What's an IRB?
- Who and what needs approval?
- Types of IRB reviews
- IRB protocol
- Issues and tips in preparing protocols for IRB review
- Consent documents
- Submitting online

Key information: http://www.uiw.edu/orgs/irb/index.html

What’s an IRB?

An institutional review board (IRB) is a committee that has been formally designated to approve, monitor, and review **research** involving **human subjects**.

Why do they need to do that?

- If an institution takes federal funding, they have to have a Federalwide Assurance (and an IRB)
- Federalwide Assurance: A formal, written, binding attestation in which an institution ensures to the Department of Health and Human Services (HHS) that it will comply with applicable regulations governing research with human subjects.

Also…

- IRB process is consistent with the UIW Mission:
  - Upholds the dignity and well being of all persons in the highest regard
- The IRB process is founded on:
  - Respect for persons – protecting autonomy
  - Beneficence – making sure risks are balanced by benefits
  - Justice – ensuring procedures are reasonable, well-balanced, and fair

What does the IRB do?

- The UIW IRB reviews human subjects research by UIW faculty, staff, and students, regardless of the location of the research or source of funding.
- Any UIW employee or **agent** who **engages** in **human subjects research** under a UIW appointment or affiliation is required to submit a protocol for review by the IRB.

What’s an agent?

An **agent** is any individual performing institutionally designated activities (including students) or exercising institutionally designated authority or responsibility.

What’s engagement?

An institution is considered **engaged** in human subjects research when its employees or 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

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 **or** an individual who is or becomes a participant in research, either as a recipient of the test article or as a control.

- 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 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

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?
  - When in doubt, just call or email the ORD.
- 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. Read the UIW IRB Manual: http://www.uiw.edu/orgs/documents/irb-manual-100516.pdf
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 ORD
  - 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 or involves special populations

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.

Exemption 1

- Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:
  - Research on regular and special education instructional strategies, or
  - Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods

Scholarship of Teaching

Exemption 2

- Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
  - Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; **and**
  - Any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation

Exemption 4

- Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available **or** if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects

  - Portions of U.S. Census data, data from the National Center for Educational Statistics, National Center for Health Statistics, etc.

Expedited Research

- Type of review that can be conducted by one or more IRB members
- Applies to research that present no more than minimal risk: The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Full Board Research

- Research which poses greater than minimal risk is not eligible for review under the above criteria as exempt or expedited and requires review by the full Board

IRB Application Elements

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

http://www.uiw.edu/orgs/irb/index.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

Purpose

- Communicate the intent of your study – what do you propose to do?
  - Instruction: This section must briefly and succinctly state the purpose of the study and should derive logically from the summary of background and significance.
  - Advice: Write this section in one or two sentences

Background and Significance

- Place the research within the context of the discipline and demonstrate the significance of anticipated outcomes.
  - Advice: This section can be communicated within a few paragraphs
- This is not a lit review
- Build it from the base up (think inverted pyramid)
  - Describe the larger field
  - Describe the specific field
  - Describe your particular study

- Significance: The [positive] effect your anticipated outcome will likely have on other things.

Location, Facility and Equipment

- What sites will you use?
- What are you using to collect / analyze data?
- Where does the data “live”?

Subjects and Informed Consent

- Who are you studying? How are they selected? How will you make sure they know what they're saying yes to?
  - Number of subjects, source, and demographics
  - How will subjects be identified, approached, and recruited?
  - Will you include or exclude anyone? Why?
  - How will consent be obtained (particularly for any studies involving special populations or sensitive information)?

Compensation

- Will you offer compensation to subjects?
- How much?
- When will they be paid?
  - Advice: If none, simply state “This study will not provide compensation for participants.”

Duration

- How long will this study take?
  - Describe the anticipated duration of the whole study
  - Break out the time for subject recruitment, data collection, and analysis

Research Design

- How are you going to do what you want to do?
  - Describe the approach and rationale for the approach
  - Describe how how the study will be conducted
  - What methods will you use?
  - Talk about the design of the experiment
    - How will you assign or randomize subjects?
  - How long will each part take?
  - What are you using to collect data?
  - If you'll work with subjects for more than one session, how long is each session? What's the total time needed from the subjects?
  - **Justify the number of subjects needed for the study.**
  - If you're working in a team, who's doing what part?

Risk Analysis

- How risky is this?
  - What are the risks to the subjects? Is this minimal or more than minimal risk?
  - How often will they occur?
  - How bad will they be?
  - What will you do to prevent risk?
  - Advice: Every action brings some type of risk – don't limit yourself to imagining physical harm as "risk". Include emotional and social risk.

Confidentiality

- How will you keep subjects' data confidential?
  - How will you safeguard individual subject records and computer files?
  - How will you ensure confidentiality of the data in presentation?
  - Or will you?
  - Who will you share items with?
  - For what purpose?
  - Which parts will you share?

Cited Literature

- Who did you cite in the other sections?

Attachments

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

Application Support

- UIW IRB Webpage
  - uiw.edu/research
  - Select “Human Subjects Research”
- IRB Rep & IRB Chair
- Research Officer
  - IRB Office Hours: Tuesdays from 3-5 and Thursdays from 9-11
- Faculty Supervisor

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
- Design should match the question and problem
- 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

Purpose of Informed Consent

- Informed consent is an ongoing process
  - Begins with recruitment and screening of a subject
  - Includes signing the consent document
  - Continues throughout the subject's involvement in the research

Improving Understanding

- Use language that is understandable to the subject or his/her representative
- Provide translated informed consent document (make sure it’s accurate)
- Give the person enough time to think about the research
- Give the person the opportunity to ask questions

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.
- Procedures to screen potential subjects for eligibility must protect the rights and welfare of prospective subjects.
- Advertising cannot be coercive or make false promises or claims.
  - Bad flyer example
  - Good flyer example

Voluntary Agreement

- From the subject or the subject's legally authorized representative
- Remember: subjects may withdraw at any time
- Verify the subject's continued interest in participating in the study

Waiving Informed Consent Documentation

- The only record linking the subject and the research would be the consent document and the principal risk is a breach of confidentiality.
  - Each subject will be asked whether they want documentation linking them with the research, and the subject's wishes will govern.
- The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

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

Questions?

Contact:

Ana Hagendorf, PhD, CPRA

Research Officer

wandless@uiwtx.edu

(210) 805-3026