Institutional Review Board

Protocol Review Process

Campbell University

What is research?

- Research is defined as “a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.”

- You must ask yourself: “Am I doing research?”

Am I doing research that involves human subjects?

- The human subject is “a living individual about whom an investigator (whether professional or student) conducting research and:
  - Obtains information or biospecimens through **intervention** or **interaction** with the individual, and uses, studies, or analyzes the information or biospecimens

  OR

  - Obtains, uses, studies, analyzes or generates **identifiable** private information or **identifiable** biospecimens

- If you are unsure: use the Human Subjects Research Determination Worksheet.

Not Research vs Not Human Subjects Research (NHSR)

Not Research*

- Scholarly And/or Journalistic activities
- Public health surveillance activities
- Criminal Justice Agency collection & use
- Intelligence, homeland security, defense, or other national security missions

*45 CFR 46.102(l)

Not Human Subjects Research**

- Not obtaining information/biospecimens by intervention or interaction
- Not obtaining, using, studying, analyzing, or generating individual identifiable information/biospecimens.
- Information/biospecimens used to support marketing under FDA regulations.

**45 CFR 46.102(e)

Not Human Subjects Research – Additional Categories

- Quality Improvement/Quality Assurance/Program Evaluations
- Case Reports*
- Course-Related Activities
- Research Using Public or Non-Identifiable Private Information about Living Individuals
- Research Using Health Information from Deceased Individuals*
- Instrumentation/Questionnaire Development

* HIPAA or other state/local laws may still apply.

The IRB Process at Campbell University

1. All study personnel who is interacting with study participants or their data should have human subjects training.
2. See the "new protocol submissions" page for information on how to prepare study documents
3. Guidelines on how to submit to the IRB can be found in the submission documents
4. The IRB coordinator will do a prereview to prepare you for IRB review. The coordinator may ask you to make revisions.
5. The IRB board will review your proposal and make a decision on approval. You may be asked to make revisions.
6. The IRB staff will send you a final determination/approval letter. No study activities may be started before the letter is received.
7. After approval you may need to submit additional documents to the IRB. Please read your IRB final determination/approval letter for guidance.
   a) **Amendments**: Any changes in research protocol or materials should be submitted to the IRB
   b) **Renewals or Closures**
   c) Reporting of any **adverse events** in the study

Human Subjects Research Protection Training

- You will need to identify your research team.
  - All research personnel will need to complete the human subject research training requirement.
- IRB requirements for conducting research are located on the IRB website.
- Typically, CITI Program training selection titled “Biomedical Researchers” should be chosen by medical students conducting research.
- SBE – Social, Behavioral & Educational Training is appropriate for other types of research.

Prepare Study Documents

- New Protocol Submission Form
- Research Plan
- Recruitment Materials
- Informed Consent/Assent Forms
- Data Collection & Research Instruments
- Data Monitoring Plan
- Multi-site Research Documents
- Other Required Documents

New Protocol Submission Form

- Provides the IRB with specific regulatory information to determine what type of IRB review must be conducted.
  - Principal Investigator (PI) must be Faculty with offices at Campbell University.
  - Students must have a Faculty Advisor to serve as the PI.
  - Explanation for risk category
  - Multi-site information
  - Ancillary Committee Decisions, if required
- Will prompt when additional required documents are required to be included in the submission.

Research Plan ≠ Research Protocol

- The IRB research plan is focused on human subjects research protections, identification of risks and benefits, and methods used to reduce risks.
- It includes elements in found in a research protocol.
- It requires detailed information regarding research activities, a recipe for your research project.
- Research Protocol contents are usually defined by the sponsoring agency.

IRB Research Plan template & Research Plan Guidance Document

- Complete both documents after you have developed your research protocol.
- Use the Research Plan Guidance Document and resources on the IRB website when competing the Research Plan template.
- The IRB has specific criteria that must be met before a reviewer or the IRB Committee can approve a protocol.
- Use of these documents will ensure completeness and clarity in your submission.

How to Submit

- Follow the instructions on the top of the New Protocol Submission Form.
- Use the Electronic Application Form, **DO NOT** email your submission.
- You will be prompted in the form to attach additional documents.
- Complete the New Protocol Checklist at the end of the submission form.
- Double check that all additional required documents are attached to the electronic application form prior to saving.

Pre-Review and Review

- Pre-Review consists of the IRB Coordinator ensuring all documents are included and basic IRB criteria for review have been met.
- The IRB may request changes be made prior to forwarding for review.
- Review of a research is conducted by a designated review or by a fully convened IRB dependent on the level of risk involved in the research protocol.
- The designated review or IRB Committee may approve outright or return for modifications prior to final approval.
- **This takes time.**

Determination or Approval

- You will receive a determination/approval letter.
- No research activities may be started or conducted prior to receiving the determination/approval letter from the IRB.

Post-Approval Submissions

- Changes must be submitted prior to the IRB before they are implemented.
- Protocol deviations or reportable events must be submitted.
- Progress Reports or Continuing Review submissions may be required.
- Closure Submission when the research has been completed.

How long does this process take?

It depends!