IRB Application Process

Research Type	СІТІ	Complete Application	Submit Application	Review	Decision
 Select proper application Human Rights in Research (Human Subjects) (HRRC), Hazardous Materials Research and Safety (HRS), or Institutional Animal Care and Use Committee (Animal Research) (IACUC) 	 Complete Required CITI trainings www.citiprogra m.org 	 Complete all Sections of Application Obtain all needed signatures 	 Submit Completed application Offices to submit SBE 310 (alternate offices SBE: 311, or 339) 	 OSRP will determine review type (exempt, expedited or full committee) Application review 	 Decision for U.S. research will be sent to proposer, generally within 2 business weeks International Research requires full review and a minimum of 20 business days for review

Can Research be conducted without IRB approval?

•No member of the FSU community, administration, faculty, staff or student may conduct human research on behalf of FSU without FSU IRB approval.

 No outside member may conduct research on FSU without FSU IRB approval

Types of Review

- Exempt
- Expedited
- Full Committee
- International

Research Question Parameters

- 1. You must have a well defined research question (note- it must end in a question mark)
- 2. Your methods must support answering the question
- 3. The data gathered must support answering the research question
- 4. The data analysis method must be well defined and must help answer the research question
- 5. You cannot ask questions or conduct other research on participants outside of the scope of the research question

Working with Human Subjects

- 1. When working with humans, there is no such thing as "no risk" research.
- 2. The lowest level of risk when working with humans is "minimal risk".
- 3. Risks to the participants must be fully explained on the application along with mitigation strategies.
- 4. There must be a benefit to the research and this must be written clearly in the Risks and Benefits section of the application

Informed Consent

- 1. There must be no coercion, direct or indirect for subjects to participate
- 2. There must be no undue influence or incentive for participation
- 3. All participation must be strictly voluntary
- 4. Participants must be capable of consent
- 5. Even after starting as a participant, individuals have the right to cease participation at any point

Juvenile Assent

Children cannot agree to participate in any research with out custodial consent.

To include a juvenile in research:

- 1. Parental consent must be first obtained; this must include exactly what the research is, what the risks are and a request to ask their child to participate. In your methods section you must include a method for obtaining parental consent.
- 2. After parental consent is obtained, then juvenile assent must also be obtained.
- 3. Even after parental consent the juvenile can refuse to participate

Debriefing Statements

There are 4 required parts to a debriefing statement:

- 1. The word "research" must be used.
- 2. The researchers name and affiliation with the university must be included.
- 3. The purpose of the research must be clearly stated.
- 4. Where in the individual can go for medical or other help, in case participation in the research has caused distress or any other medical condition, with contact information and that this help will be at no cost to the participant.

Format Parameters

- 1. If you use a reference in the application, you must include the full citation in the section in which the reference was used,
- 2. In A.P.A. formatting, dissertation titles must be composed of 12 or less words.
- 3. Full sentences, with correct grammar must be used throughout the application.
- 4. Do not use acronyms that you have not defined.

Protected Populations

- Juveniles
- Pregnant women
- Prisoners
- Individuals with diminished capacity
- Military and their family- specific to our area

Participant Confidentiality

Participation in all research is voluntary and must be kept confidential Things to think about:

- 1. How will you recruit participants? (recruitment scripts needed)
- 2. How will you gain consent and protect the consent forms from all outside eyes?
- 3. Where will you secure the original data and who has access? If you have an office at home and your family has access then this is not acceptable

Participant Confidentiality- cont.

- 4. If conducting interviews, how will you maintain confidentiality? Who will be present? Where will it occur? How long will it take?
- 5. Remember to restrict your data collection to data that helps answer your research question
- 6. How, when and where will the original data be destroyed?

Training

Go to www.citiprogram.org Register as a new user Affiliate with FSU

Select: Ethics for Researchers Social and Behavioral Research (a.k.a biomedical responsible conduct of research)

What to Submit with Your Application

You must have completed both CITI trainings, Ethics for Researchers, and Social and Behavioral Research.

Submit:

- 1. Fully completed and fully signed application
- 2. All instruments to be used in the research (if you are conducting online research questionnaires, then submit copies form the site of all questions)
- 3. All scripts
- 4. Consent forms (and Assent forms when applicable)
- 5. Consent or contact forms from other IRB's

Filling out the Application

Remember, the IRB application is not your dissertation proposal.
 The IRB application needs specifics, the practice, not the theory.
 Do NO cut and paste from your dissertation and try to make it fit into the application.

Applications available at <u>https://www.uncfsu.edu/research/forms</u>

Important Links

IRB's and Applications
 www.uncfsu.edu/research/for-researchers

Required Ethics & Compliance Trainings
 www.citiprogram.org

Funding Opportunities

 <u>https://www.uncfsu.edu/research/funding-opportunities</u>