

Conducting the Dissertation Research

After the Dissertation Proposal has been approved by the University Graduate School, the process of gathering the research data may begin. If the student's Dissertation involves the use of primary or secondary data on animals or human subjects, both administrative approval and FIU Institutional Review Board approval must be obtained before data collection begins.

Administrative Approval.

The student must secure a letter from the appropriate official in the research setting, which states that the study described may be conducted there. When the study is to be conducted in a setting outside of the University, administrative approval must be obtained prior to requesting approval from the FIU Institutional Review Board. If the study is to be conducted within a health care setting, approval must be obtained from that institution's Human Subjects Committee before securing administrative approval. Policies and procedures related to approval may differ at outside institutions. It is the student's responsibility to determine if differences exist and to adhere to policies and procedures of the institution.

FIU Institutional Review Board (IRB) Approval

Students are required to follow the policies and procedures of the FIU Institutional Review Board (IRB) when conducting research on animal or human subjects. There is human subjects involvement when living human beings are asked to participate physically in an activity or to donate their tissue, organs, fluids and other bodily materials; when human beings or their environment is manipulated; when information is sought from them directly (as through interview, examination, or questionnaire) or indirectly (as through observation), and when information concerning specific, individually identifiable human beings is asked for from third parties--whether through access to files, data banks, or other depositories--or through direct inquiry.

Animal subjects are any live, vertebrate animals used or intended for use in research, research training, experimentation, or biological testing or for related purposes. Research or experiments utilizing animal subjects, including tissue taken from live vertebrates for the purpose of research, must be submitted for review by the IACUC.

The IRB reserves the authority to suspend or terminate approval of research. Anyone conducting human subjects research without the approval of the IRB may be subject to a finding of research misconduct. For information on conducting research at FIU see ***Institutional Review Board for the Use of Human Subjects*** Here are some topics on the IRB web site menu:

- What's New?
- Guidelines & Forms
- Human Subject Training Module
- Privacy Practices

- FAQs Just for Students
- Board Submission Schedule
- Board Membership
- Using Animal Subjects
- Using Human Subjects
- Biohazard Material
- Intellectual Property

The FIU Institutional Review Board web site has up-to-date information, current policies and procedures related to research, and required forms to be completed. Since students may be engaged in the Dissertation project over an extended period of time, he/she must access the IRB web site on a regular basis to determine if there is new information or policies/procedures have been revised. For general guidance on student research, see: ***Institutional Review Board for the Use of Human Subjects*** and then click on ***STUDENT SUBMISSION***.

The following links provide information, resources and IRB forms:

INFORMATION & RESOURCES

IRB Manual - The IRB Manual provides an outline of procedures and policies for Investigators

Exempt and Expedited Research Criteria - Revised list for use with FORM A

Informed Consent- The Who, What, Where, Why and How's of obtaining consent

Student Submission - FAQ's and Guidance for students submitting for IRB approval

Data & Safety Monitoring

Adverse Event Reporting

Human Subjects Decision Charts Charts to assist in determining types of IRB review

Data Sets Approved for Use - Data sets that can be used without obtaining IRB approval

Certificates of Confidentiality

Guidance on Coded Research- Coded private information or biological specimens

INSTITUTIONAL REVIEW BOARD FORMS

IRB Application (FORM A) - For Initial Review ONLY

IRB Application (FORM A-1) - For Determination and Affidavit of Research with Non-Human Subjects

IRB Application (FORM B-1) - For Research Amendments or Modifications and Student Submissions to an Approved Faculty Project

IRB Application (FORM B-2) - For Annual Renewal (Continuation of an Approved Project) or Project Completion Report

Consent Documentation - Sample Consent Documents [***Generic University Letterhead***]

Informed Consent Document

Translation Affirmation Form - To Be Submitted With Translated/Back-Translated

Consent Documents

IRB Proposal Formal - Outline for Use with FORM A

Statistical Consulting

Statistical Consulting at FIU provides free assistance to doctoral students on experimental design, data coding data analysis, statistical packages, and interpreting output.

Report of Annual Dissertation Progress Conference

Once the student passes the Proposal Defense and is engaged in the research process, the student must meet with the full Dissertation Committee at least annually to report progress. The student is responsible for arranging a meeting with the Committee and obtaining signatures/comments for the report. To obtain a copy of the report form, see FIU ***Graduate Student Forms*** and then ***Form D-4 Dissertation Committee Report of Annual Dissertation Conference***. The report must be filed with the University Graduate School.