FIU IRB Guidelines for Investigators

I. RESPONSIBILITIES FOR CONDUCTING RESEARCH

1. **Principal Investigators** must possess skills adequate to their proposed research. Only Faculty Members are permitted to serve as a Principal Investigator on a student's research project. Principal Investigators are required to:
    a. Submit fully detailed research plans,
    b. Ensure that no human subject be enlisted without prior informed consent,
    c. Take all necessary safeguards to minimize risks and to protect the interests of vulnerable populations,
    d. Maintain the confidentiality of human subject data,
    e. Promptly report, in writing and verbally to IRB Chairperson, IRB Coordinator, ORI Director, or VP for research, any injuries or other unanticipated problems.
    f. Assure the adequate training of their personnel including Human Subjects Training and Adverse Event procedures,
    g. Adhere to high ethical standards, and
    h. Read, sign, and comply with the Affirmation of Compliance on the applicable IRB Application Form.

2. **Student Investigators** can serve as Co-Investigators on research project, but there must be a Faculty Member serving as the main Principal Investigator of the project. Data that is obtained without IRB approval may be deemed unusable for a Master's Thesis or Dissertation. The IRB cannot give retrospective approval to any project.

3. **Faculty Advisors** are responsible for providing students with:
    a. Timely information and guidance regarding proposal preparation, conduct and responsibilities. This is most important because the IRB CANNOT give retrospective approval nor can it approve a research study that does not protect the rights of the potential subjects;
    b. Information to foster responsible research conduct and independence.
    c. In this light, it is imperative that faculty advisors:
        i. Complete the Human Subject training required by FIU and federal regulations,
        ii. Remain up-to-date with IRB procedures and policies as well as those of the Graduate School.
    d. It is important to note that delinquency in the submission of requested information and forms by a particular faculty advisor and his/her students will delay the review of subsequent submission: and,
    e. Have the necessary expertise to advise and supervise students performing human subject research.

4. **Educational Responsibilities**
    a. Federal regulations require that ALL Principal Investigators and Key Personnel obtain training in human subject protections. FIU only accepts the CITI IRB Online Training, which allows you to print a completion report certificate upon successful completion of the training. A copy of the certificate for all members of the research team must be kept for your records. Before new members can be added to the research project, they must also complete the web-based IRB training and you will need to add them onto your project via the IRB Amendment Form.

II. GENERAL GUIDELINES FOR OBTAINING IRB APPROVAL

1. **TOPAZ Electronic Protocol Submission System.** Investigators are required to utilize the online TOPAZ Electronic Protocol Submission System for sending through an application for review. More information about using the system and submitting an application can be accessed from the main TOPAZ Information Page.

2. **Determine if IRB Review is Applicable.** IRB approval is only applicable if the project involves "human subjects" and meets the definition of "research." An investigator may optionally complete the following form within the TOPAZ system if he/she is unable to determine if IRB review is applicable (and needs a written determination from the Office of Research Integrity):
    a. IRB HSR Determination Form (used for determining the applicability of IRB review)

    Visit the Determine if You Need IRB Approval web page.

3. **Application Preparation.** IRB applications for conducting research with human subjects will go under one of the following three review processes: Exempt, Expedited, or Full Board Review. Investigators need to select between two different types of submission forms within the TOPAZ system:
    a. IRB Exempt Form (used for Exemption determination submissions)
    b. IRB Approval Form (used for Expedited and Full Board submissions)

    A basic determination of the review category is accomplished by comparing the research idea to the Exempt and Expedited Categories. These categories are not written to be all-inclusive, however the concepts of participant protection and minimization of risks can be applied to varying types and constructs of research.

    A project must involve no more than minimal risk to be eligible for Exempt or Expedited Review. Projects involving more than minimal risk will automatically require a Full Board Review.

    Visit the Types of IRB Review web page.

    If additional assistance is required during the preparation of an application investigators may contact the IRB Coordinator, or an IRB Member (see a list of IRB Members).

4. **Informed Consent.** All Expedited and Full Board protocol submissions require the use of informed consent (unless waived by the IRB). Investigators are required to use the FIU Informed Consent Templates. Signed Informed Consent Forms need to be stored for at least three years after the completion of the research. Learn more about obtaining Informed Consent.

    All protocol submissions that will be using Protected Health Information (PHI) are required to obtain HIPAA authorization from the participant (unless waived by the IRB). Signed HIPAA Authorization Forms need to be maintained for at least six years from the date of creation or the date when it was last in effect, whichever is later. Learn more about HIPAA Requirements.

5. **Application Submission**. All applications regardless of review category are submitted through the online TOPAZ Electronic Protocol Submission System.

a. Exempt and Expedited protocol reviews occur throughout the month.
b. Full Board protocol reviews need to follow the Full Board Meeting Submission Schedule.

Applications are submitted based on what the investigator is requesting or reporting. Each of the following review types requires a different application form within the TOPAZ system:

a. Initial Original Submission
b. Modification/Amendment
c. Continuing or Annual Review
d. Event Report (i.e., Adverse Event or Deviation)
e. Project Completion.

6. **Application Review.** The IRB Coordinator has the authority to review Exempt submissions and Human Subject Research Determination submissions. Individual IRB Members have the authority to review and approve Expedited applications and certain Exempt submissions that require IRB Limited Review as determined by the federal regulations. All other studies involving human subjects will be referred to Full Board review.

7. **IRB Action.** After reviewing the project, the representative recommends one of the following actions:
   a. Approved,
   b. Conditionally approved: approved pending minor modifications,
   c. Tabled: requires modifications/ revisions and resubmission, or
   d. Requires Full Board review.

   Requested modifications/revisions are inputted directly into the protocol application within the TOPAZ Electronic Protocol Submission System. Investigators are notified by email regarding the need to modify or revise an application. It is important that investigators address any inquiries, perform modifications and provide such documentation to the person indicated on the memorandum. The PI may not commence the research study until full approval is received.

8. **Approval.** IRB approval is granted when all requirements are met based on the federal regulations and FIU IRB policies. Upon approval, the PI is sent written notification inclusive of the IRB approval number and expiration date. This memo from the IRB Coordinator is the PI's record of approval and is to be used to provide official documentation to university departments and funding agencies. Upon receipt of the IRB approval the PI may commence the research project.

9. **Approval Requirements.** After receipt of initial approval, investigators are required to:
   a. Utilize the stamped version of the Informed Consent Forms (when applicable);
   b. Submit for Continuing IRB Review and receive approval;
   c. Submit Amendments to the IRB for review;
   d. Report Adverse Events as they occur;
   e. Report Protocol Deviations as they occur;
   f. Submit Completion Report at end of study

   Investigators affirm their understanding of their responsibilities when they sign the "Affirmation" section of the IRB form. Information regarding investigator responsibilities and IRB requirements is also provided on the approval memorandum for the convenience of the

investigator.

10. **Continuing Review.** The date for continuing review will be noted in the IRB approval letter when applicable. Continuing review shall occur up until the point that the remaining activities are the analysis of identifiable data/biospecimens and/or obtaining follow-up clinical data with already enrolled participants.

    Renewal submissions are submitted via the "IRB Renewal Form" within the online TOPAZ Electronic Protocol Submission System. Investigators are responsible for ensuring that their protocols are renewed prior to their expiration dates. Investigators are not permitted to conduct research with human subjects once the IRB approval has expired.

11. **Modifications/Amendments.** Any additions or changes in the procedures involving human subjects must be submitted to the IRB for review and approval. Modifications, whether new or approved during the term of approval, should be integrated into the documents being submitted for continuing review. A PI need not submit both an Amendment Form and a Renewal Form.

    Minor changes to an approved that do not increase the risks to subjects will typically go under an Expedited review. More than minor changes (or changes that increase the risks to subjects) will be reviewed by the Full Board.

    Amendment submissions are submitted via the "IRB Amendment Form" within the online TOPAZ Electronic Protocol Submission System. The IRB must approve these changes PRIOR to implementing them in the study.

12. **Adverse Events.** The PI is responsible for reporting serious unanticipated events within 5 days, and non-serious events within 10 days of the occurrence. All key personnel need to be familiarized with AE procedures and aware of the appropriate contact persons in case of an event. The Adverse Event Table (AE Table) must be used with projects required to have a Data Safety Monitoring Plan. The adverse event procedures can be accessed online. Adverse Events are sent through the online TOPAZ Electronic Protocol Submission System.

13. **Protocol Deviations.** The PI is responsible for reporting all instances that involve a deviation from the IRB approved protocol. A protocol deviation occurs when there is a variance in a research study between what is described in the protocol (reviewed and approved by the IRB) and the actual activities performed by the research team.

    Protocol Deviations are submitted via the "IRB Event Report Form" within the online TOPAZ Electronic Protocol Submission System.

14. **Project Completion.** The PI is required to submit a completion report when the study is no longer recruiting subjects, all the data has been analyzed, and all other human subject research activity related to this project has ceased. Studies completed prior to the end of the approval term may submit their completion report through the online TOPAZ Electronic Protocol Submission System.

III. ADDITIONAL INFORMATION

1. **Important Reminders for a Timely Application Review and Approval.**
    a. Only a Faculty Member can serve as a Principal Investigator on a student project.
    b. Only the Principal Investigator is permitted to provide an e-signature confirming the affirmation of compliance on the IRB application form.
    c. All personnel are required to complete the online CITI IRB Training.
    d. All Expedited and Full Board submissions require a Consent Form (unless waived).
    e. All Consent Forms must utilize the FIU Informed Consent templates.

2. **Submission to Fulfill UGS Thesis/Dissertation Requirements**
    a. Student Co-Investigators who intend to use humans subjects in research projects as fulfillment of the University Graduate School (UGS) requirements for thesis or dissertation must:
        i. Obtain IRB approval prior to beginning research activity and submit the IRB approval memorandum as a part of the M-2 or D-3 submission to UGS.
    b. Form M-2 (thesis) or D-3 (dissertation) submissions to the Graduate School require the inclusion of an approval memorandum from the IRB Coordinator for research involving human subjects.
    c. Deadlines are associated with submissions to the IRB and the Graduate School. Timely submissions will prevent the return and delay of acceptance of Form M-2 or D-3 submissions.
    d. The Calendar of the Graduate School deadlines can be found at: http://gradschool.fiu.edu/calendars.html
    e. Thesis/dissertation submissions are flagged by the UGS if the proposed research involves humans. Provide adequate information in your research proposal to assist with the determination of involvement of human subjects.
    f. Form M-2 or D-3 submissions will not be accepted by UGS if you suggest the use of human subjects and there is no memorandum of IRB approval or a memorandum indicating that the project does not meet the criteria for "research involving human subjects". These memorandums are generated by the IRB Coordinator.
    g. Data collected without prior approval will not be accepted for use with a thesis or dissertation. UGS submission requirements regarding research involving human subjects are located in Chapter IV of the UGS Thesis/Dissertation Preparation Manual.
    h. UGS does not waive requirements of rules or deadlines.
    i. All questions regarding the submission of UGS forms or requirements for graduation must be directed to the University Graduate School.

3. **Annual Renewal for projects initially reviewed by Full Board**
    a. All projects initially reviewed by the convened board must be reviewed annually by the Full Board based on the Federal Regulations. There are only three (3) exceptions, listed in the Expedited Research Criteria (Category #8), by which a project initially reviewed by the convened board may subsequently be reviewed by an expedited process.
    b. Principal Investigators who have projects initially approved by the Full Board need to submit their request for annual renewal in a timely manner in order to be have a project reviewed and approved by the convened board prior to the end of the approval period. Please review the IRB Meeting Schedule.

4. **Funded Projects**
    a. In the review of IRB applications, Investigators should be reminded to initiate their

applications in order to meet the following requirements:

i. Federal, State, and most local funding agencies require documentation of approval of human or animal subject involvement. Requirements regarding the time of submission (i.e., during proposal or prior to award) differ.

b. Agencies that require documentation of approval for the use of human or animal subjects will not release funding until they have received the appropriate documentation. Some agencies will release funding for research identified as "Exempt".

c. FIU requires the following regarding funding and IRB approval:

i. Submission to the IRB according to the agency requirements for submission of approval documentation;

ii. IRB approval must be obtained prior to the release of funds regardless of the review category;

iii. An IRB approval must remain current in order for subsequent funds to be released for use by a PI.

IV. CONTACT INFORMATION

- **If there are any questions, please contact:**

  - The IRB Coordinator
  - Your College / School's IRB Member
  - Your Faculty or Graduate Advisor

- **Correspondence to the IRB Coordinator may be directed to:**

  - Maria Melendez-Vargas, MIBA
    Office of Research Integrity
    Office: MARC 414
    E-mail: mdemelen@fiu.edu
    Phone: 305-348-8311