***Date of this Application:***

**IRB Number**:

**Project Title:**

# A. Project Contact Information:

**ROLE Name E-mail Phone Fax**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **FDU Principal Investigator:**  |  |  |  |  |
| **Type of Student:** | [ ]  **Doctoral** [ ]  **Master’s** [ ]  **University Honors** [ ] **Other Undergraduates**[ ]  **Other: (specify)** |
| **Faculty Mentor:** |  |  |  |  |
| **Co-Investigator (Student as specified above):** |  |  |  |  |
| **Co-Investigator:** |  |  |  |  |
|  |  |  |  |  |
| **Campus:** |  | **College/School/Department:** |  |
| **Mailing Address/Mail Stop:** |  |

# B. Amendment Requirements:

Federal Regulations require that when a change occurs to an IRB approved study; these changes must be reviewed and approved by the IRB before the change(s) take place. Amendments may include: changes to the subject population, addition of study sites, recruitment plans, advertising materials, research procedures, instruments/measures/questionnaires, sites or research personnel who are instrumental to the design or execution of the study. The application and all revised documents must be submitted electronically via e-mail to the fduirb@fdu.edu e-mail address. If the amendment increases the risk to subjects, this amendment is required to be reviewed by the IRB at a convened meeting. Please ensure all meeting deadlines are met to not delay review.

**C. Change in Principal Investigator: (please append a copy of the New PI’s CV)**

|  |  |
| --- | --- |
| **Name of New PI:** |  |
| **Reason for Change:** |  |
| **Date Change is to take in effect:** |  |

# D. Addition of Member to the Research Team

**Each NEW member of the research team must complete training in the Protection of Human Participants in Research. Each member of the research team must submit a certificate verifying completion of education in the Protection of Human Subjects in Research CITI Tutorial. Instructions and the tutorial link may be accessed here:** <http://view.fdu.edu/default.aspx?id=5825>.  **A research team member is defined as anyone who has contributed to the research design (e.g., specific aims/hypotheses) and/or shall have contact with human participants and/or their data for purposes of conducting this investigation. The certificate must be current in the past three (3) years. *After the tutorial is completed, the Human Research Compliance Manager will be automatically notified* *by CITI*. Please ensure information provided below matches the information sent to the HRCM. Details on replacement of research team members must be described below in Amendment/Project Changes Details.**

**Name of New Team Member** **Date Completed**

Click here to enter text. Click here to enter a date.

Click here to enter text. Click here to enter a date.

Click here to enter text. Click here to enter a date.

# E. Consent/Assent Form Change(s):

|  |  |
| --- | --- |
| **The consent form is being changed at this time and requires re-evaluation and approval *(attach an electronic copy with all changes highlighted or underlined and a clean electronic copy for inclusion of the new IRB approval date)*.** | **[ ] Yes [ ] No** |
| **Description and justification for the changes made:** |  |
| **Will current subjects enrolled need to be re-consented, re-assented or both?**  | **[ ] Yes [ ] No****If yes, please explain how subjects will be notified:****If no, please provide a justification:**  |

# F. Amendments/Project Changes Details

**Before the change is implemented, the IRB must approve any amendments made to the project such as, changes in subject population, recruitment plans, advertising materials, research procedures, study sites, study measures/questionnaires/instruments, or to investigators/personnel that are instrumental to the design or execution of the study.**

|  |  |
| --- | --- |
| **Itemize the revisions to the project:** |  |
| **Provide a justification for each proposed revision:** |  |
| **Changes increase the risks to subjects, is considered a major change and full board review is required.**  | **[ ]  Yes** **[ ]  No**  |
| **Electronic copies of all revised documents must be appended with all changes highlighted or underlined. Please ensure pages are numbered to ease reference.** |

**G. Signatures**

**Signature of the Principal Investigator (PI):**

As the Principal Investigator, I am responsible for the protection of the rights and welfare of human subjects, conduct of the study, and the ethical performance of the project. In the case of student protocols, the Faculty Mentor and the student share responsibility for adherence to all state and federal law and regulations and FDU policies.

I certify the protocol will be performed by qualified personnel according to the approved IRB proposal.

All changes in the protocol and consent form will be approved by the IRB before initiated, except when it is necessary to eliminate an immediate hazard(s) to the subject(s).

Informed Consent will be obtained from human subjects as required.

If I leave FDU, I will assure that all appropriate documents, constituting a final report are submitted to the IRB for review.

Date:

Print Name:

Signature:

**Signature of the Faculty Mentor (FM)- Required for all student researchers and all non-FDU researchers:**

I certify and attest that I have read the application for continuation submitted to the IRB for review and approval. I further agree to provide appropriate education and supervision of the student investigator to provide appropriate oversight of the non-FDU Investigator who signed above as the Principal Investigator.

Date:

Print Name:

Signature:

***IRB OFFICE USE ONLY:***

IRB Receipt date: Agenda Date:

IRB#:

**Submission Instructions (PLEASE DO NOT SUBMIT THIS PAGE)**

All requests must be submitted electronically via e-mail to the IRB at fduirb@fdu.edu.

Please submit the following documents: Completed Application, all revised documents (protocol/project plan, consent form, assent form, advertisements, recruitment efforts, etc.) with all changes underlined or highlighted, new documents with version dates and clean copies of all recruitment efforts, consent forms, assent form, etc. that require an IRB approval stamp and approval dates.

Documents that cannot be scanned or sent electronically via e-mail should be hand delivered or mailed to the IRB at the Grants and Sponsored Projects Office. The Grants and Sponsored Projects Office mail code is: T-BE2-02. The office is located on the Metropolitan Campus, Becton Hall, Room 200. Please ensure your IRB# is affixed to your documentation to ease tracking of your project.

**Required Documents:**

[ ]  Completed Amendment/Proposed Changes Application;

[ ]  Revised documents with underlined or highlighted changes;

[ ]  New proposed documents;

[ ]  Signatures (electronic signature is accepted, however name should not be typed) on the completed

 Application form;

[ ]  Clean copies of revised forms that need the IRB approval stamp and approval dates as described above;

[ ]  Copy of CV for a change in the Principal Investigator;

[ ]  Letters of Permission to conduct research/IRB Approvals of added/changed external sites;

### Review Time Frame

The IRB convenes once a month with the exception of the Winter Holiday Break and Summer Schedule (see below). Only proposals designated as Full Board are subject to the calendar restrictions and deadlines. Please allow sufficient time as per the [IRB schedule](http://view.fdu.edu/default.aspx?id=8248) to ensure that your proposal is reviewed and approved to allow adequate time for the conduct of your investigation. Any proposal that is received after the meeting deadline date will be delayed and placed on the next scheduled meeting agenda.

Amendments that are minor may be approved via an Expedited review process. Amendments that are considered major or increase the risk to subjects are required to be reviewed by the full board. These are typically reviewed within 15 business days after receipt of your proposal. Please allow at least 15 business days from the date of receipt for the IRB to respond. If the IRB needs to receive additional information or revisions to complete the review, the 15 business day turnaround time begins at the time the additional information is received.

Please note that a final determination on the submission cannot be made until all required and requested revisions, materials, documents, etc. have been received and reviewed by the Human Research Compliance Manager.

### Winter (Holiday) and Summer Schedules

**Holiday Schedule**

The IRB does not convene during the Winter Holiday Schedule which begins after the November IRB meeting. Therefore, any proposal requiring Full Board review will be delayed until the January meeting.

The IRB administrative office will continue to accept applications during the Winter holiday schedule (with the exception of the University’s holiday leave calendar for employees/staff). The review process will be completed as soon as possible. Submissions received one week before holiday leave will be confirmed but processed upon the re-opening of the office. Please note additional time may be needed for review of applications depending on the availability of committee members during the final exam period.

**Summer Break**

The IRB will continue to review exempt and expedited projects throughout the summer break. However, the IRB does not convene during the summer months of June, July or August except on an as needed basis or for emergency circumstances.

These schedules are subject to the academic calendar as published by the University, and the IRB reserves the right to adjust its calendar and review practices as necessary. Applicants are encouraged to check the IRB Announcements section of the website frequently for changes to the calendar.

If you require any assistance, please contact Kim Diccianni, CIP, Human Research Compliance Manager at (201) 692-2219.