**Date of this Application:** **School/Department**:

**Campus:**

**Project Title:**

# A. Administrative Information:

**ROLE Name & Degree E-mail Phone Fax**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Principal Investigator:**  |  |  |  |  |
| **If Student, Type:** | [ ]  **Doctoral** [ ]  **Master’s** [ ]  **University Honors** [ ] **Other Undergraduates**[ ]  **Other: (specify)** |
| **Faculty Mentor:** |  |  |  |  |

# B. Study Funding

**Funding is being sought and/or is available to support this project:** **[ ] No** **[ ] Yes**

**If yes, please complete the following and attach a copy of the grant proposal, contract and/or reward letter, if applicable:**

|  |  |
| --- | --- |
| **Name of your funding source:** |  |

# C. Conflict of Interest (see Conflict of Interest in Research Policy at <http://view.fdu.edu/default.aspx?id=9542>)

**Do you or any of the Investigators and yours/their immediate family members have any financial interest related to this study?**

**[ ] No [ ] Yes**

**If yes, please list each Investigator/family member and identify the financial interest:**

|  |  |
| --- | --- |
| **Name of Investigator/Family Member** | **Description of Financial Interest** |
| Click here to enter text. | Click here to enter text. |

# D. Project Purpose

**Please provide a lay term description of the project. Please include your intent and what you hope to learn plus goals.**

Click here to enter text.

# E. Describe all Project Procedures

**If a survey or interview is to be completed, please append a copy of the survey/interview and/or place in link to electronic survey**

Click here to enter text.

# F. Is Your Project Quality Assessment/Quality Improvement?

**Quality Assessment and/or Quality Improvement are activities completed to assess, analyze, critique and improve current processes/practices in an institutional setting, involving data-guided, systematic activities designed to bring about prompt improvements. These improvements may be shared internally or a report made in a journal.**

|  |  |
| --- | --- |
| **Does your project meet the above definition?:** | **[ ]  Yes [ ]  No** |
| **Will the activity involve randomization into different intervention groups?:** | **[ ]  Yes [ ]  No** |
| **Is the activity primarily designed to:*** **Improve a program or activity at FDU or to improve some other program?**
* **Show outcomes that will be generalized for other populations, organizations, programs or services?**
 | **[ ]  Yes [ ]  No****[ ]  Yes [ ]  No** |

# G. Is Your Project Research?

**Research is defined as a systematic investigation, including development, testing and evaluation, designed to develop or contribute to generalizable knowledge. (45 CFR 46.102(d))**

|  |  |
| --- | --- |
| **Does your project meet the above definition?:** | **[ ]  Yes [ ]  No** |
| **Is the activity a systematic investigation, including (but not limited to) a hypothesis, research development, testing and evaluation?:** | **[ ]  Yes [ ]  No** |
| **Is the activity primarily designed to develop new knowledge?:** | **[ ]  Yes [ ]  No** |
| **Is this activity for a publication, scholarly presentation, thesis or dissertation research?:** | **[ ]  Yes [ ]  No** |
| **Is the activity primarily designed to:*** **Improve a program or activity at FDU or to improve some other program?**
* **Show outcomes that will be generalized beyond your specific study population?**
 | **[ ]  Yes [ ]  No****[ ]  Yes [ ]  No** |

# H. Does Your Project Activity Involve Human Subjects?:

|  |  |
| --- | --- |
| **Are your subjects living individuals?:** | **[ ]  Yes [ ]  No** |
| **Is an intervention involved such as physical procedures, manipulating a person or a person’s environment?**  | **[ ]  Yes [ ]  No** |
| **Is there an interaction (communication with persons/observation of private behavior) with individuals such as: surveys (in-person & internet based), interviews (in-person, telephone, etc.), e-mail, chat room conversations, etc.?: Please ensure to attach a copy of the interview, survey or test questions.** | **[ ]  Yes [ ]  No** |
| **Are you obtaining identifiable private information specifically about the living individual?** | **[ ]  Yes [ ]  No** |
| **Does your project involve the use of existing data or specimens?** | **[ ]  Yes [ ]  No** **If no, no need to continue to the next set of questions.** |
| **Describe the data source:** |  |
| **Is this data publicly available:** | **[ ]  Yes [ ]  No** |
| **Are you able to identify or ascertain, if data is de-identified, the specific person providing the data:** |  |
| **If the data is de-identified?** | **[ ]  Yes [ ]  No****If yes, who did, or will de-identify the data and their relationship to the research team:**  |
| **Is the data coded?** | **[ ]  Yes [ ]  No****If yes, will have access to the code key?: [ ]  Yes [ ]  No****Were you apart of the original collection?: [ ]  Yes [ ]  No** |
| **Was the data originally collected for this project?** | **[ ]  Yes [ ]  No** |
| **Was the data originally collected as part of clinical care?** | **[ ]  Yes [ ]  No** |
| **Was the data originally collected for research purposes under an FDU IRB approved protocol?**  | **[ ]  Yes [ ]  No** **If yes, please provide the IRB#:****If not, please attach a copy of the consent form under which the data was obtained.**  |

**For FDU IRB USE ONLY: Signature of Reviewer: Date:**

**Activity is NOT human subjects research. [ ]  Activity is research involving human subjects. IRB approval required. [ ]**

**Submission Instructions** **(PLEASE DO NOT SUBMIT THE INSTRUCTION PAGES TO THE IRB)**

This form must be submitted via email to Kim Diccianni, CIP at dicciann@fdu.edu.

This will allow for ease of dissemination and timely review of the submission. Whenever possible, supporting documentation should be scanned and sent electronically with your proposal. Documents that cannot be scanned or sent electronically should be mailed to the IRB or hand delivered to the IRB at the Grants and Sponsored Projects Office, Metropolitan Campus, Becton Hall, Room 200 (please include appropriate reference to your proposal). Examples of such documents include, questionnaires/tests/measures/scales, copyrighted materials, and/or original signed forms such as PI Agreements, Faculty Agreements, etc.

### DOS

* Allow PLENTY of time for a literature review, proposal preparation, and submission of suggested modifications and sufficient time for IRB review.
* Provide specific information to the research that you are completing and ensure all requested documentation is supplied in a timely manner.
* Become familiar with the types of proposal classifications (i.e., Full, Expedited or Exempt). You are encouraged to consult with the Human Research Compliance Manager for clarification and guidance of your specific investigation. It is recommended that you draft a timeline for proposal preparation, IRB review/approval and conduct of your research investigation as a planning strategy.

### DON’TS

* **Do NOT send your application to the IRB Chairperson. Sending your application to anyone other than the IRB Administration will delay the review of your application.**
* **Handwritten applications or scanned hand written documents are NOT accepted. These documents will be returned without review.**

### Appended Documents- Please use the check boxes to assist you in ensuring all information is submitted. NOTE: Some documents may not be applicable to your project.

[ ]  Completed Research with Human Subjects Determination Form;

Also submit the following if applicable to your project:

[ ]  Survey, Measures;

[ ]  Interview Questions;

[ ]  Test Questions;

[ ]  Grant Proposal;

[ ]  Funding Award Letter;

[ ]  Other documentation necessary to provide evidence necessary to assist the reviewer in making a determination.

### E-mail requirements

1. Include a description of your submission type in the subject heading of your email to the IRB, i.e. · New Project; Continuing Review; Amendment; Final Report; Complaint of a Participant; Notification of a Harmed Participant; etc.
2. In the body of your e-mail provide:
	* The Project Title, Principal Investigator, Faculty Mentor (if applicable)
	* A list all of the documents that you will be attaching to your e-mail or sending via regular mail, e.g.. Application, Consent Document(s), Methods and Procedures, Protocol Summary, Interview script, Questionnaire, Advertisement, TV/Radio Ad Script, PI Agreement, Faculty Agreement, Grant Application, Dissertation, Thesis, etc.
	* Provide a version date for each document.
	* Make sure all documents are attached before you send the e-mail.
	* Scan, whenever possible, and send any documents with signatures required
	* Documents are accepted in PDF, JPEG or Microsoft Word formats. However, all Consent/Assent Forms are required to be submitted in Microsoft Word format.

### Confirmation of Receipt

Once your project has been received, the IRB administrative office within fifteen (15) business days after receipt, will send an e-mail confirming receipt of the project. An internal Project Number will be assigned. Please reference this number in all future correspondence with the IRB regarding your project.

### Review Time Frame

The IRB convenes the third Wednesday of each 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. 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.

All other proposals are designated as either Expedited or Exempt by the IRB administrative office. 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 IRB 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.