IRB Receipt date (IRB Use Only): IRB# (IRB Use Only):

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

**Campus:**

**Project Title:**

**Estimated project timeline: (Enter the anticipated dates the project is to be completed. These are estimates and are not binding)**

**Start Date: End Date:**

# A. Administrative Information:

**All faculty, staff, doctoral, master’s and university honors students may serve as principal investigators. All student PIs must have a Faculty Mentor listed. All other students must identify a faculty member as the Principal Investigator and add his/her information as a co-Investigator.**

**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. Human Subject Protection Education

**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.**

**Name of 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.

# C. Study Funding

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

**If yes, please complete the following and check all that apply:**

|  |  |
| --- | --- |
| **External Government and Private Funding Sources: (Please append a copy of your grant application, contract or any other additional information.)** | **[ ]  Federal Agency: (specify)****[ ]  State Agency: (specify)****[ ]  Sub-Contract: (specify Primary Institution and originating source of funding, e.g., federal, state, foundation)****[ ]  City and Local Government Agency: (specify)****[ ]  Private grant and/or Foundation: (specify)****[ ]  Other: (specify)** |
| **FDU Funding Sources: (Please append a copy of your grant application.)** | **[ ]  SEED Grant****[ ]  Other: (specify)** |
| **Investigational or other products provided by an outside sponsor:** | **[ ] No [ ] Yes Specify:** |

# D. 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. |

# E. Study Type (Check all that apply)

**[ ]  Doctoral Dissertation [ ]  Master’s Thesis** **[ ]  Undergrad Honors Thesis** **[ ]  Evidence-Based**

**[ ]  Chart Review** **[ ]  Single Center Study** **[ ]  International Research** **[ ]  Questionnaire/Survey**

[ ]  **Investigator Initiated Study/Traditional Single Grant** **[ ]  Cooperative Grant** **[ ]  Career Development**

**[ ]  Curriculum Development**

**[ ]  Multi-Center: Identify the Project Director and Coordinating Center:** Click here to enter text.

[ ]  **Other (specify):**

# F. Study Review Type (Check all that apply)

**[ ]  Full Board Review- Project is greater than minimal risk.**

**[ ]  Expedited Review- Project is minimal risk and meets at least one of the following categories: [ ]  1 [ ]  2 [ ]  3 [ ]  4 [ ]  5**

 **[ ]  6 [ ]  7**

**A list of the categories may be found here:** [**http://www.hhs.gov/ohrp/policy/expedited98.html**](http://www.hhs.gov/ohrp/policy/expedited98.html)

***The 8 and 9 categories are ONLY for continuing review studies and are not applicable to new projects*.**

# G. Location where the study will be conducted

**Please note that all sites you are recruiting from need to be identified and also ensure that you have contacted that recruitment site’s IRB to see if IRB approval is necessary before recruitment begins. If IRB approval is required, the information should be forwarded to the IRB office. Indicate all site(s) where research for this study will be conducted:**

|  |  |
| --- | --- |
| **Study site(s): (Select all to the right that apply)** | **[ ]  FDU Campus/es: (specify)****[ ]  FDU Center for Psychological Services (METRO)*****(Complete Section 1, below)*****External Sites *(Identify type and complete Section 2, below):*****[ ]  Other University: (specify)** **[ ]  Other School: (specify)****[ ]  Nursing Home or other Health Care facility: (specify)****[ ]  Hospital/Medical Center: (specify)****[ ]  Other Collaborators: (specify)** |
| **Indicate the FDU Campus/Building(s) and room number(s) or address of non-FDU sites where the study will take place and/or data will be stored** | Click here to enter text. |

***SECTION 1: Complete the following section ONLY if the study is being completed at******FDU- Center for Psychological Services (Metro Campus)***

|  |  |
| --- | --- |
| **Has the project been submitted to the Director for the Center for Psychological Services?** | **[ ] No [ ] Yes****If no, please do not submit your project until it has been reviewed and approved by the Director of the Center for Psychological Services.****If yes, please ensure the Director’s signature is included below where indicated.** |
| **This project has been reviewed , is in compliance with all current Center for Psychological Services Policies and Procedures and is approved to be completed at the Center.**  | **Signature of the Director of the Center for Psychological Services:****Date:** |

***SECTION 2: Complete the following section ONLY if the study is NOT being completed at FDU.***

|  |  |  |  |
| --- | --- | --- | --- |
| **Does the Site have an IRB?**  | **[ ] No [ ] Yes** | **Do you have the Site’s IRB approval?** | **[ ] No [ ] Yes** **If yes, append a copy of the IRB approval documentation.** |
| **Has the site granted permission for the research to be conducted on site?** | **[ ] No [ ] Yes****A copy of their Institutional Permission Correspondence approving the research to be completed must be appended to this submission.** |
| **Contact information of the site’s IRB:** | Click here to enter text. |

# H. Study Subjects

For purposes of this form, the term “subjects” should be read to refer to all participants, patients, etc.

|  |  |  |  |
| --- | --- | --- | --- |
| **The estimated number of subjects anticipated to be approached about and/or screened for participation in this study;** |  | **Literature search has been conducted:** | **[ ] No [ ] Yes** |
| **Estimated # of subjects to be enrolled (consented) at FDU and at Other Sites, if applicable.** | FDU=Other Sites= | **Will the FDU Subject Pool be utilized?** | **[ ] No [ ] Yes;** **If yes, please append listing to be included on the SONA system and any other recruitment efforts.** |
| **Subject ages:** | [ ]  Children, aged 0-7 (parental consent and oral assent as appropriate are needed).[ ]  Children, aged 8-17 (parental consent and written child assent as appropriate  are needed).[ ]  18 years and older (consent is needed). |
| **Will subjects be screened to include or exclude on:** | **Gender [ ] No [ ] Yes****Ethnicity [ ] No [ ] Yes****Race [ ] No [ ] Yes*****If yes is answered to any of the above, justification must be provided.*****Justification:** Click here to enter text. |
| **Describe the specific characteristics of your subjects. For ex., this study will seek subjects who are juvenile offenders who live in Any Town, NJ.** | Click here to enter text. |
| **Will screening tools be used to select your subjects?** | **[ ] No [ ] Yes If yes, append screening tools.** |
| **Are materials you are using copyrighted?** | **[ ] No [ ] Yes Specify:** |

## Subject Populations (if applicable)

**These categories identify study populations to determine if additional protections may be needed and/or those who may be susceptible to coercion. The IRB may need to ensure certain regulations are met or processes are included when for example, children or prisoners are included, or that certain coercive practices such as the following do not exist; a student enrolling in a teacher’s project so that he/she may receive extra credit that is not granted in some manner to the whole class or a student who would have his/her grade decreased if he/she did not participate.**

**The subject population includes the following (please check all that apply):**

[ ]  **FDU Students** [ ]  **FDU Employees** **(Faculty or Staff)** [ ]  **Children (Under the age of 18)**

[ ]  **Prisoners (incarcerated, detained pending arraignment, trial, or sentencing, on parole)** [ ]  **Pregnant Women**

[ ]  **Human fetuses** [ ]  **Cognitively Disabled or Impaired persons** [ ]  **Elderly** [ ]  **Terminally Ill**

[ ]  **Diminished capacity to give informed consent** [ ]  **Illiterate persons**

[ ]  **Persons who cannot read English** [ ]  **Persons who cannot speak English**

[ ]  **Persons who are under the authority of the research team, e.g., students, staff, patients, clients.**

[ ]  **Persons who are institutionalized, e.g., hospice patients, hospital patients, nursing home patients,**

 **rehabilitation centers, homeless shelters, holding centers for immigrants.**

[ ]  **Other:(specify)**

# I. Subject Recruitment/Privacy and Confidentiality

|  |  |
| --- | --- |
| **Is there Inclusion/Exclusion Criteria?** | **[ ] No [ ] Yes; describe screening process:** Click here to enter text. |
| **Have you included all of your recruitment materials for review (including advertisements, flyers, posters, internet postings, e-mails, radio scripts, in-person recruitment script, SONA posting, etc.)** *Please note that* ***ALL*** *recruitment materials must be reviewed and approved by the IRB before use.* | **[ ] Yes [ ] No***If no, please e-mail all to* *fduirb@fdu.edu* *or provide justification for not including:* Click here to enter text. |
| **Explain how your recruitment will be done.** | Click here to enter text. |
| **Describe provisions to protect the *privacy* of subjects during the course of the study, (e.g.. Recruitment- discussing the project in a closed office especially if a sensitive subject; have subjects drop completed surveys in a drop box away from the classroom used for recruitment or in an envelope whether completed or not; utilizing only messaging via Facebook to group members after the group provided permission, etc.)****Also include methods used to ensure that information obtained during the study about subjects is not improperly divulged.** |  |
| **Describe provisions to maintain the *confidentiality* of the data. (e.g., where/how information is stored, who has access to the data, and how access to the data is controlled).** |  |
| **How many sessions are planned for the participant to complete? Indicate the length of each session and how long it will take for the subject to complete the study.** |  |

# J. Study Details

**Does your research involve any of the following? Check all that apply.**

**a. Deception, incomplete disclosure and/or restrictions that the research [ ] Yes [ ] No**

 **team does not disclose the true nature of the research to the participants?**

**b. Administration of drugs?** **[ ] Yes [ ] No**

**c. Covert Observation? [ ] Yes [ ] No**

 **Ex) Chat room research where researcher takes on the presence as**

 **one who is involved with the group, setting up a “fake” Facebook profile/group**

 **for research purposes and those subjects are not told.**

**d. Induction of mental and/or physical stress specific for the research? [ ] Yes [ ] No**

 **Ex) Strenuous exercise, extreme pressure or mental manipulation that may**

 **cause mental and physical stress that could hospitalize the subject or visit**

 **the Emergency Room.**

**e. Materials/issues commonly regarded as socially unacceptable? [ ] Yes [ ] No**

 **Ex) Use of pornography, drugs, dog fighting, incest, polygamy, pedophilia, etc.**

**f. Information regarding sexual attitudes, preferences or practices? [ ] Yes [ ] No**

**g. Information regarding the use of alcohol, drugs or other addictive behaviors? [ ] Yes [ ] No**

**h. Information pertaining to illegal conduct? [ ] Yes [ ] No**

**i. Genetic information (pedigree, heritage and/or testing)? [ ] Yes [ ] No**

**j. Information from a medical record? [ ] Yes [ ] No**

**k. Information from a student’s educational record? [ ] Yes [ ] No**

**l. Information pertaining to a person’s psychological health or well-being? [ ] Yes [ ] No**

**m. Procedures that may be regarded as an invasion of privacy? [ ] Yes [ ] No**

 **Ex) Collection of license plate #s to be used to identify and contact subjects**

 **who were covertly observed for research purposes.**

**n. Information that if released could reasonably damage an individual’s**

 **financial standing, employability or reputation within the community? [ ] Yes [ ] No**

**o. Questions included that may not be age appropriate or may [ ] Yes [ ] No**

 **be controversial for children to answer due to family dynamics,**

 **religious beliefs, regarding political affiliations, etc.?**

**For every item checked yes above, provide justification and describe protections that will be put in place to minimize the risks to the subjects.**

|  |  |
| --- | --- |
| **Item Letter**  | **Justification and protections to decrease harm to the subjects.** |
|  |  |
|  |  |
|  |  |
|  |  |

**Will any of the data be gathered using audio and/or video recording? [ ] Yes [ ] No**

**Will any of the data be gathered using survey, questionnaires or interviews? [ ] Yes [ ] No**

**Will the research team collect information about the participants that could**

 **be linked directly to them? [ ] Yes [ ] No**

**Will the research team use a linking code with the data? [ ] Yes [ ] No**

**Will the research team share identifiers or linking codes with anyone**

 **outside the research team? [ ] Yes [ ] No**

**Will the research team request a Certificate of Confidentiality? [ ] Yes [ ] No**

**Will the Principal Investigator and/or the research team comply with the**

 **privacy measures of Health Insurance Portability and Accountability**

 **Act/Health Information Privacy Act (HIPAA)? (if applicable) [ ] Yes [ ] No**

 **See link for additional information:**

**Will the Principal Investigator and/or the research team comply with the**

 **Privacy measures of Family Education Rights Protection Act (FERPA) (if applicable)? [ ] Yes [ ] No**

 **See link for additional information:**

# K. Research Proposal Summary

**Please provide a summary of your research proposal. The information should be provided in each of the following boxes. For dissertations and thesis projects, a copy of your project write up reviewed and approved by your committee must be appended. For projects that have a research protocol, please append as all information below will be reviewed to ensure all information matches the protocol.**

|  |  |
| --- | --- |
| **A. Study Specific Aims:** |  |
| **B. Recruitment Processes:** |  |
| **C. Methods of Data Collection and Analysis:** |  |
| **D. Potential Risks to Participants:** |  |
| **E. Precautions taken to moderate risks identified (Examples provided):** |  |
| **F. Potential Benefits:** **If there are no direct benefits to the subject please state and provide any information on potential benefits to society, future, etc. *Compensation is not considered a benefit and should not be included in this section.* Benefits should be tangible, e.g. supported through publication.** |  |
| **H. Step by Step Description of the Procedures that will be used in the project:** |  |

L. Payments, Incentives and Costs to Subjects

**Please note that any compensation, payments and incentives such as course credit to subjects is NOT considered a study benefit to the subject. Investigators must make a reasonable effort to avoid offering excessive or inappropriate financial or other inducements for participation since they may be viewed as coercive. When offering professional services, investigators should clarify the nature of the services, as well as the risks, obligations and/or limitations.**

**The University’s Department of Finance has policies that pertain to certain forms of compensation to research subjects that may be accessed at** [**http://view.fdu.edu/default.aspx?id=8918**](http://view.fdu.edu/default.aspx?id=8918%20) **. If your project has a Certificate of Confidentiality or if the identification of the subject on the required informational list places the subjects at risk, the IRB requires that a non-identifying code be used on their form instead of the subject’s name and/or identifiable information.**

|  |  |
| --- | --- |
| **Will the study provide payment, course credit or any other incentives to subjects?** | **[ ]  No [ ]  Yes** |
| **Type of payment or incentive?**  | **[ ]  Money [ ]  Prizes** **[ ]  Gifts [ ]  Cash****[ ]  Gift Certificates/Cards [ ]  Course Credit** **[ ]  Other: (specify)**  |
| **Total proposed amount of incentive per subject:** | **Explain what the incentive is expected to cover (e.g., transporation, parking)** **Explain the payment schedule, amount of credit, e.g., frequency, at the onset of the study, etc.** |
| **Who will be responsible for distributing the payment/incentive?** | **[ ]  Principal Investigator****[ ]  Other: (specify)** |
| **Will it cost participants to be in the study?** | **[ ]  Yes [ ]  No** |
| **If yes, describe any anticipated costs: [ ]  Transportation [ ]  Parking Fees [ ]  Childcare** **[ ]  Other: (specify)** |

# M. Informed Consent

**Informed Consent is a person’s voluntary permission or that of their legally authorized representative, based upon adequate knowledge and understanding of the relevant information, to participate in research or to undergo a diagnostic, therapeutic, or preventive procedure. *Informed Consent is required unless waived by the IRB.* (For request for waivers please see: insert URL). The investigator may determine which method or process would best serve the interests of the subject population, but the IRB reserves the right to require alternative or more stringent means of securing consent.**

**Please Note: In giving their consent, subjects may not waive or appear to waive any of their legal rights, or release or appear to release the investigator, the sponsor, the Institution or agents thereof from liability for negligence [Federal Policy 116; 21 CFR 50.20 and 50.25]. Please note that a subject may withdraw at any time during the course of the investigation.**

|  |  |
| --- | --- |
| **Type of Consent Process(es):****(check all that apply)** | [ ]  **Comprehensive written informed consent****[ ]  Verbal Consent****[ ]  Letter Consent****[ ]  Internet-based consent****[ ]  Telephone consent****[ ]  Surrogate Consent****[ ]  Assent for Children and populations of diminished capacity who may not be able to consent for themselves** |
| **Method Used for Obtaining Consent:** | [ ]  **Informed Consent will be obtained from all subjects and documented with a signed, written consent form.****If checked, complete sections Informed Consent Process and Documentation of Consent found below.****[ ]  Informed Consent will be obtained from subjects, but no signed document will be obtained. For this to be approved, a Waiver of Documentation of Consent must be approved. This includes oral consent (e.g. done over the telephone) and implied consent (e.g., completing a survey).****If checked, answer the questions in Informed Consent Process.****[ ]  Fully informed consent will not be obtained from all subjects as approved under a Waiver/Alteration of Informed Consent. This includes withholding information, etc.** **[ ]  Other Method: Describe** |
| **The study’s consent procedure will require these waivers.**  | **[ ]  Waiver of/Alteration to Informed Consent****[ ]  Waiver of Documentation of Informed Consent** |
| **More than one consent form will be used for this study (not including language translations)** | **[ ]  No****[ ]  Yes; list each consent subject heading:** |
| **This study involves audio/videotape or other electronic recording:** | **[ ]  No****[ ]  Yes; (specify):** |

# N. Informed Consent Process

**The process by which informed consent is documented and obtained is the responsibility of the Principal Investigator and/or Faculty Mentor.**

|  |  |
| --- | --- |
| **Describe how the required information is being presented to subjects (written consent form, orally, information sheet, letter, internet based consent, etc.)\*** |  |
| ***\*Append a copy of the Informed consent document, oral consent script, letters to parents, parent consent, assent for children, etc. Any method you propose for IRB review and approval must comprehensively include and document all elements of informed consent. INSERT LINK HERE. The IRB Consent Form template may also be used for your project.*** |
| **Describe the circumstances under which consent will be obtained, including where the process will take place.** |  |
| **Who will obtain consent? Describe their expertise and training (e.g., NIH or CITI tutorials) in obtaining consent from subjects or how the process will be supervised.** |  |
| **How will it be determined that the subjects or the subjects’ representatives understand the information presented? For example, are subjects provided sufficient time to ask questions or relate back knowledge of the study and requirements for participation?** |  |
| **This study’s subject population will require foreign language consent forms.** | [ ]  **No****[ ]  Yes; (list languages)\*** |
| **If English is not the subjects’ native language, how will the study seek consent from the subjects?** |  |
| **Who will translate the consent(s) and/or assent(s), if applicable?** | All translations must be approved by the IRB. |
| **\* *The IRB must receive a copy of each translated consent form and documentation of attestation after the English version is approved. This can be done via an amendment once IRB approval is received.*** |
| **When the Study involves Children or Cognitively Impaired subjects, will the study seek Assent\* from Participants?** | [ ]  **No; (Explain why assent cannot be sought):**[ ]  **Yes** |
| *\** ***Assent is typically required when the individual is not allowed or competent to give legally valid Informed Consent to participation in the Study whether by law or by capacity for understanding. You are referred to the Assent Template to respond to these regulations.*** |
| **Would the Study best be served by administering Assent orally?** | [ ]  **No****[ ]  Yes; (Explain):** |

# O. Documentation of Informed Consent Form

**Note: Signed, written consent forms are required unless waived by the IRB, but are not the only-or most effective- forms of documentation. You must append all copies of all written consent forms to this application.**

|  |  |
| --- | --- |
| **How will the subjects’ informed consent be documented? Please indicate all the ways in which consent is documented?** |  |
| **If non-English speaking subjects will be included, describe how the translation of consent forms will be provided.** | \*\* |
| **\*\* *all translated consent forms must be submitted to the IRB along with back translations.*** |
| **If the subjects cannot read the consent form, due to literacy or language problems, how will consent be documented?** |  |

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

All IRB proposals must be submitted via email to the IRB administration at fduirb@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.**

### Required 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 Full/Expedited Review- New Project Application;

[ ]  Signed Principal Investigator’s Agreement; (see <http://view.fdu.edu/default.aspx?id=5826>)

[ ]  Signed Faculty Mentor Agreement; (see <http://view.fdu.edu/default.aspx?id=5826>)

[ ]  Informed Consent Form or equivalent such as telephone consent script, internet consent for web based project;

[ ]  Assent Form or equivalent such as verbal assent script, if applicable;

[ ]  Debriefing Form if deception is included as part of this project.

[ ]  Questionnaires, Surveys, Measures, Interview Questions, etc.;

[ ]  Recruitment Efforts: (Ads, flyer, poster, script of in-person recruitment, e-mail solicitation, letter solicitation, radio ad script, TV ad script, etc.);

[ ]  Proposal Defense Signature Form/Dissertation Committee Approval, etc., if applicable;

[ ]  Research Protocol or Dissertation/Thesis proposal reviewed and approved by Committee documentation, if applicable;

[ ]  Copy of the grant application for private and/or federal funding, if applicable;

[ ]  Letter of Permission, IRB Review/Approval or equivalent from the Institution if subjects are being recruited at another site;

[ ]  Any additional material that will be given or read to subjects for their participation in this study.

### 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.