LOYOLA UNIVERSITY NEW ORLEANS

OFFICE OF THE PROVOST

**INSTITUTIONAL REVIEW BOARD FOR THE PROTECTION OF HUMAN SUBJECTS IN RESEARCH**

Applications for IRB review must include all elements to be considered complete. **Allow a minimum of two weeks for processing and initial review of your application**. Please send all materials in one email, preferably in one PDF document, to the responsible chair. We cannot accept linked documents.

Protocols must be sent by the PI (this is the faculty mentor on all student projects) in confirmation that the protocol has been thoroughly reviewed and approved by the mentor.

The narrative (items 1-7 below) should be succinct yet provide sufficient detail for the IRB to conduct its review. Please use black font.

**Primary Investigator (Faculty Supervisor if student researcher)**:

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**Student Investigator**:

_____

**Secondary Investigator(s) (if applicable)**:

_____

**Title of Research Project**:

_____

**Granting Organization Funding the Project:**

_____

**Anticipated project start date**:

_____

**Anticipated project end date** (otherwise one year after formal approval for non-exempt studies):

_____

1. **INTRODUCTION**: Succinctly summarize the background, nature, rationale and significance of the proposed study. Any references should be placed in the appendix.

2. **SPECIFIC AIMS/QUESTIONS:** In outline form, state clearly the objectives of the research including aims and hypotheses and/or research questions. (This is not where you put your survey/interview questions - those go in the appendix.)

3. **RESEARCH PROTOCOL:**
    a. Setting: Describe the setting in which the study will be conducted. Explain the source of participants, how many participants will be recruited, any inclusion or exclusion criteria, how participants will be recruited, whether they will be provided any incentive or compensation for participation, and if so, the process for doing so. If the project will use human participants at another institution or location, the principal investigator must provide a letter from a responsible official at that institution/location giving permission. Such evidence must be attached to the protocol.
    b. Consent: Explain procedures for obtaining informed consent from adults. If applicable, explain how assent will be secured from children or others who, by definition, cannot legally give consent (e.g., adults with legal guardians). **Attach copies of informed consent and assent documents/information, and any foreign language translations for populations who cannot read English, if necessary**. If a waiver of consent is required, please fully outline why and how benefits outweigh risks.
    c. Protocols: Describe the activities in which subjects will engage and the data collection procedures. Explain what data will be collected and duration of participation in activities. **Attach all measures and instruments**.

4. **INVESTIGATOR EXPERIENCE:** For all individuals involved in conducting the study, provide appropriate certification of training. All individuals involved in human subjects research are required to provide proof of a training course. Individuals at Loyola University should complete CITI training using their Loyola email address. Please attach a copy (a screenshot is fine) of the certificate provided at the conclusion of the course.

5. **DATA:** Describe the following:
    a. How data will be analyzed or studied.
    b. How data will be reported (e.g., aggregated, anonymity of participants, pseudonyms for participants).
    c. Where data will be stored, who will have access to them, how data will be used (e.g., in presentations, thesis, publications), and, where applicable, what will happen to video/audio recordings at the end of the study.

6. **RISKS:** All research carries some degree of risk, even if minimal (the risk of everyday life). Identify possible risks to subjects, including, where applicable, physical, psychological, legal, social, and economic (loss of employment) and explain measures in place to minimize any risk. Also address issues of confidentiality and risks associated with a breach of confidentiality.

7. **BENEFITS:** Explain the benefits of participating in the study **for participants and in general.** In studies involving risk, describe the relationship between risks and benefits. Note, compensation is not a benefit and belongs under recruitment procedures.

**ATTACH:** Copies of all consent and assent documents/information, copies of questionnaires, guiding questions, survey instruments, tests, debriefing materials, and other pertinent documentation (e.g., letters from collaborating sites, certifications).

Consent forms must include IRB contact information (see consent form template on website or here).