**Institutional Review Board**

**Initial Application for Full Review**

**Office Use Only - IRB Protocol Number**: Click or tap here to enter text.

Project Title: Click or tap here to enter text.

Principal Investigator(s): Click or tap here to enter text.

Advisor, if PI is a student:Click or tap here to enter text.

1. **Full Review Research Categories**

*Check all categories that apply. Verify that your study does not qualify for an exempt or expedited review. If you are unsure, consult the IRB chair (*[*irb@delval.edu*](mailto:irb@delval.edu)*). Categories are defined by the HHS Office for Human Research Protections.*

1. The research involves participants who are prisoners, fetuses, pregnant women, seriously ill, or mentally or cognitively impaired adults.

2. The research involves the collection of information regarding sensitive aspects of participants’ behavior (including, but not limited to, drug or alcohol use, illegal conduct, sexual behavior).

3. The research procedures involve **more than minimal risk** to the participants. The probability and/or magnitude of harm or discomfort anticipated is greater than that ordinarily encountered in daily life or during the performance of routine physical or psychological tests.

4. The research does not fall into any of the categories explicitly identified as qualifying for exempt or expedited review.

*If you have checked* ***at least one*** *box in Part I, proceed to Part II on the next page. Otherwise, your study may qualify for an exempt or expedited review. If you are unsure which review level best suits your study, you may consult with the IRB chair (*[*irb@delval.edu*](mailto:irb@delval.edu)*).*

1. **Study Description**

*Please answer all questions below in the provided text boxes. These boxes will expand to allow complete answers. Reviewers may come from outside of your discipline. Be clear and precise.*

1. What is the purpose of the proposed study? Provide a brief description of the background research, with citation, that informs your study. Provide references at the end of your text.

Click or tap here to enter text.

1. What is/are your research questions and hypotheses?

Click or tap here to enter text.

1. How will this research contribute to existing knowledge within the field?

Click or tap here to enter text.

1. How many participants are expected for this study? Click or tap here to enter text.
2. Describe the participants. What population will they be drawn from? How will you gain access to the participants? How will they be recruited? Include desired demographics and selection criteria/procedures to be used. Attach drafts of any communications, written or verbal, you intend to have with participants through the duration of your study. **If you are drawing participants from a particular institution, including DelVal, you must include a letter of support from an appropriate administrator at that institution showing that they understand what you wish to do and give permission for you to use their members are participants, pending IRB approval.**

Click or tap here to enter text.

1. If your research involves participants who are prisoners, fetuses, pregnant women, the seriously ill, or mentally or cognitively impaired adults, explain why their participation is scientifically necessary.

Click or tap here to enter text.

1. Which type(s) of Informed Consent will you obtain? Choose all that apply.

N/A – using existing data or specimens with broad consent

N/A – using existing data or specimens without broad consent

Signed Informed Consent – hard copy

Unsigned Informed Consent – hard copy or electronic copy

Assent (participants under 18, usually also requires parental permission)

Parental Permission – signed

Parental Permission – unsigned

Other, specified here: Click or tap here to enter text.

**You must provide copies of all consent documents/scripts with your application.**

1. Describe the consent process. How, when, and where will consent be obtained?

Click or tap here to enter text.

1. Describe your research procedures. What will participants be asked to do? Approximately how much time will they be asked to invest? How many waves of data collection will there be?

Click or tap here to enter text.

1. Describe all instruments, surveys, demographic questions, interview questions, interventions, or other materials that are part of data collection. Provide citations in text and references at the end of this section. **Include copies of all materials with your application**.

Click or tap here to enter text.

1. How will data be recorded (e.g. pen-and-paper, electronically, video/audio recording, etc.) For any use of online data collection, transcription, or other services, provide security information from the online host that shows participant data will be confidential.

Click or tap here to enter text.

1. How will data be stored? Describe how you will preserve anonymity or confidentiality. How long will data be stored, where will it be stored, how will it be disposed of? This information must also be communicated to participants on your consent document.

Click or tap here to enter text.

1. Describe all risks that present the possibility of discomfort and/or harm greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.
   1. Identify all risks (physical, psychological, financial, social, legal, other) connected with the proposed procedures.

Click or tap here to enter text.

* 1. Indicate how such risks to participants are reasonable in relation to anticipated benefits.

Click or tap here to enter text.

* 1. Describe how you have designed your study to minimize such risks to participants.

Click or tap here to enter text.

* 1. Assess the likely effectiveness of your plans to minimize risks. Why are these sufficient?

Click or tap here to enter text.

1. If deception is part of your planned procedure, provide a scientific justification for it and describe your debriefing procedure (oral or written). Provide a copy of your debriefing materials. If it will not be possible to debrief all participants regarding the deception, explain and justify that absence.

Click or tap here to enter text.

1. Describe any incentives offered to participants (e.g. payments, extra credit, entries into raffles, etc.). Include the value of such incentives, how and when they will be distributed, and how you will handle incentives for participants who withdraw from the study.

Click or tap here to enter text.

1. Assess the benefits of this research to both the participants in the study as well as society at large and explain how these benefits outweigh the risks involved. Benefits **DO NOT** include incentives described in the previous question.

Click or tap here to enter text.

1. Describe any possible conflicts of interest or multiple relationships between any researchers, funders, and participants (e.g. teacher-student, manager-employee, friendship, etc.). If any such relationships exist, describe how you will ensure that participants are free to decline participation without actual or perceived penalty and that no participants are directly, indirectly, or perceived to be coerced to participate.

Click or tap here to enter text.

**Once you have completed this application, save it as a .docx, .doc, or .pdf file and submit it, along with all of your other materials, to the IRB chair (**[**irb@delval.edu**](mailto:irb@delval.edu)**). Review the *IRB Proposal Checklist* to ensure you have assembled all required materials before submitting.**