DELAWARE STATE UNIVERSITY

Institutional Review Board – Human Subjects Protection Committee

Application for Approval of Investigations Involving Human Subjects

Please Read Carefully and COMPLETE ALL ITEMS:

1. **Principal Investigator's Name:** _____
(Student, Faculty, Staff — Circle or **Bold** one.)

Principal Investigator's email address: _____

Co-Investigator Name: _____
(Student, Faculty, Staff — Circle or **Bold** one.)

Department: _____ **Phone:** _____

2. **If you are a student, provide the following:**

Faculty Sponsor: _____ **Department:** _____

Faculty Sponsor Phone: _____

Is this your class research project/assignment? Yes _____ **No** _____

Thesis? Yes _____ **No** _____

Dissertation Research? Yes _____ **No** _____

3. **Title of project:** _____

4. **Project Period: From:** _____ **To:** _____

5. **Has this project previously been considered by any IRB? Yes** _____ **No**_____

If yes, give approximate date of review. _____

6. **Is a proposal for external support being submitted? Yes _____ No _____**

If yes, you must submit one complete copy of that proposal as soon as it is available and complete the following:

a. Is notification of Human Subject approval required? Yes _____ No _____

b. Is this a renewal application? Yes _____ No _____

c. Sponsor's Name: _____

d. Project Period: From: _____ To: _____

7. **You must include copies of all pertinent information such as a copy of the questionnaire you will be using or other survey instruments, informed consent documents, letter of approval from cooperating institutions, copy of external support proposals, etc. For graduate students, include a copy of your prospectus.**

8. **If approved by Delaware State University IRB, the approval expires one year after the date noted on the Approval Letter.**

If the application is the same without changes, and the project needs to continue past the one year approval, a Continuing Review Form must be submitted to the IRB for consideration.

The Principal Investigator is responsible to complete a Final Study Report Form when the project is completed and forward the report to the IRB.

I have read and understood the above requirements.

_____

Signature --- Principal Investigator

Provide the following information, using the application format, to the Institutional Review Board - Human Subjects Protection Committee. *Please number all pages.*

I. PROPOSED RESEARCH PROJECT

A. **Provide a brief summary of the proposed research. Include major hypotheses and research design.**

B. **Describe the sources(s) of subjects and the selection criteria. Specifically, how did you obtain potential subjects, and how will you contact them?**

C. **Informed Consent: Describe the consent process and attach all consent documents. Elements of informed consent are:**

1. **A clear statement that "the study involves research"**
2. **All the research purposes are clearly stated**
3. **The expected procedures to be followed**
4. **The duration of involvement by the subject**
5. **When procedure(s) are experiential**
6. **Reasonably foreseeable discomfort and risks**
7. **If more than minimal risk, "In case of injury or severe adverse reaction..."**
   - **a. is medical care available? By whom? Where?**
   - **b. is compensation available? How?**
   - **c. whom should the subject contact?**
8. **Reasonably expected benefits to subject and others**
9. **How and where will the data be published?**
10. **The alternatives to the research's diagnostic method or treatment**
11. **How confidentiality or anonymity are maintained**
12. **Who will answer questions about the research itself?**
13. **Who will answer questions about the subject's rights?**

D. **Procedures: Provide a step-by-step description of each procedure, including the frequency, duration, and location of each procedure.**

E. **How will confidentiality of the data be maintained?**

F. **Describe all known and anticipated risks to the subject including side effects, risks of placebo, risks of normal treatment delay, etc.**

G. **Describe the anticipated benefits to the subjects, and the importance of the knowledge that may reasonably be expected to result from the research.**

H. Provide a copy(s) of the Letter of Approval from the attending/employed institution's IRB committee.

Additions or changes in procedures involving human subjects, as well as any problems connected with the use of human subjects once the project has begun, must be brought to the attention of the IRB - Human Subjects Protection Committee. Please visit http://www.desu.edu/research/sponsored-programs/forms-library and download the Guidelines for a Writing Informed Consent.

II. SIGNATURES

SECTION 1. FOR FACULTY / STAFF ONLY

A. I certify that to the best of my knowledge the information presented herein is an accurate reflection of the proposed research project.

Principal Investigator (Print Name**):**_____

(Faculty, Staff--Circle or **Bold** one.)

Signature _____ **Date** _____

Co - Principal Investigator (Print Name**):**_____

(Faculty, Staff--Circle or **Bold** one.)

Signature _____ **Date** _____

B. Approval by Departmental Chair / Supervisor

I confirm the accuracy of the information stated in this application. I am familiar with, and approve of the procedures that involve human subjects.

Departmental Chair/ Supervisor
(Print Name**):**_____

Signature _____ **Date** _____
Departmental Chair/ Supervisor

C. Approval by Departmental Dean

I confirm the accuracy of the information stated in this application. I am familiar with, and approve of the procedures that involve human subjects.
Departmental Dean
(Print Name**):**_____

Signature _____ **Date** _____
Departmental Dean

SECTION 2. REQUIRED FOR ALL STUDENTS ONLY:

A. I certify that to the best of my knowledge the information presented herein is an accurate reflection of the proposed research project.

Principal Investigator (Print Name**):**_____

Signature _____ **Date** _____
Principal Investigator

Co - Principal Investigator/s (List Names)

B. Approval of Faculty Sponsor:

I affirm the accuracy of this application, and I accept the responsibility for the conduct of this research, the supervision of human subjects, and maintenance of informed consent documentation as required by the IRB - Human Subjects Protection Committee.

Faculty Sponsor (Print Name**):**_____

Signature _____ **Date** _____
Faculty Sponsor

C. Approval by Departmental Chair and **Program Director**

I confirm the accuracy of the information stated in this application. I am familiar with, and approve of the procedures that involve human subjects.

Departmental Chair

Department Chair (Print Name**):**_____

Signature _____ **Date**_____
Departmental Chair

Departmental Program Director

Department Program Director (Print Name**):**_____

Signature _____ **Date**_____

Departmental Program Director

[Required For Dissertation and Thesis Research]

D. Approval by Departmental Dean

I confirm the accuracy of the information stated in this application. I am familiar with, and approve of the procedures that involve human subjects.
Departmental Dean

(Print Name**):**_____

Signature _____ **Date** _____
Departmental Dean