For Office Use Only:

Date Reviewed: _____ **IRB Case No:** _____

Action: ☐ **Exempt** ☐ **Expedited** ☐ **Full Review** **IRB Reviewer:** _____

☐ **Not Approved**

WHEATON COLLEGE INSTITUTIONAL REVIEW BOARD (IRB)
RESEARCH PROPOSAL FOR HUMAN PARTICIPANTS

The Wheaton College IRB reviews requests to conduct research involving human participants. It is the investigator's responsibility to give complete information regarding procedures and the informed consent process. If the principal investigator is a student, the application must be approved and signed by the applicant's faculty sponsor or the department chair.

After completing the application and obtaining required signatures, one original copy of the application and all supporting materials must be forwarded to Joel Relihan, Executive Secretary of the IRB, Park Hall 200. The IRB will notify each applicant of the IRB's decision. If you have questions, please contact the IRB Executive Secretary at (508) 286-3497.

The Principal Investigator must supply the required documentation listed below:

☐ A copy of all questionnaires or survey instruments
☐ Informed consent document(s) or minor assent document(s)
☐ Letters of approval from cooperating institutions (if appropriate)
☐ All required signatures

Please type or print responses. Failure to provide all required information will result in the return of this application for correction prior to IRB review.

PROJECT TITLE:

1. Principal Investigator's Name: _____
   Department: _____ Phone: _____
   Mailing Address: _____
   Email: _____

   For Students Only

   Faculty Sponsor: _____
   Department: _____ Phone: _____

Is this a class project? ☐ yes ☐ no Thesis? ☐ yes ☐ no
Other? _____

2. Project Start Date: _____ Project End Date: _____

3. Is a proposal for external support being submitted? ☐ yes ☐ no
Agency or Sponsor: _____ Deadline: _____
If yes, you must submit one complete copy of the proposal with this application.

a. Is this a continuation of an IRB project? ☐ yes ☐ no
If yes, previous IRB case number: _____

4. **PROJECT DESCRIPTION**: *The IRB must have sufficient information about what will happen to the subjects in order to evaluate and estimate possible risks. Assurance from the investigator, no matter how strong, will not substitute for a description of the transactions between the investigator and subject. Provide a brief, nontechnical summary of the proposed research.*

5. **SUBJECT SELECTION**:
All individuals involved will be informants.

Will subjects be less than 18 years of age? ☐ yes ☐ no
Age range of subjects: From _____
Will subjects be students at Wheaton College? ☐ yes ☐ no
How many subjects will participate? _____
How will subjects be selected, enlisted or recruited?

6. **INFORMED CONSENT PROCESS**: Describe the informed consent process and attach a copy of all consent and/or assent documents. Describe the process of both consent & withdrawal. If appropriate, describe how assent will be obtained from children and/or developmentally delayed persons. When the consent of a legally authorized representative is substituted for consent of the adult participant, explain why this is necessary. If non-English-speaking participants will be enrolled, a consent form should be prepared in their foreign language. Someone who is fluent in the participants' language must be available to interpret. Attach a copy of all written informed consent documents.

7. **PROCEDURES**: Provide a step-by-step description of each procedure, including the frequency, duration, and location of each procedure. Include the type of experimental design, study procedures: sequential description of what will be asked of/done to participants; assignment of participants to various arms of the study if applicable; kinds of data to be collected; primary outcome measurements; and follow-up procedures, if any. Attach relevant materials and add extra pages as needed.

8. **CONFIDENTIALITY AND ANONYMITY**: How will subjects' privacy be maintained and confidentiality be guaranteed?

9. **RISKS**: Describe all known and anticipated risks to the subject, paying close attention to the potential physical, emotional, and psychological effects of all procedures. Include risk of psychosocial harm (e.g., deception, emotional distress, embarrassment, breach of confidentiality, etc.) economic harm (e.g. loss of insurability) and legal jeopardy (e.g., disclosure of illegal activity) as well as known side effects of study medication, if applicable, and risk of pain or physical injury. *State clearly EITHER 1) that an individual's participation in the project is completely anonymous; OR, 2) that an individual's participation in the project is confidential. If the latter, state how confidentiality will be ensured and maintained, including where data will be kept & who will have access to it during & after the study.*

10. **BENEFITS**: Describe what benefits, if any, the subjects may derive from participation in your study. The possibility of benefits to society should be clearly distinguished from the possibility of benefit to the individual participant, if any. If there is no direct benefit to the individual participant, say so. Do not list monetary payment as a benefit.

RESPONSIBILITIES OF THE PRINCIPAL INVESTIGATOR:

- *Any additions to or changes in procedures in this protocol must be submitted to the IRB for written approval prior to the changes being put into practice.*
- *Any problems connected with the use of human subjects once the project has begun must be brought immediately to the attention of the IRB Executive Secretary.*
- *The principal investigator and his or her designee(s) are responsible for retaining informed Consent Documents for a period of three years after the completion of the project.*

The principal investigator may not initiate any research involving human subjects until written notification of IRB approval of this research protocol has been received. Formal approval by the IRB may include specific directives concerning the responsible conduct of research for particular aspects of the project, or may specify steps necessary for compliance in certain contingencies. The investigator must indicate to the Executive Secretary the acceptance of such modifications before research may begin.

SIGNATURES: *I certify to the best of my knowledge the information presented is an accurate reflection of the proposed research project and that I intend to comply with the letter and spirit of the Wheaton College Policy on the Protection of Human Subjects in Research.*

A. _____ _____
Principal Investigator Date

B. Approval by faculty sponsor (required for all students): *I confirm the accuracy of this application, and I accept responsibility for the conduct of this research, the supervision of human subjects, and maintenance of informed consent documentation as required by the IRB.*

_____ _____
Faculty Sponsor Date

C. Approval by Department Chair (required for all students):

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

_____ _____
Department Chair Date