Appendix H

**PLYMOUTH STATE UNIVERSITY**

**Institutional Review Board**

**Application for Approval for Research Involving Human Subjects**

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Full Review  Expedited Review  Exempt Review

Proposed Start Date Click here to enter text.

Is research being funded? Yes  No  Source of funding: Click here to enter text.

Title of Study Click here to enter text.

Investigator:

Name Click here to enter text.

Position Click here to enter text.

Phone Number Click here to enter text.

Email Click here to enter text.

Faculty Advisor Name (if applicable) Click here to enter text.

Qualifications to Conduct this Research Click here to enter text.

Additional Research Staff and Qualifications to Conduct Research

Click here to enter text.

Describe your research question and the background for the study. Include a brief literature

**1. Purpose of the Study and Brief Background and Review of Literature**

review with supportive references.

Click here to enter text.

**2. Recruitment Procedures and Participant Population**

A. List the expected number of participants Click here to enter text.

B. Does the research involve special populations specifically, children, prisoners, or individuals who are cognitively impaired? Yes  No

C. Describe who is going to participate in the research (i.e. age, demographic characteristics, etc.).

Click here to enter text.

D. Indicate whether anyone might be *excluded* from the research and why.

Click here to enter text

E. Discuss how and by whom participants will be recruited, selected, and assigned to groups. Attach flyers, posters, oral or written communication, or other recruitment materials used to contact potential subjects as an appendix.

Click here to enter text.

A. Materials: Describe the apparatus, stimuli, questionnaires, or any type of measures to be used in the study. Attach questionnaires, interview guidelines, and measures to be used as an appendix.

**3. Procedures and Methodology**

Click here to enter text.

B. Describe each step of the procedure or study protocol, including the instructions participants will be given and any experimental manipulations that will be administered. Indicate where the research be conducted.

Click here to enter text.

C. State the specific dates/timeframe in which you plan to conduct your research.

Click here to enter text

**4. Informed Consent Process**

A. How and when will you explain the study and the informed consent?

Click here to enter text

B. If there are subjects under the age of 18, how will the study be explained to them? How will parental consent and child assent be handled?

Click here to enter text.

C. Indicate the primary language(s) of the participants. If not English, explain how you will ensure the participants understand the informed consent and procedures of the study. Discuss the need for foreign language translations, if applicable.

Click here to enter text.

**5. Participant Debriefing**

Will participants be exposed to deception? Yes  No

If yes, how will the participants be debriefed?

Click here to enter text.

A. What kind of risks, if any, will the participants be exposed to?

**6. Risks and Safeguard Procedures to Minimize Risk**

***The risks you describe here should match the risks you list in the informed consent form.***

**Guidelines for Determining Risk.**

Risk relates to the probability of harm or injury (physical, psychological, social, economic, legal) occurring as a result of participation in a research study. Risks also include invasion of privacy and loss of confidentiality. Types of risk include: (1) physical, (2) psychological, (3) social, (4) legal and (5) economic harm. A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Click here to enter text.

B. What efforts will be made to minimize the risks?

Click here to enter text.

C. Discuss how participants’ rights to privacy and confidentiality will be protected. Discuss how and where data will be stored and how long the data will be kept. Who will have access to the data and how will access be limited?

Click here to enter text.

D. Alternative Therapies or Procedures: Indicate if there are any alternatives. If there are none, indicate the alternative is not to participate in the study.

Click here to enter text.

**7. Benefits**

Discuss the potential benefits to participants and society, science, and/or knowledge development.

Click here to enter text.

**8. References**

List supportive references used in the application.

Click here to enter text.

**9. Assurances**

***Investigator’s Assurances:***

I certify that the information contained herein is complete and accurate. I agree to conform to the procedures as described and to conduct the research with the highest respect and regard for the participants’ right to be protected from undue risk or invasion of privacy. If changes to the procedure become necessary, I agree to seek prior approval from the IRB.

In the case that a student is the principal investigator, if changes to the procedure become necessary, I agree to seek prior approval from the IRB as well as to inform my research supervisor and the Director of my program. Finally, I agree to keep my research supervisor informed of my progress and of any complications that may arise.

Name: Click here to enter text.

Signature: Click here to enter text. Date: Click here to enter text.

***Assurances of Faculty Research Supervisor:***

I certify that the information contained herein accurately represents the student’s complete and final research study and that it has been reviewed and approved by all responsible for the supervision of the work. I agree to periodically review the student’s progress and make sure that the procedures are being carried out as approved.

Name: Click here to enter text.

Signature: Click here to enter text. Date: Click here to enter text.

**INSTITUTIONAL REVIEW BOARD (IRB)**

**Conflict of Interest Disclosure Statement**

Name:Click here to enter text. Department/Unit: Click here to enter text.

Phone: Click here to enter text. E-mail:Click here to enter text.

An investigator has a **Conflict of Interest** in a research study when she/he or any member of his/her immediate family (spouse/spousal equivalent, parents, and children) has interests in the design, conduct, or reporting of the research that might compromise the integrity of the research. Conflicts of interest can be financial, personal, supervisory, academic, or professional. For further guidance, the University’s general Conflict of Interest Policy is set forth on the back of this Statement. The investigator has an ethical responsibility to disclose a potential conflict of interest or a possible appearance of a conflict of interest to the IRB and to potential research subjects as part of the informed consent process. If an investigator or his/her immediate family member is directly involved in potential subjects' health care, professional or academic supervision/evaluation, precautions must be undertaken to avoid the appearance of coercion or conflict of interest in the recruitment process. Please check all applicable boxes.

1. I and no member of my immediate family have any **financial conflict of interest** (a)that is related to or would reasonably appear to be affected by the proposed research; or (b) in external entities whose financial interests would reasonably appear to be affected by such activities.

2. I am disclosing the following **financial conflict(s) of interest**:

Salary, consulting fees, or other payments for services

Equity or ownership (stock, stock options, partnership interests or other ownership)

Intellectual property rights (patents, trademarks, copyrights, licensing rights, etc.)

Honoraria, royalties for books, publications or lectures, gifts or other payments

Positions in entity related to research (board member, officer, etc.)

Other financial interests that could affect or be perceived to affect the results of research or educational activities proposed for funding

3. I and no member of my immediate family have a **personal/professional dual role conflict of interest** related to this proposed research.

4. I am disclosing the following **personal/professional dual role conflict(s) of interest:**

Supervisory role as faculty/teacher, direct supervisor/manager

Healthcare provider

Family/friend relationships

Other

If you have identified any conflict of interest (numbers 2 and/or 4), please provide additional details below. Describe how the investigator plans to manage, reduce, or eliminate the conflict. Describe how any identified conflicts of interest will be managed

Click here to enter text.

I certify, as an investigator of this research, that I am in compliance with and will continue to comply with Plymouth State University’s policy and procedures pertaining to financial and/or personal/professional CONFLICT OF INTEREST. I further certify that I will comply with any conditions or restrictions imposed by the University IRB to manage, reduce, or eliminate actual or potential conflicts of interest.

***I attest to the accuracy of these answers and, should circumstances change in the future, I will contact the Plymouth State University IRB to update this disclosure statement.***

***Name:*** Click here to enter text.

Signature: Click here to enter text.

Date: Click here to enter text.

**\*All investigators listed on IRB application must complete and sign a conflict of interest form.**