APPENDIX C. REQUEST FOR REVIEW FORM

(This form is available at https://www.augustana.edu/academics/institutional-review-board)

Augustana Institutional Review Board
Request for Review of Research Using Human Participants

- Only faculty, administration, or staff may submit a Request for Review (RFR) form to the IRB (this excludes students).
- Electronic submission of this form and supporting documents must be made via electronic submission at: https://www.augustana.edu/academics/institutional-review-board
- Your answers to the following questions may be copied and pasted from a Word document or typed in.
- You should receive a confirmation email when the electronic submission of your RFR is completed.
- If the IRB committee requested modifications to your documents or proposal, please re-submit all updated documents to the IRB committee via electronic submission.
- Please allow a minimum of one week for review.

Principal Investigator and/or faculty adviser and email:

Student researchers and/or other investigator names:

Department:

Project Title:

Review of this project is requested on which basis:

____ Regular review. Complete all items and attach questionnaires, non-standard tests, consent forms, cover letters, and other supporting documents.

____ To confirm exempt status. Complete items 1 through 8. Under which exempt category, as designated in section D. of the IRB guide, do you think this project qualifies for exemption? (Give paragraph letter/number.) _____

Please type your responses to items 1-11 below. Add additional space as needed to give sufficient information for the committee to be able to evaluate the risks and benefits of your research project.

1. If any pre-approved departmental or other protocols will be followed for this project, please indicate the name of the protocol.

2. Brief Project Description. Please write for a lay audience and explain any technical terminology

a. Purpose, hypothesis, or research question:

b. Procedures:

3. Participants

a. Age and approximate number:
b. Inclusion/exclusion criteria, if any:
c. Method of recruiting:
d. Inducement for participation (include the source of any funding for participant compensation):
e. Are you collecting data on participants' gender identity?
If yes, provide the following options as responses to the question “What is your gender identity?”: woman, trans woman, man, trans man, non-binary, self-identify.
f. Are you collecting data on participants' biological sex?
If yes, provide the following options as responses to the question “What is your sex assigned at birth?”: female, male, intersex, self-identify.

4. Indicate the level of risk to participants: ___ minimal risk ___ moderate risk ___ significant risk

DO NOT state "no risk" in this request or on the copy of the Informed Consent document, as any intervention with human participants for the purpose of research contains inherent minimal risk. If there are no additional risks specific to your protocol, use both in this form and in your Informed Consent document the following uniform minimal risk language, or similar language, from the manual: "The risks to you by participating in this study are minimal. It is possible that you will experience mild, temporary negative emotions when responding to some of the study measures, but this risk is similar to those you encounter in your everyday life.

a. Please describe participant risk

b. Steps taken to minimize risk

5. Are illegal activities involved? (If 'yes,' describe)

6. Is deception involved (e.g., withholding information, providing misinformation, using confederates)? (If 'yes', please describe. Explain why it is necessary, explain how participants will be debriefed, and, if applicable, attach a copy of the debriefing statement.)

7. What are the anticipated benefits to the participants? If there are no direct benefits, say so.

8. How will informed consent be obtained? (Attach copies of consent forms and/or cover letters if they are to be used. Please see the Informed Consent Document checklist below.)

9. If extra credit is used as an inducement for participation, what alternatives for gaining extra credit are offered to participants?

10. Describe the procedures relating to the anonymity of participants, if applicable, and procedures for keeping participant data confidential and secure. For example, what documents or databases will contain names or participant numbers, who will have access to these, and how will they be physically or otherwise secured? When will the research materials gathered from or about individual participants be destroyed? Will the data be used in future studies? Are identifiers removed for future research?

By submitting this RFR to the Augustana IRB, I am agreeing that I have reviewed the Augustana College Policies and Guidebook for Research Involving Human Participants and I agree to adhere to the responsibilities of investigators as specified in Section B. I also agree to report any significant and relevant changes in the procedures or instruments to the Committee for additional review.

Continue to next page for Supporting and Informed Consent Document checklists

Supporting Document Checklist
Please check off the following items that have been submitted as supporting documents for this proposal. Generally, all should be submitted when applicable to the project. If an original document cannot be submitted, such as a national standardized test, a description should be provided.

____ Informed Consent Document (unless requesting a waiver)
____ Cover letter for solicitation of participants
____ Survey form
____ Interview questions or protocol description
____ Debriefing statement or protocol description
____ Other supporting documents (please list)
____ Certificate of Completion of Protection of Human Research Participants Training Module

Informed Consent Document Checklist
Please verify that the informed consent document and/or other cover materials contain the following (all of these items should be included in your consent form).

____ A statement that the study involves research
____ An explanation of the purposes of the research
____ The expected duration of the participant's participation
____ A description of the procedures to be followed
____ A description of reasonably foreseeable risks or discomforts to the participant
____ A description of any benefits to the participant or to others which may reasonably be expected from the research
____ A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained
____ An explanation of whom to contact for answers to pertinent questions about the research and research participants' rights, and whom to contact in the event of a research-related injury to the participant
____ A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and the participant may discontinue participation at any time without penalty or loss of benefits, to which the participant is otherwise entitled
____ For student projects, the names of the students and faculty/staff sponsor involved, and the course for which the research is being conducted or the requirement that is being satisfied
____ A statement of any publications, presentations or other expected outcomes of the study
____ The Augustana IRB approval notice: This research project has been reviewed and approved by the Augustana Institutional Review Board, which can be contacted at IRB@augustana.edu.
____ A statement describing that the data will be stored for five years after completion of the research, or if not retained, that the data will be destroyed at the conclusion of the study
____ A statement that the participant's de-identified data could be used for future research studies; or a statement that the data will not be used or distributed for future research studies.

Document Clarity and Language:
Have all documents that will be given to participants been reviewed by a native speaker for language use, inappropriate technical jargon, spelling, and grammar? __Y __N

Has the informed consent form been reviewed to verify clarity for the intended participants? __Y __N
(Particularly suggested when dealing with children, non-English speakers, etc.)

Attach human participant research training certificate for PI and all other research members

Comments or additional notes (please include previous approval number)

APPENDIX D. INFORMED CONSENT DOCUMENT REQUIRED COMPONENTS

Informed consent includes a clear explanation of the purpose, risks, benefits, and procedures involved in participating in a research project. The obligations and commitments of the researchers and participants also need to be explicitly stated.

The consent form is a written document provided to participants, containing information regarding informed consent. It also has lines for signatures and dates, and once signed, a copy should be offered to each participant.

The consent form needs to provide participants with an understanding of:

- the voluntary nature of their participation
- the purpose of the research
- the expected duration of their participation
- selection basis, including inclusion/exclusion criteria
- the procedures (where the study will take place, who will participate, what will be expected)
- possible risks and discomforts
- expected benefits to the subject or to others
- available alternatives or courses of treatment (if therapeutic)
- the confidentiality of their records
- participant reporting responsibilities
- who is conducting the study, including researcher name and contact information, and an offer to answer questions
- the plan for storage of their data
- the possibility of using their data in future studies, even if identifiers are removed
- participant rights, which include a statement about all of the following, where applicable:
    - confidentiality
    - compensation (or intervention in therapeutic studies)
    - ability to withdraw without risk (noncoercive disclaimer)
    - information on any changes in risks
    - knowledge of time and inconvenience
    - any change in use of procedures or materials
    - availability of results