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).
- Submission of this form and supporting documents should be made electronically 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:

Department:

Date Submitted:

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, sex, and approximate number:
- **b.** Inclusion/exclusion criteria, if any:
- **c.** Method of recruiting:
- d. Inducement for participation:
- 4. Indicate the level of risk to participants: ____ minimal risk ____ moderate risk ____ significant risk
- 5. Describe the risks and steps taken to minimize risks.

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

7. 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.)

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

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

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

11. 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
- _____ Oral interview questions or protocol description
- _____ Debriefing statement or protocol description
- _____ Other supporting documents (please list)
- _____ Certificate of completion of training

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
- A statement that participation is voluntary, refusal to participate will involve no penalty of 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 for English usage, 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.)