



Policies and Guidebook for Research Involving Human Participants

**Augustana College
Rock Island, IL**

FWA number: FWA00022229 (exp. 7 July 2028)
IORG number: IORG0008248 (exp. 13 October 2028)
IRB number: IRB00009887

1 September 2026

Preface

Federal regulations require that all research involving human participants be reviewed by an authorized institutional review board. Augustana policies extend this review requirement to include certain other activities other than generalizable research in which human participants may be put at risk. At Augustana, the Augustana Institutional Review Board (IRB) is a faculty/administrative committee that acts as the institutional review board.

This guidebook has been developed by the IRB to assist faculty, staff, and students conducting research involving human participants. It is designed to help you:

1. understand federal regulations and college policies regarding the protection of human participants in research
2. determine if a research or other activity needs review by the IRB
3. understand some common risks to research participants, and how to minimize them in the research design
4. understand the criteria and procedures for IRB review
5. prepare informed consent documents, if needed
6. prepare a request for review document for submission to the IRB
7. locate Internet resources relating to the protection of human participants

The committee is sensitive to the need to review proposals in a timely fashion and has established an electronic submission process for submitting proposals and an email process for facilitating review. The committee expects that most proposals suitably prepared in accordance with this guidebook can be reviewed within two weeks (occasionally longer if IRB regulations are not followed, modifications are requested, or sufficient votes for approval are not received).

For clarification of policies or procedures, please contact the IRB committee chair, IRBchair@augustana.edu. Please submit proposals for review using the online Request for Review (RFR) form available at: <http://www.augustana.edu/academics/institutional-review-board>.

This guidebook was reviewed and approved by the Faculty Senate in the 2002-2003 academic year but may be changed as the committee adjusts procedures or has a need to clarify items. As any changes are made, the most current version of the guidebook, the request for review form, a sample Informed Consent Document, and other IRB documents will be available electronically at: <https://www.augustana.edu/academics/institutional-review-board>.

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Augustana College Policies and Guidebook for Research Involving Human Participants

A. INTRODUCTION

Except where explicitly exempted below, ALL RESEARCH INVOLVING HUMAN PARTICIPANTS conducted at Augustana College, or under its sponsorship, must be reviewed and approved by the Augustana Institutional Review Board (FWA00022229, IORG0008248, IRB00009887), which acts as the College's institutional review board (IRB). This generally includes, for example, all surveys of students, even if done as part of a class project. The definitions and discussion of exclusions below should be helpful in determining whether a research project requires IRB review. Researchers in doubt should submit a request for review of research or contact the IRB Chair.

Requests for review of research should be made using the "Request for Review of Research Using Human Participants Proposal Form," which is available on the IRB website or in the appendix of this guidebook. All research proposals must be submitted using the online Request for Review (RFR) form available at <http://www.augustana.edu/academics/institutional-review-board>. General information regarding IRB structure, purpose, etc., can be found in Appendix A.

It is the general concern of the College that research done under its jurisdiction does not expose persons who participate as participants or respondents to unreasonable risks to their health, general well-being, or privacy. Specifically, the College is concerned that, in all research, instruction, and related activities involving the use of human participants:

- a. the rights and welfare of the individuals involved are adequately protected;
- b. participation is based on freely given, legally effective, informed consent; and
- c. risks to the participants are appropriately minimized and so outweighed by the sum of the benefit to the participant and the importance of the knowledge to be gained as to warrant a decision to allow the participants to accept those risks.

These policies also stem from the desire of the College to comply with federal regulations governing research on human participants and requiring the establishment of an institutional review board. Applicable Federal policy and regulations include:

- Protection of Human Subjects [Code of Federal Regulations 45 CFR 46, revised June 19, 2018, effective January 21, 2019]
<https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html>
- The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research
<https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html>

Additional web resource links can be found on the Augustana IRB website:

<https://www.augustana.edu/academics/institutional-review-board>.

Finally, in making research proposals, faculty and staff are asked to consider and respect the values of the college (see statement in E.9. below).

B. RESPONSIBILITIES OF INVESTIGATORS

The primary responsibility for assuring that the rights and welfare of human participants involved in research are protected rests with the principal investigator(s) conducting the research. This responsibility is shared by others engaged in the conduct of the research. Faculty who assign or supervise research conducted by students have an obligation to consider carefully whether those students are qualified to safeguard adequately the rights and welfare of participants.

All investigators should familiarize themselves with this guidebook, the Belmont Report, and the federal regulations on the protection of human participants cited above. Specific responsibilities of investigators are:

- a. Submit an adequately prepared RFR form for each research project involving human participants and to discuss with committee members any questions regarding proposed research activities; see Appendix C to view the RFR form.
- b. Complete an online training module on the protection of human subjects and provide proof of completion of the training course. This ensures all investigators involved in human subject research are prepared to protect the rights and welfare of their participants. Training is available through the CITI Program <https://about.citiprogram.org/>. Select Register and type in Augustana College. All investigators should complete training as appropriate in the role as a Augustana community member (student, faculty, staff, or IRB member). All investigators listed on the RFR form will be asked to show evidence of their completion of this course by attaching the Certificate of Completion to their electronic RFR submission. Faculty will be responsible for completing training every three years, and student investigators only once as undergraduates. Graduate students must complete training at Augustana before conducting research.
- c. Retain administrative records relating to an IRB approved project for at least three years following the completion of the project. This would include, for example, approval notices, signed informed consent documents (when documented informed consent is required), original copies of surveys, cover letters, other documents given to participants, and any documents necessary to demonstrate compliance with government and institutional regulations relating to human participant research. Research data relating to individual participants, such as completed surveys, video tapes, databases, etc., should be retained and destroyed in accordance with the protocol approved by the IRB as part of the RFR.
- d. Take proper measures to ensure confidentiality and security of all information obtained from the participants.
- e. Notify the IRB of any anticipated problems suffered by a participant or others including physical, psychological, or social injury due to participation in the research activity.
- f. Request a continuing review if the research extends beyond one year and requires a full IRB review to approve the project.

C. ACTIVITIES SUBJECT TO REVIEW

Unless it qualifies as an exempt activity as specified in section D, a project or activity is subject to review if:

- a. a procedure is introduced to gain information from or about the participant for scholarly and/or educational purposes; or
- b. information is used for a scholarly and/or educational purpose when that information was obtained because of the participant's status as client, patient, student, or employee; or
- c. the activity is a research activity involving human participants.

D. ACTIVITIES EXEMPT FROM REVIEW

Some research activities are exempt from formal IRB review. Being exempt from review by the IRB does not mean that a project is not required to meet the standards specified under this policy for protection of human participants, merely that the risks of harm appear to be sufficiently minimal that the investigator can be entrusted to assume this responsibility without the committee's overview. Further, it is the responsibility of the IRB committee, not the investigator, to determine if the research activities are exempt from review. Therefore, investigators should file a Request for Review form and indicate that an exemption is requested when completing research that qualifies as exempt from full review.

1. The following activities are *exempt* from formal review as per the Code of Federal Regulations Title 45, §46.104 if the principal investigator is a faculty or staff member.

- a. Research involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
- b. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human participants can be identified, directly or through identifiers linked to the participants; and (ii) any disclosure of the human participants' responses outside the research could reasonably place the participants at risk of criminal or civil liability, or be damaging to the participants' financial standing, employability, educational advancement, or reputation.

If a survey procedure is to qualify for exemption from review under this section, it must be completely anonymous and contain no sensitive questions or topics. For more information on the requirements for anonymity and sensitive personal information, please see the definitions in section F.

- c. Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection, unless: (i) information obtained is recorded in such a manner that human participants can be identified, directly or through identifiers linked to the participants; and (ii) any disclosure of the human participants' responses outside the research could reasonably place the participants at risk of criminal or civil liability, or be damaging to the participants' financial standing, employability, educational advancement, or reputation.
- d. Secondary research involving the collection or study of existing data, documents, records, or biospecimens, if these sources are publicly available, or if the information is recorded by the investigator in such a manner that participants cannot be identified, directly or through identifiers linked to the participants, the investigator does not contact the subjects, and the investigator will not re-identify subjects.
- e. Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, improve, or otherwise examine: (i) public benefit or service programs, (ii) procedures for obtaining benefits or services under those programs, (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.
- f. Taste and food quality evaluation and consumer acceptance studies (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the

level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

- g. Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.

The 2018 Revised Common Rule notes that particular types of projects (e.g., “oral histories, journalism, biography”) undertaken frequently by specific disciplines are often exempt given that they fall outside the definition of “research” (see section F). That is, if an oral history or a biography “collect[s] and use[s] [] information [] that focus[es] directly on the specific individuals” and is not a “systematic investigation... designed to... contribute to generalizable knowledge,” it is exempt from IRB review.

If, however, such an otherwise exempt activity meets the definition of research, it remains under IRB’s oversight. Consequently, all projects that involve human participants must still submit a Request for Review to determine their exempt status. If you are seeking an exemption for one of the above-listed projects, please explain clearly in your request why it is not research that contributes to generalizable knowledge and how the project will instead focus on the individual participants and their responses.

2. Additional activities qualifying for *exempt* from formal review include:

- a. the use of records for the administrative purposes of the College;
- b. the analysis and evaluation of information that is in the public domain if the report of the activity identifies no participant;
- c. the analysis and evaluation of physical traces or artifacts which do not stem from the introduction of an investigative procedure administered to human participants;
- d. doing the analysis and evaluation of existing research data if:
 - 1) the data were collected prior to the establishment of this review policy or the data were collected by individuals outside the College; and
 - 2) the report of the project identifies no participant;
- e. activities involving students in college courses if the activity only involves individuals enrolled in the course, the activity does not pose more than minimal risk to student participants, and:
 - 1) the activity consists of improving the curriculum of the course in which the participants are enrolled and the instructor believes the activities serve the specific educational goals of the course; or
 - 2) the project serves as a didactic device involving only individuals enrolled in the class; or
 - 3) the activity provides training in the conduct of such professional activities as interview procedures and the administration of standardized tests and involves only individuals enrolled in the class.

3. Student research done under faculty sponsorship is exempt *only* if it meets the criteria for course-related research. Course-related research projects are projects done as classroom assignments. Even if they do not contribute to generalizable knowledge, they may place participants at risk. Therefore, course-related research projects completed by students under faculty sponsorship must be reviewed unless ALL of the conditions below are true:

- a. The project is limited to educational tests, survey procedures, interview procedures, or observations of public behavior directly related to the topic(s) being studied in the course.
- b. Information recorded from the participants is anonymous and does not contain sensitive personal questions or cover sensitive topics that would place the participants at risk (see definitions in part F).
- c. The project does not assess a sensitive personality or psychological measure.
- d. The project does not involve deception or false feedback.
- e. The participants are not from a vulnerable population that requires extra protections (pregnant people, prisoners, children under age 18, individuals with an intellectual disability).
- f. The results of the assignment are confined to the course and to the participants.
- g. No instructor, investigator, or participant receives monetary compensation from an external source for collecting, analyzing, or reporting the results of the project.

For course-related research projects, all instructors should discuss research ethics and the protection of human participants with their classes prior to making research assignments.

E. OVERVIEW OF THE REVIEW PROCESS

1. Who May Submit a Request for Review

Requests for review of research must be submitted by members of the faculty, staff, or administration of the College. Proposals sent from students or individuals from another institution will not be accepted, and should be submitted by the faculty, staff, or administration sponsor.

2. Faculty Research

Augustana faculty conducting research involving human participants must conduct that research in compliance with federal codes, the ethical standards for research in their discipline, and Augustana policies. All research that involves Augustana students or other personnel as participants, uses Augustana facilities, is funded by Augustana, is represented as sponsored by Augustana, or that uses the faculty member's position at Augustana as part of the informed consent process to induce the participation of participants, is subject to these review policies. Additionally, Augustana faculty who participate as researchers in off-campus projects under non-college sponsorship have a professional obligation to verify that appropriate IRB approval has been granted for the project or to obtain appropriate IRB approval.

3. Cooperative Research

[Cooperative projects](#) are those projects involving more than one institution and may require approval by each institution's IRB. Individuals from an institution other than the College who wish to conduct research: on Augustana's campus; with Augustana faculty/staff/students; in conjunction with Augustana faculty/staff/students must be sponsored by a faculty, staff, or administrative member of the College before conducting research in any of the above capacities. If a research project is to be co-sponsored by Augustana and other institutions, documentation of the IRB proposal and approval at all co-sponsoring institutions should be submitted to the IRB using the regular IRB Request for Review form. In the "Other researchers" space, include outside affiliations in parentheses and indicate, if not Augustana, the PI(s) of the primary institution. Though IRB approval may be required at all participating institutions, a single institution's IRB (that of the PI) is responsible for review and regulatory oversight. Proposal documents, including the approval letter of the primary institution if outside Augustana, should be submitted using the electronic submission system by the Augustana faculty, staff, or administrative member. For projects in which the PI is affiliated with Augustana and Augustana is the primary institution, the outside research member should submit to their institution Augustana's approval letter.

4. Student Research

Students attending the College are bound by the same procedures and policies as the faculty and staff, with the additional requirement that student research projects must be sponsored by a faculty or staff member. The student's sponsor is responsible for informing the student of the necessary procedures and assisting the student in preparation of the forms and necessary documentation for submission to the IRB.

5. Completion of Training on Protection of Human Research Participants

All investigators listed on the RFR form, including faculty sponsors and student investigators, will need to complete an appropriate Human Subject Research training module. Augustana College provides training through CITI Program: <https://www.citiprogram.org/index.cfm?pageID=154&icat=0&ac=0®ion=1&message=0> (effective fall 2022, Augustana IRB no longer accepts other certifications, with one exception detailed below). This course prepares investigators involved in the design and/or conduct of research involving human subjects to understand their obligations to protect the rights and welfare of subjects in research. Faculty, staff, and administration submitting an RFR form will need to show evidence of the completion of training, which can be done by submitting a Certificate of Completion with the RFR materials. This certification of completion is required for all investigators listed on the RFR form. Research members unaffiliated with Augustana, if not participating in the certification for adults with disabilities described below, can create a CITI account using their personal email address while still selecting Augustana's training modules. Faculty will need to complete the training module every three years; undergraduate students must complete training only once while at Augustana. Students conducting research while enrolled in a Master's program at Augustana College must complete training before beginning any such research—preferably in their first year—irrespective of when any similar training was completed during their undergraduate studies either at Augustana College or another institution.

Research Ethics for All (RE4ALL, <https://re4all.org/>) “provides community research partners with developmental disabilities accessible education in ethical issues in social and behavioral research with people.” Training through RE4ALL will be accepted only for research projects that include adults with disabilities as members of the research team. The PI of such projects must be CITI certified and include their CITI certificate with the RFR. Once the PI is trained using the RE4ALL materials and is able to subsequently train and certify the remaining research members, their RE4ALL certificates must also be included with the request.

6. Deadline for Submission of Requests for Review

Requests for review can be submitted at any time through the IRB website using FormStack. Reviews are generally conducted via email, with review typically requiring at least seven business days (K.3.b). Proposals that involve more than minimal risk may require a full review (K.3.a) and a meeting of the IRB committee; however, advisors will be notified when that is the case. Meetings are scheduled on as needed based each semester. When possible, submission of requests for review should be made before finals week during the semester, and summer requests should be kept to a minimum and may take several weeks to approve.

7. Review Criteria

When reviewing research proposals, the IRB primarily is interested in safeguarding the rights and well-being of the human participants and in assessing the ethical implications of the proposed procedures. In these contexts, the IRB may pass judgment on “research design,” but only to the extent that such design affects the rights or well-being of human participants. In analyzing the risk/benefit ratio of a research activity, both the stated purpose and the scientific merit of the research will be considered. Therefore, the research must be described to the IRB in a clear and complete manner that allows adequate review of all these aspects of the research.

To approve research covered by this policy, the IRB shall determine that all of the following requirements are satisfied:

- a. Risks to participants are minimized by using procedures that are consistent with sound research design, and which do not unnecessarily expose participants to risk.
- b. Risks to participants are reasonable in relation to anticipated benefits, if any, to participants, and the importance of the knowledge that may reasonably be expected to result. The IRB will consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (e.g., the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.
- c. Selection of participants is equitable. For example, research that might benefit all gender identities should ordinarily include all gender identities as participants. The IRB will be particularly cognizant of the special problems of research that involve a category of subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.
- d. When appropriate, informed consent will be sought from each prospective participant or the participant's legally authorized representative, and properly documented.
- e. When appropriate, the research plan makes adequate provision for monitoring and storing the data collected to ensure the safety of the participants.
- f. When appropriate, there are adequate provisions to protect the privacy of participants, and to maintain the confidentiality of data.
- g. Additional safeguards have been included in the study to protect the rights and welfare of students if their participation as participants is part of a course requirement or is otherwise coerced.
- h. All documents presented to participants (e.g., informed consent forms, cover letters, survey instruments) are clear in explanation and meet reasonable standards of professionalism in design and usage of language appropriate for the participants so as to not compromise standards for informed consent or be unsuitable for the research intent. Research that requires documents in languages other than English must be reviewed for clarity, professionalism, and appropriateness by a native speaker of the language with an accurate translation submitted with the RFR to the IRB in addition to the original-language documents.
- i. In any study that involves the ingestion of materials (e.g., pharmaceuticals, herbal teas, etc.), a physician's statement should be filed with the request for review that assesses the risk of the material

for the average person, and any restrictions that should be placed on the use of the material or in the selection of participants. The committee may waive this requirement for clearly benign substances such as ordinary foods taken in ordinary amounts.

In applying these criteria, the committee has adopted the following as general guidelines:

For benign studies in which there is minimal apparent risk to the participant, the faculty sponsor should be considered responsible for the methodology of the study and the professionalism of materials, and the IRB will generally not make stipulations requiring changes. The committee may pass along comments or suggestions, however.

For anonymous surveys that request incidental private data but otherwise do not ask sensitive questions or deal with sensitive topics, the methodology will be reviewed to the extent that it is relevant to ensure privacy and confidentiality of data during gathering, storage, and reporting. For example, anonymity should not be compromised in reporting by the ability to disaggregate responses.

So that the college is reflected favorably, the committee will expect that high standards of professionalism in aspects such as survey design and use of language will be met in any research materials to be distributed off campus. Any documents not in English, whether used off-campus or presented to participants, must be reviewed by a native speaker, and an English translation must be included in the RFR materials in addition to the original-language documents.

In any study that involves more than minimal risk, including those that deal with a highly sensitive topic or involves the possibility of physical, social, or psychological harm, the committee will assess fully the research design, the extent to which knowledge is likely to be gained, and the benefits of any new knowledge likely to come from the research. For such studies, the proposals should have a clear research hypothesis, the rationale for the research hypothesis should be explained, and researchers should have completed a literature review and be able to explain the contribution of the knowledge to be gained from the research to the research literature. The rigor of the methodological review may vary with the degree of risk, but above minimal risk proposals should be expected to be scientifically competent and involve a research question of significance.

8. Continuing Review

For investigations lasting more than one year from the date of approval, the principal investigator must advise the IRB annually as to the status of the project, including an explanation of any changes in protocols. Substantial changes to a project must be approved by the IRB. This requirement is applicable to research requiring review by the convened IRB at intervals appropriate to the degree of risk. Continuing review is not required for research that is approved under exempt review, or for research that involves data analysis of an IRB-approved study. The updated documents for continuing review can be submitted to the IRB chair using the electronic submission system.

9. Special Institutional Review

Federal policy stipulates that research approved by an IRB may be subject to further appropriate review by institutional officials, although officials may not approve research if it has not been approved by an IRB. At Augustana, special institutional reviews, when deemed necessary, will be conducted as specified below.

The ethical principles of the Belmont Report for treatment of human participants, namely respect for individuals, beneficence, and justice will be the primary ethical criteria for the standard review by the IRB. In exceptional cases, however, the IRB, Faculty Council Chair, or President may request an additional review of research that has been approved by the IRB in order to consider broader institutional considerations. This institutional review shall be conducted by an especially constituted review committee to be appointed for the purpose by the Nomination and Rules Committee and shall consist of four randomly selected tenured faculty, one from each division (but excluding members of the same academic department as the faculty investigator/sponsor of the proposal). In addition, the committee shall include as non-voting members a faculty liaison from the IRB and a non-cabinet level administrator appointed by the Dean of the College. No member should have a conflict of interest relating to the specific proposal. The institutional review will be based on the values of the college as approved by the Board of Trustees:

The primary and clarion values of the College community are those values associated with authenticity—truthfulness, excellence, genuineness, and faithfulness to mission. As evidence of our commitment to these values, we seek to:

- a. cherish academic excellence*
- b. foster critical thinking, creativity, and an active life of the mind*
- c. encourage both intellectual and spiritual development*
- d. embrace diversity, civility, integrity, and respect for others*
- e. respect academic freedom and traditions of academic governance*
- f. ensure a student-centered approach and attitude*
- g. act collaboratively within the College while seeking partnerships within the community*
- h. remain accountable to our students and to our mission*

F. DEFINITIONS

Activities within the scope of the IRB's responsibilities include research and related activities that normally would be construed as biological, behavioral, or psychological investigations involving human participants.

For the purposes of IRB review, the College stipulates the following definitions:

1. Research: A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute "research" for the purposes of this policy whether or not they are considered research in other contexts. Research activity typically would include the following:

- a. Persons or programs requesting extramural (federal, state, or private) funds for research or training.
- b. Individual faculty members (as well as members of the staff and administration) engaged in research as part of their professional role within the College or as part of their job assignment.
- c. Students performing research as part of an independent study or senior project.
- d. Individuals (including students or persons from outside the College) other than faculty, staff, or administration, conducting research at the College.

2. Human subject (participant): A living individual about whom an investigator (whether professional or student) conducting research:

- a. obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
- b. obtains, uses, studies, analyzes, or generates identifiable private information or biospecimens.

3. Minimal Risk: The probability and magnitude of harm or discomfort anticipated in the 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. (Investigators have the obligation to request a clarification by the IRB regarding activities or procedures that are seen by the investigator as questionable in terms of their inclusion in this description.)

4. Benefit: A research benefit is considered to be something of health-related, psychological, or other value to an individual research participant, or something that will contribute to the acquisition of knowledge that is reasonably expected to result. The long-range effects of applying knowledge gained should not be considered benefits from the study. Money or other compensation for participation in research is also not considered to be a benefit, but rather compensation for research-related inconveniences.

5. Anonymous procedures: Research procedures are anonymous to the extent that the identities of the participants are unknown and unknowable by the researchers and other individuals. To be anonymous, the research materials must (a) contain no personally identifiable information (names, ID numbers, etc.), (b) not contain such detailed demographic or other information that identities may be inferred indirectly, and (c) be gathered in a manner that preserves the privacy of the participant. For survey research specifically, the privacy provision requires that the participants be given the opportunity to use a private space to complete the survey and that privacy be maintained when the survey is collected. In a computerized survey, privacy of the computer screen must be ensured.

6. Children: Persons who have not attained the legal age (18 years old) for consent to the treatment or procedures involved in the research.

7. Consent form: A form containing all relevant research information explained in lay terms and documenting voluntary participation. It includes a statement about potential risks and must address each of the twelve elements required by the federal regulations (see the basic elements of informed consent list below). This is presented to and signed by the participant or legally authorized representative. An original is retained by the investigator as part of the participant's record, and a copy is provided to the participant.

8. Informed consent: The *process* of information exchange between researcher and participant prior to written consent to participate in research. Information includes recruitment information, written materials, verbal instructions, and question and answer sessions about the research and its procedures. Participants are given the opportunity to choose research involvement based on information, comprehension, and willingness to volunteer.

9. Private information: Includes information about behavior that occurs in a context in which an individual can reasonably expect that that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (e.g., a medical record or academic record). Private information must be individually identifiable (i.e., the identity of the participant is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human participants.

10. Sensitive personal information: Personal information is sensitive if disclosure of the information might damage the person's financial standing, employability, or reputation, or embarrass the individual. This includes, for example, information about alcohol/drug use, sexual behavior/attitudes, criminal activity, violent or antisocial behavior, medical history, grades/test scores, or financial resources. This also includes psychological or personality measures that might stigmatize or emotionally upset participants, even if the information is not disclosed to anyone other than the participant.

11. Vulnerable participants/population: Individuals/groups that cannot give informed consent because of limited autonomy (e.g., children, prisoners, individuals with intellectual disability), or who may be unduly influenced to participate (e.g., students, subordinates, individuals who are terminally ill).

12. An identifiable biospecimen: A biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

13. Legally authorized representative: An individual or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

G. IDENTIFYING, ASSESSING, AND MINIMIZING RISKS

All research with human participants involves some measure of risk to those participants. Risks to participants may result from the interventions involved in the research, validity design features, or the procedures for handling private or confidential information. Risks may be physical, psychological, social, or economic.

The risk of *physical harm* involves exposure to minor pain, discomfort, or injury.

Psychological risks include changes in thought processes and emotions, such as depression, feelings of stress or guilt or embarrassment, confusion, or loss of self-esteem. Psychological risks can occur in surveys or interviews by simply asking participants to think about sensitive subjects such as drug use, sexual preferences, or violence. They may result from experimental techniques that alter the participants' environment, such as in experiments that gauge reactions to fake emergencies. The risk of psychological harm is particularly pronounced in behavioral research when deception is used, especially if false feedback is given to participants about their performance on tests, psychological measures, etc.

Social or economic risks include social embarrassment, loss of status, loss of employment, or criminal prosecution. Particularly sensitive is research involving alcohol or drug abuse, sexual behavior, illegal activities, medical conditions or mental illnesses that might stigmatize an individual, such as in HIV research.

Invasion of privacy is a risk that involves access to a person's body or behavior without consent. In observational studies, it may result from observation of behaviors that the participant considers private.

Breach of confidentiality results when data that are voluntarily provided by a participant for a restricted context are used in another context without consent. Reducing this risk involves safeguarding data from improper disclosure, both by physically controlling access to data and by not reporting data at a level of detail that might allow an individual's identity to be ascertained.

H. SUGGESTIONS FOR MINIMIZING RISK

Ensuring Anonymity/Confidentiality/Privacy

A procedure is *anonymous* to the extent that the identities of the participants are unknown even by the investigators and that identities cannot be construed from the materials gathered. A procedure is *confidential* if identities are known to the investigator(s) but kept secret. If a study might involve risk and the identities are not needed, it is best to conduct the study anonymously.

A survey, for example, might be done anonymously by not requesting personally identifiable information or such detailed information that an individual could be identified indirectly and by reporting information only in a form sufficiently aggregated that no individuals can be identified by implication. The ability to infer individuals should be considered carefully when asking about sensitive, potentially embarrassing, or illegal matters. For instance, if the sample for a study contains only one or two senior biology majors who identify as women, asking participants for their gender, class, and major, or reporting results for this subgroup, would compromise anonymity. To minimize this risk, surveys should not ask for information at a level of detail beyond that which is needed and reasonable for the study. For example, individual majors would be unlikely to be useful in a research design intended to generalize about all Augustana students based on a sample of size 100. Instead, groupings of majors, such as natural sciences, social sciences, etc., might be more suitable for the research design and also provide more anonymity for the participants.

In repeated measures designs, it may be possible to maintain a high level of anonymity within the participant group by the use of pseudonyms. This involves having the participants report their data, or otherwise gathering the data, using a fictitious name assigned to or selected by each participant. For example, if participants complete a weekly survey of activities, they might report it using a pseudonym or code that they choose that is easy for them to remember and that only they know.

In some cases, using a randomly-assigned participant number with data and documents, rather than a name, may be helpful to protect identities from inadvertent disclosure. If a list linking the participants' identities to their numbers is kept, it should be kept secure, physically stored in a place separate from the other data, and destroyed on completion of the project.

Faculty sponsors should seek research designs that minimize access to sensitive information about individually identifiable participants by student researchers. It may be desirable to use numerical identifiers, with the linking list kept in confidence by the faculty sponsor.

Confidential materials should be kept secure using such devices as locked offices and cabinets, computer passwords, etc. If they pose a risk, materials that might identify participants should be destroyed when no longer needed or at the end of the project.

Researchers should be concerned about the privacy of participants while they are participating in research activities. Good practice in conducting a survey involving sensitive topics, for instance, would include providing a private space for completing an online survey, and, if it is to be turned in directly to the surveyor, providing a means to hand it in anonymously, such as individual, sealed envelopes and/or placing the completed forms in a sealed ballot-type box or large envelope. The privacy of the computer screen should be considered in online surveys.

I. MINIMAL VS. MORE THAN MINIMAL RISK

Risks may vary from minimal to significant. Following federal policies, only a definition of minimal risk is given, as stated in the definitions. The following would be examples of common types of research done at Augustana that would, unless unusual, be considered minimal risk by the IRB:

- a. Surveys on non-sensitive, non-controversial, and non-private issues. (Surveys that ask about sexual practices or orientation, substance abuse, illegal activities, physical or mental disabilities, parental or

student income, grade point averages, or ACT/SAT scores, for example, would *not* fall into this category.)

- b. Anonymous surveys, interview procedures, or observation of public behavior, where information is obtained, recorded, and reported in such a manner that none of the human participants can be identified directly through identifiers linked to the participants or inferentially from recorded or reported data.
- c. Research on cognitive processes such as memory or response times where deception or the loss of self-esteem is not involved.
- d. Physical studies involving the participants' normal activities and that do not add to the participants' risk of injury. (Note that some normal activities, such as sports activities, may under some conditions be deemed to involve added risk when done as part of a research protocol. A weight-lifting methods study, for example, might have different levels of risk depending on the experience of the participants, the risks of the maneuvers, and other conditions of the study.)

Research that involves no more than minimal risk must still state so both in the Request for Review (RFR) and the Informed Consent Document (ICD) (i.e., investigators cannot claim that no risk is involved). Requests that state "no risk" on the RFR and/or ICD will be returned with a request for modification or resubmission. If there are no specific risks associated with your research, you may use the following uniform language (or some variation thereof) for the general minimal risk that accompanies research with human participants: "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."

J. INFORMED CONSENT

Informed consent refers to a person's freely given decision to participate in a research project based on full knowledge of relevant aspects of the project and the implications of the participation for the participant's welfare. See Appendix D for the list of required components for an informed consent document.

1. Federal Guidelines for Informed Consent

No investigator may involve a human being as a subject in research unless the investigator has obtained the legally effective informed consent of the participant or the participant's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

2. Basic Elements of Informed Consent

In seeking informed consent, the following information shall be provided to each participant or the representative:

- a. a statement that the study involves research
- b. an explanation of the purposes of the research
- c. the expected duration of the participant's participation
- d. a description of the procedures to be followed
- e. identification of any procedures that are experimental
- f. a description of any reasonably foreseeable risks or discomforts to the participant
- g. a description of any benefits to the participant or to others which may reasonably be expected from the research
- h. a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant
- i. a statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained
- j. for research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained

- k. 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
- l. a statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the participant otherwise is entitled, and the participant may discontinue participation at any time without penalty or loss of benefits to which the participant otherwise is entitled
- m. for research involving the collection of identifiable private information or identifiable biospecimens, a statement that identifiers might be removed from the data and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies, if this might be a possibility; or a statement that the subject's information or biospecimens will not be used or distributed for future research studies
- n. 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.

When appropriate, additional elements of informed consent shall also be provided to the participant:

- a. a statement that the particular treatment or procedure may involve risks to the participant which are currently unforeseeable
- b. anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the participant's or representative's consent
- c. any additional costs to the participant that may result from participation in the research
- d. the consequences of a participant's decision to withdraw from the research and procedures for orderly termination of participation by the participant
- e. a statement that significant new findings developed during the course of the research which may relate to the participant's willingness to continue participation will be provided to the participant
- f. the approximate number of participants involved in the study.

When written consent cannot be obtained, a short form written consent document stating that the elements of informed consent have been presented orally to the participant is required. When this method is used, there shall be a witness to the oral presentation. Additionally, a verbal script of what is to be said to the participant must be submitted with the protocol. The participant shall sign the short form, and the witness shall sign both the short form and the verbal script. Finally, the individual obtaining consent shall sign the verbal script.

3. Additional Notes Concerning Informed Consent for Augustana Research Projects

For most surveys, the basic elements of informed consent may be stated in the preface to the survey and/or an accompanying cover letter. Completing and submitting the survey then will be construed as consent. When informed consent is sought for participation in other types of research, the informed consent form should clearly indicate the department of the faculty sponsor, preferably by using the appropriate Augustana letterhead (or a photocopy). It also should include a signature and date line for the participant and the researcher. Each participant should be offered a copy of their signed informed consent form. Documentation of informed consent is required only in research involving more than minimal risk.

Studies that offer extra credit for participation in research studies should take note of item l. in the list of basic elements of informed consent. If extra credit is offered, reasonable alternatives for earning equivalent credit should be offered prior to obtaining informed consent to those who choose not to participate in a study. Once participation begins, participants who choose to withdraw may not be penalized by the loss of any extra credit offered. If an instructor plans to include extra credit research participation as part of a course, information and policies on extra credit and alternatives should be included in the course syllabus.

K. IRB PROCEDURES AND ADMINISTRATION

1. Membership

The IRB is a standing college committee with responsibility primarily to the administration. The IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities conducted at the College. The IRB shall be sufficiently qualified through the experience and expertise of its members (professional competence) and the diversity of its members, including race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. The specific membership structure is as follows:

- a. The chair of the committee is to be appointed by the President or Provost.
- b. The administrative member is the Dean of Students or a designee from the Dean of Students Office.
- c. Five other faculty beyond the chair appointed by the Nominations and Rules Committee for three-year staggered terms. Faculty members should represent at least three divisions. At least one member should have research experience that does not involve human participants; at least one member should have research experience that primarily includes human participants.
- d. One outside member, appointed by the chair on the advice of the committee, who is not affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.
- e. One advocate for incarcerated individuals, appointed by the chair, who votes as an *ad hoc* member on requests for reviews that involve participants who are incarcerated (see below)
- f. Two student members (non-voting) who discuss and vote on changes to policies and protocols
- g. The committee should have diverse representation in all its forms.

The most current IRB membership roster can be found in the college-wide list of committee membership published by Nominations & Rules.

The IRB may, at its discretion, invite individuals with competence in special areas to assist in the review of issues requiring expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

[Subpart C of the Common Rule](#), 45 CFR 46, requires additional protections for participants who are incarcerated. As a vulnerable population, incarcerated individuals are especially susceptible to coercion and feelings of pressure in violation of the voluntary nature of participation in research. Whenever incarcerated people are participants, the prisoner advocate *must* review the request. If federal funding supports the research project, the prisoner advocate must still review the request, and additional certifications with the government are required (see the link above).

The prisoner advocate, selected by the chair, “shall be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity[.]” As per the Cooperative Research policy, only one institution—that of the PI—needs prisoner advocate approval for such projects. If the designated prisoner advocate submits their own review request to conduct research with incarcerated individuals, the chair will designate a back-up prisoner advocate for just that review under the regulation that no IRB member can review their own request.

The duties of the prisoner advocate are to ensure that the following federal protections are followed (as found in 45 CFR 46 Subpart C §46.305):

- (1) The research under review represents one of the categories of research permissible under [§46.306\(a\)\(2\)](#);
- (2) Any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired;
- (3) The risks involved in the research are commensurate with risks that would be accepted by nonprisoner volunteers;
- (4) Procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the principal investigator provides to the Board justification in writing for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project;
- (5) The information is presented in language which is understandable to the subject population;
- (6) Adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole; and

(7) Where the Board finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact.

2. Meetings

The IRB committee meetings are scheduled as needed. Contact the IRB Chair to request a meeting. The IRB conducts requests for review via email, occasionally supplemented by telephone conversations. No research proposal will be disapproved without a full review by the committee. Applicants should allow for at least seven days for the committee to make an initial review of a proposal when school is in session.

3. Procedures for Review and Approval

- a. Full Review. Upon receipt of request for review materials using the online submission process, the IRB Chair will conduct a preliminary review within three business days to ensure submissions are complete and appropriate attachments are present and that the necessary description of the research is provided. The online submission of the RFR form will provide evidence of the investigator's request for review. Proposals (a) with more than minimal risk (social/emotional, moderate, or significant risk), (b) with vulnerable populations, or (c) that involve deception require full review by the entire IRB committee and a majority vote for approval.
- b. Expedited Review. The IRB Chair is authorized to review under expedited protocol proposals that do not meet one of the three criteria above for full review. If the Chair determines after preliminary review that the proposal (a) does not involve more than minimal risk or is a renewal of an already-approved research project in which no substantive changes have been made, (b) does not involve vulnerable populations, and (c) does not involve deception, the proposal qualifies for expedited review. Expedited proposals are approved within the same timeline as proposals undergoing full review: at least seven business days following the Chair's preliminary review. The difference is that, given the lower risk assessment, the Chair along with two other members of the committee may act with the authority of the committee to approve the request for review but may not deny research proposals, instead referring the request for review to the entire committee. The Chair will send all committee members copies of proposals that are approved on an expedited basis and allow three business days for committee members to object.
- c. Exempt Status. The Chair also will make a determination on requests for exempt status. If the Chair determines that the activity should be exempt from review, the Chair will notify the committee members and allow three business days after the Chair's preliminary review for committee members to object. If there are no objections within three business days, the request is approved by consent.
- d. If the research proposal is deemed not exempt and requires regular review, the IRB Chair will distribute the request for review materials to all committee members.
- e. Deliberation on the request for review may be via email or at a convened meeting. If email deliberation is deemed suitable, it will be conducted as follows:
 - 1) After sending the materials, the Chair shall set a timely deadline for member email discussion and voting, ordinarily one week. Email comments and votes included in the committee's deliberation should be sent to all committee members.
 - 2) The Chair may attempt to resolve reservations or concerns of committee members with the applicant prior to determining the final vote.
 - 3) Approval of the research proposal via email will require unanimous vote by a quorum of members including the Chair.
 - 4) If approval is granted, notice of the approval, including any restrictions, will be emailed to the applicant with a carbon copy to all committee members.
 - 5) If the vote is not unanimous, approval will be neither granted nor denied, and the Chair shall convene a regular meeting to consider the request for review.
- f. The investigator may be asked to provide additional information or to appear in person before the committee to present a full explanation of risks and protection for the human participants. Any investigator may ask to appear before the committee to describe the proposed research.

- g. The committee may invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available to the committee. Such individuals shall not vote.
- h. A necessary quorum for the IRB to consider a proposal is a majority of the total membership.
- i. Minutes will be taken at all IRB meetings. The minutes will include the members present, a record of all actions, the tally of votes for and against all research proposals, and a brief description of the discussion of all disputed items. Records will be retained by the IRB for a period of three years.
- j. A member may not participate in the proceedings in which they have a conflict of interest, except to provide information requested by the committee, and should be absent from the room during the committee's deliberations. As the chair must review all requests, research proposals submitted by the chair will be overseen by a *chair pro tem*, designated by the chair and selected from the regular members, whose limited role is to preliminarily review, distribute to the committee, and approve the chair's proposal.
- k. The IRB will decide by a majority of the members present: (a) to approve the proposal, (b) to approve the proposal with modifications, (c) to defer approval of the proposal, pending modifications in the request for review or receipt of additional information from the investigator or consultants to the IRB, or (d) to deny the proposal.
- l. The IRB Chair will inform the principal investigator in writing of the decision of the committee.
- m. If a proposal is approved subject to modifications: (a) the IRB Chair or designated member will communicate these in writing to the investigator, (b) modifications in the proposal made by the investigator should be submitted electronically to the committee, (c) the IRB Chair or a designated member will be responsible for review and approval of the investigator's submitted modifications, (d) if the Chair or designated committee member determines that the modifications do not address the committee's concerns, the investigator will be requested in writing to submit the proposal to the full committee for further review.
- n. If a research proposal is denied, the notice shall include a statement of the reasons for the decision, and the investigator shall be given an opportunity to respond in person or in writing. Denial may be appealed by requesting re-review of the proposal.
- o. The IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with IRB requirements or that has been associated with unexpected harm to participants. A list of the reasons for any suspension or termination will be provided to the investigator, appropriate institutional officials, and department chair.

Portions of this guidebook have been adapted from the "Code of Federal Regulations, Title 45, Part 46," the "Institutional Review Board Guidebook" of the Office of Human Research Protection, U.S. Office of Health and Human Services, the "Policies & Procedures of the Institutional Review Board for the Protection of Human Subjects" of the University of Scranton, and the human research guidelines of the University of Iowa.

APPENDIX A. IRB COMMITTEE GENERAL INFORMATION

Augustana Institutional Review Board (IRB)

1. Formation of the Committee

Formed as a committee primarily responsible to the administration in response to federal regulations requiring all institutional research involving human participants be reviewed by an authorized IRB. At Augustana, policies extend this review requirement to include certain other activities in addition to generalizable research in which human participants may be put at risk. The committee formed when the federal regulations were enacted.

2. Committee Membership

Committee membership is dictated, in large part, by the federal regulations, which require at least five total members. Membership for the 2025-2026 academic year is as follows (term limits indicated in parentheses):

Megan Lorenz, chair (2029)
Meg Kunde (2027)
Lisa Milford (2027)
Jeff Mettler (2028)
Young Yoo (2028)
Michelle Hinzman-Ferris (2029)
Katherine E. Brown, incarcerated persons advocate (appointed by chair)
Damilola Ajayi, administrative member (2028)
Eric Welsh, community member (2027, one-year term, renewable)
Cristina Costa, non-voting student member (2027, one-year term)
Avery Spacek, non-voting student member (2027, one-year term)

3. Appointments

The chair has traditionally been held by either a faculty member or an administrator. The chair is appointed by the Academic Dean or the President of the College.

- a. Current chair is Megan Lorenz (2029)
- b. Additional faculty members are appointed by the Nominations and Rules committee for 3-year terms.

4. Purpose

Committee is unique and necessary. Its purpose is twofold:

- a. To review research and scholarly investigations that involve human participants on our campus.
- b. To review research and scholarly investigations that a member of our campus is conducting on off-campus participants.

5. Workload

Workload on this committee is substantial and continues throughout the academic year, with some work required over the summer.

- a. Chair coordinates all reviews via email; meetings called when questions/problems arise.
- b. Chair keeps all records and electronic copies of approvals.
- c. Majority of business conducted via email; ~1,000-1,200 emails generated per year.
- d. Committee receives and reviews ~130 proposals per year.
- e. Chair spends ~6 hours per week throughout an academic year.
- f. Members spend ~2-3 hours per week throughout an academic year.

APPENDIX B. ELECTRONIC RESOURCE LINKS

Code of Federal Regulations Title 45 Part 46: Protection of Human Subjects (2018 Requirements):

<https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html>

Informed Consent Checklist:

<https://www.hhs.gov/ohrp/regulations-and-policy/guidance/checklists/index.html>

Informed Consent Tips:

<https://www.hhs.gov/ohrp/regulations-and-policy/guidance/informed-consent-tips/index.html>

The Belmont Report:

<https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html>

U.S. Office of Health and Human Services, Office for Human Research Protection:

<https://www.hhs.gov/ohrp/>

CITI Program Human Participant Research training. From the link, type in Augustana College, and choose the appropriate Course Learner Group (Student, Faculty/Staff, IRB member).

<https://www.citiprogram.org/index.cfm?pageID=154&icat=0&ac=0®ion=1&message=0>

Augustana Institutional Review Board online Request for Review (RFR) form and Policy Manual:

<https://www.augustana.edu/academics/institutional-review-board>

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 two weeks 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

APPENDIX E. PROTOTYPE INFORMED CONSENT DOCUMENT FOR STUDENT PROJECT

This prototype document may be used as a starting point for an informed consent document. If used, it should be adapted as needed for particular projects. A copy should be offered to each participant.

Informed Consent for Research Participants

Augustana College Department of _____
Faculty Advisor's Name:
Student Researcher(s) Name(s):
Research Project Title:

Purpose and Description of this Research Project:

Description of the involvement by participants (procedures, duration, possible risks, or benefits):

The faculty/staff sponsor that is available to answer any question regarding your participation is _____ and his/her contact information is _____@augustana.edu.

This research project is a class project for (name of course or specify the requirement).

This research project has been reviewed and approved by the Augustana Institutional Review Board, which can be contacted at IRB@augustana.edu.

I hereby give my consent to participate in this research study. I understand that:

(Edit, add, or delete items as appropriate for your research project.)

- I must be at least 18 years old to participate in this study.
- My participation is entirely voluntary, and I may terminate my participation at any time prior to the completion of the study without penalty.
- Any information I may give during my participation may be recorded and will be employed for research only and will not be used in future studies.
- Any information I may give will be kept confidential and physically secure.
- The results of this study will be reported without identifying individuals directly, and any reported statistical data will be aggregated so as to make indirect identification of individual participants very unlikely or impossible.
- Any information provided by the participants will be kept either without any personal identifiers, or identified only by participant numbers. If participant numbers are used, the data and name/participant number list will never be stored in the same location or in the same computer.
- The research materials gathered from individual participants, e.g. survey forms, tape recordings, etc., will be destroyed ... (Specify: e.g., upon completion of the research report, within 5 years after completion of the research report, etc.)

Signature of Participant: _____ Date: _____

Signature of Investigator: _____ Date: _____

APPENDIX F. PROTOTYPE INFORMED CONSENT DOCUMENT FOR COMPUTER SURVEY

Description of the Study and Recruiting Statement

"Early Feeding and Prelinguistic Vocal Behaviors in Infants and Toddlers Who Later Were Diagnosed with CAS"

This survey is being conducted by undergraduate student Jessica xx, and supervised by faculty adviser Kathy Jakielski, Ph.D., CCC-SLP, at Augustana College in Rock Island, Illinois, as part of Ms. xx's senior thesis research. We are trying to determine if children who were later diagnosed with CAS exhibited early signs of feeding and/or pre-speech delays.

This survey is intended to be completed by a primary caregiver of a child with CAS, with only one set of survey responses completed for a single child.

If you are a primary caregiver of a child who has been diagnosed with CAS, then we would appreciate your help in completing this survey. The survey takes approximately 20 minutes to complete and it must be finished in one setting (that is, it cannot be saved and returned to later). It is possible that you may feel discomfort when asked questions about your child's diagnosis of CAS. You are welcome to skip any questions you wish not to complete, or discontinue the survey at any time without penalty. There are no direct benefits to you to completing the survey.

By submitting your responses, you are consenting to participate in the study. The survey is anonymous and your name will not be included in any publications or presentation of the research. We will retain the anonymous survey results for no more than five years. Your data will be employed in this research only and not in any future research studies.

This study has been approved by the Augustana College Institutional Review Board, which can be contacted at IRB@augustana.edu. Dr. Jakielski can be reached by phoning (309) 794-7386 or by emailing kathyjakielski@augustana.edu.

Results of this study will be published in an upcoming Apraxia-Kids newsletter and a link to the study results will be available via the Apraxia-Kids website.

By clicking on the "continue" button, you can begin the survey. Thank you for your participation!

APPENDIX G. SAMPLES OF COMPLETED PROPOSAL DOCUMENTS

Below is a sample research proposal. The level of detail required increases with the potential risks to participants and should be sufficient to allow the committee to make a determination based on the review criteria specified in the guidebook, including the ability to estimate both the benefits and risks of the research.

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

Principal Investigator and/or faculty adviser: John Smith, Jane Doe, Dr. Bell, faculty adviser

Department: Psychology

Date Submitted: February 8, 2010

Project Title: Effects of Study Habits on College GPA

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 7. Under which exempt category (give letter and, where applicable, number), as designated in the IRB guide, do you think this project qualifies for exemption? _____

Please type your responses to items 1-11 below.

1. If any pre-approved departmental or other protocols will be followed for this project, please indicate the name of the protocol.
None.

2. Brief Project Description

a. Purpose, hypothesis or research questions:

This study will investigate whether studying effort has an impact on the college GPA, after controlling for academic ability as measured by ACT composite score.

b. Procedures:

An anonymous survey instrument (see attached) will be sent by campus mail to a random sample of 200 students that will request information on study habits, ACT score, and college GPA.

3. Participants

- Age, sex, and approximate number: Random sample of size 200 from all enrolled students, representative of all students. Both sexes, mostly 18-22 years old.
- Inclusion/exclusion criteria, if any: see above.
- Method of recruiting: Solicited by campus mail.
- Inducement for participation: Voluntary. No monetary or other inducement.

4. Are participants at risk? The only apparent risk from this study would come from a potential breach of confidentiality if an individual's college GPA or ACT score were revealed.

5. Steps taken to minimize any risks identified in #4.

The survey instrument will be administered anonymously by campus mail and may be filled out in private by the individual. A return envelope will be provided, and the return envelope and survey form will not contain any information that will enable the identity of respondents to be directly ascertained. Care will be taken in reporting the results to make sure that no respondent can be identified by implication from the data reported.

6. Are illegal activities involved?

No.

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.)

No.

8. What are the anticipated benefits to the participants?

The results of this study will be informative about the impact of study habits on college GPAs. The student investigators involved will gain training in survey techniques and the statistical analysis of data.

9. How will informed consent be obtained?

The preface to the survey instrument will contain the required elements for informed consent, including the nature and procedures for the study and contact information for the faculty adviser. Filling out and returning the survey will be construed as consent.

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

NA, no extra credit will be provided.

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?

The survey instruments will be kept in a locked file, the computer database constructed for analyzing the data will be password protected, and the survey instruments and raw data file will be destroyed upon completion of the project. The data will be used in this study only, and not be in 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.

Below is a sample preface to an anonymous survey that includes the required elements for informed consent.

Study Habits and College GPA Survey

We are asking you to complete this voluntary 5 minute survey as part of a research project investigating the relationship of student study habits to college GPAs. The survey is anonymous; your identity is not requested on the survey, and no data will be reported from which individual identities might be ascertained. Please assist us by completing the survey and returning it in the return envelope provided. There are no direct benefits to participating in this research, though the results of this study will help researchers to understand the impact of study habits on college GPAs. Your data will be used in this study only, and survey forms will be destroyed upon completion of the project.

This survey is being conducted as part of an approved class project for PS999; questions can be addressed to Dr. xxx xxxxx., Department of xxxxx. The results of the project will be presented at an upcoming campus-wide event, Celebration of Learning.

This research project has been reviewed and approved by the Augustana Institutional Review Board, which can be contacted at IRB@augustana.edu.

Below is a sample preface to a confidential but not anonymous survey.

Study Habits and College GPA Survey

The Augustana College Dean's Office is investigating the relationship between student study habits and college GPAs. We are asking you to complete this voluntary 5 minute survey as part of a research project. The survey asks for your college ID number so that your responses can be matched to academic record data in the college's database, which is a possible risk. All information you provide will be kept in strict professional confidence, and only aggregated statistical data will be reported. There are no direct benefits to participating in this research, though the results of this study will help researchers to understand the impact of study habits on college GPAs. Your data will be used in this study only, and survey forms will be destroyed upon completion of the project.

Please return the survey using the enclosed return envelope by campus mail to the Dean's Office, Founders Hall. Questions about this survey can be addressed to Dr. xxx xxxxx, Director of xxxxxxx. The results of the project will be presented at a campus-wide event, Celebration of Learning.

This research project has been reviewed and approved by the Augustana Institutional Review Board, which can be contacted at IRB@augustana.edu.

Below is a sample informed consent document for participation in a research study.

Informed Consent for Research Participants

Augustana College Department of Psychology

Researcher's name: Dr. John Smith, Asst. Prof. of Psychology

Research project title: Math Anxiety

Purpose and description of this research project:

The purpose of this experiment is to examine relationships between math skills, personality characteristics and math anxiety. You will be asked to complete a short math exam, rate your level of mathematics anxiety, and complete a personality questionnaire. Your participation will take approximately one hour.

There are risks involved in participating in this study, which include anxiety while taking the short exam and discomfort while completing the personality questionnaire. At any time, you may skip a question or discontinue participation, and no harm will come to you. By completing this study, we will learn more about math anxiety that will, in turn, help students and those educating students in mathematics. We anticipate presenting the results of this study at an upcoming Celebration of Learning conference at Augustana College.

The faculty/staff sponsor that is available to answer any question regarding your participation, and his/her contact information is: Dr. John Smith, Augustana College Department of Psychology, jsmith@augustana.edu, 309-794-5555.

This research project has been reviewed and approved by the Augustana Institutional Review Board, which can be contacted at IRB@augustana.edu.

I hereby give my consent to participate in this research study. I understand that:

- I must be at least 18 years old to participate in this study.
- My participation is entirely voluntary, and I may terminate my participation at any time prior to the completion of the study without penalty.
- Any information I may give during my participation may be recorded and will be employed for research only and not used in future studies.
- Any information I may give will be kept confidential and physically secure.
- The results of this study will be reported without identifying individuals directly, and any reported statistical data will be aggregated so as to make indirect identification of individual participants very unlikely or impossible.
- Any information provided by the participants will be kept either without any personal identifiers, or identified only by participant numbers. If participant numbers are used, the data and name/ participant number list will never be stored in the same location or in the same computer.
- The research materials gathered from individual participants, e.g., survey forms, tape recordings, etc., will be destroyed within 5 years of the completion of this project.

Signature of Participant: _____

Date: _____

Signature of Investigator: _____

Date: _____