Augustana University
Institutional Review Board for the Protection of Human Subjects

Human Participants in Research Policy

I. Introduction

A. Augustana University is required by federal law to establish a committee responsible for reviewing such proposed research to ensure that the rights and welfare of the subjects are protected. The rules governing human subject research are described in the Code of Federal Regulations (CFR) at 45 CFR 46.

B. To comply with these regulations, Augustana University has established the Institutional Review Board for the Protection of Human Subjects in Research, "the IRB." IRB policy includes the minimum guidelines established by the regulations, as well as additional policies for research conducted at Augustana University. Augustana University IRB policy requires that all research involving human subjects, whether funded or regulated by an external organization or not, must comply with Augustana University and federal regulations.

C. Persons conducting research involving human subjects have an ethical as well as professional obligation to ensure the safety, protection, and rights of participants. It is the intent of Augustana University, through the IRB, to assist investigators engaged in human subject research to conduct their research along ethical guidelines reflecting professional as well as community standards. Augustana University has a duty and obligation to protect the rights and welfare of human subjects of research, regardless of the source of funding.

II. The Institutional Review Board

A. The IRB at Augustana University is administered through the Office of the Provost and Executive Vice President for Academic Affairs, with language about the IRB appearing in the Faculty Handbook, Section 3 VII.F.1-2.

B. Composition of the IRB

1. The IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of 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.

2. The IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice.

3. The IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.

4. The IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution. The board shall consist of the following: One faculty member from each division, one administrator, and one community member. Additional members may be appointed to assure that the IRB has sufficient representation and expertise to accomplish required functions.

5. IRB members will be appointed by the Provost and Executive Vice President for Academic Affairs.

6. Terms of Office
   a. The Institutional Review Board for Human Subjects (IRB) will be composed of a minimum of four faculty members (at least one from each Division) and two representatives from the off-campus community. Since research expertise and extensive training is required for IRB Committee membership, members will be appointed by the Provost for four-year terms, with a two consecutive term limit. An Augustana faculty member will serve as Chair, elected biennially by the IRB Committee.

7. IRB Meeting Procedures
   a. Meetings (proposal review, assessment, and IRB training) will be called on a regular basis, typically monthly during the academic year.

8. Review and Consideration of Protocols
   a. The principal investigator (P.I.) or his/her designee shall submit (electronic preferred) to the Provost's office one copy of the Institutional Review Board Proposal Submission Form and all other pertinent materials.
   b. This material shall be submitted a minimum of 30 days before the research is ready to begin.
   c. The principal investigator (P.I.) or his/her designee shall be available to members of the IRB/the Provost to clarify relevant portions of the protocol and project.
   d. Members of the IRB are required to disclose any conflict of interest related to a proposed study, and recuse him/herself from the review panel for the study.
   e. Members of the IRB are authorized to ask any questions pertaining to the study in order to reach a conclusion regarding risks, benefits, safety, and protection of human subjects.
   f. Members of the IRB may reach one of the following conclusions relevant to the proposed research and protocol:
      (1) APPROVAL: protocol and consent form(s) are satisfactory as presented, and investigator may begin research immediately;
      (2) CONDITIONAL APPROVAL: project is not satisfactory as submitted. P.I. must make modifications and/or alterations to protocol and/or consent form(s) as

directed by the IRB. Revisions and modifications to the satisfaction of the Provost (acting on behalf of the IRB) may then result in APPROVAL;

(3) DEFERRAL: insufficient information to reach any definitive conclusion regarding the protocol. Investigator will be asked to revise the protocol and resubmit for full IRB review at a later meeting;

(4) DISAPPROVED: protocol places subjects at unacceptable risk relative to benefits; research project as designed and described is not suitable for involvement of human subjects.

9. The Code of Federal Regulations requires the following minimum information to be included in IRB meeting minutes:
    a. Minutes of IRB meetings shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions, including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.
    b. These minutes shall serve as IRB records of full review proceedings. All remarks, commentaries, opinions, and votes of board members are eligible to become part of the official record of the meeting.

10. The Code of Federal Regulations requires the following minimum criteria for IRB review of research.
    a. The IRB shall conduct continuing review of research deemed to require a full Board review at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research.
    b. The IRB shall have the authority to physically inspect any research premises or review non-confidential research documents relating to the protocol and procedures being used in human subject experimentation. Generally, the investigator will be asked to provide copies of relevant and necessary documents for IRB review.
    c. The IRB shall notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity.
        (1) If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.
    d. The IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, appropriate institutional officials, and the (appropriate federal) department or agency head.
    e. Research covered by this policy that has been approved by the IRB may be subject to further appropriate review and approval or disapproval by officials of the institution.

However, those officials may not approve the research if it has not been approved by the IRB.

C. The IRB may request brief biennial reports from projects reviewed under the expedited procedure as a matter of internal policy (not continuing reviews). These periodic check-ins will include (but are not limited to) reminders that the requirements to submit amendments and report safety events to the IRB remain in place, requests for updates as to whether the research has been completed, or for a brief summary if the research is ongoing.

D. The Provost will serve as the institutional contact on consent forms, should participants have questions or concerns about a particular research study.

III. What Activities Require IRB Review?

A. Any systematic investigation involving human subjects which is designed to develop or contribute to generalized knowledge requires IRB review. IRB review is required when the subject is a living individual about whom an investigator obtains information or biospecimens through intervention (physical procedures, manipulations of the subject or the subject's environment) or interaction (communication, interpersonal contact) with the individual and uses, studies, or analyzes the information or biospecimens. IRB review is also required when identifiable private information or biospecimens are obtained, used, studied, analyzed or generated. Information is considered identifiable when the individual's identity is or may readily be ascertained by the investigator or associated with the information. Private information involves behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place or information that has been provided for specific purposes and the individual can reasonably expect that the information will not be made public. An identifiable biospecimen is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

B. Any investigator (faculty, staff, student) affiliated with Augustana University who plans to conduct research involving human subjects must file a request for review with the Augustana University IRB in time to obtain IRB approval before the research begins, and before any contact is made with prospective subjects. In the case of student projects, a faculty member must serve as principle investigator and be responsible for project oversight. All student projects should be fully reviewed and vetted by faculty prior to being submitted to the IRB.

C. Augustana University faculty on developmental leave and/or sabbatical who conduct research involving human subjects on the Augustana University campus must file for IRB review and approval through the same channels and regulations as do active Augustana University faculty. If a faculty member on developmental leave/sabbatical plans to conduct human subject research at another institution, it is the obligation of the researcher to obtain review and approval from a legally constituted IRB at the host or research-site institution. A copy of the host-institution IRB approval must be filed with the Augustana University IRB.

D. Visiting faculty from another institution who conduct research involving human subjects while at Augustana University must obtain Augustana University IRB approval.

E. When an investigator wishes to conduct a research project (either to recruit subjects or perform an experiment) off campus, either at another university, a hospital, or other agency or organization and if the research project is conducted by an Augustana University-affiliated person, or if anyone associated with Augustana University is involved as an investigator in the study (i.e., student, faculty, or staff), the project MUST be approved by the Augustana University IRB. In some cases, the site of the investigation may also request their own IRB review and approval of the research project.

F. It is the responsibility of the Augustana University investigator to seek and obtain any off-campus IRB approvals required. The Augustana University IRB will not act on behalf of any investigator to obtain approval from another IRB. Non-Augustana University IRB approval, that is, approval from another IRB, DOES NOT substitute for Augustana University IRB review and approval. However, should a written agreement (permissible under DHHS regulations Section 46.114) be signed by Augustana and another institution designating that institution as the "IRB of record" for a specific proposal, that agreement will be honored.

G. Research not funded via any Augustana University organizational unit that is conducted off-campus by non-Augustana University personnel does not require Augustana University IRB approval. Exceptions are:

1. If the research involves funding granted or channeled through any Augustana University organizational unit; or
2. If the protocol was designed by Augustana University staff, faculty, or student members and/or the data will be collected by any Augustana University-affiliated personnel. In these cases, prior Augustana University approval must be obtained.

IV. Informed Consent – Informed consent, containing all federally required elements of informed consent, will be sought from participants involved in human subjects research.

A. Informed consent process: 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. Conceptually, some sort or consent of participants is always necessary for permissible research. In some cases, particularly those that are exempt from IRB review, consent to the research and its risks is implied. In other cases, consent is more explicitly informed, either verbally or in writing. In any case, an investigator shall seek informed consent only under circumstances that provide the prospective participant or their legally authorized representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence.

B. Legally effective consent: No investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject'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 participant or the legally authorized representative shall be in language

understandable to the subject or their representative. To safeguard the rights and welfare of vulnerable populations, verbal or written assent procedures will be used, as appropriate, when the subject is not capable of or qualified to enter into a legally effective consent agreement. No informed consent, whether oral or written, may include any exculpatory language through which the participant or their representative is made to waive or appear to waive any of the participant's legal rights, or releases or appears to release the investigator, the sponsor, the University or its agents from liability for negligence.

C. Implied consent: Consent is implied if and when the participant chooses to be involved in a project or engage in a normal activity in which there is virtually no risk to the participant or the research is exempt from review by the IRB. In the case of classroom research on subject matter intrinsic to the course, carried out with methodologies intrinsic to the course, consent is implied by course registration itself as long as the research involves no more than minimal risk or minimally deceptive practices and the participant's identity will not be known beyond the investigative personnel. These situations do not absolve investigators of their responsibility to inform the participant of the nature and benefits of the project, where this is possible. In the case of a mailed questionnaire, for example, the requisite information is given by means of a cover letter.

D. Waiver or alteration of consent process: Under some circumstances elements of consent disclosure may be waived by the IRB. Waivers may be granted for research involving concealment of the purpose of the research, withholding information about the procedures in the research, or use of a placebo.
In order to be considered for a waiver or alteration of consent, the following conditions must be present: a) the research involves no more than minimal risk to the subjects; b) the waiver or alteration must not adversely affect the rights and welfare of the subjects; c) the research could not practicably be carried out without the waiver or alteration; and d) whenever appropriate, the subjects will be provided with additional pertinent information after participation; e) if the research involves identifiable private information or identifiable biospecimens this research could not be carried out practicably without using the information/specimen in an identifiable form. Where deception is involved, debriefing will be provided to fully disclose information about the study, correct misconceptions, and provide opportunity for subjects to withdraw from participation.

E. Documentation of informed consent: The signed consent of subjects, or an IRB approved waiver of documentation of consent is required for all projects that are subject to expedited and full review. In cases where the documentation requirement is waived, the IRB may require that the investigator provide subjects a written statement regarding the research.

1. The consent form must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research.
2. The consent forms must include the following federally required elements of informed consent documentation:
    a. a statement that the study involves research, an explanation of the purposes of the research and the expected duration of the individual's participation, a description of the procedures to be followed, and identification of any procedures which are experimental
    b. a description of any reasonably foreseeable risks or discomforts to the participant

c. a description of any benefits to the participant or to others which may reasonably be expected from the research
d. a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant
e. a statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained
f. 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
g. an explanation of whom to contact for answers to pertinent questions about the research and research subject's rights, and whom to contact in the event of a research-related injury to the participant
h. 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.
i. a statement that collection of identifiable private information and/or identifiable biospecimens
    1) may be de-identified and used for future research or be given to another investigator for future research without additional Informed Consent

       OR

    2) will not be used or distributed for future research even if de-identified

3. In addition, the consent form should contain the following information if appropriate:
    a. a statement that the particular treatment or procedure may involve risks to the subject which are currently unforeseeable.
    b. anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.
    c. any additional costs to the subject that may result from participation in the research.
    d. The consequences of a subject's decision to withdraw from the research and any procedures for orderly termination of the participant by the subject.
    e. a statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject.
    f. a statement as to whether clinically relevant research results will be shared with the subject and under what conditions
    g. the approximate number of subjects involved in the study.
    h. a statement that biospecimens, even if de-identified, may be used for commercial profit and whether/if that profit will be shared
    i. a statement as to whether the research will or might include whole genome (or whole exome) sequencing of biospecimens in the future

4. The consent document may not include any exculpatory language waiving or appearing to waive any of the subject's legal rights, or releasing the principal investigator and/or sponsor from liability for negligence.

5. If deception will be used in the study, some of the elements of consent may be postponed until the debriefing process. In this case, both a justification of the deception and a detailed description of the debriefing must be submitted with the proposal.

6. The IRB may grant a waiver for the requirement of a signed informed consent for some or all subjects if it finds either:
   a. that the only record linking the subject and the research would be the consent document and the principal risk of a signed consent document would be the potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and subject's wishes will govern; OR
   b. that the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context
   c. where the participants are members of a cultural group in which signing forms is not a normal/acceptable practice

V. IRB Review Categories - Research projects submitted to the IRB for approval are screened by the Chair and placed in one of three review categories: exempt, expedited review, or full board review.

A. Exempt

Research activities in which the only involvement of human subjects will be in one or more of the categories found in **Table A** are exempt from IRB review. However, the investigator may not determine the exempt status of a project himself/herself. Investigators should contact the Chair of the IRB for guidance on exempt status. Investigators are advised that written documentation from the IRB that a study has been reviewed and determined to meet exempt criteria may be required for funding, publication or dissemination of study findings. To determine whether a proposal submitted qualifies for exempt status, the Chair will review the proposal and also send it to a second board member for review. If both reviewers agree, the investigator will be notified the study has been deemed exempt. If the reviewers do not agree, they will proceed with expedited review per the procedure in V.B.

B. Expedited Review

1. The IRB may use the expedited review procedure to review the following:
   a. some or all of the research appearing on the list in Table B. and found by the reviewer(s) to involve no more than minimal risk,
   b. minor changes in previously approved research during the period for which approval is authorized,
   c. research for which limited review is a condition of exemption (See section V. D.).

2. Research activities involving no more than minimal risk and in which the only involvement of human subjects will be in one or more of the categories found in **Table B** (carried out through standard methods and involving no additional methods) may be reviewed by the IRB through the expedited review procedure.

3. Under an expedited review procedure, the review will be assigned to two reviewers from those on the approved list of expedited reviewers (one of whom may be the Chair). In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research.

4. All protocols within the expedited review category will be reviewed by at least two IRB members. If a reviewer has concerns about a project, the IRB chairperson or his/her designee will attempt to resolve the concerns through communication with the investigator. If a reviewer's concerns cannot be resolved to his or her satisfaction, the protocol must be referred to the full Board for review at a convened meeting.

5. When the IRB uses an expedited review procedure it shall adopt a method for keeping all members advised of research proposals which have been approved under the procedure.

C. Full Board review procedures.

1. When the Chair of the IRB determines that a project requires full Board review, the investigator will be notified in writing of the date, time, and location of the IRB review. The investigator may be requested to be present at the portion of the meeting in which his/her protocol will be reviewed. S(he) will be asked to give a short verbal description of the project, and may be asked to answer questions regarding the project. The investigator will then be thanked and dismissed, following which the IRB Chair will call for a "motion to consider" from Board members.

2. Investigators will be notified of the Board's decision within ten days from the date of review.

D. Limited Review

Four of the exempt categories include a provision for limited IRB review (See Table A, Categories 2, 3, 7, and 8). Limited review consists of increased oversight by the IRB of particular types of low-risk research to ensure that either 1) identifiable private information or biospecimens collected have the appropriate data security and privacy protections in place to reduce the chance of inappropriate disclosure or 2) that broad consent was obtained for the use of stored identifiable data or biospecimens.

The IRB will conduct limited IRB review during the initial review of the submitted project. Two reviewers (one of whom may be the Chair) will review the proposal. Reviewers may exercise all of the authorities of

the IRB except that the reviewers may not disapprove the research. Investigators are required to submit changes to the IRB when the context or conditions of the original limited IRB review change (e.g., if the location for the storage and protection of the data change). In addition, limited IRB review for exemption 8 ALSO requires the IRB determines that the proposed secondary research is within the scope of the broad consent.

For exempt category 7, limited IRB review is always required and the criteria are based on the broad consent and its details. Exempt categories 7 and 8 are only available for use when broad consent will be (or has been) obtained. Limited review under exempt category 7 is much more extensive than for the other categories and includes: the consent process, both required and "as applicable" consent elements, documentation of consent or a waiver of documentation, and privacy and confidentiality (if changes are made to storage or maintenance).

VI. Criteria for IRB Review and Approval of Research - In order to approve research covered by this policy, the IRB shall determine that all of the following requirements are satisfied:

A. Risks to subjects are minimized:

1. by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and
2. whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

B. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should 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 (for example, 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 subjects is equitable. In making this assessment, the IRB should take into account the purposes of the research and the setting in which the research will be conducted, and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.

D. Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with requirements for informed consent (See Section IV.A-D)

E. Informed consent will be appropriately documented in accordance with requirements for informed consent (See Section IV.E).

F. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

G. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

H. The IRB will review investigator qualifications and must be assured that

1. the investigator has the appropriate qualifications and/or licensure to carry out the procedures involving human subjects with an acceptable degree of potential risk, and
2. the investigator has adequate facilities and equipment to conduct the research with an acceptable degree of potential risk.
3. the investigator and all research staff who will have contact with research participants and/or data must show proof of training in the protection of human subjects in research within the past three years (e.g., NIH, CITI).

I. The IRB will review experimental design in order to be assured that the potential risks to the subjects are minimized and the potential benefits maximized by using procedures consistent with sound research design.

VII. Determination of Risk

A. The IRB will make a decision based on common sense and sound professional judgment as to whether or not the proposed research places the subject "at risk."

B. A subject is considered to be at risk if he/she is exposed to the possibility of harm, whether physical, psychological, sociological, economic, or other, as a consequence of any activity that goes beyond the application of those established methods necessary to meet his/her needs.

C. Minimal risk means that 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.

D. If it is determined that a subject will be placed at risk, the IRB will perform a risk/benefit analysis.

1. In research involving a non-therapeutic intervention, the potential risk to the subject must be outweighed or balanced by the potential benefit to the subject and/or by the knowledge to be gained.

2. In therapeutic research involving more than minimal risk, the potential risk should be outweighed or balanced by the potential benefit to the subject. In addition, the relation of

the anticipated benefit to the risk must be at least as favorable to the subject in the non-research context. No subject is allowed to continue participating in a research protocol if therapy of proven superior nature becomes available to the subject.

3. In research where a standard therapy not part of the research protocol is employed solely for the benefit of the subject along with additional procedures performed solely for research purposes, the anticipated benefits of the therapy cannot be used to justify exposing subjects to the risks associated with the research procedures. Such risks can only be justified in light of the potential benefits of the research procedures. Conversely, only the risks associated with the research procedures should be used in determining the risk/benefit ratio.

4. In research involving a therapy employed for the potential benefit of a subject suffering from a life-threatening illness, the risk of serious adverse effects may be acceptable providing there are no other therapeutic alternatives available to the subject that offer a more favorable risk/benefit ratio.

5. In research where no direct benefits to the subject are anticipated, the IRB will evaluate whether the risks and/or discomfort presented by procedures performed solely to obtain generalizable knowledge are ethically acceptable.

VIII. Additional Protections Involving Categories Vulnerable to Coercion or Undue Influence

A. In order to assure the protections of a vulnerable category of subject such children, prisoners, physically disabled, or individuals with impaired decision-making capacity, consideration will be give to the inclusion of one or more IRB reviewers who are knowledgeable about and experienced in working with these subjects. Additional protections apply to protected groups in accordance with federal regulation CFR 45 Part 46 Subparts as follows:

1. Subpart B *Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research Sec.*
2. Subpart C *Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects*
3. Subpart D *Additional Protections for Children Involved as Subjects in Research*

B. Specific Protections Involving Children

1. Research involving no more than minimal risk must include provisions for soliciting the assent of the children and the permission of their parents or legally authorized representative.

2. Research involving greater than minimal risk may be approved where i) the risk is justified by the anticipated benefit to the subjects; ii) the relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches; and iii) adequate provisions are made for soliciting the assent of the children and permission of their parents or legally authorized representative.

3. See Subpart D for additional provisions relative to projects involving greater than minimal risk

and no prospect of direct benefit to individual subjects.

IX. IRB Approval of Research

A. The IRB shall notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity or of modifications required to secure IRB approval of the research activity.

1. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

2. Investigators will be notified of the Board's decision within ten days from the date of review. Notification will be in the form of a letter or email communication from the IRB chairperson. The letter will describe any changes to protocol or consent form that are required for final IRB approval.

3. If APPROVED, the investigator may begin the proposed research project.

B. If CONDITIONALLY APPROVED, the investigator will be notified of the specific changes to the protocol and/or consent form necessary to proceed with IRB approval of the research protocol

1. The chairperson of the IRB will communicate, in writing, the findings of the IRB and the necessary modifications. Until the investigator convincingly demonstrates, in writing, that all required changes have been made to the IRB's satisfaction, the project CANNOT begin.
2. If the investigator does not respond to the IRB's notification of required changes within 30 calendar days of receiving CONDITIONAL APPROVAL, the proposed project must be resubmitted for full review again at the next regularly scheduled IRB meeting.

C. If DEFERRED, the investigator will be notified in writing that the project as described provides insufficient information to reach a decision for approval or disapproval. The investigator will be asked to resubmit for a later regularly scheduled meeting. In addition, the findings of the IRB that resulted in the decision to defer the project will be conveyed in writing to the investigator.

D. If DISAPPROVED, the reasons for disapproval will be conveyed in writing to the investigator.

E. Approval is for one year for full board reviews. Proposals reviewed under the expedited process do not have to file for annual review, but please see II.C and X.A. for other requirements.

X. Investigator Reporting Requirements

A. Augustana University IRB policy requires the following written reports from investigators conducting IRB-approved research:

1. annual progress reports (only required from projects approved after full board review, with the exception of FDA regulated research),
2. requests for approval of change in protocol or consent form,
3. reports of injury or unanticipated problems, and
4. project completion reports.

Table A. Exempt Categories
(Refer to Section V.A.)
Any research that involves greater than minimal risk to human participants cannot qualify as exempt. General limitations for qualifying for any exempt status include 1) no individuals with impaired decision-making capacity 2) may involve children only where specifically indicated 3) may include prisoners only under very specific conditions. Note that Exemption 6 is the only exemption that is allowable for FDA-regulated research.

Table may be used as a worksheet to determine whether a particular proposal meets the criteria for exempt status. See Section V. A.

Exemption 1	**Must check ALL 3 boxes on the left.**
	Research will take place in established or commonly accepted educational setting(s) and involve normal educational practices.
	Unlikely to adversely impact student learning.
	Unlikely to adversely impact teacher assessment.
Exemption 2	Interactions – Education, surveys, interviews, observations
	Research involves data collection only (no interventions) and involves educational tests (cognitive, diagnostic, aptitude, achievement), surveys, interviews, observation of public behavior (including visual or sound recordings) **Must check box on the left AND at least one of the following 3 criteria:**
i	Subjects' identities cannot readily be ascertained, directly or indirectly (Data are recoded; may involve children)
ii	Disclosure of subjects' responses outside the research could not reasonably harm subjects (criminal, civil, reputation, employability, financial standing, etc.) (may involve children)
iii	Information is recorded such that the identity of subjects can readily be ascertained, and IRB conducts a limited IRB review with regard to protection of privacy of subjects, and confidentiality of data (no children)
Exemption 3	Benign Behavioral Interventions (no medical interventions)
	Research involves benign behavioral interventions, data are collected as verbal or written responses, or audiovisual recordings. Subjects are adults, must agree before any intervention begins, there is no deception (some exceptions), AND at least one of the following must apply: **Must check box on the left AND at least one of the following 3 criteria:**
i	Subjects' identities cannot readily be ascertained, directly or indirectly

ii	Disclosure of subjects' responses outside the research could not reasonably harm subjects (criminal, civil, reputation, employability, financial standing, etc.)
iii	Information obtained is recorded such that the identity of subjects can readily be ascertained, and IRB conducts a limited IRB review (See V. D.) with regard to protection of privacy of subjects, and confidentiality of data.
Exemption 4	**Secondary** research with **identifiable** private health information (PHI) or **identifiable** biospecimens. NO primary collection of information or biospecimens.
	Secondary research with **identifiable** PHI or biospecimens and consent is not required if at least one of the following 4 criteria apply. **Must check box on the left AND at least one of the following 4 criteria:**
i	Identifiable PHI or biospecimens are publicly available
ii	Subjects' identities cannot readily be ascertained, directly or indirectly. Investigator does not contact subjects, and will not re-identify subjects.
iii	Data includes only identifiable health information already protected by HIPAA and it remains covered within HIPAA-covered entities.
iv	Research is conducted by or on behalf of a Federal Department or Agency using government data obtained for nonresearch reasons, and if identifiable, adheres to specified privacy standards.
Exemption 5	Federal Exemption
	Research and demonstration projects that are conducted or supported by a federal department or agency, or otherwise subject to the approval of Department or Agency heads, and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs. Exemption only permitted if the research is listed on a federal website (or other similar mechanism). **Must check box on the left.**
Exemption 6	Taste & food quality evaluation and consumer acceptance studies may be exempt: **Must check box on the left AND at least one of the following 2 criteria:**
i	if wholesome foods w/out additives are consumed
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 FDA or approved by the EPA or the Food Safety and Inspection Service of the USDA.
Exemption 7 **Exemption 8**	Both involve secondary research and a new type of consent called broad consent*. For the near future Augustana will not implement the use of broad consent and will continue using informed consent on a case-by-case basis. Exemptions 7 and 8 will be implemented when capacity to meet technical and regulatory requirements has been confirmed. Contact the IRB Chair with questions.

*Broad consent is a new type of consent (2018) as an alternative to informed consent. It is specifically for the storage, maintenance, and secondary research uses of identifiable private information and identifiable biospecimens and is tied to the new exempt research categories 7 and 8. Broad consent includes all the elements of informed consent and several new required elements. The IRB may not waive or alter the elements of broad consent.

Table B. Expedited Categories
(Refer to Section V. B.)

1. Research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required and for which the drug or device is used in accordance with its cleared/approved labeling.	
2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture from:	• Healthy adults who weigh at least 110 pounds, in amounts not exceeding 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week • From other adults and children, considering age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser amount of 150 ml or 3 ml per kg in an 8 week period
3. Prospective collection of biological specimens (excluding blood and not requiring sedation) for research purposes by noninvasive means such as:	• Hair and nail clippings in a non-disfiguring manner Deciduous teeth at time of exfoliation or in the case of routine extraction • Excreta and external secretions including sweat, uncannulated saliva, placenta removed at delivery, and amniotic fluid at the time of rupture of the membrane prior to or during labor • Supra- and sub-gingival dental plaque and calculus, provided the procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques • Mucosal and skin cells collected by buccal scraping, swab or mouth washings • Sputum collected after saline mist nebulization

4. Collection of data through noninvasive procedures (not including general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. This includes the use of the following:	• Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of matter or significant amounts of energy into the subject • or an invasion of the subject's privacy • Weighing or testing sensory acuity • Imaging electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, diagnostic echography, and electroretinography • Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual
5. Research involving materials (data, documents, records, or specimens) that have been, or will be collected solely for non-research purposes (such as medical treatment or diagnosis) (NOTE: some research in this category may be exempt from federal regulations – See Section V.A).	
6. Collection of data from voice, video, digital, or image recordings made for research purposes	
7. Research on individual or group characteristics or behavior (including, but not limited to), research on:. (NOTE: some research in this category may be exempt from federal regulations – See Section V.A.)	• perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior • or research employing survey interview, oral history, focus groups, program evaluation, or quality assurance methodologies