MISERICORDIA UNIVERSITY.

Misericordia University

POLICY MANUAL

Interim Institutional Review Board Policies and Procedures

January 2019

Misericordia University's IRB, at its option, may change, delete, suspend, or discontinue parts of the policy in its entirety to comply with guidelines from the DHHS-OHRP or other federal agencies. In the event of a policy change, a notice will be posted on the IRB website.
Section I

A. Introduction

Misericordia University (MU) established an Institutional Review Board (IRB) to review all research involving human subjects and to implement institutional policies and procedures regarding such research. The use of human subjects in research imposes both ethical and legal responsibilities upon the university, the IRB and those conducting the research to ensure that the rights and welfare of those subjects are adequately protected. The primary function of the IRB is to protect the rights of human subjects. Review and approval by the IRB is meant to aid both the subjects and the researchers by bring scrutiny to research protocols by a group of peers who can objectively assess the potential risk and accommodations made to minimize them.

All research involving the use of human subjects conducted by Misericordia University’s faculty, staff or students or sponsored by the university must be reviewed and approved prior to the start of the research. Once initiated, the research must be conducted in full compliance with IRB policies and procedures.

According to 45 CFR 46, research is defined as a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge, and a human subject means a living individual about whom an investigator (whether professional or student) conducting research:

1. Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
2. Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens

It is the responsibility of researchers to refer their protocols (planned research studies) to the IRB whenever human subjects are used in research, even if the researcher does not consider the subjects to be at risk. Current law places the burden for negligence and harm directly on the researcher and the university. These policies and procedures are executed for the specific purpose of protecting human subjects.

If you have questions about these policies and procedures, contact the IRB chairperson, the IRB administrator, or any member of the IRB. The names and contact information for these individuals can be found at http://www.misericordia.edu/irb.

B. Background

The Public Health Services Act (Title IV, Part G, Section 491a) required the Department of Health and Human Services (DHHS) to issue regulations for the protection of human subjects of research and to implement a program of instruction and guidance in ethical issues associated with such research. The regulations are codified as Title 45 Part 46 of the Code of Federal Regulations (45 CFR 46), issued on June 18, 1991 and revised and published on January 19th, 2017. In accordance with Misericordia University’s IRB Policies and Procedures and the Federalwide Assurance for the Protection of Human Subjects (#00008971), Department of Health and Human Services (DHHS), Office for Human Research Protections (OHRP) (ORHP registered IRB Organization Number IORG0004091), all research conducted by or under the

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auspices of Misericordia University must be performed in accordance with 45 CFR 46 and
conform to federal, state, and local laws.

C. Authority

In connection with research conducted or proposed to be conducted on human subjects, the IRB
performs critical oversight functions to ensure applicable scientific, ethical, and regulatory
standards are met. The IRB reviews and monitors research sponsored by the University and/or
conducted by:

1. Misericordia University faculty, staff, and students
2. Agents of Misericordia University in connection with their institutional
   responsibilities or using any institutional property or facility
3. Non-Misericordia University investigators when Misericordia University faculty,
   staff, or students are involved

The Institutional Official (IO) grants the IRB the responsibility and authority to:

1. Review, approve, modify, or disapprove new and continuing research projects involving
   human participants
2. Monitor and review, approve, modify, or disapprove approved projects including
   regularly scheduled continuing review at least every twelve months
3. Verify compliance with approved research protocols
4. Review, approve, modify, or disapprove all planned changes to protocols prior to
   implementation
5. Review all adverse events occurring in approved projects or in other projects related in
   context to the approved projects
6. Restrict approved research activities to protect participants when necessary
7. Suspend/terminate previously approved protocols for non-compliance with established
   policies
8. Observe, or have a third party observe, the consent process
9. Observe, or have a third party observe, the conduct of research

The establishment of Misericordia University’s IRB and its policies and procedures are derived
primarily from 45 CFR 46. The policies and procedures are intended to provide a resource for
the preparation and submission of research protocols for IRB reviews. A copy of 45 CFR 46 and
the Belmont Report (http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html) are
provided to IRB members to guide them in their decision making relative to each research
and 45 CFR 46 (http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html) are available
for anyone wishing access to them at the websites provided.

D. Ethical Principles and Issues for the Use of Human Subjects in Research

The regulations in 45 CFR 46 are based on the Belmont Report
(http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html) which was developed in the
1970's by the National Commission for the Protection of Human Subjects of Biomedical and
Behavioral Research. The report presented three basic ethical principles. The principles of
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respect for persons, beneficence, and justice remain as essential requirements for the ethical conduct of research involving human subjects. Respect for persons recognizes personal dignity and autonomy of individuals and protection of those that have diminished autonomy. Beneficence includes an obligation to protect individuals from harm by minimizing risks of harm and maximizing benefits. Justice requires that the burdens and benefits of research be distributed fairly.

In addition to the aforementioned principles, the IRB will be considering the following areas in determining the nature of risks and the extent to which the benefits of the study justify exposing the subjects to risk:

D.1. Voluntary Participation

Participation by human subjects must be voluntary, i.e., must occur as a result of free choice, without compulsion or obligation, based upon disclosure of relevant information in a clear, concise and understandable way. The researcher must take care to avoid coercing participation by subjects.

D.2. Inducement to Participate

Subjects are frequently offered some form of incentive or reward for their participation, such as extra credit from a professor or a small gift or prize. In general, inducements are allowable as long as they are minimal and are not more attractive to some subjects than to others. The primary ethical issue involves the extent to which an inducement might be sufficiently large enough to cloud a person’s judgment about whether or not participation in the study is in his/her best interest. In cases where students may earn extra credit from professors, other options to earn extra credit besides research participation must be available. Alternatives to participating in research should be comparable in time and effort to participation in the research study.

Researchers who are professors must not do recruiting of research subjects in their classes. They may have one of their colleagues or research assistants do the recruitment. Precautions must be taken to safeguard against students’ perceptions that they are expected to participate in studies conducted by their professors in order to remain in good standing.

A second issue involves the extent to which individuals can reasonably choose not to participate, especially in a case where they are approached as a large group such as in a class. This is particularly problematic when the research involves a sensitive issue. For example, if the study focuses on AIDS and a person chooses not to participate, it could be interpreted that the person has AIDS. In such cases, the researcher/recruiter must demonstrate that he/she has recognized this risk and taken appropriate action to protect those who may be at risk. For example, the researcher provides a means of recruitment that does not openly implicate those who choose not to participate.

D.3. Informed Consent

Before involving a human subject in research covered by this policy, an investigator shall obtain the legally effective informed consent of the subject or the subject’s legally authorized representative. An investigator shall seek informed consent only under circumstances that provide the prospective subject or the legally authorized representative sufficient opportunity to discuss and consider whether or not to participate in a way that minimizes the possibility of

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coercion or undue influence. The information that is given to the subject or the legally authorized representative shall be in language understandable to the subject or the legally authorized representative. The prospective subject or the legally authorized representative must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information. Informed consent 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. This part of the informed consent must be organized and presented in a way that facilitates comprehension. Informed consent as a whole must present information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject’s or legally authorized representative’s understanding of the reasons why one might or might not want to participate. No informed consent may include any exculpatory language through which the subject or the legally authorized 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.

D.3.1. Required Elements of Consent

Informed consent 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. This part of the consent must be organized and presented in a way that facilitates comprehension.

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

(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject’s participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

(2) A description of any reasonably foreseeable risks or discomforts to the subject;

(3) A description of any benefits to the subject or to others that may reasonably be expected from the research;

(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

(6) 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;

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(7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject;

(8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

(9) One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:

(i) A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens 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 without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or

(ii) A statement that the subject’s information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

D.3.2. Additional elements of informed consent.

When appropriate, one or more of the following elements of information shall also be provided to each subject or legally authorized representative:

(1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;

(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or the legally authorized representative’s consent;

(3) Any additional costs to the subject that may result from participation in the research;

(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

(5) 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; and

(6) The approximate number of subjects involved in the study.

(7) A statement that the subject’s biospecimens (even if the identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit.

(8) A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions.

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(9) For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e. sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequencer of that specimen).

(10) The amount and schedule of all payments to the participant.

The informed consent requirements in this policy are not intended to preempt any applicable Federal, state, or local laws (including tribal laws passed by the official governing body of American Indian or Alaska Native tribe) that require additional information to be disclosed in order for the informed consent to be legally effective. Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable federal, state, or local law (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe).

**D.3.3. Waiver of Informed Consent**

An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

1. The research involves no more than minimal risk to the subjects;
2. The research could not practicably be carried out without the waiver or alteration; and
3. Research involving identifiable private information identifiable biospecimens could not be practically carried out using non-identifiable information or biospecimens;
4. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
5. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent for research involving public benefit and service programs conducted by or subject to the approval of state or local officials provided the IRB finds and documents that:

1. The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, 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; and
2. The research could not practicably be carried out without the waiver or alteration.

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An IRB may approve a research proposal in which an investigator will obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective subjects without the informed consent of the prospective subject or the subject’s legally authorized representative, if either of the following conditions are met:

a. The investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative, or

b. the investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens

D.3.4. Documentation of Informed Consent

Informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or subject’s legally authorized representative. A written copy shall be given to the person signing the form. The consent form may be either of the following:

(1) A written consent document that embodies the elements of informed consent described above. This form may be read to the subject or the subject’s guardian, but in any event, the investigator shall give either the subject or the legally authorized representative adequate opportunity to read it before it is signed; or

(2) A short form written consent document stating that the elements of informed consent as stated above have been presented orally to the subject or the subject’s guardian.

A short form written informed consent form stating that the elements of informed consent required by 46.116 have been presented orally to the subject or the subject’s legally authorized representative, and that the key information required by 46.116(a)(5)(i) was presented first to the subject, before other information, if any, was provided. The IRB shall approve a written summary of what is to be said to the subject or the legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Only the short form itself is to be signed by the subject or the subject’s legally authorized representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the subject’s legally authorized representative, in addition to a copy of the short form.

46.117(a) now specifically allows electronic signatures and specifies that a written copy must be given to the person signing the consent form. In addition, 46.117(b)(1) specifically allows, but does not require, consent forms to be read to the subject.

An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds any of the following:

(1) That the only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject (or legally authorized representative) will be asked whether the subject wants documentation linking the subject with the research, and the subject’s wishes will govern;

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(2) 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; or

(3) If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

**D.3.5. Child Assent**

Federal and state law stipulates that a person must be 18 years or older to enter into a contract. Subjects under the age of 18 years may participate in research only with the signature of their parent or legal guardian. A guardian according to Pennsylvania State Law is "a person lawfully invested with the power, and charged with the duty, of taking care of and managing the property and rights of another person, who, for some peculiarity of status, or defect of age, understanding or self-control, is considered incapable of administering his or her own affairs" (26 Pennsylvania Law Encyclopedia, 2d, Guardian and Ward 1, p. 120). This also applies to the completion of anonymous questionnaires. Children should have information about their participation in a research study explained to them in language that is understandable, and, if possible, children should sign consent forms – this is called assent. Assent means a child’s affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

Like the informed consent process, the assent process is intended to be an ongoing, interactive conversation between the research team and the child or young adult. The process is not about getting the young person "to sign on the dotted line"; rather, it is about making sure they understand the research and what it means to participate. By engaging young people in understanding the research project, researchers and children become partners in the research process. Children are likely to feel more in control and more involved in the research as a result. When the IRB determines assent is required, it must also determine whether and how assent must be documented.

Fundamentally, before the assent process can begin, parents or guardians must give permission for their children to participate and it shall be documented in accordance with and to the extent required by 46.117. Then, the child or teenager may be provided with a form that explains, in concrete and age-appropriate terms, the purpose of the research, what they will be asked to do, and what procedures they will undergo. For older adolescents (ages 16 or older), this might look very much like the adult informed consent document. For younger children, the terms and explanations will be greatly simplified into words they can understand. Where parental permission is to be obtained, the IRB may find that the permission of one parent is sufficient for research to be conducted under 46.404 or 46.405. Where research is covered by 46.406 and 46.407 and permission is to be obtained from parents, both parents must give their permission unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child. In addition to the

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provisions for waiver contained in 46.116 of Subpart A, if the IRB determines that a research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children), it may waive the consent requirements, provided an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and provided further that the waiver is not inconsistent with Federal, state, or local law. The choice of an appropriate mechanism would depend upon the nature and purpose of the activities described in the protocol, and the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition.

Assent from children must be obtained and documented when they are capable of providing it. In determining whether children are capable of providing assent, consider the age, maturity, and psychological state of the child/children involved. This determination can be made for all children to be involved in the research under a particular protocol, or for each child, as appropriate.

- The requirement for obtaining the assent of children involved in the research may be waived if:
  1. The capability of some or all of the children is so limited that they cannot reasonably be consulted;
  2. The intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research; or
  3. Under circumstances in which consent may be waived in accord with 46.116 of Subpart A.

**D.3.6. HIPAA and Informed Consent**


The university is classified under HIPAA as hybrid entity, meaning that it has divisions which fall under HIPAA regulations and those which do not. Human subject’s research is not considered health care and is therefore not a covered entity.

When using research subjects at a covered entity (e.g., hospital, clinic, doctor’s office, or other health care facility), the investigator must abide by that institution’s regulations. The University’s IRB will require an authorization from the covered entity to use protected health information (PHI) as an addendum to the consent form.

**D.4. FERPA**

Regarding research with students at Misericordia University, anytime the Family Educational Rights and Privacy Act (FERPA) regulations are applicable, the IRB cannot make a determination about whether or not the research is acceptable in terms of FERPA regulations and Misericordia University policy as that is outside of the scope and purview of the IRB. The Office Misericordia University’s IRB, at its option, may change, delete, suspend, or discontinue parts of the policy in its entirety to comply with guidelines from the DHHS-OHRP or other federal agencies. In the event of a policy change, a notice will be posted on the IRB website.
of the Registrar is responsible for the proper execution of the FERPA rules. Therefore, the Office of the Registrar will conduct ancillary review any time an IRB application involves and/or potentially involves FERPA protected data. The IRB office will send the application packet to the Office of the Registrar for review. The Office of the Registrar will communicate any concerns, needed clarifications or corrections, to the IRB. The IRB will then review the application and provide feedback to the researcher(s). Once any/all issues have been resolved concerning FERPA, the Office of the Registrar will issue either an approval or disapproval and send it to the IRB office. The IRB office will not issue a final determination concerning approval, until all issues raised by the Office of the Registrar have been addressed and/or a final determination has been issued by the Office of the Registrar.

D.5. Identifying and Minimizing Risks

Virtually all research involves some risk, even though it may be minimal (e.g. embarrassment over performance on a task). A risk may be of a physical, social, economic, and/or psychological nature. The IRB will consider the extent to which the researcher has attempted to identify the potential risks to the subject and the extent to which those risks have been minimized without interfering with the integrity of the research purpose. In cases where there is a possibility of more than minimal risk to subjects, approval will depend on the following: (1) the benefits of the research; (2) the expertise and prior experience of the researcher(s) in conducting this type of research; (3) the level of inducement to participate; (4) the extent to which the subject is fully informed of the possible risks, and (5) the compensatory treatment or follow-up designed to alleviate any negative consequences from participation. A research procedure may not be used if it is likely to cause serious or lasting harm to subjects (e.g. health problem).

D.6. Fairness

The research should be designed to treat all individuals fairly. The selection of subjects must be based upon fair procedures and not overburden, overuse, or unfairly favor or discriminate against any group.

D.7. Confidentiality and Anonymity

In all research involving human subjects, it is important to assure the subjects of the confidentiality of their responses. This is especially important in cases where the study involves asking personal questions about the subjects or obtaining other information that might put the subject at risk, if the information was made public. Total anonymity (e.g. where the subject’s name or face is never associated with his/her response) is preferable, especially in the case of extremely sensitive or personal information. This generally means that the subject must be able to provide information in complete privacy and to submit the information in such a way that it is mixed in with other subjects’ data before it is retrieved by the researcher. Where it is necessary to have the subjects’ names or identification numbers associated with their responses (e.g. in order to collate several sets of responses by the same subject), the subjects need to know who will see their data and specifically how this information will be kept confidential.

If anonymity or confidentiality cannot be maintained, the subjects have the right to know how the information will be used, with whom it will be shared and the right to elect not to participate given the inability to maintain anonymity or confidentiality.

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D.8. Deception

In some types of research it may be necessary to withhold some pertinent information from subjects when disclosure of such information would likely impair the validity of the study. In all such cases, subjects should be told that they are invited to participate in research where some features will not be revealed until the research is concluded. Complete nondisclosure of information about the study or its purpose is only justified when the research solely involves observation of a person’s behavior in locations where the person might reasonably expect that his/her behavior may be observed by others. In research that involves incomplete disclosure, the following conditions must be met: (1) the research involves no more than minimal risk to the subjects; (2) the waiver or alteration will not adversely affect the rights and welfare of the subjects; (3) the research could not practically be carried out without the waiver or alteration; and (4) whenever appropriate, the subjects will be provided with additional pertinent information after participation. If asked directly by research subjects about some part of the study that in not being fully disclosed, researchers must answer the question truthfully even if disclosure has the potential to impact study outcomes.

D.9. Debriefing

In most cases, it is desirable for subjects to be debriefed after their participation in the study (e.g. given information about the study and given a chance to ask questions). There are three cases in which debriefing are required: 1) when the research involves incomplete disclosure; 2) when subjects may be left with misleading or potentially harmful perception or inaccurate information; and, 3) when compensatory treatment or follow-up is needed. Debriefing should not be treated as a substitute for informed consent prior to or during the subject’s participation in the research.

In some cases, debriefing may not be possible immediately after the study due to a concern about other potential subjects finding out about a deceptive aspect of the study that would preclude further data collection. In these cases, debriefing statements or descriptions must be provided to subjects at a later date through an appropriate means. In rare instances, debriefing may itself pose a social or psychological risk to a subject. In such cases, it may be in the best interest of the subject to forego the debriefing procedure. However, this situation must be presented to the IRB. The IRB will take into consideration the particular elements in the situation and will determine the risk of debriefing the subjects. In most cases this can be avoided by disclosing to the subjects prior to their participation that some harmful information may be uncovered in the course of the study. This falls under the obligation to disclose any risks that are more than minimal.

D.10. Compensatory Follow-up

In cases where some physical or psychological harm might result from the subjects’ participation, plans for compensatory treatment or follow-up counseling should be provided.

D.11. Vulnerable Populations

Per 45 CFR 46.111(b), 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 disadvantaged persons, additional safeguards must be included in the study to protect the rights and welfare of these subjects including the justification for the use of a vulnerable population. Some groups of individuals by virtue of their situation have been identified by DHHS as vulnerable populations.

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D.11.1. Research Involving Pregnant Women or Fetuses

Misericordia University’s IRB subscribes to the federal policy on research with pregnant women or fetuses. The federal policy relating to this information can be found by following the link http://www.hhs.gov/ohrp/index.html and be used for guidance on working with this population.

D.11.2. Research Involving Neonates

Misericordia University’s IRB subscribes to the federal policy on research with neonates. The federal policy relating to this information can be found by following the link http://www.hhs.gov/ohrp/index.html and be used for guidance on working with this population.

D.11.3. Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects

Misericordia University’s IRB subscribes to the federal policy on research with prisoners. The federal policy relating to this information can be found by following the link http://www.hhs.gov/ohrp/index.html and be used for guidance on working with this population.

D.11.4. Additional Protections for Children

The IRB will approve research which demonstrates that there is no greater than minimal risk to children and only if the IRB finds that adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians.

Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects will be considered if the IRB finds that an intervention or procedure holds out the prospect of direct benefit for the individual subject, or that a monitoring procedure is likely to contribute to the subject's well-being. This will be considered only if the following conditions are met:

1. The risk is justified by the anticipated benefit to the subjects;
2. 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
3. Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians. For information on the requirements for assent, please see section 2.6.1.3.3.

E. Institutional Review Board

E.1. Membership

The MU IRB includes an Administrator, a Chair, a Coordinator, an Analyst, and board members. Members of the IRB are recommended by the IRB chair to the Vice President of Academic Affairs (VPAA) and the University President in accordance with 45 CFR 46 Section 46.107, which requires members of the IRB be sufficiently qualified through experience or expertise and diversity of its membership including consideration of race, gender, cultural backgrounds and sensitivity to issues of community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition, every effort should be made to ensure that IRB members are balanced with regard to gender and background (no IRB can

Misericordia University’s IRB, at its option, may change, delete, suspend, or discontinue parts of the policy in its entirety to comply with guidelines from the DHHS-OHRP or other federal agencies. In the event of a policy change, a notice will be posted on the IRB website.
consist entirely of members of one profession). The IRB must include at least one member whose primary concerns are in a scientific area and at least one whose interests are in a non-scientific area. The IRB shall also include at least one member who is not otherwise affiliated with the institution and who is not of the immediate family of a person who is affiliated with the institution. The University President and the Vice President of Academic Affairs have the responsibility of approving or disapproving the recommendations forwarded to him/her.

The chair of the IRB and the IRB Administrator are appointed by the University President and the Vice President of Academic Affairs.

There will be at least five members of Misericordia University’s IRB. Current members’ names and contact information can be found by following the link to the Misericordia website http://www.misericordia.edu/irb.

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

In addition, the IRB may not have a member participate in the IRB’s initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

**E.1.1 Alternate Membership**

The IRB includes at least one alternate member. These members are eligible to replace members when they are unable to attend. Before an alternate can act on behalf of a regular member, he/she must have attended at least two meetings as an observer. Alternates receive the same materials provided to regular members of the IRB. They must also complete the required education program before participating as an alternate at a meeting.

**E.1.2. Institutional Review Board Member Responsibilities**

All IRB members have specific responsibilities related to their role on the IRB. These responsibilities should be accepted with a clear understanding of the critical importance of the activities completed by the IRB. Members are asked to carefully consider these responsibilities prior to assuming the role. If members’ responsibilities within the university increase and do not permit full participation in the responsibilities outlined, members should request that they be replaced.

1. **Chair**

   - Consult with the IRB Administrator to determine IRB application type: Exempt Expedited, or Full Board.
   - Develop rotating IRB member review schedule for exempt and expedited studies.
   - Distribute new applications and reviewer checklists to appropriate IRB members.
   - Participate as an IRB reviewer as needed for exempt and expedited applications.
   - Review all full board applications.
   - Communicate with IRB members concerning status of applications.

Misericordia University’s IRB, at its option, may change, suspend, or discontinue parts of the policy in its entirety to comply with guidelines from the DHHS-OHRP or other federal agencies. In the event of a policy change, a notice will be posted on the IRB website.
• Consult with IRB members regarding application reviews.
• Collect and review IRB members’ recommendations and completed checklists.
• Prepare letters to applicants to denote application status (approved, approval withheld pending revisions, denied) including revisions required or the reason for denial of approval.
• Collaborate with IRB administrator to establish the agendas for IRB meetings.
• Maintain currency in IRB & FWA regulations.
• Assist IRB Administrator in updating IRB policies and procedures to be in compliance with regulations.
• Maintain appropriate record of actions.
• Forward applications to IRB secretary following review and action.
• Delegate review of annual updates as appropriate by type of review.
• Inform IRB members of change in protocols and initiate deliberation as appropriate.
• Review end-of-project reports.
• Participate in unanticipated risk to subject deliberations.
• Maintain open communication with the Office of the Vice President of Academic Affairs.
• Participate in quality assurance monitoring.

2. Members

• Attend monthly IRB meetings as scheduled. Communicate anticipated absences to IRB chair or the IRB coordinator prior to meetings.
• Complete review of exempt and expedited applications in a timely manner.
• Make recommendations related to applications reviewed. For expedited reviews, IRB members collaborate to determine recommendations and approval status.
• Communicate recommendations and approval status to IRB chair in writing at least two days prior to IRB meetings.
• Review all full board IRB applications.
• Complete required human subjects protection educational program.
• Participate in ongoing human subjects review education.
• Review annual updates as requested by IRB chairperson.
• Participate in change of protocol deliberations as requested.
• Participate in unanticipated risk to subject deliberations .
• Participate in quality assurance monitoring.
• Seek consultation as necessary with IRB members, the IRB Chair, or IRB Administrator.

E.1.3. Responsibilities of Institutional Review Board Staff

1. Administrator

• Assure IRB compliance with FWA regulations.

Misericordia University’s IRB, at its option, may change, delete, suspend, or discontinue parts of the policy in its entirety to comply with guidelines from the DHHS-OHRP or other federal agencies. In the event of a policy change, a notice will be posted on the IRB website.
• Maintain currency in IRB & FWA regulations.
• Serve as contact person with U.S. Office of Human Subject Protection.
• Provide guidance to IRB in Human Subjects and FWA regulations.
• Provide administrative support to the IRB, including but not limited to initial application review, supervision of secretarial support, maintenance of records, form development/revision, oversight of IRB budget and web page set-up and maintenance.
• Collaborate with the IRB chair to update IRB policies and procedures.
• Attend IRB meetings and serve as non-voting member of IRB.
• Collaborate with IRB chair in development of IRB meeting agendas.
• Maintain IRB records.
• Inform IRB chair of Annual Update and End-of-Project Reports.
• Report to the IO monthly actions taken by the IRB and on IRB and FWA compliance concerns.
• Develop and implement quality assurance monitoring system.
• Make recommendations to improve IRB functioning.
• Coordinate implementation of unanticipated risks to subjects process.
• Inform IRB chair of change in protocol requests.

2. **IRB Coordinator/Analyst**

• Maintain FWA.
• Determine application type: Exempt, Expedited, Full board.
• Develop rotating IRB member review schedule for exempt and expedited studies.
• Assign new applications to appropriate IRB members.
• Provide administrative support for the IRB.
• Develop IRB meeting schedule and make room reservations.
• Manage records of educational certificates for IRB members.
• Manage electronic data files of protocols.
• Monitor IRB budget including annual contract payments.
• Manage protocol record maintenance.
• Assist with preparation of correspondence.
• Assist with policy and technical consultation.
• Advise IRB members regarding review requirements based on regulation.
• Coordinate with grant services.
• Provide advisement on regulatory compliance to administration.
• Provide consultation, assistance, and dissemination of information regarding the review process.
• Direct, coordinate, and supervise administrative and clerical functions of the IRB office.
• Complete required human subjects protection educational program.
• Participate in ongoing human subjects review education.

Misericordia University’s IRB, at its option, may change, delete, suspend, or discontinue parts of the policy in its entirety to comply with guidelines from the DHHS-OHRP or other federal agencies. In the event of a policy change, a notice will be posted on the IRB website.
E.2. Term of Office

Members of the IRB are appointed for a three year term and may be reappointed when the term expires. No more than 1/3 of the membership may be replaced annually. Members who miss two consecutive meetings can be asked to relinquish their appointment.

The chair of the IRB is appointed for a two year term and may be reappointed when the term expires. It is highly recommended that the chair be selected from IRB membership following at least two years of participation in IRB review.

E.3. Meetings

The IRB meets monthly from August until May. One meeting will be held during the summer months. A schedule of meeting dates is available by following the link below
http://www.misericordia.edu/page.cfm?p=782

E.4. Minutes

Minutes will be taken at all IRB meetings. Records will be retained for at least three years.

E.5. Scope of IRB Responsibilities

The IRB’s responsibility includes the review of research which would normally be viewed as biological, behavioral, or psychological investigations involving human subjects.

The IRB is responsible for review of all research activities that involve human subjects including research:

- conducted at the University or its sites;
- by any employee or student whose research commences during the time of his or her employment or affiliation with the University,
- and who represents him or herself to the subjects or to the population to which the results will be disseminated, as an affiliate of the University. This includes master’s theses or doctoral dissertation research conducted by faculty, staff or students;
- conducted by external researchers who wish to have access to Misericordia University students, faculty or staff as part of their subject pool.

Human subjects research includes not only studies involving adults and children, but also:

(a) use of graphic, written, or recorded information about individuals even when this information has been collected by other institutions or researchers;

(b) investigations of prenatal life;

(c) studies or procedures utilizing organs, tissues or body fluids of humans; and

(d) investigations of organizations.

E.5.1. Institutional (Internal) Research

Internal institutional research is the gathering of data from employees and students which will be used solely for internal program improvement, informational or required data-collection purposes. For example: course evaluations; surveys to improve institutional services or Misericordia University’s IRB, at its option, may change, delete, suspend, or discontinue parts of the policy in its entirety to comply with guidelines from the DHHS-OHRP or other federal agencies. In the event of a policy change, a notice will be posted on the IRB website.
processes; data collection to establish opinions, experiences or preferences of the University community or information used to characterize the institution.

IRB approval is not required for institutional research EXCEPT when one of the two conditions exists:

(a) the information deals with sensitive subject matter and disclosure of the responses outside of the research could place the subject at criminal or civil liability or be damaging to the subject’s reputation, employability or financial standing; or

(b) it is anticipated that the data generated will be used for research, the results of which will be disseminated outside of the university.

E.6. Responsibilities of IRB

The IRB has the responsibility to review research protocols and the authority to approve, require modifications, or disapprove all research activities conducted by Misericordia University faculty, students or staff even if the research is not conducted at the University.

The IRB will require that information given to subjects as part of informed consent is in accordance with 46.116 of 45 CFR 46. The IRB may require that information, in addition to that specifically mentioned in 46.116, be given to the subjects when in the IRB’s judgment the information would meaningfully add to the protection of the rights and welfare of subjects.

The IRB will require documentation of informed consent or may waive documentation in accordance with 46.117 of 45 CFR 46.

The IRB will notify researchers 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. 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.

The IRB will conduct continuing review of all approved protocols at intervals appropriate to the degree of risk, but not less than once per year, and has the authority to observe or have a third party observe the consent process and implementation of the protocol.

IRB members will not review protocols initially or for continuing review for which a conflict of interest can be construed.

The IRB also has responsibility for assuring adequate monitoring of the quality of research which it has approved. This responsibility for monitoring resides with the IRB administrator or designee. Reports of protocol monitoring activities must be made at least annually to the IRB.

E.7. Review Process

The IRB meets monthly. Protocols for review are to be submitted on iMedRIS. Full board protocols are to be submitted not less than two weeks before the meeting date of the IRB. All protocols will be assigned to IRB members based on the type of review required. Outcomes will be communicated to the researcher in writing and are reported to the IRB at its regularly scheduled meetings. Additionally, the researcher will receive a copy of the informed consent form which is date stamped. This is the approved form and the only one that is to be used. If Misericordia University’s IRB, at its option, may change, delete, suspend, or discontinue parts of the policy in its entirety to comply with guidelines from the DHHS-OHRP or other federal agencies. In the event of a policy change, a notice will be posted on the IRB website.
revisions/amendments are requested by the IRB, they must be received within 60 days or IRB approval will be terminated and a new application will be required.

E.8. Record Keeping

The Office of the Vice President of Academic Affairs prepares and maintains Misericordia University IRB Policies and Procedures and the IRB membership list, research protocols, and all related documentation (for a period of three years after the date of study completion). Minutes of IRB meetings are stored within iMedRIS. All IRB members have access to IRB membership, Misericordia University Policies and Procedures, the Common Rule document (45 CFR 46), the Belmont Report, monthly minutes, and other documents related to its work as they become available (e.g. HIPAA requirements).

E.9. Appeal Process

If the protocol is disapproved, the researcher has the right to appeal the decision. The researcher must submit a letter to the IRB chairperson requesting another review and provide the rationale for the request. Every attempt will be made to resolve the identified problem(s). However, the IRB retains the responsibility for determining the risk to human subjects.

E.10. Administrative Oversight

The IRB administrator has the responsibility of communicating to the University administration the outcomes of the reviews conducted by the IRB. A report will be made to the IO following each IRB meeting.

The University administration has the right to refuse to support a protocol approved by the IRB; however, it does not have the right to approve a protocol not approved by the IRB.

E.11 Educational Program

All Misericordia University faculty, staff, students, individuals obtaining consent, or key research personnel are required to complete training in the protection of human research participants, specifically Collaborative Institute Training Initiative (CITI) courses, prior to obtaining IRB approval. This training is required regardless of level of review (exempt, limited, expedited, or full). Certificates will need to be renewed every three years. CITI training certificates for all research personnel listed on an application must accompany the IRB application. Applications that include research personnel without the appropriate training certificate, as outlined above, will not be reviewed until this requirement is satisfied.

If an investigator is not associated with, or external to Misericordia University, s/he must submit proof of having completed human participants protection training. However, the IRB reserves the right to require the external investigator to complete some or all of the elements of the training module used to satisfy the Misericordia University requirement.¹

¹ Language adapted from the University of Connecticut Policies and Procedures
Misericordia University's IRB, at its option, may change, delete, suspend, or discontinue parts of the policy in its entirety to comply with guidelines from the DHHS-OHRP or other federal agencies. In the event of a policy change, a notice will be posted on the IRB website.¹
E.12. Quality Assurance

Ongoing review of research activities may require random selection and review by the IRB of approved protocols for assessment of compliance with approved procedures. This review may be conducted by members of the IRB or the IRB administrator. All approved protocols will be reviewed at least annually. The IRB can prescribe more frequent review of protocols if it determines the need for them.

F. Types of Review

Protocols can be submitted for review by faculty, staff, students, and agents of Misericordia University. Student submissions must be accompanied by a faculty sponsor. Similarly, those from outside of the institution who wish to conduct research at Misericordia University must secure a sponsor from within the institution.

Misericordia University’s IRB will make the final determination on the type of research review required. Therefore, all research protocols should be submitted to the IRB for review unless they meet the requirements noted under Institutional (Internal) Research.

F.1. Exempt Review (Formerly Type I)

Certain research may be determined exempt from review by the IRB under 45 CFR 46:101(b). Although minimal risk, it is still the ethical responsibility of the researcher to protect human research subjects, and all researchers must apply and receive approval for exempt status before initiating the research study. Exempt applications will be reviewed by the chair or at least one member of the IRB. The reviewer(s) will determine whether the submission meets the criteria for exemption. The reviewer(s) may exercise all the authorities of the IRB except to disapprove the research. A research activity may be disapproved only after a review by the convened IRB.

Research exempt from full IRB review must meet the following guidelines:

1. Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students’ opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

2. Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior, if at least one of the following criteria is met:

   a. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

Misericordia University’s IRB, at its option, may change, delete, suspend, or discontinue parts of the policy in its entirety to comply with guidelines from the DHHS-OHRP or other federal agencies. In the event of a policy change, a notice will be posted on the IRB website.
b. Any disclosure of the human subjects’ responses outside the research would not reasonably place the subject at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, educational advancement, or reputation; or

c. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by 46.111(a)(7).

3. Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written response or audiovisual recording if the subject prospectively agrees to intervention and information collection and at least one of the following criteria is met:

a. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to them;

b. Any disclosure of the human subjects’ responses outside the research would not reasonably place the subject at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, educational advancement or reputation; or

c. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by 46.111(a)(7).

For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.
4. Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

a. The identifiable private information or identifiable biospecimens are publicly available;

b. Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

c. The research involves only information collection and analysis involving the investigator’s use of identifiable health information when that use is regulated under CFR Parts 160 and 164 (the Health Insurance Portability and Accountability Act), for the purposes of “health care operations”, or “research” as those terms are defined at 45 CFR 164.501 or for “public health activities and purposes” as described under 45 CFR 164.512(b); or,

d. The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

5. 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 (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public health benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers or otherwise mandatory requirements using authorities such as sections 1115 and 1115A or the Social Security Act, as amended.

Misericordia University’s IRB, at its option, may change, delete, suspend, or discontinue parts of the policy in its entirety to comply with guidelines from the DHHS-OHRP or other federal agencies. In the event of a policy change, a notice will be posted on the IRB website.
Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

6. 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 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 Environment Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

These exemptions do not apply to research involving prisoners, exempt for research aimed at involving a broader subject population that only incidentally includes prisoners. Further, exemption 2 a and c may only apply to children in research involving educational tests or the observations of public behavior when the investigators (s) do not participate in the activities being observed.

F.1.1. Limited Review

Certain exempt categories require a limited review by the IRB to ensure adequate protections are in place for protecting privacy and maintaining confidentiality. Limited review will be conducted by the chair and/or at least one member of the IRB. Under limited review, the IRB does not need to make the determinations at 46.111 paragraphs (a)(1) through (6). The reviewers(s) may exercise all the authorities of the IRB except to disapprove the research. A research activity may be disapproved only after a review by the convened IRB.

F.2. Expedited Review (Formerly Type 2)

An IRB may use the expedited review procedure to review the following:

(i) Some or all of the research appearing on the list described in this section, unless the reviewer determines that the study involves more than minimal risk;

(ii) Minor changes in previously approved research during the period for which approval is authorized; or

(iii) Research for which limited IRB review is a condition of exemption

The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no Misericordia University's IRB, at its option, may change, delete, suspend, or discontinue parts of the policy in its entirety to comply with guidelines from the DHHS-OHRP or other federal agencies. In the event of a policy change, a notice will be posted on the IRB website.
more than minimal risk to human subjects. Expedited applications will be reviewed by the chair
and/or at least one member of the IRB. The reviewer(s) will determine whether the submission
meets the criteria for expedited review. The reviewers(s) may exercise all the authorities of the
IRB except to disapprove the research. A research activity may be disapproved only after a
review by the convened IRB.

The categories in this list apply regardless of the age of subjects, except as noted.

The expedited review procedure may not be used where identification of the subjects and/or their
responses would reasonably place them at risk of criminal or civil liability or be damaging to the
subjects’ financial standing, employability, insurability, reputation, or be stigmatizing, unless
reasonable and appropriate protections will be implemented so that risks related to invasion of
privacy and breach of confidentiality are no greater than minimal. If the reviewer determines the
research to be more than minimal risk, documentation of such is required.

The expedited review procedure may not be used for classified research involving human
subjects.

Research Categories

(1) Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

(a) Research on drugs for which an investigational new drug application (21 CFR Part
312) is not required. (Note: Research on marketed drugs that significantly increases the
risks or decreases the acceptability of the risks associated with the use of the product is
not eligible for expedited review.)

(b) Research on medical devices for which (i) an investigational device exemption
application (21 CFR Part 812) is not required; or (ii) the medical device is
cleared/approved for marketing and the medical device is being used in accordance with
its cleared/approved labeling.

(2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

(a) from healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects,
the amounts drawn may not exceed 550 ml in an 8 week period and collection may not
occur more frequently than 2 times per week; or

(b) from other adults and children, considering the 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 of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more
frequently than 2 times per week.

(3) Prospective collection of biological specimens for research purposes by noninvasive means.

Examples: (a) hair and nail clippings in a non-disfiguring manner; (b) deciduous teeth at
time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent
teeth if routine patient care indicates a need for extraction; (d) excreta and external
secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated
fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution
to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of

Misericordia University’s IRB, at its option, may change, delete, suspend, or discontinue parts of the policy in its
totality to comply with guidelines from the DHHS-OHRP or other federal agencies. In the event of a policy change,
a notice will be posted on the IRB website.
rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

(4) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject’s privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) 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 collected, 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 the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

(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 perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101 (b)(2) and (b)(3). This listing refers only to research that is not exempt.)

(8) Continuing review of research previously approved by the convened IRB as follows:

(a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or

(b) where no subjects have been enrolled and no additional risks have been identified; or

(c) where the remaining research activities are limited to data analysis.

(9) Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but
the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

**F.3. Full Board Review (Formerly Type 3)**

Unless research qualified for exempt or expedited as described previously, it requires full board review. Full board review means that each member of the IRB is responsible for reviewing the entire protocol. Following the review, an in-depth discussion will occur among the IRB members at a scheduled meeting. The majority must be present for the vote and a least one non-scientist must be present for the discussion and vote. A majority decision must be achieved for the proposal to be approved. For a full board protocol, the full board will make one of the following determinations: 1) approved; 2) approval withheld pending submission of revision and/or additional information; 3) disapproved. If a protocol is determined to need revision, the researcher cannot collect data until the full board has re-reviewed the protocol and voted to approve it. At the time of the approval vote, the IRB will determine if continuing review will be required in less than one year. As a matter of course, review must occur at least once a year. The IRB will use the skills of its membership to determine if more frequent review is required. This will be based on the IRB concluding that there is adequate risk to require more frequent review.

In order to approve research, the IRB will be certain that all of the following requirements are satisfied:

(1) **Risks to subjects are minimized:**

   (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and

   (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

(2) **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.

(3) **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, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

(4) **Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by 46.116**

(5) **Informed consent will be appropriately documented, in accordance with, and to the extent required by 46.117.**

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

(7) 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, pregnant women, individuals with impaired decision-making ability, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

**F.4. Continuing Review and Annual Update**

The IRB can request a review sooner than one year if it deems appropriate. More frequent review is required for proposals that the IRB determines to be of more than minimal risk. This will be determined on an individual basis and investigators will be notified of the dates of protocol review at the time of approval.

For research projects that continue beyond the initial approved period, they must indicate 1) the number of subjects accrued; 2) a summary of adverse events and any unanticipated problems (see section 2.6.4) involving risks to subjects or others and any withdrawal of subjects from the research or complaints about the research since the last IRB review; 3) a summary of any relevant recent literature, interim findings, and amendments or modifications to the research since the last review; 4) any relevant multi-center trial reports (if applicable); 5) any other relevant information, especially information about risks associated with the research; and 6) a copy of the current informed consent document and any newly proposed consent documents. A continuation/annual update or end of protocol form must be submitted prior to the expiration date of the study approval. If the researcher fails to complete the required form by the expiration date, IRB approval will be terminated and a new application will be required. If revisions/amendments are requested by the IRB, they must be received within 60 days or IRB approval will be terminated and a new application will be required.

Review will be conducted following the procedures for initial review: exempt – IRB chair or at least one member of the IRB; limited - IRB chair and/or at least one member of the IRB, expedited – IRB chair and/or at least one member of the IRB; and full board review. All documentation related to the protocol will be available for reviewers.

**Note:** From time to time, the IRB during its’ review process may determine that additional information is necessary in order to assure adequate review. The additional information may take the form of that which the investigator can provide or that which requires verification from sources other than investigator. When information is to be requested from outside sources, the investigator will be notified via a letter that verification is being sought.

The determination of the need for verification from sources other than the investigator to assure that the protocol has been implemented as approved can be conducted using the following criteria: (1) randomly selected projects; (2) complex projects involving unusual levels or types of risk to subjects; (3) projects conducted by investigators who previously have failed to comply with federal or local IRB requirements or IRB determinations; and (4) projects where concern

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about possible material changes occurring without IRB approval have been raised based upon information provided in continuing review reports or from other sources.

**F.5. Reporting Changes in a Research Protocol**

Researchers must submit all proposed changes to an approved protocol for review and approval prior to instituting the change. Examples of changes requiring approval include but are not limited to: submission for external funding, increase in risk, change in subject recruitment criteria, and inclusion of vulnerable populations. The only exception is in the event that the immediate change is necessary to eliminate a hazard to subjects. However, the IRB must still be notified as soon as possible.

Once received, the IRB chairperson will determine the appropriate level of review. Following the review, the investigator will be notified in writing of the IRB’s decision regarding the change(s). If revisions/amendments are requested by the IRB, they must be received within 60 days or IRB approval will be terminated and a new application will be required.

**F.6. Procedures for Reporting Unanticipated Risks to Subjects**

Researchers are required to notify the Office of Institutional Review Board within 3 working days of any identified unanticipated risks or adverse events to subjects or to others and the proposed action to correct the situation via the electronic reporting system. The investigator(s) will also notify subjects. The IRB administrator will report to the IRB and to the IO within 3 working days of this notification, the identified unanticipated risk and the plan for correction of the problem. The IRB and the IO will jointly determine the effectiveness of the plan. The investigator will be notified within 48 hours of review of the action of the acceptability of the plan or additional information and/or actions to be taken. The IRB can choose one of three actions: (1) approve plan as submitted; (2) ask for modifications to the plan to assure protection of human subjects, or (3) refuse to accept the plan of action and direct the researcher to halt all research activities and notify study subjects.

For funded projects, notification will also be made by the Office of Institutional Review Board to the appropriate federal agency or department and OHRP with 14 days of investigator notification of approval of the correction plan.

**F.7. Notification on Non-Compliance or Research Misconduct**

All members of the University community bear responsibility for compliance with IRB policies and procedures related to research that includes human subjects. If anyone identifies an activity or activities that violate these policies and procedures, the individual has the responsibility of reporting this to the IRB Administrator or the IRB chair. A report may be brought to the IRB in a number of ways including but not limited to self-report, audits conducted by the IRB, or by another member of the University community. Once a report is received, the IRB Chair will report these to the IRB Administrator and the IRB Administrator will report these to the IO. Examples of violations of Misericordia University IRB policy include, but are not limited to, failure to:

1. submit a human subjects research protocol to the IRB
2. submit a change in research protocol

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3. report adverse events in a research study
4. report unanticipated problems
5. submit an annual update or end-of-project report.

If the infraction is not substantive or continuous, the IRB may request additional written information from the researcher to assess the potential level of risk for the participants. This information is required within 60 days of the request or IRB approval will be terminated and a new application will be required.

If the infraction is substantive or continuous, within two working days of notification of a suspected violation, the IRB Chair will notify at least two IRB members of the suspected infraction. These members, in conjunction with the IRB Chair, will begin an investigation. Upon investigating the suspected violation, the reviewing members may: (a) deem the violation unfounded, (b) recommend that the IRB reprimand the researcher via a letter (without sanctions), or (c) recommend to the President appropriate sanctioning of the researchers. If the recommendation is for b or c, the reported violation will then be reviewed by the entire IRB. The researcher in question will be invited to attend the IRB meeting. After careful review of the material presented, the IRB will conduct a vote for or against reprimand or sanctioning; in the event of sanctioning, the type and duration of sanctions will be recommended. If sanctioning is recommended and approved by a quorum of IRB members, then the IRB will recommend to the IO the sanctions to be administered. When agreed upon, the President will send a letter to the researcher that outlines the sanctions and the appropriate supervisors will be copied. These may include, but are not limited to, suspension or elimination of:

1. research projects(s), including IRB approval
2. research support – financial, equipment, space, etc.,
3. professional development funding;
4. grant funding;
5. research release time; or
6. the right to conduct future research while a member of the Misericordia University Community

In addition, the IRB may require corrective actions that may include, but are not limited to:

1. Disclosure to publication editors or presentation editors that the data were collected without approval from Misericordia University IRB
2. Disclosure to the involved research participants regarding the investigator’s lack of compliance and solicitation of permission
3. The completion of additional human research participants safety training
4. Modification of all or parts of the research
5. Destruction of data

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If deemed a serious or continuing noncompliance, a report will be made to the OHRP outlining the misconduct/noncompliance and the action taken on behalf of the University. The following will always be considered a serious noncompliance:

1. research conducted without IRB approval

2. accessing protected health information (PHI) for research purposes without IRB approval and HIPAA authorization (or IRB-granted waiver of HIPAA authorization)

3. accessing certain Misericordia University records for research purposes without IRB approval.

The IRB also has the authority to suspend, place on temporary hold until specified conditions are met, or terminate (end) IRB approval when:

1. Research is not conducted in accordance with IRB requirements
2. Research is associated with unexpected serious harm to participants

F.8. End of Project Reporting

When the research study is completed, the researcher must submit and end of project report on iMedRIS. The completion of protocols will be reported to the IRB at its monthly meetings. Failure to complete this report by the study approval expiration date will result in a termination of IRB approval.

G. Student Research

Students are held to the same standard for research protocol submission as members of the University faculty and staff. Faculty members are responsible for screening student research projects. They also are responsible for assisting students in the development of the application. Faculty members hold the responsibility for assuring that student submissions meet the standards set by the IRB. Proposals that do not respond to all areas of the application or are poorly written will be returned to the faculty sponsor. The faculty sponsor holds the responsibility for assuring that student proposals are of high quality therefore the faculty member is responsible for working with the student to assure a high quality submission.

If the student project is assigned for the purpose of producing generalizable results that may be presented outside of the class or be published they must comply with the policies and procedures for human subjects’ protection. Students must complete an application and receive approval before initiating the project.

Class assignments that are intended to provide research experiences are expected to adhere to the same ethical standards and use of informed consent/assent described in this document.

H. Cooperative Research with another Institution

When cooperative research occurs with another institution, one institution may agree to delegate responsibility for initial and continuing review of all or a portion of the research activity to another IRB. This can occur if the other institution and its IRB agree to assume responsibility for the review and if the delegating institution agrees to abide by the reviewing IRB decisions.

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Misericordia University's IRB retains the right to make this decision. Researchers who are conducting research outside of the institution have the responsibility of notifying the IRB of their work. This includes dissertation and collaborative work. The University's IRB or designee will review the research and determine whether a cooperative agreement is optimal for the project. The IRB may also request a copy of the cooperating institution's IRB policies and procedures to determine their compliance with standards set by Misericordia University.

FWA requires that cooperative agreements be documented with OHRP for all federally funded research. This documentation must be completed by the IRB administrator. Official approval is then provided by the cooperative institution via an on-line documentation system. When the cooperative agreement is authorized, the IRB administrator will notify the researcher(s) involved.

Researchers are advised to bear in mind that submission to another IRB will require review of its procedures, local laws, institutional policies, professional and community standards, and population differences. It may be useful to seek IRB counsel prior to engaging in cooperative research involving the use of human subjects. As a general rule, the University's IRB will not delegate responsibility to another IRB if Misericordia university faculty, students or staff are subjects in the study.

The agreement by a cooperative institution's IRB to assume responsibility for a protocol's review must be documented in writing with copies furnished to all involved with the agreement and Misericordia University. If the University's IRB determines that it will accept a cooperative agreement with another institution for IRB approval, the researcher must supply to the IRB administrator a copy of the protocol and the approval letter from the cooperating IRB. Regardless of the agreement, each institution bears responsibility for safeguarding the rights and welfare of human subjects.

I. International Research

Procedures for reviewing research in foreign countries may differ from those set forth in this document and in federal regulations. Such ethical principles as the Nuremberg Code and Declaration of Helsinki present broad policies, but are not considered sufficient for an institution having FWA. Because of the varied policies and procedures involved with conduct of research in foreign countries, it is best that researchers discuss research projects with the IRB during planning phases.

Instructions for Initial Application for Review of Research Involving Human Subjects

Prior to submitting an application, be sure that you have carefully reviewed Misericordia University's IRB Policies and Procedures. Researchers are requested to determine the level of review that their proposal will require. Ultimately, the final determination will be made by the IRB chairperson in consultation (as necessary) with the IRB administrator. Research involving human subjects may not be initiated until you have received notification of IRB approval and agree to comply with the contingencies in connection with that approval.

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The electronic proposal form must be completed. Please visit http://www.misericordia.edu/irb for instructions on submitting your IRB application.

Please note, researchers must retain the approved application and signed consent forms for a minimum of three years following the completion of the study. HIPAA Authorization forms must be kept for six years. For student research studies, the faculty must retain the approved application and signed consent forms. The IRB may request these.
GLOSSARY

ADVERSE EVENT: Any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporarily associated with the subject’s participation in the research, whether or not considered related to the subject’s participation in the research.

ASSENT: This is the child’s affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

ASSURANCE: A formal written, binding commitment that is submitted to a federal agency in which an institution promises to comply with applicable regulations governing research with human subjects and stipulates the procedures through which compliance is achieved. This is also known as Federal Wide Assurance (FWA).

BELMONT REPORT: A report upon which the Department of Health and Human Services regulations are based. It describes the ethical principles and guidelines for the protection of human subjects in research.

CHILDREN: These are persons who have not attained the legal age for consent to treatments or procedures involved in research, under the applicable law of the jurisdiction in which the research is conducted.

CONFIDENTIALITY: Protection of human subjects in a research study so that their individual identities will not be linked to information they provide and will never be publicly shared.

CLINICAL TRIAL: A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

DEBRIEFING: Communication with study subjects usually after they have participated in study activities regarding various aspects of the study.

GUARDIAN: According to Pennsylvania State Law a guardian is a person lawfully invested with the power, and charged with the duty, of taking care of and managing the property and rights of another person, who, for some peculiarity of status, or defect of age, understanding or self-control, is considered incapable of administering his or her own affairs.

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HUMAN SUBJECT: A living individual about whom an investigator (whether professional or student) conducting research: Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

INTERVENTION: This includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

IN WRITING: Writing on a tangible medium (e.g., paper) or in an electronic format.

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 performance of routine physical or psychological examinations or test.

MINOR: According to the Pennsylvania Code, Rule 801, a minor is a person under the age of 18.

NURENBEG CODE: A code of ethics developed during the trials of Nazi war criminals following World War II and widely adopted as a standard during the 1950s and 1960s for protecting human subjects during research.

PARENT: A child's biological or adoptive parent.

PERMISSION: This is the agreement of a parent or guardian to the participation of their child or ward in research.

PRINCIPAL INVESTIGATOR OR RESEARCHER: The scientist or scholar with primary responsibility for the design and conduct of a research study.

PRISONER: An individual involuntarily confined or detained in a penal institution or an alternative facility including those detained pending arraignment, trial or sentencing.

PRIVACY: Control over the extent, timing, and circumstances of sharing oneself (intellectually, physically, behaviorally) with others.

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PRIVATE INFORMATION: This includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).

RESEARCH: Research means 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 purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. For purposes of this part, the following activities are deemed not to be research: 1. 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. 2. Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters). 3. Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes. 4. Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

RESEARCH PROTOCOL: The formal design or plan of an experiment or research activity: specifically, the plan submitted to the IRB or designated representative for review.

UNANTICIPATED PROBLEM: According to OHRP, the incident or outcome must meet ALL of the following criteria: (1) unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied; (2) related or possibly related to participation in the research (possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and (3) suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

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VOLUNTARY: A subject’s decision to participate (or continue to participate) in a research activity that is made free of coercion, duress, or undue inducement.

Thomas J. Botzman, Ph.D.
University President

1Adapted from Montclair University “The Institutional Review Board (IRB) for the Protection of Human Participants in Research” Internal Policies and Procedures

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