### Section I

#### Introduction

Misericordia University 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.

Research is defined by the Common Rule: <http://www.hhs.gov/ohrp/humansubjects/commonrule/> also known as 45 CFR 46 as “a systematic investigation, including research, development, testing and evaluation, designed to develop or contribute to generalizable knowledge.” It includes research that is conducted on or off campus by university employees. Questionnaires, interviews, surveys, tests, observations and experiments constitute research even if the work is preliminary (pilot work) to a more extensive study. It also includes systematic collection of data from human subjects that occurs in conjunction with classroom projects, unless the work is done as a learning exercise for the student and will never be published or presented outside of the course.

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 in the Office of the Associate Vice President of Academic Affairs or any member of the IRB. The names and contact information for these individuals can be found at <http://www.misericordia.edu/page.cfm?p=782>.

#### 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 on June 23, 2005. These regulations apply to all research involving human subjects that is conducted or supported, in whole or in part, by DHHS in foreign or domestic settings.

The establishment of Misericordia University’s IRB and its policies and procedures are primarily derived 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 protocol. The Belmont Report (<http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html>) 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.

#### 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 *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:

##### C.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.

##### C.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.

##### C.3. Informed Consent

All subjects must be properly informed about what the participation will entail. This should be fully explained during the recruitment process by having subjects read, understand and sign an informed consent before agreeing to participate. Also, it is crucial that researchers ensure to the best of their ability that the potential subjects fully understand what is being explained to them. Consent must be given freely with the subject understanding the nature and consequences of what is proposed. Consent is an ongoing process and not a single occurrence. Researchers must inform subjects and/or guardians of any important new information that might affect their willingness to continue in the study.

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.

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.

Fundamentally, before the assent process can begin, parents or guardians must give permission for their children to participate. 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 (Adapted from the NCI webpage: http://www.misericordia.edu/page.cfm?p=782

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 age, maturity and psychological state of the 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

The requirements for a waiver of informed consent found in 46.116 which can be obtained at <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.116> are met.

###### C.3.1. HIPAA and Informed Consent

Informed consent shall comply with all requirements of the Health Insurance Portability and Accountability Act (HIPPA), PL104-191 (<http://aspe.hhs.gov/admnsimp/pl104191.htm>) and the Standards for Privacy of Individually Identifiable Health Information (Privacy Rule) 45 CFR 160 and 164 (<http://www.hhs.gov/ocr/privacy/hipaa/understanding/summary/introduction.pdf>).

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.

##### C.4. 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).

##### C.5. 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.

##### C.6. 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 confidentially 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.

##### C.7. 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.

##### C.8. 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.

##### C.9. 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.

##### C.10. Vulnerable Populations

Some groups of individuals by virtue of their situation have been identified by DHHS as vulnerable populations. The following shares special considerations to be made when involving them in research.

###### C.10.1. 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](http://www.hhs.gov/ohrp/index.html%20) and be used for guidance on working with this population.

###### C.10.2. 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](http://www.hhs.gov/ohrp/index.html%20) and be used for guidance on working with this population.

###### C.10.3. 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](http://www.hhs.gov/ohrp/index.html%20) and be used for guidance on working with this population.

###### C.10.4. 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.

#### Institutional Review Board

##### D.1. Membership

Members of the IRB are recommended by the IRB chair to the Vice President of Academic Affairs (VPAA), the Associate Vice President of Academic Affairs 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 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 the Vice President of Academic Affairs, and the Associate Vice President of Academic Affairs, have the responsibility of approving or disapproving the recommendations forwarded to him/her.

The chair of the IRB is appointed by the University President, the Vice President of Academic Affairs, and the Associate Vice President of Academic Affairs.

There are eight 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/page.cfm?p=782>

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.

###### D.1.1 Alternate Membership

The IRB includes two alternate members. 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.

###### D.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: Type 1 (Exempt), Type 2 (Expedited), or Type 3 (Full Board).
* Develop rotating IRB member review schedule for type 1 and type 2 studies.
* Distribute new applications and reviewer checklists to appropriate IRB members.
* Participate as an IRB reviewer as needed for type 1 and 2 applications. Review all type 3 applications.
* Communicate with IRB members concerning status of applications.
* 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 (See section 2.6.1.5.6)
* Maintain open communication with the Office of the Associate Vice President of Academic Affairs.
* Participate in quality assurance monitoring

1. **Members**

* Attend monthly IRB meetings as scheduled. Communicate anticipated absences to IRB chair or the Associate Vice President of Academic Affairs prior to meetings.
* Complete review of Type 1 and 2 applications in a timely manner.
* Make recommendations related to applications reviewed. For type 2 reviews, IRB members collaborate to determine recommendations and approval status
* Communicate recommendations and approval status to IRB chair in writing (using the Reviewer Checklist) at least two days prior to IRB meetings.
* Review all type 3 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 (See section 2.6.1.5.6)
* Participate in quality assurance monitoring.
* Seek consultation as necessary with IRB members or the Associate Vice President of Academic Affairs.

###### D.1.3. Responsibilities of Institutional Review Board Staff

1. **Administrator**

* Assure IRB compliance with FWA regulations.
* 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 President 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 (See section 2.6.1.5.6).
* Inform IRB chair of change in protocol requests.

1. **IRB Secretary**

* Provide secretarial support for IRB including but not limited to application status letter preparation, development of application files, procurement of reviewer signatures for protocol files as directed by IRB chair or administrator and preparation of annual update or end-of-project notification
* Assist Administrator in development of IRB meeting schedule and room reservations
* Maintain records of educational certificates for IRB members.
* Maintain electronic data files of protocols.
* Monitor IRB budget
* Assist Administrator in protocol record maintenance.

##### D.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.

##### D.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>

##### D.4. Minutes

Minutes will be taken at all IRB meetings. Records will be retained by the IRB Administrator in the Office of the Associate Vice President of Academic Affairs for at least three years.

##### D.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:

1. use of graphic, written, or recorded information about individuals even when this information has been collected by other institutions or researchers;
2. investigations of prenatal life;
3. studies or procedures utilizing organs, tissues or body fluids of humans; and
4. investigations of organizations.

###### D.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 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:

1. 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
2. it is anticipated that the data generated will be used for research, the results of which will be disseminated outside of the university.

##### D.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 improved. 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.

##### D.7. Review Process

The IRB meets monthly. Protocols for review are to be submitted to the Office of the Associate Vice President of Academic Affairs (Mercy Hall, Room 206), or electronically to [bnowalis@misericordia.edu](mailto:bnowalis@misericordia.edu) not less than two weeks before the meeting date of the IRB. The IRB coordinator will review the applications for completeness and assign the protocol a submission number. The protocol then is forwarded to the IRB chairperson within two working days of receipt. The IRB chairperson will then assign the protocol to IRB members based on the type of review required.

Type 1 (exempt) protocols will be reviewed by at least one member of the IRB. Upon completion of the Type 1 Justification Form review, the IRB member with review responsibilities will determine whether the submission meets the criteria for exemption. If it does, the reviewer will send the recommendation to the IRB chairperson who will communicate the outcome to the researcher in writing. If it does not meet the criteria for exemption, the researcher will be asked to submit a full proposal for Type 2 or 3 reviews. In addition to the forms required for Type 1 review, investigators may be asked to submit an informed consent.

Type 2 (expedited) protocols will be reviewed by two members of the IRB. The two reviewers for a Type 2 protocol will independently review it, then discuss the recommendation between them, make a determination and send their decision to the IRB chairperson at least two days prior to the scheduled meeting of the IRB. IRB members will be notified at the scheduled meeting of the determination. One of three determinations can be made on a Type 2 protocol: 1) approved; 2) approval withheld pending submission of revision and/or additional information; 3) disapproved. Upon receipt of the recommendation by the reviewers, a letter will be sent to the researcher by the IRB chairperson indicating the outcome.

All requested revisions to protocols must be incorporated into the original submission.

The outcome of Type I and II reviews are reported to the IRB at its regularly scheduled meetings.

Type 3 (full board review) protocols will be reviewed by all members of the IRB. The reviewers will review the protocol and prepare their response to it. For a Type 3 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. The full board must vote on the protocol. In order to conduct a full board review, the majority of members must be present and voting and a member who is a non-scientist must be present for the vote. 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.

Following the IRB’s decision, a letter will be sent to the researcher by the IRB chairperson indicating the outcome. In addition, 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.

##### D.8. Record Keeping

The Office of the Associate Vice President of Academic Affairs prepares and maintains documentation of IRB activities. These documents include: Misericordia University IRB Policies and Procedures, IRB membership list, copies of research protocols and all related documentation (for a period of three years after the date of study completion); and minutes of IRB meetings.

All IRB members are provided with a copy of 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. HIPPA requirements).

##### D.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.

##### D.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 University President 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.

##### D.11 Educational Program

Educational training in human subjects’ protection is required for all members of the IRB, researchers and faculty sponsors involved in Type 2 & 3 protocols submitted for review. Data collectors must also complete the educational program and sign the *Researcher Assurance Statement.* It is highly recommended that researchers involved in Type 1 complete the educational program as well.To be in compliance with the educational requirement, all investigators are to attach to their protocols a certificate documenting the completion of a human subjects review education program. The program currently required by the IRB can be found at [http://phrp.nihtraining.com/users/login.php](http://phrp.nihtraining.com/users/login.php" \t "_blank)

Training requirements adhere to the standards and regulations set forth by the Office of Human Subjects Research Protection (OHRP) of the United States Department of Health and Human Services (DHHS) or required under the University’s federal wide assurance (FWA). Institutions engaged in human subjects research supported or conducted by DHHS must obtain an assurance of compliance approved by OHRP. Misericordia University’s FWA covers all research including human subjects that is sponsored by it.

##### D.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.

#### Types of Review

Protocols can be submitted for review by faculty, staff and students. 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 has chosen to 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 2.6.1.4.5.1 (Institutional (Internal) Research).

##### E.1. Type 1 (Exempt Review)

Type 1 (Exempt Review – Exempt is the federal classification for the minimal level of review. Exempt for Misericordia University purposes means that the study does not need full Board Review, however all studies are reviewed by the IRB to assure human subjects protection). The Type 1 Justification Form can be found in section 2.6.4.

Researchers conducting Type I research are required to complete the Type 1 application found in section 2.6.4. The review process for this level of review can be found in section 2.6.1.4.7 of this document.

Type 1 research also referred to as exempt in the federal regulations is research that meets the following guidelines:

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:

(i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if:

(i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

(4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

(5) Research and demonstration projects which are conducted by or subject to the approval of federal department or agency heads, and which are 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.

(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 and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

##### E.2. Type 2 (Expedited Review)

Researchers conducting Type II research are required to complete the application. The review process for this level of review can be found in section 2.6.1.4.7 of this document.

Type 2 research also referred to as expedited in the federal regulations is research that meets the following guidelines:

Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the categories listed below. 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 more than minimal risk to human subjects.

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.

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 children2, 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 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. 45CFR 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.

##### E.3. Type 3 (Full Board Review)

Unless research qualified for Type 1 (Exempt) or Type 2 (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. A complete description of the review process for this level of review can be found in section 2.6.1.4.7 of this document.

In order to approve research determined to be Type 3, 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.

(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, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

##### E.4. Continuing Review and Annual Update

Applications are approved for a maximum of one year. 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 (see section 2.6.1.4.7).

For research projects that continue beyond the initial approved period, they must have a substantive and meaningful annual review. To fulfill this requirement, researchers must complete the *Request for Annual Update Form* including 1) 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.This form must be submitted and approved prior to the end of the year in which the study was approved. If the *Update* is not completed and approved prior to the date determined by the IRB for completion, the study must be suspended until the review is completed.

Review will be conducted following the procedures for initial review: Type 1 – (exempt) one IRB member review; Type 2 (expedited) – two IRB members review; and Type 3 – full Board review. At the time the review is being conducted, the original protocol with the initial reviewers’ comment forms will be provided to the reviewers in addition to the continuing review documents. If reviewers do not have copies of meeting minutes for Type 3 protocols at which action was taken, these will be supplied to the reviewer upon request by the Office of Institutional Review Board.

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

##### E.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 based on the initial type of review whether the change requires review by one, two or all members of the IRB. Following the review, the investigator will be notified in writing of the IRB’s decision regarding the change(s).

##### E.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. The investigator(s) will also notify subjects. The IRB administrator will report to the IRB and to the President of the University within 3 working days of this notification, the identified unanticipated risk and the plan for correction of the problem (See section 2.6.4 for reporting form). The IRB and the President of the University will jointly determine the effectiveness of the plan. The investigator will be notified within 48 hours of review of the action of the acceptableness 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 Intuitional Review Board to the appropriate federal agency or department and OHRP with 14 days of investigator notification of approval of the correction plan.

##### E.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 a member of the University community identifies activities that violate these policies and procedures, the individual has the responsibility of reporting this to the IRB administrator in the Office of the Associate Vice President of Academic Affairs. The IRB administrator will report these to the IRB Chair and to the President of the University. 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
  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 substantive or continuous, within two working days of notification of a suspected violation, the IRB Chair will notify two IRB member**s** of the suspected infraction. In conjunction with the IRB Chair, an investigation will ensue. 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 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 majority of a quorum of IRB members, then the IRB will recommend to the President the sanctions to be administered. The President will send a letter to the researcher that outlines the sanctions. These may include, but are not limited to, suspension or elimination of:

* 1. research projects(s)
  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

If the violation involves research being conducted in conjunction with a federal agency or department, a report will be made to that office and OHRP outlining the misconduct/noncompliance and the action taken on behalf of the University.

##### E.8. End of Project Reporting

When the research study is completed, the researcher must submit and *End of Project Report* to the Office of the Associate Vice President of Academic Affairs. The completion of protocols will be reported to the IRB at its monthly meetings.

#### 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.

#### 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. 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’s Office of Sponsored Research. 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.

#### 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.

### Section II

### 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.

#### Submission of Initial Application Materials

1. For **Type 1** (exempt) review submit an electronic copy of the required documents: Type 1 Justification Form and abstract of the study, the signed cover sheet, assurance statement and initialed conflict of interest statement. The electronic copy should be sent to the IRB Coordinator, bnowalis@misericordia.edu. Following the assignment of a protocol number, the application will be forwarded to the IRB chairperson for distribution. After review by at least one member of the IRB, the researcher will be notified in writing if the reviewer concurs that the study is exempt. The directions for Type 1 applications can be found in Section III. Applicants may be asked to prepare an informed consent form.
2. For **Type 2** review, submit an electronic copy of the required documents: The signed cover sheet, assurance statement, initialed conflict of interest statement and educational certificate should accompany the submission. The electronic copy should be sent to the IRB Coordinator, bnowalis@misericordia.edu. Following the assignment of a protocol number, the application will be forwarded to the IRB chairperson for distribution. After review by at least two members of the IRB, the researcher will receive one of the following decisions:
3. Application approved as submitted.
4. Approval withheld pending submission of revision and/or additional information.
5. Application disapproved.
6. For **Type 3** review, submit an electronic copy of the required documents: The signed cover sheet, assurance statement, initialed conflict of interest statement and educational certificate should accompany the submission. The electronic copy should be sent to the IRB Coordinator, bnowalis@misericordia.edu. Following the assignment of a protocol number, the application will be forwarded to the IRB chairperson for distribution. After review by the IRB, the researcher will receive one of the following decisions:
7. Application approved as submitted.
8. Approval withheld pending submission of revision and/or additional information.
9. Application disapproved.

#### Application Instructions

Justification

Type 1 exemptions are explained in section 2.6.1.5.1 of this document. If you believe your study fits the criteria for exemptions, please submit an abstract of your work which describes the purpose of the research, location(s) of data collection, individuals to be interviewed including age range, methods of data collection, instruments to be used to collect data, and the benefits of the research. Please attach a copy of your data collection instrument. Also complete the Justification Form and Assurance Form found in Section 2.6.4. After review, you may be asked to submit an informed consent based on the risk to human subjects.

TYPE 2 & 3 Applications

The IRB is composed of both scientific and non-scientific members. For this reason, the application should be written so that it is understandable to individuals outside of the field who may be unfamiliar with scientific terms. If specific terminology is used (e.g. tests, procedures, equipment), the terms should be explained or a glossary should be attached. It is difficult for the IRB to make a competent judgment about the risks involved in the study if the application is not clearly written. Technical terminology often confuses the issues and may delay approval of the protocol.

Please use the format described including numbers, letters and headings. Please answer each item completely. You may use N/A (not applicable) where appropriate.

1. Application Cover Sheet
   1. Complete only the top half of the page.
   2. Check the appropriate box at the top of the cover sheet to indicate the proposed level of review.
   3. Provide a clear, concise, descriptive title for the protocol.
   4. Include projected research start and stop dates.
   5. Attach documentation of investigator(s) education
2. Researcher Assurance Statement (must be completed for initial and continuing review)
   1. Read, sign and attach the *Researcher Assurance Statement.*
   2. Each researcher initials the conflict of interest questions and responds where necessary.
3. Description of the Research
   1. Provide a description of the proposed research study. Include the problem to be studied, the purpose(s) of the study, the research design and a brief description of the data collection procedures. Include objectives if necessary. Please use clear, non-technical language.
   2. Indicate the sites where the research will be conducted. If the research will involve children in a school setting, it may be necessary to obtain consent from school officials. Please check with the school district and provide documentation that the study has been approved by the appropriate individual(s). Additionally, a letter is required showing approval from any agencies where data will be collected. If IRB approval is required before a letter can be obtained, please explain the situation.
   3. State who will conduct the research. Include names, position titles and area of expertise. This helps to demonstrate the competence of the researchers.
   4. Describe the training procedures for persons conducting or assisting in the conduct of the research.
4. Characteristics of subjects
   1. Identify the subjects (potential subject pool)
   2. Describe the procedures used to recruit and select research subjects. Attach advertisements, notices, flyers or letters that will be used for recruitment purposes.
   3. Describe the research sample in terms of the number of subjects, age range, gender, ethnic background and health status (if relevant).
   4. If using a special population (children, pregnant women, fetuses, mentally disabled, prisoners, or vulnerable populations) describe your rationale.
   5. State the frequency and duration of subject participation.
   6. If there are rewards or compensation for participation, explain how they are described to subjects. Describe how coercion will be minimized.
5. Procedures/Instrumentation
   1. In non-technical terminology fully describe the means that will be used to gather data (including demographic data). Include procedures for video or audio taping (if appropriate).
   2. Attach copies of data collection instruments. For open-ended or unstructured interviews, attach a copy of sample questions to show the range of issues that might be covered in the interviews. If you think that your description of equipment may not be understood, include pictures or drawings.
   3. If data are to be collected in a classroom setting, explain what activities students who are not engaged in the research will be doing.
6. Benefits
   1. Describe the benefits to the subjects.
   2. State the importance of the expected outcomes to be gained.
7. Risks and protection of subjects
   1. Describe the nature and likelihood of possible physical, psychological, social or economic risks or discomforts. Include any potential reactive effects of instrumentation as well as treatments (procedures).
   2. Describe the measures insuring professional intervention in the event of adverse effects to subjects.
8. Privacy and confidentiality
   1. Privacy refers to the control over the extent, timing, and circumstances of sharing oneself (intellectually, physically and behaviorally) with others. Describe precautions that will be taken to ensure privacy of subjects, especially those involving special populations.
   2. Confidentiality refers to the protection of participants in a research study such that their individual identities will not be linked to the information they provide and will never be publicly divulged. Describe how you will ensure that there will be no unauthorized access to confidential information from the subjects.
      1. If selection of subjects is based on primary documents (e.g. student records, agency application forms, medical charts), describe how you will obtain access and permission to use these records. If appropriate explain how HIPPA requirements will be met. See section 2.6.1.3.3.1.
      2. If selection of subjects is based on primary data collection (e.g. inclusion and exclusion criteria gathered after the individual has agreed to participate), potential subjects must understand this during the initial consent process. Provide the IRB with an example of appropriate debriefing information for individuals who will be removed from the study based on inclusion or exclusion criteria.
   3. Regarding data collection, respond to the following:
      1. How will data be stored?
      2. Who will have access to the data?
      3. How long will the data be kept?
      4. What are the plans for data disposition following completion of the study?
   4. Present any risks of a breach of confidentiality. Indicate what precautions will be taken to minimize these risks. Include a description of how confidentiality of data will be maintained. If the subjects have been assured anonymity, describe the specific coding procedures you will use.
   5. If the data are collected in an electronic format (audio or video tape), answer the following questions
      1. Who will transcribe audio tapes and how will confidentiality be maintained?
      2. Who will have access to the transcriptions? Will they be coded? If so, explain.
      3. Describe any plans to use taped information for purposes other than research.
   6. Informed consent and child assent
      1. Describe how informed consent/assent will be obtained.
      2. Attached the materials you will use to obtain consent/assent. See Section 2.6.4 for model consent/assent statements.
      3. When assent is used, explain the procedures for obtaining parental or guardian consent.
      4. The informed consent must be written in language that is easily understood by the general population or should reflect language that is appropriate to the age group from whom the consent will be obtained. Please see that the elements included below are part of the informed consent. Attach the consent form to the protocol. In instances when the researcher believes that informed consent/assent is not required, clearly explain the rationale for this decision.

##### General Requirements for Informed Consent.

A researcher shall seek informed consent only under circumstances that provide the prospective subject or the guardian with sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the guardian. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the researcher, the sponsor, the university or its agents from liability for negligence.

(a) Basic elements of informed consent. Except as provided in paragraph (c) or (d) of this section, in seeking informed consent the following information shall be provided to each subject:

(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 which 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;

(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; and

(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.

(b) Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:

(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 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.

(c) 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 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.

(d) 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 waiver or alteration will not adversely affect the rights and welfare of the subjects;

(3) The research could not practicably be carried out without the waiver or alteration; and

(4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

(e) The informed consent requirements in this policy are not intended to preempt any applicable federal, state, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.

(f) 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.

##### Documentation of Informed Consent.

(a) Except as provided in paragraph (c) of this section, informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's guardian. A copy shall be given to the person signing the form.

(b) Except as provided in paragraph (c) of this section, 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 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. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the 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 guardian, in addition to a copy of the short form.

(c) An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

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

(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.

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.

#### Record Keeping

Researchers must retain the approved application and signed consent forms for a minimum of three years following the completion of the study. For student research studies, the faculty must retain the approved application and signed consent forms. The IRB may request these.

**SECTION III**

1. APPLICATION COVER SHEET

*For Office Use Only*

Protocol Number:

**MISERICORDIA UNIVERSITY**

**APPLICATION COVER SHEET FOR INITIAL IRB REVIEW**

Type 1 Review Type 2 Review Type 3 Review

Name of contact person:

Department/Program:

Address:

Phone:

Email address:

Faculty Research Advisor (for student research):

Advisor’s Telephone Number:

Advisor’s email address:

Project Title:

Proposed Project Dates: from to

**PLEASE DO NOT INDICATE A START DATE ANY SOONER THAN THE MONDAY FOLLOWING THE IRB MEETING DATE AT WHICH YOUR PROTOCOL WILL BE DISCUSSED.**

**NOTE:** **DO NOT BEGIN DATA COLLECTION UNTIL YOU RECEIVE NOTIFICATION THAT YOUR APPLICATION HAS BEEN APPROVED.**

**Type 1 Review:**

Action:

Approved as submitted

Application disapproved as Type 1, resubmit as \_\_\_\_\_ Type 2 \_\_\_\_\_\_ Type 3.

Signature of Reviewers \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

The reason(s) for disapproval are:

**Type 2 Review:**

Action:

Approved as submitted

Approval withheld pending submission of revision and/or additional information.

Application disapproved.

Signature of Reviewer #1 Date

Signature of Reviewer #2 Date

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Type 3 Review:**

Action:

Approved as submitted

Approval withheld pending submission of revision and/or additional information.

Application disapproved.

Signature of IRB Chair/Designee on Behalf of IRB Date

1. Type 1 aPPLICATION – jUSTIFICATION – ANSWER ALL QUESTIONS – Respond to narrative questions at the end of the form, if Applicable.

Name of Researcher:

Name of Study:

Date of Submission:

YES NO

1. Will your research be conducted in an educational setting?

* If you answered no, move to question #4.

2. Will it be conducted in an existing setting? If yes, describe below.

3. Is your study focused on a normal practice, such as normal educational practices? If yes, describe these below.

4. Will you collect information that exists in a public forum, such as information in public records?

5. Will the information you are collecting be recorded anonymously?

6. Are you collecting data about adults through educational tests, surveys, interviews or observations of public behavior?

* If you answered no, move to questions #9

7. Are the data that you will collect from adults recorded anonymously OR considered benign information?

* If you answered yes because you consider the information to be benign, answer the following questions:

Individuals who provide information are at-risk of criminal or civil liability

Individuals who provide information place their financial standing at-risk

Individuals who provide information risk their current employment or future employability

Individuals who provide information place their reputations at-risk

SKIP TO QUESTION #9, if your research DOES NOT include minors

8. If you are collecting educational testing information passively from minors (no active engagement), will the information be recorded anonymously?

If you answered NO, answer the following questions:

Minors who provide information are at-risk of criminal or civil liability

Minors who provide information place their financial standing at risk

Minors who provide information risk current employment or future employability

Minors who provide information place their reputations at-risk

YES NO

9. Are you collecting data from public officials or candidates?

* If you answered no, please proceed to question #11.

10. Does your data collection involve examining public benefit or service programs?

If you answered yes, is the work to be completed with or approved by a federal agency or department director?

11. Does your data collection involve food quality and consumer acceptance? If you answered NO, do not respond to item 12.

12. Are the foods to be consumed *wholesome* AND without additives?

* If you answered NO to Questions # 2, 3, 5, 7, 8, 12 or if you responded YES to any of the sub questions in # 7 or 8, you must complete the application for TYPE II or III.

Response to Question #2 (if applicable):

Response to Question #3 (if applicable):

In addition to this form, submit an abstract of your work which describes the purpose of the research, location(s) of data collection, individuals to be interviewed including age range, methods of data collection, instruments to be used to collect data, and the benefits of the research. Also attach a copy of your data collection instrument and a signed copy of the Application Cover Sheet and Assurance Form found in Section III. You may be asked to submit an informed consent depending on the risk to human subjects.

C. Researcher Assurance Form

**MISERICORDIA UNIVERSITY**

**RESEARCHER ASSURANCE STATEMENT**

I understand Misericordia University’s IRB policies and procedures concerning research involving human subjects and I agree to:

1. accept responsibility for the ethical conduct of this research;

2. obtain approval from Misericordia University’s IRB prior to instituting any changes in this project;

3. report to Misericordia University’s IRB serious adverse reactions or unexpected effects on subjects;

4. complete all required reports in a timely manner; and

5. disclose any financial or personal conflict of interest.

a.

Researcher’s printed name Department/Program

Researcher’s signature Date

b.

Researcher’s printed name Department/Program

Researcher’s signature Date

c.

Researcher’s printed name Department/Program

Researcher’s signature Date

d.

Researcher’s printed name Department/Program

Researcher’s signature Date

e.

Researcher’s printed name Department/Program

Researcher’s signature Date

**For student research**

I have approved the procedures of the research project described in the attached application. I agree to assist the student with application of the policies and procedures involving human subjects’ protection.

Faculty research advisor printed name Department/Program

Faculty research advisor signature Date

**Conflict of Interest Questions (each researcher must initial each statement):**

1. Are you aware of any relationships between yourself and/or a member of your family that might affect the outcome of this study?

YES NO

If YES, please describe

2. Do you or a member of your family have any financial interests in the outcome of this study?

YES NO

If YES, please describe

D. ANNUAL UPDATE FORM

**MISERICORDIA UNIVERSITY**

**ANNUAL UPDATE FOR RESEARCH INVOLVING HUMAN SUBJECTS**

Researcher Name(s):

Department/Program:

Address:

Phone:

Email Address:

Faculty Research Advisor Name (for student research):

Advisor’s Phone Number:

Advisor’s Email Address:

Project Title:

Project Dates: from to

* 1. Number of subjects enrolled in the study:
  2. Please provide a summary of adverse events and any unanticipated problems or complaints related to the research:
  3. Please attach a summary of relevant literature, interim findings, amendments or modifications:
  4. Include any multi-center research trial reports (if applicable):
  5. Attach a copy of the informed consent

Researcher signature(s):

Date:

For student research:

Faculty Research Advisor’s Signature:

Date:

Approved by: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

E. Request for Change in Protocol Form

**MISERICORDIA UNIVERSITY**

**REQUEST FOR CHANGE IN PROTOCOL FOR RESEARCH INVOLVING HUMANS SUBJECTS**

Researcher Name(s):

Department/Program:

Address:

Phone:

Email Address:

Project Title:

Project dates: from to

Description of proposed changes:

Justification of proposed changes:

Researcher signature(s):

Date:

For student research:

Faculty Research Advisor’s Signature:

Date:

Approved by: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

F. END OF PROJECT REPORT FORM

**MISERICORDIA UNIVERSITY**

**END OF PROJECT REPORT FORM FOR RESEARCH INVOLVING HUMAN SUBJECTS**

Researcher name(s):

Department/program:

Address:

Phone:

Email Address:

Project Title:

Project dates: from to

This is to verify that the named research involving the use of human subjects was performed according to the procedures approved by the IRB. The research is now complete.

Total number of subjects completing the study:

Total number of subjects who voluntarily withdrew from the study:

Total number of subjects who experienced complications, adverse reactions or injuries as a result of their participation:

ALL RECORDS MUST BE MAINTAINED FOR THREE YEARS BY THE RESEARCHER, INCLUDING INFORMED CONSENT FORMS. THEY WILL BE ACCESSIBLE AND AVAILABLE FOR REVIEW SHOULD THE IRB REQUEST THEM.

Faculty members are responsible for maintaining files of student research for which they served as advisors.

Faculty, staff or external researchers whose protocols have been approved by the IRB must maintain the records AND submit updated contact information to the IRB for the three year post the completion of the study.

Researcher signature(s):

Date:

For student research:

Faculty Research Advisor’s Signature:

Date:

Approved by: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. Type I Continuation/End-of-Project Form

**Misericordia University**

**Institutional Review Board**

**Type 1 Continuation Form/End-of-Project Form**

Please check the appropriate box above

Continuation Completed Project

Date:

Researcher Name(s):

Department/Program:

Address:

Phone:

Email Address:

Faculty Research Adviser Name (for student research):

Advisor’s Phone Number

Advisor’s Email Address:

Project Title:

Number of Subjects Recruited:

Have there been any changes to this protocol: YES NO

If yes, please complete the Change in Protocol Form.

Anticipated Data Collection Completion Date:

Researcher signature(s):

Date:

For student research:

Faculty Research Advisor Signature:

Date:

Approved by: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

h. Unanticipated Problem Report Form

**MISERICORDIA UNIVERSITY**

**UNANTICIPATED PROBLEM REPORT FORM FOR RESEARCH INVOLVING HUMAN SUBJECTS**

The following questions must be answered when reporting an adverse event or any other incident, experience, or outcome as an unanticipated problem to the IRB:

1. Provide identifying information for the research protocol, such as the title, the investigator(s) name(s), and the protocol identification number;
2. A detailed description of the adverse event, incident, experience or outcome;
3. An explanation of the basis of determining that the adverse event, incident, experience, or outcome represents an unanticipated problem; and,
4. A description of any changes to the protocol or other corrective actions that have been taken or are proposed in response to the unanticipated problem.

**IV. MODEL CONSENT STATEMENTS FOR RESEARCH INVOLVING HUMAN SUBJECTS**

1. **Model Statements for Informed Consent**

The following are model statements for a consent form. They contain the elements common to many informed consent forms. You should use language that is appropriate for your project and understandable to the research subjects. The italicized language is offered as an example only. See Section II of the Application for the specific elements of informed consent.

**Include the title of the project and the names of the researcher(s).**

**Invitation to Participate:** *You are invited to participate in this research study. The following information is provided to help you make an informed decision whether or not to participate. If you have any questions, please do not hesitate to ask them.*

**Expectations:** This section should include the purpose, the expected duration of involvement, a description of the procedures, and identification of any procedures which are experimental.

*The purpose of this research is to better understand which method of pain management works better. Each person in the study will be assigned by the researcher to one of two groups. One group will receive a one half hour back massage for back pain which is considered a normal treatment for the type of back pain you have. The other group will receive one half hour of back massage and the application of a heating pad for one half hour. The addition of the heating pad is a new addition to the treatment of this type of back pain. These treatments will occur once a week for four weeks. You will receive the treatment for one-half to one hour depending on which group you are assigned to for the four weeks of the study. You will be placed into one of the two groups based on a chance drawing.*

**Risks and Benefits:** Explain the risks or discomforts associated with the procedures as well as what the benefits might be. Also be sure to let the subjects know if there are other treatments that might be beneficial.

*The back massage may make you uncomfortable because of the requirement to lie on your stomach for one half hour. The heat treatment may result in redness and/or irritation of your skin. The current normal treatment for the type of back pain you have is the back massage, however some health care providers add pain medicine to the treatment. On the day of treatment, we are asking that you not take pain medicine so that we can more accurately determine the benefit of the treatment. The potential benefit is that your back pain will improve and you will not require long term treatment.*

**Confidentiality:** Explain what you will do to protect the identity of the people in your study.

*Personal information about you or your back pain will only be viewed by the two researchers conducting this study, Dr. Jones and Jackson. Once they leave the treatment site, your identifying information will be maintained in a locked file cabinet in Dr. Jones’ office. It will be kept for three years and then destroyed. When the study findings are reported, your name and information will not be reported. Information will only be shared as a group. For example: the subjects in the group that received the massage and heat treatment demonstrated increased pain relief.*

**Compensation:** If the subjects will be compensated in any way for their participation, let the subject know.

*If you choose to participate, you will be paid mileage at the rate of $.42/mile for your travel to and from the treatment site. You will also receive a $25.00 gift certificate to the university bookstore.*

**Requests for Information:** All subjects should have contact information so that they can ask questions or report unexpected events. If there is more than minimal risk, you will need to identify how this will be handled. Specifically who will handle physical, psychological or social effects of the research.

*If you have any questions about this study or need to report any unexpected events, you can call Dr. Jones at 570 673-2294 or Dr. Jackson at 570 673-9980.*

**Right to refuse or withdrawal from the study:** All subjects must be informed that they have the right to refuse to participate or to withdraw from the study at any time without penalty.

*Please know that you have the right to choose not to participate in this study. Also, it is important to share that if you decide that you don’t want to continue at any time during the study you can stop without penalty or obligation.*

**Other areas to consider (if appropriate):**

1. If the study includes treatments or procedures that may have unforeseen risks, subjects should be informed.
2. The subjects have the right to know if under some circumstance you might choose to remove them from the study.
3. You should let subjects know if there are costs involved that will not be covered as part of the study.
4. Subjects should be informed if there will be consequences to their withdrawal from the study.
5. Information should be provided about preliminary findings that may affect their willingness to continue. For example, if you were conducting a study on behavior modification techniques and you discovered that behaviors were actually becoming worse during the study, how will you inform subjects so they can make a decision about whether or not to continue?
6. If appropriate, share the number of individuals in the study.

**Signature:** Subjects should be provided with the opportunity to sign and date the consent form. There needs to be a place for a witness to sign if the study involves more than minimum risk and finally the researcher should sign the informed consent. Unless there is a reason that has been addressed in the protocol that subjects will not be provided with a copy of the consent, all subjects should receive one.

B. **Model Statements for Child Assent**

The following are model statements for a child assent form. They contain the elements common to many informed consent forms for children. You should use language that is appropriate for your project and understandable to the research subjects. The italicized language is offered as an example only. See Section II of the Application for the specific elements of informed consent.

**Include the title of the project and the names of the researcher(s).**

**Invitation to Participate:** *You are invited to participate in my work. In the next part of this, I will explain to you what I want you to do, if you want to be part of my work. If you have any questions, please do not hesitate to ask them.*

**Expectations:** This section should include the purpose, the expected duration of involvement, a description of the procedures, and identification of any procedures which are experimental.

*The purpose of my work is to better understand if certain kinds of toys work better for kids who have trouble holding onto things. Each child who decides to be work with me will be given different toys to play with. One group of children will get toys that are the kind you would buy in Wal-Mart. The other group will get toys that have been changed to work better for kids who have trouble holding onto things. You will be asked to play with the toys for 15-20 minutes three times, once each day in the afternoon for three days in a row.*

**Risks and Benefits:** Explain the risks or discomforts associated with the procedures as well as what the benefits might be. Also be sure to let the subjects know if there are other treatments that might be beneficial.

*Since this will be play time, it should be a time that you enjoy. If the toys that I’m changing are helpful to you, then I will have a better idea of how to help children who have trouble holding onto things.*

**Confidentiality:** Explain what you will do to protect the identity of the people in your study.

*I will also be talking to your mom and dad about this and letting them know that I will not share how you did with anyone else.*

**Compensation:** If the subjects will be compensated in any way for their participation, let the subject know.

*The kids who work with me will get the toys that we work.*

**Requests for Information:** All subjects should have contact information so that they can ask questions or report unexpected events. If there is more than minimal risk, you will need to identify how this will be handled. Specifically who will handle physical, psychological or social effects of the research.

*If you have any questions, I’ll be here every day while I’m watching how you do. I will be giving your mom and dad my phone number so that if you want to call me and ask me anything you can.*

**Right to refuse or withdrawal from the study:** All subjects must be informed that they have the right to refuse to participate or to withdraw from the study at any time without penalty.

*If you don’t want to do this, that’s fine. You’ll still see me around this floor and we can talk about anything that you want to. If you do decide to work with me on this, and then change your mind – that’s okay too, we’ll still see each other and talk.*

**Other areas to consider (if appropriate):**

1. If the study includes treatments or procedures that may have unforeseen risks, subjects should be informed.
2. The subjects have the right to know if under some circumstance you might choose to remove them from the study.
3. You should let subjects know if there are costs involved that will not be covered as part of the study.
4. Subjects should be informed if there will be consequences to their withdrawal from the study.
5. Information should be provided about preliminary findings that may affect their willingness to continue. For example, if you were conducting a study on behavior modification techniques and you discovered that behaviors were actually becoming worse during the study, how will you inform subjects so they can make a decision about whether or not to continue?
6. If appropriate, share the number of individuals in the study.

**Signature:** Subjects should be provided with the opportunity to sign and date the consent form. There needs to be a place for a witness to sign if the study involves more than minimum risk and finally the researcher should sign the informed consent. Unless there is a reason that has been addressed in the protocol that subjects will not be provided with a copy of the consent, all subjects should receive one. You will also be obtaining consent from the parents or guardians so you will need a consent form for them as well.

**SECTION V: 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, temporally 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.

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

**GUARDIAN: A**ccording 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

**HUMAN SUBJECT:** A living individual about whom an investigator conducting research obtains information.

**INTERVENTION:** This includes both physical procedures by which data are gathered and manipulation of the subject or the subject’s environment that are performed for research purposes.

**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.

**NURENBERG 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.

**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 which as been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (e.g. medical records).

**RESEARCH**: This is the systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

**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.

**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.