

**Millikin University Institutional Review
Board for Human Participants Research**

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Millikin University Institutional Review Board Guidelines

1. Introduction

Institutional Review Boards (IRBs) are mandated by Federal law to guarantee the protection of human participants in research and to ensure full compliance by both investigators and institutions with federal regulations. These regulations are based on ethical principles established by the Nuremberg Code and the Belmont Report, and are explicated in the Common Rule for the Protection of Human Participants (45 CFR 46).

- 1.1. Nuremberg Code. The extent to which humans could be exploited in the name of research was reported during the war criminal trials following World War II. The 1947 Nuremberg Code was written as a result of the unethical human behavior that occurred. The Nuremberg Code consists of 10 guidelines for ethical research.
http://www.hhs.gov/ohrp/archive/irb/irb_appendices.htm#j5
- 1.2. Belmont Report. Multiple codes for the purpose and responsible conduct of human experimentation have been adopted by organizations since 1947. In 1978, the National Commission for the Protection of Human Participants of Biomedical and Behavioral Research was formed. The goals of this commission were to identify basic ethical principles that should guide the conduct of human participant research and develop guidelines based on the ethical principles. The report published in 1979 was entitled, "The Belmont Report." The Belmont Report identified 3 basic ethical principles:
 1. Respect for Persons – research subjects should have autonomy and self-determination. Persons with diminished autonomy are protected from exploitation in research studies.
 2. Beneficence – research should be designed and conducted so as to maximize potential benefits and minimize potential risks to subjects.
 3. Justice – the risks and potential benefits of research should be equally distributed between research subjects and the public who may benefit from the research.
<http://archive.hhs.gov/ohrp/humansubjects/guidance/belmont.htm>
- 1.3. The Common Rule. The Department of Health and Human Services (HHS) published general guidelines for research that have been revised over time. The Common Rule for the Protection of Human Participants (45 CFR 46) is federal policy and applies to all research involving human participants (see <http://www.hhs.gov/ohrp/humansubjects/commonrule/>).

The Millikin University Institutional Review Board implements the foregoing ethical principles, follows federal regulations (45 CFR 46), and campus policies and procedures in carrying out the responsibility to safeguard human research participants.

2. The IRB Committee

The guidelines for the Millikin IRB Committee membership, composition, qualifications, ethics training and certification, term of appointment, purpose and operation, and prevention of conflict of interest are as follows:

- 2.1. Membership Selection. Millikin University IRB chairperson and members will be appointed by the Provost following recommendations from the Deans. Appointments go into effect August 1 of each year.
- 2.2. Membership Composition. In accordance with federal regulations, the Millikin University IRB shall have at least five members with varying backgrounds to promote complete and adequate review of research activities conducted within the institution. See 45 CFR 46.107.
- 2.3. Member Qualifications. The IRB members will be sufficiently qualified on the basis of expertise, training, and diversity to ensure the University's and researcher's respect for the committee's advice and counsel on safeguarding the rights and welfare of human participants. The IRB will be diverse and will not consist of entirely men, entirely women, or represent one academic discipline or profession. The IRB will include at least one scientific member as well as one non-scientific member such as a lawyer, ethicist or clergy person.
 - 2.3.1. At least one member, who is not otherwise affiliated with Millikin University and who is not part of the immediate family of a person who is affiliated with Millikin, will be appointed by the Provost to serve on the IRB.
 - 2.3.2. Alternate IRB members, appointed by the Provost, may be used to ensure a quorum (a majority of all appointed members including one whose primary focus is nonscientific) when conflicts of interest or schedule conflicts occur for regular IRB members. Alternate IRB members may also attend IRB meetings and review proposals for training purposes. Alternate IRB members may attend and participate in IRB meetings, but may not vote unless they are filling in for a regular IRB member who is absent. The appointment, expertise, ethics certification, and term of service of an Alternate IRB member are the same as that for regular members.
 - 2.3.3. At the IRB's discretion, individuals with competence in special areas may be invited to assist in the review of complex issues which requires expertise beyond, or in addition to that available on the IRB. Invited experts may not vote on research proposals under consideration by the IRB.
- 2.4. Ethics Training & Certification. All full-time members of the Millikin IRB will complete the "IRB Members – Basic/Refresher" training modules of the Collaborative Institutional Training Initiative (CITI) Program, <https://www.citiprogram.org/index.cfm?pageID=22>, within 6 months of becoming a board member, and maintain that requirement for the duration of the time they are on the board. This needs to be renewed every 3 years. IRB members currently certified by the NIH Extramural Research Office <https://phrp.nihtraining.com/> or HHS http://ori.hhs.gov/education/products/montana_round1/research_ethics.html must provide documentation of their certification to the IRB Chair. NIH and HHS certification may be used until it expires. When the HHS or NIH ethics certification of

a member still serving on IRB expires, this IRB member must then complete the CITI Program "IRB Members – Basic/Refresher" training modules of the CITI Program within 6 months of the expiration of his or her HHS or NIH ethics credentials.

- 2.5. Term of Appointment. The standard term of the appointment for regular and alternate members of the IRB will be 3 years with the option for reappointment by the Provost. IRB members may be reappointed for 2 consecutive terms (6 years) before being required to rotate off the IRB for 1 year. Under extenuating circumstances the Provost may reappoint a member for a 1 year term. Rotation of members on and off the board will be staggered to ensure the majority of members are CITI Program certified, experienced, and diverse.
- 2.6. Purpose and Operation. The IRB committee is charged with a variety of tasks that promote the safe and responsible conduct of research with human participants.
 - 2.6.1. The IRB will review all non-exempt human participant research proposals to be performed within Millikin University as well as external proposals involving Millikin faculty, personnel, or students as investigators.
 - 2.6.2. The full IRB holds regularly scheduled meetings on a monthly basis and may hold special meetings to deal with unexpected or serious issues as they arise (e.g., adverse event).
 - 2.6.3. Except in the case of expedited review proposals, research applications will be reviewed at regularly convened meetings with a quorum of members present.
 - 2.6.4. The IRB reviews research proposals according to accepted ethical principles, legally binding federal regulations (45 CFR 46), campus policies, procedures, and practices, and other professional guidelines mindful of the risk-benefit ratio for the protection of human participants.
 - 2.6.5. [The IRB reviews ethical and legal matters related to research and as such, is the University entity charged with assuring proper use of copyrighted materials in research.](#)
 - ~~2.6.5.~~2.6.6. The IRB is delegated the authority to approve, require modifications, or disapprove proposals based on consideration of human participants protections.
 - ~~2.6.6.~~2.6.7. The IRB may terminate or suspend projects not being conducted in accordance with federal regulations (45 CFR 46), campus policies and procedures or projects that have been associated with unexpected serious harm to participants. A record of all correspondence associated with this action will be placed in the permanent research proposal file, and reported and submitted to the Provost and appropriate external agencies as stipulated by 45 CFR 46.113.
 - ~~2.6.7.~~2.6.8. A principal investigator (PI) may request permission to attend an IRB meeting to answer questions regarding a proposal under review. This allows for increased transparency and communication that may help to streamline the IRB communication process. The request should be sent to the IRB Chair and administrative assistant one week in advance of the scheduled meeting. Non-members may only attend that part of the meeting that addresses their

proposal and must leave before the IRB discusses their proposal or conducts any other IRB business.

~~2.6.8:~~2.6.9. If a researcher believes that an IRB decision is unfair or unreasonably restrictive the matter should first be discussed with the IRB Chair. The researcher should present reasons why he or she believes that the proposed research is in compliance with University policy and Federal regulations for the protection of human participants. If this negotiation fails, the investigator has the right to formally appeal the IRB decision.

~~2.6.9:~~2.6.10. Appeals to an IRB decision on a proposal should be submitted in writing and will be considered by the full IRB. The researcher is encouraged to seek the advice or opinion of an objective, qualified consultant to support the claim that the proposed research is in compliance with Federal regulations for the protection of human participants. The principal investigator must appear before the IRB to present the appeal and any supporting documentation obtained through consultation. Based upon analysis of this appeal, the IRB will issue a final determination on the proposed research.

~~2.6.10:~~2.6.11. To assure the protection of human participants and to comply with federal law, all non-exempt research projects involving human participants or human material must be reviewed and approved by the IRB, regardless of the research method used, source of funding and/or location of the study sponsored or conducted by Millikin faculty, personnel or students, and/or using Millikin facilities or equipment.

2.7. IRB Member Conflict of Interest Policy. To ensure fairness in deliberation and decision making when reviewing research proposals, the IRB will use the following guidelines to avoid conflict of interest. If any of the following criteria apply (2.71- 2.76), the IRB member will be recused from reviewing that research proposal, may not be present during the IRB discussion of that proposal, and may not vote on the outcome of that proposal. For the purpose of providing answers to questions about the proposal, the IRB may invite the recused IRB member to that portion of the IRB meeting to reply to their questions, with the recused member's attendance and participation limited to this information gathering period. The criteria for recusal include:

- 2.7.1. If the IRB members has disclosed, as required, any financial relationships or financial interests that could cause potential or actual conflicts of interest when reviewing a specific research proposal submitted to the Millikin IRB for review.
- 2.7.2. If an IRB member is the principal investigator (PI) or a co-investigator on a research proposal submitted to the IRB for review.
- 2.7.3. If the IRB Chair is the PI, a co-investigator, or the supervisor of a PI or co-investigator on a specific proposal.
- 2.7.4. If an IRB member is the research supervisor or the teacher requiring the proposed research project for his or her course
- 2.7.5. If an IRB member is a family member of the PI or any of the co-investigators on a proposal.

2.7.6. If an IRB member feels that involvement in the deliberations and vote on a specific research proposal places them is inappropriate. In these circumstances, the IRB member should privately discuss their concerns with and seek the advice of the IRB Chair.

3. Classification of Research Studies

All research activities conducted within Millikin University, or under its auspices, by its faculty, staff, students, or external researchers in which human participants take part will be classified as one of the following: exempt from IRB review, eligible for expedited IRB review, or requiring a full IRB review. These 3 classification categories found in 45 CFR 46.101, 46.108, 46.109, and 46.110 are defined as follows:

3.1. Exempt: Researchers who believe their study is exempt from review, are nonetheless urged to submit their proposal to the Millikin IRB for verification of exemption. Being exempt does not mean that a study is not required to meet the Federal standards for the protection of human participants; merely that the risks of harm appear to be sufficiently minimal that the investigator can be entrusted to assume this responsibility without IRB review. Peer-reviewed journals may also request verification that a study has been reviewed by an IRB prior to publication even if the research was found to be exempt. The IRB will not retroactively review studies.

Researchers should electronically submit an "Application for Exemption from Review" request form (Appendix A, found on the Millikin IRB webpage) with all supporting documents to the IRB for review. Review of proposals meeting exempt criteria may be conducted by the IRB Chair or an IRB member designated by the Chair and can generally be completed within two weeks of submission. If the IRB member(s) reviewing the research proposal finds that the proposal does not meet exempt from review status, then the proposal will be forwarded to the IRB Chair with the recommendation for an expedited or full review of the research proposal.

Unless research is covered by other parts of this policy, a research activity using human participants is classified as exempt if it falls into one of the following categories (45 CFR 46):

3.1.1. 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.

3.1.2. research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, UNLESS: (a) information obtained from these sources is recorded in such a manner that participants can be identified, directly or through identifiers linked to the participants, AND (b) any disclosure of the human participants' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, or reputation.

- 3.1.3. 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.
- 3.1.4. 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 3.1.3 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.
- 3.1.5. 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.
- 3.1.6. Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, 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.
- 3.1.7. 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.
- 3.2. Expedited Review. An expedited review is conducted by a subcommittee of the IRB consisting of the IRB Chair and one or more IRB members designated by the Chair or by two or more experienced reviewers designated by the Chair from among members of the IRB. An expedited review can generally be completed within two weeks of submission. In an expedited review the subcommittee may not disapprove the research proposal. If the IRB subcommittee cannot approve the research, then the proposal is presented to the IRB at the next regularly scheduled meeting for full board review.

Researchers should electronically submit the completed "Review Request" form (Appendix B, found on the Millikin IRB webpage) with all supporting documents

prior to IRB review. The IRB may use an expedited review procedure for research in either or both of the categories published by HHS in the 45 CFR 46.110, if:

- 3.2.1. The research involves no more than minimal risk of physical or psychological harm or discomfort.
- 3.2.2. The research is an ongoing, previously approved project that has not changed, or has changed in a way that will not affect the participant's rights regarding informed consent, deception, the right to withdraw, confidentiality, or risk. All continuing research must be submitted for review annually unless the IRB stipulates otherwise.
- 3.3. **Full IRB Review.** All research involving human participants that does not fall into the categories for exempt or expedited review will undergo a complete review by the full IRB at one of its regularly scheduled meetings. Researchers should electronically submit the completed "Review Request" form (Appendix B, found on the Millikin IRB webpage with all supporting documents prior to IRB review).
- 3.4. **Ongoing Research.** All researchers conducting ongoing human participant research must request annual renewal to continue the research beyond one year of the original IRB study approval date. Some studies with more than minimal risk may be required to undergo semi-annual review. Researchers should complete the "Research Continuation Review Request" form (Appendix G, found on the Millikin IRB webpage) and electronically send this to the IRB Chair prior to the one year anniversary of the original IRB approval date.

4. Institutional Review Board Responsibilities

The IRB is charged with providing services to the University, faculty, staff, and students. These duties include, but are not limited to:

- 4.1. The IRB Chair is responsible for communicating with the Provost regarding IRB actions, concerns, requests. Communication with the investigators will also be the responsibility of the IRB Chair or a member of the IRB designated as Chair Pro Tem.
- 4.2. Individual IRB members are responsible for conducting initial and continuing review of research proposals as assigned in a timely manner and reporting findings to the IRB Chair.
- 4.3. Rendering a research proposal ruling of approved, tabled pending revisions, or disapproved after deliberations or a vote on the proposal.
- 4.4. Determining which projects require semi-annual rather than annual progress reports and which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review. Frequency of review will be based on assigned classification of risk and reports of adverse events.
- 4.5. Ensuring prompt researcher reporting to the IRB of any changes in previously approved research procedures or activities while the research is being conducted.
- 4.6. Ensuring that changes in approved research may not be initiated without prior IRB approval except to eliminate apparent immediate hazards to the human participants.

- 4.7. Ensuring timely review of proposed research with written feedback to the primary investigator within 30 days of submission of a complete review request. If the proposal is tabled pending modification or due to a request for information, the review time may be extended another 30 days beginning with the researcher's submission of revisions or responses to IRB questions.
- 4.8. Recusing oneself from the initial or continuing review of proposals in which the member is deemed to have a conflict of interest, except to provide information as requested by the IRB.
- 4.9. Providing educational information as requested to investigators considering and or engaged in research involving human participants.
- 4.10. Ensuring compliance with any internal or external mandated policies and regulations. The IRB shall have the authority to observe or have a third party observe the consent process and the research as it is being conducted.
- 4.11. Reviewing final reports on completed research projects.
- 4.12. Ensuring prompt reporting of unanticipated problems involving risks to subjects and others. This includes reports to the appropriate institutional officials and federal government agencies.
- 4.13. Assessing the risks and any benefits of the research and assigning a risk classification (minimal risk, more than minimal risk, or significant risk) to each proposal:
 - 4.13.1. Minimal Risk: The risks of harm anticipated in the proposed research are not greater, considering the probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examination or tests.
 - 4.13.2. More than Minimal Risk: The anticipated risks in the proposed research exceed, either in probability or magnitude, those ordinarily encountered in daily life or during the performance of routine physical or psychological examination or tests.
 - 4.13.3. Significant Risk: The anticipated risks in the proposed research presents a potential for serious risk to the health, safety or welfare of the subject and or researcher.

5. Responsibilities of the Principal Investigator (PI), Co-Investigator (CI) and Project Supervisor (PS) (if indicated)

Students are bound by the same procedures and policies as the faculty and staff, with the additional requirement that student research projects must be sponsored by a faculty or staff member (Project Supervisor). The PS is responsible for informing the student of the necessary procedures and assisting the student in preparation of the forms and necessary documentation for submission to the IRB. Students or primary investigators from another institution must be sponsored by a faculty, staff, or administrative member of Millikin University in order to conduct research on campus. If a research project is to be co-investigated by researchers from other institutions, documentation of IRB approval at all co-sponsoring institutions should be provided.

The principal investigator and other members of the research team (CI, PS) are governed by federal regulations as set forth in The Common Rule (45 CFR 46) and Millikin policies which include the expectations that:

- 5.1. Electronic submission of the research proposal with all supporting documents is required for IRB review. Appendix A on the IRB webpage contains the application for an "Exempt from Review" proposal and Appendix B contains a copy of the "IRB Review Request" form. The IRB will not review a proposal until all documentation is complete, including required Appendixes.
- 5.2. Researchers must obtain IRB approval before beginning data collection. Participant consent and assent if applicable must be obtained before enrolling participants in the study. Researchers should customize the consent form to match the features of their submitted research proposal (e.g., adult v. child participants). A copy of the Consent Form Guidelines can be found in Appendix C on the IRB webpage. Electronic copies of the consent or assent forms should be submitted with the IRB Review Request.
 - 5.2.1 The approved consent document will be stamped by the IRB with the date of approval. Researchers must use this stamped consent form in their study and may not continue the study after one year from the stamped date without approval to continue the research (Appendix F on the IRB webpage), at which time a new stamped consent document will be provided.
- 5.3. Researchers named as the Principal Investigator (PI) and/or Co-Investigator (Co-PI), as well as the faculty/staff project supervisor (PS) of a student investigator must show they have successfully completed the CITI Program "Social and Behavioral Responsible Conduct of Research" or "Biomedical Responsible Conduct of Research" modules prior to beginning the research project. An electronic copy of this proof must be attached to the Millikin IRB Review Request. Millikin University provides free access to the CITI Program via the IRB webpage or by going directly to the CITI Program at <https://www.citiprogram.org/index.cfm?pageID=22>).
 - 5.3.1. As noted in Sections 3.2. and 3.3., research proposals will not be approved by the IRB without documentation that researchers have passed the "Social and Behavioral Responsible Conduct of Research" or the "Biomedical Responsible Conduct of Research" CITI Program course. Upon successful completion researchers can print their ethics coursework requirements report, or scan and submit it electronically.
 - 5.3.2. CITI Program coursework must be renewed every 3 years, and maintained for as long as a Millikin faculty, staff member, or student intends to conduct and/or supervise research with human participants. The Common Rule (45 CFR 46) requires every person involved in human participants research to complete ethics training covering the expectations and methods for protecting human research participants.
- 5.4. Researchers who wish to modify a current IRB approved study must obtain additional IRB approval before making any procedural changes in the study. Researchers should electronically submit the "Research Amendment Request" form (Appendix D

found on the IRB webpage) to the IRB detailing the requested changes. Following IRB review and approval of the requested changes, the researchers may change their research procedures.

- 5.5. Researchers must report any emergent problems, adverse events, or participants' ethics complaints which may affect the risk/benefit ratio for participants as soon as they become apparent by submitting an "Adverse Event & Ethics Complaint Report" (Appendix E found on the IRB webpage) See Section 14 for an explanation of types of events, reporting requirements, and other details.
- 5.6. Researchers must obtain continuation approval from the IRB for any study extending beyond one year of the original IRB study approval date by submitting a "Research Continuation Review Request" (Appendix F found on the IRB webpage). Although the IRB will send researchers a reminder one month prior to their study's expiration date, it is the responsibility of the researcher file a continuation request in a timely manner that allows the IRB enough time to review this request prior to the study's expiration date.
- 5.7. The PI must complete and submit the "Research Closure" form (Appendix G on the IRB webpage) at the end of data collection and analysis and send this file as an attachment to the IRB Administrative Assistant.
- 5.8. Researchers are expected to understand the ethical standards and regulatory requirements governing research, and will protect the rights and welfare of human research subjects. Researchers will ensure all research activities have approval from all relevant institutions' IRBs, only implement the research activity as approved by these IRB(s), and take proper measures to ensure confidentiality and security of all information obtained from the participants.
- 5.9. Researchers who fail to respond to IRB communication will have their proposals retired from IRB consideration at the end of the semester following initial submission. A new review request will need to be submitted for consideration and a new IRB number will be assigned.
- 5.10. Researchers will maintain their own written records of IRB reviews and decisions. In addition, researchers will make provisions to secure and retain completed research records for a minimum of 3 years. This includes, for example, signed informed consent documents (when documented informed consent is required), original copies of surveys, cover letters, and other documents given to participants, and any other documents necessary to demonstrate compliance with government and institutional regulations relating to human participant research. Data relating to individual participants, such as completed surveys, video tapes, databases, etc., should be retained and destroyed in accordance with the protocol approved by the IRB as part of the research review request. Researchers will ensure the confidentiality of all research data.

6. University Responsibilities

Millikin University has the responsibility to interpret Federal regulations governing IRBs and ensure the protection of human participants through IRB policies and procedures that

promote a sincere culture of compliance. [The University has the responsibility to assure that copyrighted material intended for use in research is used properly and that copyrights are not violated.](#) It is the responsibility of the University to inform the University community of the IRB policies and procedures related to the legal and ethical obligations of persons conducting research.

7. IRB Procedures and Guidelines for Reviewing Research

- 7.1. Excluding human research that meets the “exempt from review criteria,” the IRB shall review and have authority to approve, require modifications in, or disapprove all other research activities involving human participants. The IRB shall require that information given to participants as part of the consent process is in accordance both with this policy, and other legal and ethical requirements. The IRB shall require documentation of consent in accordance with the criteria set out below.
- 7.2. The IRB shall notify investigators and the institution, in writing, of its decision to approve or disapprove the research proposal, or table the research proposal until such modifications are made that secure IRB approval of the research proposal. If the IRB decides to disapprove a research project, it shall include in its written notification to the researcher a statement of the reasons for the IRB’s decision. The investigator may appeal the IRB decision in writing or request to speak to the IRB as noted in Sections 2.6.7., 2.6.8., and 2.6.9.
- 7.3. The IRB shall conduct annual reviews of continuing research covered by this policy at intervals appropriate to the degree of risk to human participants, but not less than once per year. Researchers will be notified 30 days prior the expiration date of their study to submit for a request for continuing research review. The expiration date will be based on the original approval date of the research study.
- 7.4. In order to approve research the IRB shall determine that all of the following requirements are satisfied:
 - 7.4.1. Risks to participants are minimized: (a) by using procedures which are consistent with sound research design and which do not unnecessarily expose participants to risk, and (b) whenever appropriate, by using procedures already being performed on the participants for diagnostic or treatment purposes.
 - 7.4.2. Risks to participants are reasonable in relation to anticipated benefits if any, to participants, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB will consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies participants would receive even if not participating in the research). The IRB will 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.
 - 7.4.3. Selection of participants is equitable. In making this assessment the IRB will take into account the purposes of the research and the setting in which the research will be conducted. By law, the IRB must be cognizant of the special

problems of research involving vulnerable populations defined as: children and minors, prisoners, pregnant women, human fetuses, and neonates. Additional consideration is given to the informed consent process for physically or mentally disabled persons, or economically or educationally disadvantaged persons.

- 7.4.4. Consent will be sought and documented from each prospective participant and/or the participant's legally authorized representative in accordance with, and to the extent required below (see Section 8.). In addition to consent from a participant's legally authorized representative, assent will be sought from each participant when appropriate.
 - 7.4.5. The research plan makes adequate provision for monitoring the data collected to insure the safety of participants.
 - 7.4.6. There are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data.
 - 7.4.7. When some or all of the participants are likely to be vulnerable to coercion or undue influence (e.g., children, prisoners, physically or mentally disabled, or economically or educationally disadvantaged persons), appropriate safeguards have been included in the study to protect the rights and welfare of these participants.
- 7.5. The IRB shall report any serious or continuing noncompliance by investigators to the Provost, and to the Secretary of the Department of Health and Human Services in accordance with 45 CFR 46 guidelines.

8. Informed Consent and Assent

Except as provided elsewhere in this policy, no investigator may involve a human being as a participant in research covered by this policy unless the investigator has obtained legally effective informed consent of the participant and/or the participant's legally authorized representative. Researchers must also solicit the assent of children when, in the judgment of the IRB, the children are capable to providing assent.

An investigator shall seek consent only under circumstances that provides the prospective participant and/or the legally authorized representative sufficient opportunity to consider whether or not to participate, and in a manner that minimizes the possibility of coercion or undue influence. The information that is given to the participant and/or the representative shall be in language understandable to the participant or the legally authorized representative.

No consent, whether oral or written, may include any exculpatory language by which the participant or the legally authorized representative is made to waive or appear to waive any of the participant's legal rights. Further, no consent agreement, whether oral or written, may release or appear to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

When designing a project description and consent form, the investigator may use the Millikin University Consent Form Guidelines (Appendix C on the IRB webpage) or templates from other institution's IRBs that meet the requirements below.

Basic Elements of Informed Consent. In seeking informed consent the following information shall be provided to each participant or their legally authorized representative:

- 8.1.1. A statement that the study involves research, an explanation of the purposes of the research, the expected duration of the participant's participation, a description of the procedures to be followed, the identification of any procedures which are experimental and any expected debriefing;
- 8.1.2. Description of any reasonably foreseeable risks or discomforts to the participant. If there are any known or foreseeable serious risks associated with the procedures involved in the study the researcher must disclose these to participants in the "Risks" section of the consent form.
- 8.1.3. Description of any benefits to the participant or to others which may reasonably be expected from the research;
- 8.1.4. Disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant;
- 8.1.5. A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained;
- 8.1.6. For research involving more than minimal risk, an explanation as to whether there will be 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;
- 8.1.7. An explanation of whom to contact for answers to pertinent questions about the research and research participant's rights, and whom to contact in the event of a research-related injury to the participant; and
- 8.1.8. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and that the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.

8.2. Additional Elements of Informed Consent. When appropriate, one or more of the following elements of information shall also be provided to each participant:

- 8.2.1. A statement that the particular treatment or procedure may involve risks to the participant (or to the embryo or fetus, if the participant is or may become pregnant) which are currently unforeseeable;
- 8.2.2. Anticipated circumstances under which the participant's participation may be terminated by the investigator without regard to the participant's consent;
- 8.2.3. Any additional costs to the participant that may result from participation in the research;
- 8.2.4. The consequences of a participant's decision to withdraw from the research and procedures for orderly termination of participation by the participant;
- 8.2.5. A statement that significant new findings developed during the course of the research which may relate to the participant's willingness to continue

participation will be provided to the participant so that the participant may consider whether or not to continue participation in the study;

8.2.6. The approximate number of participants involved in the study;

8.2.7. For children, an oral or written assent as appropriate, using language the participant can understand, that contains comparable study information found in the consent form provided to other participants and/or parents or legal guardians.

8.3. Documentation of Consent. The informed consent of each participant or the participant's legally authorized representative is documented in the following ways:

8.3.1. The researcher gives a written consent document stamped by the IRB and embodying all the elements of consent to the participant or the legally authorized representative. The participant or the legally authorized representative is provided with an adequate opportunity to read the consent form and ask questions. The consent form is then signed by the participant or the legally authorized representative. Each participant or legally authorized representative is provided with a copy of the IRB stamped consent form. The researcher must secure the signed consent forms to ensure confidentiality and destroy them in a timely manner when no longer needed.

8.3.2. Adequate provisions must be made to solicit the permission of parents/legal guardians and the **assent** of children participants when, in the judgment of the IRB they are capable of providing it. A written assent form may be given to children participants, which provides comparable details found in the written consent form, using language the assenting participant can understand. The IRB will determine how assent must be documented.

8.3.3. The researcher will provide a **script** embodying all the required elements of informed consent (section 8.1 and 8.2) that will be presented orally to the participant or the parent/legal guardian, with the stipulation that a witness (not a participant or the researcher conducting the session) be present during the consent process. A written version of the oral consent script (verbatim script that will be read to the participant or their parent / legal guardian) must be submitted to the IRB for approval.

A signature form noting that participants or their parent/legal guardians have been provided with oral consent information, allowed to ask questions, and voluntarily agree to participate or give permission for participation will be kept by the researcher. Participants or their parent/legal guardians will sign and date this form, as will the researcher and the witness present during the consent process. Participants with diminished autonomy or diminished capacity will not sign this form, though they may sign an assent form if appropriate. A copy of the oral consent script will be given to each participant and the parent/legal guardian.

8.3.4. The IRB may waive the requirement for the investigator to obtain a signed consent document for some or all participants if the IRB finds:

8.3.3.1. The only record linking the participant to the research project would be the consent document, and the principal risk would be potential harm

resulting from a breach of confidentiality. All participants will be asked whether they want documentation linking them with the research, and the participant's wishes will govern

8.3.3.2. The research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context; or

8.3.3.3. Except as otherwise provided by law, information in the records or possession of the University, acquired in connection with an activity reviewed by the IRB, where the information refers to or can be used to identify a particular participant, may not be disclosed except:

8.3.3.3.1. With the consent of the participant or their parent/legal guardian; or

8.3.3.3.2. As may be necessary for the Secretary of Health and Human Service to carry out the responsibilities of the office under this part.

8.4. Incomplete Disclosure. Regulations allow the IRB to approve a consent procedure that leaves out or alters some or all of the elements of informed consent. For example, some research about natural behavior may require that subjects be unaware that the research is taking place. The IRB may approve a waiver of some or all of the consent requirements provided that: (1) the research involves no more than minimal risk to 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 they have participated in the study (**debriefing**). The IRB will also determine whether the knowledge being sought is important enough to justify whatever invasion of privacy may be required either to obtain information about non-consenting (or unaware) subjects or to involve them in research under false pretenses.

9. Research Design

It is the researcher's responsibility to design research that is in conformity with such ethical guidelines as delineated by their profession, the Common Rule (45 CFR 46), and the Belmont Report.

10. Quorum Requirements and Voting

Approval of minutes, IRB policies and procedures, proposals coming to the IRB for full board review, and a ruling to suspend or terminate an ongoing study may only be voted on when there is a quorum of the IRB.

10.1. A quorum is defined as more than half of the IRB membership and must include one member whose primary concerns are in non-scientific areas.

10.2. No IRB member may 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. (See Section 2.7).

- 10.3. No IRB member may participate in the deliberations on projects in which they are involved with the exception of providing information on such projects where appropriate. See Section 2.7. for more details.
- 10.4. IRB members may not vote on projects in which they are involved; proxy votes will not be accepted. (See Section 2.7).
- 10.5. Proposals are approved if they receive a majority of the votes of eligible voting IRB members present at a convened meeting.
- 10.6. Alternate IRB members may not vote, unless they are filling in for an absent, regular member of the IRB.
- 10.7. The IRB Chair votes only when there is a tie vote among the IRB members on a particular item of IRB business, and as long as there is no conflict of interest on the part of the IRB Chair.

11. Final Approval Requirements

Before a research proposal can be implemented, all modifications required by the IRB must be made, and a corrected copy of the proposal and consent forms (with assent forms if relevant) must be filed with the IRB. Upon final review of the amended research proposal, a letter from the IRB Chair will be sent to the Principal Investigator, Co-Investigators, and the Project Supervisor (when the principal investigator is a student) indicating that the study may be initiated. All student projects must be sponsored by a faculty or staff member from the student's institution. A copy of the approved consent form that is stamped with the expiration date will be sent with this approval letter. Investigators must use copies of the IRB approved consent and assent forms.

12. IRB Documentation of Records

The IRB shall maintain a filing system in which it archives:

- 12.1. A database that documents and tracks information regarding submitted research proposals. Annually, an aggregate report will be provided to the IRB members, the University, and the Provost.
- 12.2. A copy of all research proposals submitted for review; scientific evaluations, if any, that accompany the proposals; approved sample consent documents; progress reports submitted by investigators; continuing review activities; reports of adverse events, injuries to participants; and the minutes of all meetings.
- 12.3. The minutes of IRB meetings which provide sufficient detail to show attendance at the meetings, actions taken by the IRB, the vote on IRB actions including the number of members voting for, against, and abstaining, the basis for requiring changes in or disapproving research, and a written summary of the discussion of issues and their resolution.
- 12.4. Copies of all correspondence between the IRB and investigators.
- 12.5. Research proposals and supporting documents, reviews of proposals, and other IRB materials are placed on the secure IRB Moodle page and accessible so that any IRB member can read and evaluate a proposal, and post a review. Proposals pending

review will be emailed to members and posted to the IRB Moodle page a minimum of one week prior the monthly scheduled meeting at which the proposal is to be discussed.

- 12.6. A list of IRB Board members, identified by name, earned degrees, representative capacity, indications of experience, term of appointment, employment or other relationship between the IRB member and the institution, sufficient to describe each member's anticipated contributions to IRB deliberations.
- 12.7. All written procedures and policies related to IRB activities.
- 12.8. Any statements of significant new findings provided to participants.
- 12.9. Continuing education documentation of IRB members as it relates to human participant research and IRB duties (See Section 2.4. for CITI Program certification document requirements).
- 12.10. Research records, including informed consent documentation shall be retained for at least 3 years after completion of the study by the Primary Investigator, and the records shall be accessible for inspection and copying by authorized representatives of the Department of Health and Human Services at reasonable times and in a reasonable manner.
- 12.11. IRB files will be maintained in the administrative office.

13. Continuing Review

Investigators must electronically submit a "Research Continuation Review Request" form and a copy of the currently approved consent form in order to continue research beyond the expiration date assigned to a particular protocol (Appendix F on the IRB webpage).

The IRB Chair will review requests to continue research proposals and will approve renewal requests unless the risk assessment has changed and/or there are reported adverse events. If the review of the protocol is favorable, an approval letter and a copy of the current consent form with a new expiration date stamped on it will be forwarded to the principal investigator. Should the review of the protocol suggest increased risk and/or adverse events have occurred, then full IRB review will be required.

14. Unanticipated Adverse Events – Definitions, Documentation, and Reporting Responsibilities

Institutions engaged in human participants research must have written procedures for ensuring prompt reporting by the researcher to the IRB, appropriate institutional officials, and any supporting agency of any unanticipated problem involving risk to human participants. Federal wide assurance by OHRP and HHS regulations in 45 CFR 46.103(5) require that institutions promptly report any unanticipated problems to OHRP.

- 14.1. Unanticipated Adverse Event Guidelines. Millikin University will use the following definition for adverse events:

Any unexpected untoward, or unfavorable occurrence in a human participant associated with the subject's participation in the research. Unanticipated adverse

events encompass both physical and psychological harm. (adapted from <http://www.hhs.gov/ohrp/policy/advevntguid.html#Q2>)

14.2. Definitions of Event Categories:

- 14.2.1. Serious Unanticipated Adverse Event: is any adverse event that occurs within 48 hours of participation in the research and: 1) results in death; 2) is life-threatening (places the subject at immediate risk of death); 3) results in brief or prolonged hospitalization; 4) results in persistent or significant disability/incapacity; or 5) based upon appropriate medical judgment, may jeopardize the subject's health.
- 14.2.2. Unanticipated Adverse Event: occurs when a participant has a negative experience, the nature, severity, or frequency of which is not consistent with the known or foreseeable risk of adverse events associated with the research procedures. These events, while unpleasant, do not result in death or hospitalization; do not produce a persistent or significant disability or incapacity; and are not life threatening.
- 14.2.3. Participant Ethics Complaint: occurs when a participant reports a complaint about unethical treatment (e.g., failure of the researcher to adhere to agreed commitments stipulated in the consent) to one of the researchers (PI, Co-PI, or PS) or to the IRB Chair using the contact information on the consent form. When a participant reports an ethics complaint to one of the researchers, the researcher is obligated to notify the IRB Chair of this situation.

14.3. Category Requirements for Event Reporting to the IRB. If a study has been approved by more than one IRB, reporting to Millikin's IRB does not negate the investigator's responsibility to report the unanticipated adverse event to other IRBs who have approved this research and to sponsoring agencies.

- 14.3.1. Reporting Requirements for Serious Unanticipated Adverse Events – Within 24 hours of the discovery of each occurrence, the Principal Investigator MUST complete the "Adverse Event & Ethics Complaint Report" form (Appendix E on the IRB web page) and submit copies electronically to the Millikin IRB office, the IRB Chair, and the Provost. When a serious adverse event occurs, the full IRB may opt to reexamine the overall risk/benefit ratio of the research project and decide to suspend, require modifications, or allow the study to proceed.
- 14.3.2. Reporting Requirements for an Unanticipated Adverse Event – Within 5 (five) working days of the discovery of each occurrence, the Principal Investigator MUST complete the "Adverse Event & Ethics Complaint Report" form (Appendix E on the IRB web page) and submit copies electronically to the Millikin IRB office, the IRB Chair, and the Provost. Depending on the details, the IRB may opt to reexamine the risk/benefit ratio of the research project and decide to suspend, require modifications, or allow the study to proceed.
- 14.3.3. Reporting Requirements for a Participant Ethics Complaint – Within 5 (five) working days of the discovery of each occurrence, the Principal

Investigator MUST complete the "Adverse Event & Ethics Complaint Report" form (Appendix E on the IRB web page) and submit copies electronically to the Millikin IRB office, the IRB Chair, and the Provost.

Depending on the details, the IRB may opt to reexamine the risk/benefit ratio of the research project and decide to suspend, require modifications, or allow the study to proceed.

14.4. Review of Adverse Event Reports. The IRB reviews and acts on the submission of adverse event and ethics complaints in a timely manner. The Millikin University IRB tracks all adverse events and ethics complaints by their assigned research proposal number.

14.4.1. All adverse events will be reviewed by the IRB Chair and reported to the Provost.

14.4.2. If the Millikin IRB Chair feels the adverse event requires full board consideration, the principal investigator will be notified in writing and the adverse event will be reviewed either at the next IRB meeting or a specially called meeting. The IRB may temporarily suspend the study until the adverse event is reviewed.

14.4.3. If the adverse event can be reviewed administratively, the Millikin IRB staff will process the report and the IRB Chair will submit a letter of acknowledgement. The adverse event will be reported at the next IRB meeting.

14.4.4. If the IRB records show that a reported adverse event is being experienced multiple times and is not listed in the consent form as a risk, the IRB may require that the consent form be amended and that: 1) the event be added to the amended consent form and provided to all current subjects, or 2) the event be added to the amended consent form and use with new participants enrolling in the study.

14.4.5. The IRB has the authority to request that the currently approved consent form be revised and the adverse event be reported as a risk, if the adverse event has been reported multiple times.

14.4.6. If a new risk must be added to the consent form, the IRB will provide a rationale for the proposed changes to the consent form to the researcher. The amended consent form must then be submitted to the IRB for approval prior to resumption of the study.

14.5. Reporting Adverse Events to the Appropriate HHS Entity (OHRP, NIH, & FDA). It is the responsibility of all investigators to report serious adverse events to the appropriate HHS agencies. Such reports must be made in a timely manner, as stipulated by HHS agency policies. Reports to HHS do not replace the need to report serious adverse events to all IRBs that approved the original study.

The Millikin University IRB designates the Principal Investigator as the responsible party for reporting serious adverse events to other IRBs and HHS agencies. Reporting regulations are described in 21 CFR 56.108(b)(1). For more information regarding the reporting a serious adverse event refer to www.fda.gov/oc/gcp/contactogcp.html

14.6. Consequences of Not Reporting in the Required Timeframe or of Incomplete Reporting. Reporting adverse events according to the listed time frames is a requirement of investigators. Investigators who routinely report adverse events later than the prescribed timetable or provide insufficient information face possible sanctions.

Depending on the seriousness of the offense and risk to the research subjects, Millikin's IRB may proceed to suspend and or terminate the study. Millikin University IRB will be responsible for reporting to the OHRP and/or the FDA any serious or continuing non-compliance issues.

15. Meeting Requirements of the IRB

The IRB shall meet on a regularly scheduled basis to conduct board business and review research proposals.

15.1. Based on member availability, the IRB selects a time and day of the month (e.g., 2nd Monday at 3pm) for the 5 regular, monthly fall semester meetings (August, September, October, November, & December). This meeting time and date may be revised in January for the 5 monthly spring semester meetings (January, February, March, April, & May) if IRB member's schedules change (e.g., rotation of members onto and off the IRB, class schedule changes, etc.). Once set, the monthly meeting times for the IRB are posted on the Millikin University's IRB webpage, accessible to faculty, students, and staff.

15.2. Full IRB meetings in June and July are called on an as-needed basis to review proposals or conduct IRB business.

15.3. Special meetings (in addition to the regularly scheduled meetings) of the full IRB may be called at the request of any member of the IRB, or when deemed necessary by the IRB Chair or Provost to deal with unexpected and or serious issues as they arise.

16. Organizational Structure

The IRB at Millikin University is a separate committee that reports to the Provost. In addition, the IRB Chair reports IRB activity to the campus community at Millikin University faculty meetings at least once each semester.

17. Millikin University IRB Relationship to Other IRBs

Entities external to Millikin, such as hospitals, social service agencies, professional organizations, government programs, and academic institutions are also governed by IRBs that review research for their organization. The following guidelines apply to Millikin University faculty, staff, and students who are involved in collaborative research projects that must also be reviewed by external IRBs.

17.1. Approval by another agency's or institution's IRB does not exempt a researcher from the requirement to have the research proposal reviewed by the Millikin University IRB if the research will take place at Millikin University or if the researcher is faculty, staff, or a student of Millikin University.

- 17.2. Any Millikin University faculty, staff, or student who is a Principal Investigator or Co-Investigator on a project jointly conducted by another institution or agency, must receive IRB approval from each institution's or agency's IRB, in addition to the Millikin IRB, before proceeding with the research project.

18. IRB Member Compensation

Millikin University IRB members do not receive compensation for their service on the IRB.

19. Orientation and Continuing Education

The IRB will be provided with information regarding conferences, seminars and on-line activities related to the review and conduct of human participant research. Committee members will also be provided with reference material regarding the roles of an IRB member. Committee members are expected to be familiar with the policies and procedures for the Millikin University IRB and with the U.S. Department of Health and Human Services Code of Federal Regulation "The Common Rule" (45 CFR 46). Each IRB member will be responsible for reporting to the IRB administrative assistant any continuing educational activities related to human participant research.

20. Administrative Support Staff

The Provost will designate an administrative assistant to provide administrative support to the IRB. The IRB administrative assistant is responsible for taking minutes at IRB meetings and assisting with IRB record keeping. Within one week after a monthly meeting of the IRB, investigators will be provided with an IRB approval letter, a letter requesting additional information that specifically indicates what the IRB needs, or a letter disapproving the study that stipulates the basis for IRB disapproval. These letters of notification conveying IRB decisions will be sent to the Principal Investigator with Co-Investigators and faculty Project Supervisors receiving copies.

21. Review of Policies and Procedures

Millikin University Policies & Procedures for the Protection of Human Participants will be reviewed annually by the IRB, with recommended revisions also submitted to the Provost. The Provost may meet with the IRB to discuss the recommended revisions and will forward the revised Millikin University Policies & Procedures for the Protection of Human Participants to the Board of Trustees for review and approval.

22. Glossary of Research Ethics Concepts

A glossary of the professionally accepted meaning of research ethics terms is provided as a reference.

- 22.1. **Anonymous** means that no one (not even the researcher) can identify who provided the information. For example, an anonymous survey does not ask for names, addresses, or any other identifying information (demographics) which, even in combination, could possibly be used to identify participants. Anonymous is not to be confused with confidential

- 22.2. **Confidential** means an individual's identity and participation is protected by the researcher. The researcher promises not to share the individual's information with anyone outside the research team. A confidential study may collect the names or

identifying information, but maintains strict privacy of that information. Not to be confused with anonymous.

- 22.3. **Ethical and Legal Principles** mean that research is designed and conducted to conform to legal and ethical principles that safeguard the rights and welfare of human participants in any research, development, or related activity.
- 22.4. **Human Participant** means a living individual about whom a researcher (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information. Intervention may include both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the participant or the participant's environment that are performed for research purposes.
- 22.5. **Interaction** includes communication or interpersonal contact between investigator and participant.
- 22.6. **Private Information** 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 has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the participant is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human participants.
- 22.7. **Research** means a systematic investigation including research development, testing, and evaluation designed to develop or contribute to generalized knowledge. Activities which meet this definition constitute "research" for purposes of these regulations, whether or not they are conducted under a program which is considered research for other purposes, for example, some "demonstration" and "service" programs may include research activities.