MOUNT MARTY
UNIVERSITY

Policies and Procedures for Research with Human Subjects
(Approved by IRB Committee, April 10, 2018)

Mount Marty University has established the following policies and procedures to guide research with human subjects. These policies and procedures are updated as needed to remain in compliance with federal policy. The ethical treatment of human subjects in research is guided by the Belmont Report published in 1979 (http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html)and the Code of Federal Regulations from the U.S. Department of Health and Human Services (HHS) (http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html) which are regularly updated. Many of these principles and their application in specific disciplines are explained in Research Methods Textbooks for appropriate disciplines. This section will provide a summary of these guidelines. For more information or questions about specific research issues consult the original sources.

Belmont Report
The Belmont Report states that when doing research there are three main ethical principles that must be followed. These are:
(1) Respect for Persons – Participants should be treated as autonomous individuals and all persons with diminished autonomy are entitled to protection.
(2) Beneficence – Participants are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being. The two guiding principles here are (1) do no harm and (2) maximize possible benefits and minimize possible harms.
(3) Justice – There is a sense of fairness in the distribution of benefits and risks in the study.

These three ethical principles are used to guide the research process in the following ways.
(1) **Informed Consent** – subjects, to the degree they are capable, be given the opportunity to choose what shall or shall not happen to them. There are three elements to informed consent (1) Information – participants must be given sufficient information to make an informed decision about participation. This generally includes information about the research procedure, their purposes, risks and anticipated benefits, and a statement offering the subject the opportunity to ask questions and to withdraw at any time from the research, (2) Comprehension - the material must be presented in a way that is appropriate for the intelligence, rationality, maturity and language skills of the participant, and (3) Voluntariness – an agreement to participate in research constitutes a valid consent only if voluntarily given, so there can be no coercion, or other undue influence.

(2) **Assessment of Risks and Benefits** – The assessment of risks and benefits requires a careful analysis of available data, including, in some cases, alternative ways of obtaining the benefits sought in the research. For the investigator it means to examine whether the proposed research is properly designed. For the IRB committee it is a method for determining whether the risks that will be presented to subjects are justified. There are two key elements in the evaluation of risks: (1) The Nature and Scope of the Risks and Benefits. Research must be justified on the basis of a favorable risk/benefit assessment. Both the probability and magnitude of risks need to be considered, and weighted against the probability of the benefits of the research. The most likely types of harm are psychological or physical pain or injury, but other kinds of possible harm should not be overlooked. (2) The Systematic Assessment or Risks and Benefits. The potential risk and benefits of the research should be shared equally by all participants, and all efforts must be made to minimize risk.

(3) **Selection of Subjects.** There needs to be fair procedures in the selection of research subjects. All subjects must be protected against the dangers of being involved in research solely for administrative convenience, or because they are a readily available group. This is a special concern when vulnerable populations are used.

Code of Federal Regulations
Title 45 of the Code of Federal Regulations from the U.S. Department of Health and Human Services provides details on the application of these ethical principles to specific research situations, as well as the instructions on how institutions are to protect the participants in human research. These regulations are incorporated into these Policies and Procedures and are a part of the IRB submission forms.

Institutional Review Board
Purpose: To ensure compliance with the provisions of the Belmont Report, Title 45 of the Code of Federal Regulations from The U.S. Department of Health and Human Services (45 CFR 46) and Mount Marty University policies regarding the protection of human subjects. The IRB committee has the authority to approve, disapprove, or ask for revisions all research involving human subjects.

Membership The IRB shall be comprised of no fewer than five members with varying areas of expertise and training, and must include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas. In addition, the IRB shall include at least one member who is not affiliated with the university directly or indirectly (this individual cannot be a spouse, parent, or a child of an employee or Mount Marty University). Members, including the chair, are appointed by the President of the university or the president's designee to serve staggered three year terms which may be renewed.

Chair The chair of the IRB shall create an agenda and arrange for each meeting, chair IRB meetings, and be responsible for exempt and expedited reviews. The chair shall also review each application when submitted to see that it is complete; if any part is missing it should immediately be returned for revision. The chair may appoint another person chair for a meeting or part of a meeting if necessary.

Training All members of the IRB shall complete the CITI Human Subjects Research training course. Completion of this training shall be reported to and kept on file by the Director of Institutional Effectiveness.

Meetings The IRB should have one meeting per month during academic year, although the IRB Chair may cancel any monthly meeting of the IRB if it has no business for its consideration. The IRB generally does not meet in the months of June July and August, however the chair may review applications and call a meeting if one is necessary. If necessary the chair may call interim meetings between the regularly scheduled meetings. A majority shall be necessary to constitute a quorum for the transaction of business; however the nonscientific representative must be in attendance when proposals are reviewed. The chairperson shall be a voting member of the IRB. For a research proposal to be approved, it must receive the approval of a majority of those present at the meeting. Any actions taken by the IRB shall be communicated to the appropriate parties within one week after the meeting. The IRB may invite visitors with special expertise or proposal writers to come to the meeting to share expertise or answer questions; however they must be excused before the IRB begins deliberation or votes on the proposal. Additionally if any IRB members have a conflict of interest on a proposal they may be present to answer questions however they must be excused before deliberations and voting occurs.

Minutes The minutes of each meeting shall be recorded by the IRB administrator and distributed within one week to all members of the committee. Minutes of meetings shall include who was at the meeting, actions taken by committee members on proposals between meetings that did not require full board action, the vote on each action taken during the meeting (including the number of members voting for, against and abstaining), the basis for requiring changes in or disapproving proposals, and a written summary of the discussion of controverted issues and their resolution.

Record Keeping The IRB administrator shall maintain adequate documentation of IRB activities including the following:

A. A list of IRB members including the following: name, earned degree, representative capacity, indications of experience, and any employment or other relationship between each member and the institution.
B. Copies of vita's and certificates of completion of training for all committee members.
C. Copies of all applications for review by the IRB.
D. Copies of all correspondence between the IRB and the project directors.
E. The records shall be retained for at least three years after completion of the activity, and the records shall be accessible for inspection and copying by individuals authorized by the university or by law.

IRB Review Criteria In order to approve research covered by these policies the IRB shall determine that all of the following requirements are satisfied:

1. Risk to subjects are minimized: (a) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risks, and (b) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment.
2. Risk 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 or 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 subject 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 subjects legally authorized representative, in accordance with, and to the extent required by 45 CFR 46.116.
5. Informed consent will be appropriately documented, in accordance with, and to the extent required by 45 CFR 46.117.
6. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safely to subjects.
7. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentially of data.
8. 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.

Confidentiality Material submitted to the IRB shall be considered privileged information are accessible only to the IRB committee and others deemed appropriate by the IRB.

Procedures

All faculty and student research that is completed for a master's or doctorate degree must be known to the IRB, however not all research is required to obtain IRB approval. Most undergraduate and some graduate research that is designed as part of a course requirement and involve human participants usually does not meet the federal definition of research. These activities do not require IRB review if ALL of the following conditions are true:

- The research involves no more than minimal risk.
- Vulnerable populations are not involved.
- The activity is a class assignment designed for learning purposes only and is not designed to develop or contribute to generalizable knowledge.
- Results of the research will not be made public through publication in a scientific journal or presented at a professional conference.
- The data is collected in a way that individual subjects are not identifiable.
- When appropriate, an informed consent process is in place.

It is the responsibility of the course instructor to educate students on the ethics of human subject research. Specifically the instructor should instruct students on the following:

- Understanding informed consent and developing appropriate consent documents.
- Plan appropriate strategies for recruiting subjects.
- Identify and minimize risks to subjects and asses the risk-benefit ratio for the project.
- Establish guidelines for protecting confidentiality.
- Directing students through the IRB process if it is required.

From the perspective of the IRB committee there are three kinds of research, research that is exempt from IRB review but still must be reported to the IRB, research that may receive an expedited review and research that requires a full review. Use the following questions to determine what review is required. Expedited review may be conducted by the IRB chairperson or their designee, while the full review requires deliberation by the entire IRB committee. If a researcher has a question about if their project is required to receive IRB review they should consult the chair of the IRB committee.

1. Is the activity a systematic investigation designed to develop or contribute to generalizable knowledge?
    a) Yes – go to question 2
    b) No – Does not meet the federal definition of research, **no IRB notification/approval** required.

2. Does the research involving obtaining information about living individuals?
    a) Yes – go to question 3
    b) No – Research does not involve human subjects, **no IRB notification/approval** is required.

3. Does the research involve intervention or interaction with individuals?
    b) Yes – Go to question 4
    b) No - Is the information individually identifiable?
        a) Yes – Is the information private?
            a) Yes – Go to question 4
            b) No – **IRB Notification is required, no IRB approval is required.**
        b) No – **IRB Notification is required, No IRB approval is required.**

4. Does the research involve prisoners, pregnant women, handicapped or mentally disabled persons, economically or educationally disadvantaged persons and other populations subject to coercion?
    a) Yes – **IRB Approval is required**
    b) No – Go to question 5

5. Does the research fit into any of the following exempt categories?

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

a) Yes- **IRB Notification is required, IRB approval is NOT required**

b) No – **IRB approval is required, go to question 6.**

b) Research involving the use of educational tests, survey procedures, interview procedures, or observation of public behavior.

a) Yes – Does the research involve children?

a) Yes - Does the research involve educational tests or the observation of public behavior without participation by the investigator in the activity being observed?

a) Yes – go to ** for this answer

b) No – **IRB approval is required**

b) No, ** – Is the information obtained recorded in a way that human subjects can be identified, directly or through identifiers linked to the subject AND could any disclosure of the human subjects responses outside the research reasonably place the subject at risk of criminal or civil liability or be damaging to the subjects financial standing, employment, or reputation?

a) Yes **IRB approval is required**

b) No – **IRB notification required, no IRB review is required.**

b) No **– IRB review is required, go to question 6.**

c) Research involving collection or study of existing data, documents, records, or pathological or diagnostic specimens?

a) Yes – Are these sources publically available?

a) Yes – **IRB Notification is required, no IRB approval is required**

b) No – Will data be recorded in a way that subjects cannot be identified.

a) Yes – **IRB Notification required, no IRB approval is required.**

b) No – **IRB approval is required.**

b) No – **IRB approval is required, go to question 6.**

d) Research studying, evaluating, or examining public benefit of service programs? Is the research approved by the department or agency head?

a) Yes – **IRB Notification is required, no IRB approval is required.**

b) No **– IRB approval is required, go to question 6.**

e) Research involving taste and food quality evaluation or consumer acceptance studies? Does the research involve only a taste and food quality evaluation or a food consumer acceptance study?

a) Yes – Are wholesome foods without additives consumed?

a) Yes – **IRB notification required, no IRB approval is required.**

b) No – Is food consumed that contains a food ingredient, 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?

a) Yes – **IRB notification is required, no IRB approval is required.**

b) No – **IRB approval is required, go to question 6.**

b) No – **IRB approval is required, go to question 6.**

6. Expedited Research Review The following conditions qualify research for an expedited review.

1. The research involves no more than minimal risk.

Minimal Risk - The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. (Code 45 CFR 46.102(i).

Minimal Risk – Continue with this section.

More than Minimal Risk – **Research is required to have a full IRB review.**

2. The research falls into one of the following categories. **(If yes to one category, expedited review)**

(1) Clinical studies (a) drugs for which an investigational new drug application is not required (Note: research on marketing 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), or (b) medical devices for which an investigational device exemption is not required; or 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, nonpregnant adults who weigh at least 110 pounds (Note: amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than two times per week) or (b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood collected, and the frequency with which it will be collected (Note: amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an eight week period and collection may not occur more frequently than two times per week).

(3) Prospective collection of biological specimens for research purposes by noninvasive means. Examples: (a) Hair and nail clippings in a nondisfiguring manner; (b) Deciduous teen 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); and (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 removal 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 washing; (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. When medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical devices are no generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples: (physical sensors that are applies dither 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, electroretinoraphy, 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, and 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).

(6) Collection of data from voice, video, digital, 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, social behavior), or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

7. Full IRB Research Review The full IRB committee must review research that does not meet the criteria for expedited review, or if either of the following condition are met.

(1) Research involving a vulnerable population.
(2) Research involves more than minimal risk to the participants.

Other Types of IRB Review
There are three other situations in which research may need to come before the IRB committee.

Amended Review All major and minor amendments to previously approved research must be submitted to the IRB for approval. The only type of amendment that does not require written IRB approval before it may be implemented is a change that is necessary for the safety of a subject. In this event, the protocol change may be implemented immediately, and the IRB notified after the fact. The IRB committee will then review the amendment and determine if, in its opinion, the amendment was necessary. The IRB will then notify the investigator of its approval or disapproval.

Continuing Review Studies are approved for a designated period of time that will not exceed one year. For studies that will continue beyond one year or the designated time period a continuing review form must be submitted to the IRB for review. The IRB will notify principle investigators that they must submit a continuing review form approximately one month before it is due to be reviewed by the IRB.

Reporting Unanticipated Problems Any adverse experiences associated with a study must be reported to the IRB on an unanticipated problem form within 3 working days after the incident.