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

Mount Marty College 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 College 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 college directly or indirectly (this individual cannot be a spouse, parent, or a child of an employee or Mount Marty College). Members, including the chair, are appointed by the President of the college 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 National Institute of Health (NIH) Office of Extramural Research training course on protecting human research participants on an annual basis. Completion of this training shall be reported to and kept on file by the director of institutional research.

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 NIH 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 College 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.

Mount Marty College
Research with Human Subjects
Submission Cover Sheet
(attach appropriate forms to this cover sheet)

Proposals may be submitted at any time, however proposals that require full IRB review must be submitted at least one week before a scheduled IRB meeting. Prior to the submission of the proposal the principal investigator must complete the National Institute of Health (NIH) certification on protecting human research participants and provide a copy of the certificate to the IRB administrator when the proposal is submitted. The training is found at http://phrp.nihtraining.com/users/login.php

If the research is exempt from IRB review, the researcher must submit an IRB notification form to the IRB committee before beginning research. If the research requires IRB review the forms should be submitted prior to the initiation of research, as the IRB will not approve proposals after the fact. Proposals should be submitted to the IRB administrator.

1. Project Title:

2. Principle Investigator:

3. e-mail:

4. Qualifications to do the research:

5. Date NIH Human Research Participants Training completed:
   (must be completed and documentation sent to IRB
   administrator before application is submitted to the IRB)

6. Student Investigator(s), and/or co-investigators. (copy this section as needed)
   Name:
   Role in Study:
   Date NIH Human Research Participants Training completed:
   (must be completed before participation in project begins)

7. Type of documentation attached
   [ ] IRB Notification for Exempt research
   [ ] IRB Expedited review
   [ ] IRB Full review
   [ ] Changes to a previously approved IRB proposal
   [ ] Request for continuing approval to a previously approved IRB proposal
   [ ] Reporting unanticipated problems to a previously approved IRB proposal

Submit one copy of the application form and all other appropriate materials to the IRB secretary at kristen.welker@mtmc.edu. It may also be mailed to: IRB/Kristy Welker, Mount Marty College, 1105 West 8th Street, Yankton, SD.57078.

Mount Marty College
IRB Notification of Exempt research

1. Description of the study.

2. This study is exempt for which of the following reasons.

- [] Research conducted in established or commonly accepted educational settings, involving normal educational practices.
- [] Research involving the use of educational tests survey procedures, interview procedures or observation of public behavior.
- [] Research involving the use of educational tests, survey procedures, interview procedures, or observation of public behavior that is not exempt under the item above.
- [] Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens.
- [] Research and demonstration projects which are conducted by or subject to the approval of department or agency heads.
- [] Taste and food quality evaluation and consumer acceptance studies.

3. Dive a detailed explanation of why it is exempt.

Signature of Principle Investigator:

Date:

Mount Marty College
IRB Expedited or Full review

Part I.

1. What kind of review is requested for this study?
    - [] Expedited (indicate what kind of research you will be doing)
        - [] Clinical studies.
        - [] Collection of blood samples.
        - [] Collection of biological specimens for research purposes by noninvasive means.
        - [] Collection of data through noninvasive procedures routinely employed in clinical practice.
        - [] Research involving materials that have been collected or will be collected solely for non-research purposes.
        - [] Collection of data from voice, video, digital, image recordings for research purposes.
        - [] Research on individual or group characteristics or behavior.
    - [] Full

Part II. Project Approvals

1. Has this research been approved by the students mentor or thesis/dissertation director.
    - [] Not applicable
    - [] Yes
    - [] No (Do not submit this application until approval is granted.

2. Have you or do you plan to submit this study to another IRB?
    - [] No
    - [] Yes (Submit a copy of that IRB decision and approval/disapproval when it becomes available)

Part III. Study Information

1. Describe the purpose/hypothesis of your research.

2. Describe the scientific rational of your research. What do you expect to learn from the study.

3. What research methods will you use? Give a brief, non-technical explanation. Include the study design, statistical analysis methods and sample size.

4. Describe the study population.

5. Are you targeting a specific ethnic group? If yes, describe.

6. Identify the age ranges of participants to be enrolled.

7. Identify inclusion and exclusion criteria for the study. This is the criteria for which participants are deemed eligible or ineligible to participate in the study.

8. How will potential participants be identified and recruited? Describe recruiting methods, if any, you will use. Attach all recruitment materials/activities.

9. Indicate all populations that will be enrolled in this study (check all that apply).
    - [] Children
    - [] Pregnant women
    - [] Prisoners
    - [] Fetuses
    - [] Economically/educationally disadvantaged persons
    - [] Individuals with diminished mental/physical capacity
    - [] Any population under your supervision

10. For each population specified in question 9, provide a description of the special considerations, steps, and safeguards that will be taken to ensure that the vulnerable populations will be adequately protected.

11. Explain in detail when and where participants/legally authorized representatives will be approached to obtain consent/assent.

Note: You can only obtain informed consent from "legally authorized representatives" when you have permission from the IRB to do so. If you plan on conducting research on a population that requires a "legally authorized representative," you need to submit the consent form you will use to obtain consent from "legally authorized representatives" on behalf of "Cognitively Impaired or Unable to Consent" participants.

12. Explain in detail how much time you will give the participants to consider participation in the study.

13. If any of your participants do not speak English, explain how the person obtaining consent will communicate with the participant in a language understandable to the participant/parents/legally authorized representatives.

[] All participants speak and read English.

[] Some of the participants do not speak and/or read English. Informed consent must be in the language of the participants. Explain how informed consent will be obtained for non-English speakers.

14. Explain how you will determine whether participants/parents/legally authorized representatives understand the information that was provided in the informed consent/assent document.

15. Identify each site where participants will be recruited or data will be collected. If the site is off-campus, list contact information and attach a letter or e-mail authorizing use of the site. Note if contact information is unavailable (i.e. door-to-door or telephone survey).

15a. Does this site have in IRB?

[] No

[] Yes, they have an IRB and I have applied or am in the process of applying.

[] Yes, they have an IRB, but will accept MMC IRB approval.

Provide contact person for that IRB:

16. Check all informed consent/assent documents that will be obtained from each prospective participant or the participant's legally authorized representative (LAR), and provide copies of the consent/assent documents with this application.

Adults	Assent
[] Informed Consent	[] Separate Assent Form
[] Parental Consent for children	[] Assent with Parental consent
[] Legally Authorized Representative Consent	[] Assent within LAR consent
[] Waiver of documentation of informed consent (For example: observational research)	[]Person not capable of providing assent

17. Describe your plan for voluntary withdrawal of the participants in the study.

18. How will participants be compensated? (check all that apply)

[] No compensation [] Cash: (specify amount) [] Other: (specify)

19. If medical or psychological services are needed as a consequence of the research, describe how participants will be referred to those services.

20. Describe in detail how your research data will be collected. Be sure to include the specific expectations of participants and the duration of participation.

21. List and provide copies of all surveys, interviews, tests, procedures and interventions from screening to closeout that the human participants must undergo in the research. Indicate the frequency and purpose of administration.

22. Describe how you will ensure that all study personal (students and/or co-investigators) are adequately informed about the protocol and their research-related activities.

23. Explain the steps you will take to minimize coercion and undue influence.

24. What is the anticipated completion date for this research?

Part IV. Benefits and Risks

1. What direct and societal benefits do you expect the participants you enroll to get from this study? If there is no direct benefit to the participants, simply state that there will be no direct benefit.

2. Check all risks that apply.

[] Physical	[] Use of private records including medical or educational records
[] Legal	[] Major changes in diet, exercise or sleep
[] Psychological	[] Administration of physical stimuli
[] Social	[] Possible invasion of privacy of the participant or the family
[] Economic	[] Use of audio or video for data collection
[] Other	

3. Describe the nature and the degree of risk or harm from any items checked in Question 2. The risks and harms must be disclosed ion the consent form.

4. Describe how the risks to participants are minimized (e.g. screening participants, identifying standards of care procedures, sound research design, safety monitoring and reporting).

5. As the investigator, what is your analysis of the potential risk versus potential benefit to those participating in this study? Justify the risk in terms of the potential scientific yield and in relation to the anticipated benefits to the participant.

6. Will you apply for a Certificate of Confidentiality*? (http://grants.nih.gov/grants/policy/coc/)

[] Yes [] No [] N/A

* Certificates of confidentiality are issued by the National Institutes of Health (NNIH) to protect the privacy of research subjects by protecting investigators and institutions from being compelled to release information that could be used to identify subjects with a research project. Certificates of Confidentiality are issued to institutions or universities where the research is conducted. They allow the investigator and others who have access to research records to refuse to disclose identifying information in any civic, criminal, administrative, legislative, or other proceedings, whether at the federal, state, or local level.

Part V. Privacy, Confidentiality and Protection of Data

1. When you obtain data, it will already be:
   - [] Anonymous – without any identifiers that could link the data to a specific participant.
   - [] Unlinked – collected with identifiers, but all identifiers/codes have been removed and destroyed.
   - [] Coded – linked to a specific participant by a code-link rather than direct identifiers.
   - [] Identified – linked to a specific participant by personal identifiers sufficient to identify a specific participant.

2. When you store the data, it will be:
   - [] Anonymous – without any identifiers that could link the data to a specific participant.
   - [] Unlinked – collected with identifiers, but all identifiers/codes have been removed and destroyed.
   - [] Coded – linked to a specific participant by a code-link rather than direct identifiers.
   - [] Identified – linked to a specific participant by personal identifiers sufficient to identify a specific participant.

3. Explain how the confidentiality of the study records will be maintained and how you plan to protect the confidentiality of the data.

4. Will data identifying the participants be made available to anyone other than the Principle Investigator?

5. Will identifiers be maintained?
   - [] No
   - [] Yes, explain who will have access to the identifiers and who will keep them.

6. Explain how the data will be kept secure including encryption, and transmission to others.

7. Where and how will research data be stored and ultimately disposed of to ensure confidentiality? UIf applicable, specify an address of the data storage location.

Part VI. Conflict of Interest

The following question is provided to help you understand the range of activities that can give rise to potential conflict of interest. Mount Marty College recognizes that these situations can be common and is concerned with putting mechanisms in place that will prevent any actual conflict of interest from ocuring. The purpose of this question is to allow you to describe the activities in which a potential conflict of interest exist. (Note: immediate family is defined as spouse, dependent children, or domestic partner.)

1. Check YES, if you, or a co-investigator or other study personal have…
   - [] Ownership interest related to the research >$10,000 when aggregated for the immediate family.
   - [] Ownership related to the research >5% in any one entity when aggregated for the immediate family.
   - [] Ownership interest related to the research of any amount whose value cannot be referenced to publicly traded prices or other reasonable measure of value.
   - [] Ownership interest related to the research whose values will be affected by the outcome of the research.
   - [] Proprietary interest related to the research including, but not limited to a patent, trademark, copyright or licensing agreement.
   - [] Board or executive relationship related to the research, regardless of compensation.

NOTE: Contact the IRB if you checked YES to any of the items to obtain a financial disclosure form.

Part VII. Funding/contracts

1. Is this study a department of Health and Human Services funded study?

[] No, proceed to Part VII. [] Yes

2. Indicate what type of funding and name of department, agency or sponsor.

[] Funded Internally [] Training Grant
[] Program Project Grant [] Federally Sponsored Project
[] Industry Sponsored Project

2a. Describe the source of the grant:

3. Does this study have a contract?

[] No
[] Yes. If yes provide who or what official office is responsible for signing off on the contract (with name and phone number):

Part VIII. HIPPA

If you are collecting Protected Health Information (PHI) from a hospital, medical center, doctor's office, etc. (see below for PHI), HIPPA authorization or waivers may be appropriate.

1. Are you collecting Protected Health Information (PHI)

[] Yes – go to question 2.
[] No – go to part VIII.

2.Identify the PHI you are collecting. Check all that apply.

[] Names
[] Phone numbers, fax numbers, e-mail addresses
[] Social security numbers
[] Medical record numbers
[] Geographical subdivisions smaller than a State, including street address, city, county, precinct, zip code
[] elements of dates (except year) for dates related to an individual, including birth data, date of death, and all ages over 89 and all elements of dates (including year)
[] Health plan beneficiary numbers, account numbers, certificate/license numbers.
[] Vehicle identification and serial numbers, including license plate numbers.
[] Device identifiers and serial numbers.
[] Web Universal Resources Locators (URLs), Internet Protocal (IP) address numbers, Biometric identifiers, including finger and voice prints.
[] Full face photographic images and any comparable images.
[] Any other unique identifying number, characteristic, or code (note this does not mean the unique code assigned by the investigator to code the data).

3. Does your study require HIPPA authorization or waivers?

[] No
[] Authorization Addendum – a study specific Research Subject HIPPA Authorization (stand-alone) form must be attached.
[] Full Waiver of Authorization – usually used for retrospective chart abstraction.
[] Partial Waiver of Authorization – used for recruiting, screening, and enrolling.

Part IX. Oversight and Monitoring
The IRB requires a data and safety monitoring plan (DSMP) for all studies with greater than minimal risk. For externally-sponsored studies, the DSMP is normally incorporated intot eh protocol. For an investigator-sponsored study the principle investigator is responsible for creating and implementing a DSMP. A DSMP is not required for minimal risk studies.

1. Is your study greater than minimal risk?
   [] No
   [] Yes, a DSMP is included in the protocol provided by the sponsor.
   [] Yes, I have attached the SDMP.

Part X. Principle Investigator Statement of Responsibilities and Assurances
The principal investigator undertakes the primary responsibility for protecting the rights and welfare of research participants and must be familiar with the ethical principles of human participant protection requirements of federal regulations and IRB policy and procedures.

The principal investigator agrees to:

- Conduct the research according to the IRB approved protocol and in compliance with all IRB determinations.
- Disclose any conflict of interest (financial or other) that may affect the relationship with the research participant or the outcome of the research.
- Equitably recruit and select participants.
- Seek guidance from the IRB, when needed.
- Keep current on policies and procedures that affect human participant protections.
- Quickly respond to complaints or requests for information.
- Ensure each potential participant (or participant's legal representative) is informed and understands the nature of the research, voluntarily agrees to participate, signs and dates the IRB approved informed consent form, and receives a copy of the consent document.
- Maintain copies of all study records and signed consent documents for at least three (3) years beyond the study completion date.
- Promptly report to the IRB any proposed changes to the study.
- Promptly report to the IRB all unanticipated problems involving risks to participants or others.
- Provide continuing review and closure reports to the IRB in a timely manner and in accordance with IRB policies.
- Ensure educational training on human research protections is completed by the investigators, co-investigator, study coordinators, and students materially involved with the research study. This requires completion of an online course at http://phrp.nihtraining.com/users/login.php .

_____ _____
Signature of Principal Investigator/Faculty Advisor *Date*

Part XI. Researcher's Assurance
I hereby certify that I am familiar with federal and professional standards for conducting research with human subjects and that I will comply with these standards. The above information is correct to the best of my knowledge, and I shall adhere to the procedure as I have described. If a change in procedures becomes necessary, I shall submit an amended application o the IRB and await approval prior to implementing any new procedures. If any problems involving participants occur, I shall immediately notify the IRB Chairperson.

_____ _____
Signature of Principle Investigator Date

_____ _____
Signature of Student Investigator Date

Mount Marty College
Changes to previously approved IRB proposal

I. Study Information:
1. IRB Study number

2. Title of Project

3. Principle investigator and title

II.
1. Proposed changed to the research plan.

2. How does this change impact the risk to participants?

3. What are the benefits of making this change?

Signature of Principle Investigator:

Date:

Mount Marty College
Request for continuing approval to a previously approved IRB proposal

I. Study Information:
1. IRB Study number

2. Title of Project

3. Principle investigator and title

II.
1. What is the purpose of this extension?

2. What is the anticipated completion date for this research?

Signature of Principle Investigator:

Date:

Mount Marty College
Reporting unanticipated problems to a previously approved IRB proposal

I. Study Information:
1. IRB Study number

2. Title of Project

3. Principle investigator and title

II. Unanticipated Problems
1. Description of the incident.

2. Principle investigators assessment of the incident

3. Outline any changes and the significance to the study and changes in the risk/benefit ratio.

4. Any changes that need to be made to the consent statement plus the revised form.

Signature of Principle Investigator:

Date:

IRB Determination Form for Expedited and Full Review
(To be completed by the IRB Chairperson)

Project Title:

Project Principle Investigator:

IRB Reference Number:

Date of IRB Review:

Evaluation of the Proposal

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.
   [] Yes
   [] No

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.
   [] Yes
   [] No

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.
   [] Yes
   [] No

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.
   [] Yes
   [] No

5. Informed consent will be appropriately documented, in accordance with, and to the extent required by 45 CFR 46.117.
   [] Yes
   [] No

6. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safely to subjects.
   [] Yes
   [] No

7. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentially of data.
   [] Yes
   [] No

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.
   [] Yes
   [] No

The IRB has reviewed the above research project and determined that:

[] **Approval Granted:** Proposal is approved as written.

[] **Approved Granted with required changes**: With changes study can proceed (see below).

[] **Tabled: The IRB** committee needs further information, clarification, or the proposal needs revision before an IRB decision can be made. Please revise and resubmit (see below).

[] **Approval not granted**: The proposal may be resubmitted if the concerns of the IRB committee are addressed (see below).

_____ _____

IRB Chairperson or designee Date

Comments: