

**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 CITI Training Human Subject Research course and provide a copy of the certificate to the IRB administrator when the proposal is submitted. The training is found [here](https://www.citiprogram.org/index.cfm?pageID=14).

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. Principal Investigator:

3. e-mail:

4. Qualifications to do the research:

5. Date CITI Human Subjects Research course completed:

(Must be completed and documentation sent to IRB administrator prior to submitting application to IRB)

6. Student Investigator(s), and/or co-investigators. (copy this section as needed)

 Name:

 Role in Study:

 Date CITI Human Subjects Research course completed:

(Must be completed prior to project participation)

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 administrator at kristen.welker@mountmarty.edu. It may also be mailed to: IRB/Kristy Welker, Mount Marty University, 1105 West 8th Street, Yankton, SD 57078.

**Mount Marty University**

**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. Give a detailed explanation of why it is exempt.

Signature of Principle Investigator:

Date:

**Mount Marty University**

**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 [] Economically/educationally disadvantaged persons

 [] Pregnant women [] Individuals with diminished mental/physical capacity

 [] Prisoners [] Any population under your supervision

 [] Fetuses

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 []Person not capable of providing assent

 (For example: observational research)

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 (NIH) 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 University 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 [CITI Training](https://www.citiprogram.org/index.cfm?pageID=14).

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*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 to the IRB and await approval prior to implementing any new procedures. If any problems involving participants occur, I shall immediately notify the IRB Chairperson.

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Signature of Principle Investigator Date

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Signature of Student Investigator Date