INSTITUTIONAL REVIEW BOARD

Purpose

The University of Mary is committed to ensuring that all research involving human and animal subjects at the University is conducted in accordance with ethical and professional standards. The primary mission of the institutional review board is to protect the public and protect the subjects of research. However, the students' research advisors have primary responsibility for guiding research projects and selecting appropriate methodologies. Research advisors are required to review all applications prior to the student researchers submitting them to the institutional review board. The University's Scientific Misconduct Policy can be found in the *Corporate Faculty Handbook* Appendix E.

Guidelines for Preparation of Protocols for Review by the Institutional Review Board (IRB)

Composition and Function of the Institutional Board

The Institutional Review Board (IRB) is composed of four members appointed for three-year terms by the vice president for academic affairs. Initial committee members will be appointed for terms as follows: two members for three years, one member for two years, one member for one year. The assistant vice president for academic affairs serves as board chair. The board will select from its members a secretary who will serve a one-year term without restriction of number of terms.

The chair shall call meetings as needed to accomplish the work of the board.

Except for those areas of research that are exempt, all proposals for research done under University auspices (research by students, research by faculty, and research by outside agents conducted within the University community) shall be reviewed by the board. After the initial chair review, the IRB usually determines that the following types of research are exempt from a formal review:

a) those studies which draw data only from pooled results of educational tests,
b) survey procedures,
c) observations of public behavior, and,
d) study of existing data, documents, records or specimens.

The board is charged by the University with reviewing each research protocol and subject consent form to ensure that human rights and the welfare of subjects are adequately safeguarded and that there are no undue risks to subjects or others. The board also reviews the research design in terms of producing reliable results.

Separate approval must be granted by the vice president for student development for any project (research or otherwise) involving asking University of Mary students to participate by sending information via the university's email, phone, or campus mail systems, or going door to door in the student residences.

Adoption of the U.S. Department of Health and Human Services IRB Guidelines

The University of Mary has adopted the Guidelines of the U.S. Department of Health and Human Services (HHS) for Institutional Review Boards. The University IRB follows the HHS guidebook for IRBs in the conduct of institutional review (available at: http://www.hhs.gov/ohrp/irb/irb guidebook.htm). The University complies with the processes and procedures identified in this guidebook regarding basic IRB review, considerations of research design, biomedical and behavioral research, and special classes of subjects.

Criteria for Disapproval of Projects

The IRB will not approve a proposal if it: 1) violates any laws or regulations of the United States, State of North Dakota, or University of Mary; 2) the risks to human subjects are greater than the benefits to them; 3) unnecessary risks are created; 4) selection of subjects is inequitable; 5) procedures for receiving and documenting informed consent are inadequate; 6) the IRB judges that inducements or other offered payments are likely to influence subjects unduly; or 7) if the research design is unlikely to produce reliable results.

Preparation of Proposal Protocol for Submission to the IRB

The proposal is made up of three parts: 1) a cover sheet (see pages 5-6); 2) a brief description of the study (page 7); and 3) an Informed Consent form required when human subjects are involved (see page 8-9). Directions for completion of each part are found within the Cover Sheet and the Human Subjects Review forms. Additional information regarding informed consent follows.

Content for the Informed Consent

The entire consent form must be written in a clear, concise language understandable to an average person who has no experience in science or scientific terminology. Informed consent must be obtained under circumstances that provide the subject (or legally authorized representative) sufficient opportunity to consider whether or not to participate and that minimize the possibility of subject coercion or undue influence. No informed consent, whether verbal or written, may include any exculpatory language through which the subject or his legally authorized representative is made to waive, or appear to waive, the subject's legal rights, including any release of the university or its agents from liability for negligence. The most common reason for delayed approval of a protocol from the IRB has been an inadequate or improperly prepared consent form.

In seeking informed consent, the following information shall be provided to potential subjects:

1. Explanation: An explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any treatments or procedures which are experimental.

2. Risks and Discomforts: A description of any reasonable predictive risk or discomfort to the subject including possible results if the experimental treatment or intervention should prove ineffective when the subject is a recipient of treatment for an illness or dysfunction.
3. New Information: A disclosure of new appropriate alternative procedures or courses of treatment that become available during the course of the study and that may be advantageous to the subject's condition or well-being.

4. Benefits to Be Expected: A description of any benefits to the subject or to others which may be reasonably expected from the research, including compensation (if any) offered to the subject.

5. Confidentiality: A description of the extent to which confidentiality of records identifying the subject will be maintained.

6. Contacts: A description of whom to contact for answers to any questions the subjects may have about the research, the subject's rights, or other matters. A 24 hour phone number is preferable.

7. Freedom of Consent and Approval: A description that participation is voluntary, and that refusal to participate will not result in a penalty or loss of benefits to which the subject is otherwise entitled. Also, included is a statement that the subject may discontinue participation at any time.

8. Voluntary Participation/Medical Treatment: For all studies involving human subjects the following statement **must** be included:

   My signature below acknowledges my voluntary participation in this research project. Such participation does not release the researcher, the University of Mary, or other agencies from their professional and ethical responsibilities to me. Potential risks from participation in this research project have been disclosed to me. I acknowledge that unforeseeable and/or unknown risks or discomforts may occur. In the event that medical treatment occurs as a result of normal participation in this research project, the University of Mary, or other agencies will not be responsible for my medical costs or other damages incurred in the absence of fault on their behalf.

If appropriate, the following content must also be provided on the Informed Consent Form:

9. A statement that the specific intervention or treatment may involve unforeseeable risks to the subject or embryo or fetus, if the subject is or may become pregnant.

10. Foreseeable circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.

11. Additional costs the subject may incur as a result of participation in the research project.

12. Important consequences of a subject's decision to withdraw from the research and procedures for organized termination of participation by the subject.

The Institutional Review Board may approve an informed consent procedure that alters some or all of the elements of informed consent provided that the Board finds and documents all of the following:

1. The research protocol involves no more than minimal risk to the subjects.

2. Sufficient information will be disclosed to inform the subject fairly to decide whether or not to participate in the research project.

3. Withholding or altering part of the description of the procedures will not materially affect the ability of the subject to evaluate the harm or discomfort caused by the research.

4. The project cannot practically be carried out without the withholding or alteration of the information, but with the assurance that the study's design ensures protection of the rights and safety of each individual subject with the alteration.

5. The information is not altered or withheld for the goal of eliciting participation of the subjects.

Approved
President's Council (February 22, 2010)
Executive Committee of the University of Mary Board of Trustees (March 11, 2010)

_____ Full Committee Review _____ Expedited Review _____ Exempt Review

University of Mary

INSTITUTIONAL REVIEW FOR HUMAN SUBJECTS RESEARCH

Part 1: Cover Sheet

[Submitted with Part 2: Human Subjects Review Proposal]

Project Advisor: _____ Div/Dept: _____
Print Name Credentials

Project Investigator(s) (as applicable):

_____ _____ _____

_____ _____ _____

Primary Contact Person: _____

Phone: _____ E-mail: _____ DATE: _____

Proposed Project Dates: Start: _____ Finish: _____
mm/dd/year mm/dd/year

Project Title: _____

_____

Funding Agencies (If Applicable): _____

Type Of Project:

_____ New Project _____ Continuation _____ Renewal
_____ Thesis _____ Directed Study _____ Student Research
_____ Change In Procedure For A Previously Approved Project
_____ Project To Be Undertaken As An Activity Under A Previously

Approved Training Or Division Grant Entitled:

_____

Proposed Project (Attach Research Proposal if Available):

_____ Involves A Cooperating Agency Or Program
_____ Human Subjects Would Be Involved In The Proposed Activity As Either:
_____ None Of The Following, **Or INCLUDING**
_____ Minors (< 18 Years)
_____ Individuals With Mental Health Impairments Or Disabilities
_____ University Of Mary Students
_____ Other: (Please Explain):

Please proceed to the Project Investigator Signature Page.

PROJECT INVESTIGATOR SIGNATURE PAGE

The policies and procedures on use of human subjects for research at the University of Mary apply to all activities involving use of human subjects and performed by persons conducting such activities under the auspices of the University. Research activities involving human subjects are initiated once review and approval by the Institutional Review Committee is received.

My signature below certifies that I have reviewed the institution's policies and procedures on research involving human subjects. I understand my responsibilities and agree to abide by the provisions of these policies and procedures.

For Student Projects: Please sign in the designated space:

_____ Date _____
Project Investigator

_____ Date _____
Project Advisor

_____ Date _____
Project Investigator

_____ Date _____
Chair/Program Director

_____ Date _____
Project Investigator

_____ Date _____
Project Investigator

For University Faculty and Staff and for Outside Agent Projects:

_____ Date _____
Primary Project Investigator

_____ Date _____
Project Investigator

Please forward two (2) copies: A signed original and one (1) photocopy and, if applicable, two (2) copies of the proposed consent form and two (2) copies of supporting documentation (surveys, protocols, for example) to:

Institutional Review Board (IRB)
Attn: Dr. Kimberly Long, IRB Chair
Office for Academic Affairs
University of Mary
7500 University Drive
Bismarck, ND 58504-9652

Reviewed and Revised: March 2005; May 2007; October 2008

University of Mary
INSTITUTIONAL REVIEW BOARD

Part 2: Human Subjects Review

[Must be attached to the IRB Cover Sheet]

1. PURPOSE FOR THE STUDY: Include the following: Intent, need, projected outcomes, background information, and justification or necessity for using human subjects.

2. PROTOCOL: Include a description of the research methods and design (study population, analysis of data, procedures to which humans will be subjected, potential significance of the results). Researchers are encouraged to submit the entire research proposal and to attach relevant information.

3. BENEFITS: Describe the benefits to the individual and/or humankind.

4. RISKS: Describe risks to the subject and precautions that will be taken to minimize them. The concept of risk goes beyond physical risk and includes risks to the subject's dignity and self respect, as well as psychological, emotional or behavioral risk. If data are collected which could prove harmful or embarrassing to the subject and/or to someone associated with him or her, then describe the methods to be used to insure the confidentiality or data obtained, including plans for final disposition or destruction and debriefing procedures.

5. USE OF DATA: Describe how the data will be used and who will use it; describe the method for subjects to obtain results.

6. CONSENT FORM: A copy of the CONSENT FORM to be signed by the subject [if applicable] and/or a STATEMENT to be read to the subject should be attached to this form. If no CONSENT FORM is to be used, document the procedures to be used to assure that infringement upon the subject's rights will not occur. Describe where signed CONSENT FORMS will be kept and for what period of time.

7. Forward a signed original and one (1) copy of this completed form with the IRB Cover Sheet, and where applicable, two (2) copies of the proposed Informed Consent form and supporting documentation to:

INSTITUTIONAL REVIEW BOARD
Dr. Kimberly Long, AVP for Academic Affairs
Office of Academic Affairs
University of Mary
7500 University Drive
Bismarck, ND 58504

Revised: February 2004; Review Date: February 2005; Review Date: February 2006; Revised: May 2007; Revised: October 2008

University of Mary
INSTITUTIONAL REVIEW BOARD

Part 3: Human Subjects Informed Consent

[Attach forms and letters to Parts 1 & 2]

Considerations and Guidelines for the Consent Form

The entire consent form must be written in a clear, concise language to an average person that has no experience in science or scientific terminology. Informed consent must be obtained under circumstances that provide the subject (or legally authorized representative) sufficient opportunity to consider whether or not to participate and that minimize the possibility of subject coercion or undue influence. No informed consent, whether verbal or written, may include any exculpatory language through which the subject or a legally authorized representative is made to waive, or appear to waive, the subject's legal rights, including any release of the University or its agents from liability for negligence.

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1. Explanation: An explanation of the purposes of the research and the expected duration of
   the subject's participation, a description of the procedures to be followed, and identification of any treatments or procedures which are experimental.

2. Risks and Discomforts: A description of any reasonable predictive risk or discomfort to the subject including possible results if the experimental treatment or intervention should prove ineffective when the subject is a recipient of treatment for an illness or dysfunction.

3. New Information: A disclosure of new appropriate alternative procedures or courses of treatment that become available during the course of the study and that may be advantageous to the subject's condition or well-being.

4. Benefits to Be Expected: A description of any benefits to the subject or to others which may be reasonably expected from the research, including compensation (if any) offered to the subject.

5. Confidentiality: A description of the extent to which confidentiality of records identifying the subject will be maintained.

6. Contacts: A description of whom to contact for answers to any questions the subjects may have about the research, the subject's rights, or other matters. A 24 hour phone number is preferable.

7. Freedom of Consent and Approval: A description that participation is voluntary, and that refusal to participate will not result in a penalty or loss of benefits to which the subject is otherwise entitled. Also, included is a statement that the subject may discontinue participation at any time.

8. Voluntary Participation/Medical Treatment: For all studies involving human subjects the following statement **must** be included:

   My signature below acknowledges my voluntary participation in this research project. Such participation does not release the researcher, the University of Mary, or other agencies from their professional and ethical responsibilities to me. Potential risks from participation in this research project have been disclosed to me. I acknowledge that unforeseeable and/or unknown risks or discomforts may occur. In the event that medical treatment occurs as a result of normal participation in this research project, the University of Mary, or other agencies will not be responsible for my medical costs or other damages incurred in the absence of fault on their behalf.

If appropriate, the following content must also be provided on the Informed Consent Form:

9. A statement that the specific intervention or treatment may involve unforeseeable risks to the subject or embryo or fetus, if the subject is or may become pregnant.

10. Foreseeable circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.

11. Additional costs the subject may incur as a result of participation in the research project.

12. Important consequences of a subject's decision to withdraw from the research and procedures for organized termination of participation by the subject.

The Institutional Review Board may approve an informed consent procedure that alters some or all of the elements of informed consent provided that the Board finds and documents all of the following:

1. The research protocol involves no more than minimal risk to the subjects.

2. Sufficient information will be disclosed to inform the subject fairly to decide whether or not to participate in the research project.

3. Withholding or altering part of the description of the procedures will not materially affect the ability of the subject to evaluate the harm or discomfort caused by the research.

4. The project cannot practically be carried out without the withholding or alteration of the information, but with the assurance that the study's design ensures protection of the rights and safety of each individual subject with the alteration.

5. The information is not altered or withheld for the goal of eliciting participation of the subjects.

University of Mary
INSTITUTIONAL REVIEW BOARD

Human Subjects Review

Part 4: Institutional Review Board Action

Project Title: _____ Project ID#: _____

Project Advisor/Principle Investigator: _____

_____ **The Institutional Review Board *approves* this project for the ethical use of human subjects.**

Additional Comments:

_____ **The Institutional Review Board <u>does not approve</u> the proposed project based on the following reasons:**

Recommendation:

Signatures:

_____		__ Approve	__ Not Approved
IRB Chair	Date		
_____		__ Approve	__ Not Approved
IRB Member	Date		
_____		__ Approve	__ Not Approved
IRB Member	Date		
_____		__ Approve	__ Not Approved
IRB Member	Date		
_____		__ Approve	__ Not Approved
IRB Member	Date		