Mount Saint Mary's University
Application for the Approval of Human Subjects Research

GENERAL INSTRUCTIONS

APPLICATION REVIEW

Review of applications occurs on a rolling basis and begins as soon as the Principal Investigator (PI) has submitted all application materials. Reviews typically can be completed within 2-3 weeks, at which time the Committee Chair will contact the PI with the committee's decision.

EXPEDITED REVIEW

An expedited review is simply a review by a sub-committee of the Human Subjects Committee. Expedited reviews do not guarantee a quicker process; however, since the application is being reviewed by one committee member rather than the whole committee, they typically are completed within the 2-3 week goal for completing reviews. A protocol must qualify as minimal risk in accordance with the federal regulations that govern human subjects research (45CFR 46) in order to qualify for expedited review.

Note on Exempt Status: Exempt does not mean the project is exempt from IRB review. It means that the IRB appointee decides that if there is minimal risk, there may not need to be a review by the full board; however, the researcher does not make this decision.

SIGNATURES

All signatures (***except those on the informed consent***) must be obtained prior to submission of the application/research protocol to the IRB. Student projects must have the faculty advisor's signature as well as their own added to the digital application. This can be accomplished in several ways such as copy and pasting a jpeg version of your signature. Appropriate electronic signatures are also accepted if they are done correctly.

Note to Faculty Project Advisors

Faculty signature on this Protocol Approval Form indicates that:

- You are familiar with the requirements for human subjects research as defined by 45CFR 46.
- You have reviewed this Protocol Approval Form and accompanying documentation.
- You approve of the manner in which human subjects will be involved in this study.

Online Tutorial

All Principal Investigators must take the CITI online tutorial for the protection of human subjects at and include a copy of the certificate of completion with this application. The HSC will not begin review of applications without this certification. **SEE APPLICATION FOR THE LINK.**

SUBMIT ONE Digital Copy with Signatures
(file should include ALL supplementary material including tutorial certificates, permissions, assessments, interview protocols, etc.)
Email to: rgordon@msmu.edu

Robin L. Gordon, Chair Human Subject Committee
Doheny Campus, Building 20
213-477-2620

GENERAL INFORMATION

Mount Saint Mary's University
Committee for the Protection of Human Subjects

Guidelines for Having Your Research Project Approved

This document is meant to supplement **(not replace)** the instructions provided on the Human Subjects Protocol form. If you have any questions regarding the Human Subjects Protocol Form, contact the Chair of the committee.

The Human Subjects Committee has the responsibility of examining research proposals to determine whether they meet guidelines for the protection of the welfare of human subjects. Approval for a project conducted by a faculty member, or by a student under the guidance of a faculty member, must be obtained ***prior*** to initiation of contact with human subjects. The successful application meets the following criteria and you may want to read your final draft and check off the boxes below.

- ☐ In planning the research, investigators should think carefully about potential avoidable harm to subjects, for example keeping in mind the ethical guidelines of the American Psychological Association and considering the need for cultural sensitivity in approaching subjects. Potential harm will be weighed against potential gain on each proposal reviewed by the Committee.

- ☐ **Benefits** of participation in the study should be clearly indicated in the **consent form**.

- ☐ When personal information or videotaping or voice recording is to be obtained during the course of the research, **planned disposition of that information** should be clearly stated in the consent form, i.e. explain clearly how will the participant's identity be kept confidential and what will happen to the recordings upon completion of the study.

- ☐ Remember - The protocol form is ***your*** chance to describe your project clearly to the committee. Failure to provide sufficient detail regarding your project may result in the protocol being returned to you without action causing considerable delay in your research.

- ☐ Please provide all information requested in a clear and concise manner and attach any necessary documentation. Be sure to provide information regarding all procedures and methodology, and if a control group will be used.

- ☐ A ***detailed*** description of the methods to be used must be provided. Additional sheets may be attached to the protocol form if necessary.

- ☐ The source, age(s) and number of subjects to be used in the study must be clearly stated. If the subjects will be obtained from a non-MSMU institution, a **letter of permission** from a representative of that institution must be provided.

- ☐ The **significance** of the work should be clearly described.

- ☐ A **consent form** that follows the sample format detailed in the application must be provided. However, if your protocol requires additional details beyond the example, please include them.

- ☐ The **risks** to subjects must be clearly detailed both in the application and in the consent form. **"No risk"** is never appropriate. Neither is **"passive consent"** (using a consent form that implies consent if it is not returned to the researcher). Risks may include emotional distress, physical stress, boredom, fatigue, or risk of bodily injury, as appropriate.

- ☐ There should be an indication on the consent form regarding **suggested psychological resources** and whether financial support for medical or counseling treatment is available to subjects in case of difficulties resulting from participation in the research.

- ☐ **Clear language** that is understandable by an educated layperson must be used throughout the protocol. Avoid excessive use of technical jargon.

- ☐ The **consent form** must be written at the level of an individual who would not have received any University education and has no more than an 8th grade reading level. Again, avoid technical jargon.

SEE THE FOLLOWING APPENDICES FOR GUIDELINES FOR INFORMED CONSENT AS WELL AS SAMPLES.

Appendices

- Please read the following information pages.
- Download and adapt the forms and templates as needed. Then insert them into your application.
- You must include the Subject Bill of Rights with your Informed Consent if directed by your project advisor.
- Please **do not** include the general info pages and templates in your final application.

Appendix A: Research Activities That May Be Considered to Be of Minimal Risk to Subject

Appendix B: National Institutes of Health Federal Guidelines for Informed Consent

Appendix C: How to Protect Human Subjects Requirements for Consent Form

Appendix D: Informed Consent Basic Template

Appendix E-1: to be used for studies involving medical/psychological procedures.

Appendix E-2: to be used for non-medical procedures.

Appendix E-3: Bill of Rights in Español

Appendix F: Parent Consent Requirements

Appendix G: SAMPLE OF LETTER FROM PARTICIPATING INSTITUTION

Appendix H: Parent Consent to be Used for **Education Case Study Projects** (EDU 296C/D)

Appendix I: SAMPLE CONSENT FOR ONLINE RESEARCH from the University of Wisconsin – Milwaukee Consent to Participate in Online Research

GENERAL INFORMATION

APPENDIX A

Mount Saint Mary's University
Human Subjects Committee

RESEARCH ACTIVITIES THAT MAY BE CONSIDERED TO BE OF MINIMAL RISK TO SUBJECT

1. Voice recording made for research purpose such as investigations of speech defects.

2. Moderate exercise by healthy volunteers.

3. Study of existing data, documents, records, pathological specimens, or diagnostic specimens.

4. Research on individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory, or test development, where the investigator does not manipulate subjects' behavior and the research will not involve stress to the subject.

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

6. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), if information taken from these sources is recorded in such a manner that subjects cannot be identified directly through identifiers linked to the subjects.

7. Research involving survey or interview procedures, except where:

   a. Responses are recorded in such a manner that the human subjects can be identified, directly through identifiers linked to the subjects, and . . .

   b. The subject's responses, if they became known outside the criminal or civil liability or be damaging to the subject's financial standing or employability; or the research deals with sensitive aspects of the subject's own behavior, such as illegal conduct, drug use, sexual behavior, or use of alcohol.

8. Research involving the observation (including observation by participants) of public behavior, except where the conditions listed under #7 exists.

9. Any other category specifically added to this list by HHS published in the Federal Register.

These categories are based upon the Federal Code 45 CFR.

GENERAL INFORMATION

APPENDIX B: This is informational. Please DO NOT include it with the application.

National Institutes of Health Federal Guidelines for Informed Consent

A. Basic and Additional Elements

- A statement that the study involves research
- An explanation of the purposes of the research
- The expected duration of the subject's participation
- A description of the procedures to be followed
- Identification of any procedures which are experimental
- A description of any reasonably foreseeable risks or discomforts to the subject
- A description of any benefits to the subject or to others which may reasonably be expected from the research
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject
- A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained
- For research involving more than minimal risk, an explanation as to whether any compensation, and an explanation as to whether any medical treatments are available, if injury occurs and, if so, what they consist of, or where further information may be obtained
- An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject
- A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits, to which the subject is otherwise entitled

B. Additional elements, as appropriate

- A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant), which are currently unforeseeable
- Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent

- Any additional costs to the subject that may result from participation in the research
- The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject
- A statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation, will be provided to the subject
- The approximate number of subjects involved in the study

C. Documentation Requirements for Informed Consent

Informed consent shall be documented by the use of a written consent form approved by the IRB, and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.

APPENDIX C
Mount Saint Mary's University
Human Subjects Committee

GENERAL INFORMATION

HOW TO PROTECT HUMAN SUBJECTS
Requirements for Consent Form

The consent form is designed as an agreement for the protection of the rights and welfare of any individual who participates as a subject in research. The following six elements of informed consent are required by DHHS regulations and should be covered on the consent form used.

1. **A statement of the procedure and purposes.** It must state that the study involves research, an explanation of the purposes of the research, a description of the procedures to be followed, expected duration of the participant's participation, and identification of any procedures which are experimental.

2. **A statement of any potential associated risk and/or discomfort for the subject.** It must include a description of any reasonable foreseeable risks or discomforts to the subjects.

3. **A statement of any associated benefits for the subject.** It must include a description of any benefits to the subject or to others which may reasonably be expected from the research.

4. **A statement indicating that participation is voluntary, and that the subject may withdraw at any time.** It must include a statement that the subject may refuse to participate, and may discontinue participation at any time without penalty, or loss of benefits to which he/she is otherwise entitled.

5. A **statement indicating that the subject was given the opportunity to ask questions about the procedure, and that they were answered prior to the subject's agreement to participate.** It must include an explanation of whom to contact for answers to pertinent questions about the research and research subjects' fights, and whom to contact in the event of a research-related problem. Include telephone number.

6. **A statement regarding the confidentiality of the subject.** It must include a statement describing the extent to which confidentiality of records identifying the subject will be maintained.

Appendix D: Informed Consent Template

NOTE: Due to the formatting of the consent, please use the separate file titled Required Informed Consent Template.

Appendix E-1 to be used for studies involving medical/psychological procedures.

Mount Saint Mary's University
EXPERIMENTAL SUBJECTS
BILL OF RIGHTS

The rights below are the rights of every person who is asked to be in a research study. As an experimental subject I have the following rights:

1) To be told what the study is trying to find out,

2) To be told what will happen to me and whether any of the procedures, drugs, or devices is different from what would be used in standard practice,

3) To be told about the frequent and/or important risks, side effects or discomforts of the things that will happen to me for research purposes,

4) To be told if I can expect any benefit from participating, and, if so, what the benefit might be,

5) To be told the other choices I have and how they may be better or worse than being in the study,

6) To be allowed to ask any questions concerning the study both before agreeing to be involved and during the course of the study,

7) To be told what sort of medical treatment (if needed) is available if any complications arise,

8) To refuse to participate at all or to change my mind about participation after the study is started. This decision will not affect my right to receive the care I would receive if I were not in the study.

9) To receive a copy of the signed and dated consent form.

10) To be free of pressure when considering whether I wish to agree to be in the study.

If I have other questions I should ask the researcher or the research assistant, or contact Human Subjects Committee, Mount Saint Mary's University, 10 Chester Place, Los Angeles, CA, 90007 or phone (213) 477- 2620.

X _____

Signature of Subject **Date**

Appendix E-2
To be used for non-medical procedures.

Mount Saint Mary's University
EXPERIMENTAL SUBJECTS
BILL OF RIGHTS

The rights below are the rights of every person who is asked to be in a research study. As an experimental subject I have the following rights:

1. To be told what the study is trying to find out,
2. To be told specifically what I will be asked to do,
3. To be told about the frequent and/or important risks, side effects or discomforts of the things that will happen to me for research purposes,
4. To be told if I can expect any benefit from participating, and, if so, what the benefit might be,
5. To be allowed to ask any questions concerning the study both before agreeing to be involved and during the course of the study
6. To refuse to participate at all or to change my mind about participation after the study is started.
7. To receive a copy of the signed and dated consent form.
8. To be free of pressure when considering whether I wish to agree to be in the study.

If I have other questions I should ask the researcher or the research assistant, or contact Human Subjects Committee, Mount Saint Mary's University, 10 Chester Place, Los Angeles, CA, 90007 or phone (213) 477- 2620.

X _____

Signature of Subject **Date**

Appendix E-3
en Español

Mount Saint Mary's University

Sujetos Experimentales
Declaración de Derechos

Los derechos que a continuación se mencionan, son los derechos de cada persona que participa en esta investigación. Toda persona al participar en estos estudios, tiene derecho:

1. A saber que es lo que el estudio esta tratando de investigar,
2. A estar informado de lo que sucederá, los procedimientos, los medicamentos, y los dispositivos, sean ó no diferentes a los utilizados en un precedimiento normal,
3. A saber la frecuencia y/ó el grado de riesgo, efectos secundarios, ó incomodidades que sucederan en el transcurso de la investigación,
4. A saber si hay algún beneficio al participar en el estudio, y cual sería ese beneficio,
5. A saber si existen otras alternativas que puedan ser mejores ó peores que, participar en esta investigación,
6. A que se le permita hacer preguntas antes de participar en el estudio, al igual que en el transcurso del mismo,
7. A saber que tipo de tratamiento médico (si es necesario) está disponible en caso de que ocurran complicaciones,
8. A renunciar a la participación en el estudio, aún cuando ya haya comenzado. Cualquier cambio de decisión no afectará el derecho a recibir la atención que se provería al no ser parte de esta investigación,
9. A recibir una copia firmada y fechada de la hoja donde se autorizó la participación,
10. A estar libre de cualquier presión al decidir si quiere ó no participar en el estudio.

En caso de tener preguntas, puede comunicarse con el investigador, el asistente de investigación, ó a la oficina de Human Subjects Committee, Mount Saint Mary's University, 10 Chester Place, Los Angeles, CA, 90007 ó al teléfono (213) 477- 2620.

_____ _____

Firma del participante Fecha

NOTE: If you are using a third party to hold your data or to collect data such as Survey Monkey, iCloud, etc. you MUST add this information to your consent! Then you may also use this statement:

"Although every reasonable effort has been taken, confidentiality during actual Internet communication procedures cannot be guaranteed."

OR

"Please note that the online survey is hosted by Company ABC which is a web survey company located in the USA. All responses to the survey will be stored and accessed in the USA. This company is subject to U.S. Laws, in particular, to the US Patriot Act/Domestic Security Enhancement Act that allows authorities access to the records that your responses to the questions will be stored and accessed in the USA. The security and private policy for Company ABC can be viewed at http://..."

You can use this in the confidentiality section above.

APPENDIX: F

Mount Saint Mary's University

Parent Consent Requirements

Most research involving data collected from children requires parent consent, and will be reviewed by the Human Subjects Committee on a case-by-case basis. Parent consent requirements ***may*** be waived if all of the following conditions exist:

- **All data are collected as part of the normal course of instruction or evaluation of the child (e.g., scores from testing students after a particular science unit), AND**
- **Any manipulation of teaching activities or techniques is within the realm of acceptable teaching practices, AND**
- **There is no perceived psychological or physical risk to the child.**

Even if the above criteria are met, all research proposals must be submitted to the Human Subjects Committee and receive approval or exempt status before beginning data collection. The purpose for this requirement is that any research involving human subjects by MSMU faculty, staff, or students requires approval by the HSC, even if the research is minimal/no risk or exempt. According to federal guidelines, the HSC must determine whether a proposal is no-risk or exempt and principal investigators or their advisors may not self-exempt.

Appendix G: SAMPLE OF LETTER FROM PARTICIPATING INSTITUTION

Template letter from institutional official providing permission to conduct study at their site (only for studies where subjects will be recruited from a location other than MSMU).

{Letter must be on letterhead with original signature of authorized official}

Date

Mount Saint Mary's University
Standing Advisory Committee for the Protection of Human Subjects
10 Chester Place
Los Angeles, CA 90007

Dear Committee Members:

[Insert your name(s)] has permission to conduct the project entitled [insert title of project here] at [insert name of facility]. I have reviewed the project and am aware of all the activities involved in the project including [list all that are applicable, e.g., surveys, interviews, reviewing student records].

Signed,

[Insert name and title of authorized official]

Appendix H: Parent Consent to be Used for Education Case Study Projects (EDU 296C/D)

NOTE: The following consent has been approved by the MSMU Human Subjects Committee for use by Education students who are completing a case study project in EDU 296C/D.

Other departments are welcome to revise the consent for their needs for use with the IRB application.

Parental Permission for Child Observation & Case Study

EDU 296 C/D: Case Study Inquiry & Report Seminar I & II

Instructor:
Instructor Contact:
Mount Saint Mary's University
10 Chester Place
Los Angeles, CA 90007

Date: _____

Education Student's Name: _____

Education Student's Contact Information: _____

Dear Parent or Guardian:

We are requesting your permission for a Mount Saint Mary's University Education student to complete a case study inquiry project with your child. The case study is an in-depth look at a student and is carried out in order for the teacher-candidate to learn more about a specific student in a comprehensive way. For example, with your permission, the teacher-candidate may interview you about your child and/or your child about their school experiences. Additional data that might be collected, with your permission, could be test scores, learning style assessments, and surveys about school. We hope new teachers will look at their future students as complex people with diverse backgrounds and experiences.

The case study will take place during one semester. The time involved will depend upon the assessments and/or interviews you and the Education student agree upon which may be used to learn about your child. This will lead to the preparation and writing of a case study about your child. The case study process will enable the MSMU student to gain a better understanding of the physical, social, emotional and cognitive (mental) growth and development of school age children. We hope that the knowledge gained by doing the case study will help the candidate become a more effective classroom teacher.

Your child will not be made uncomfortable in any way. All information concerning your child is considered **confidential. Participation is completely voluntary**. You or your child may decide to discontinue participation in the case study at any time.

There is minimal risk for your child to participate in the case study; however, if at any time your child feels uncomfortable about the work, you may withdraw from the study. The benefit for your child may be a better understanding of his/her classroom needs which makes modifications by the teacher, if needed, more effective.

If you wish to voice a concern about the research, you may direct your question(s) Dr. Robin Gordon, Chair of the Human Subjects Committee, 10 Chester Place, Los Angeles, CA 90007, by phone at 213-477-2620, or email at rgordon@msmu.edu.

Please complete the permission form below if you agree that the MSMU student may work with your child as described above. We greatly appreciate your cooperation in this educational experience.

Date of Agreement:_____
My Child's Name is: _____ Boy Girl
My Child's Age: _____ years _____ months_____

I, (**insert name of parent/guardian**) give permission for (**name of student-researcher**) to collect data for the purpose of writing a case study with (**name of child**) as the focus for her/his graduate courses at Mount Saint Mary's University. The courses are *EDU 296C/D: Case Study Inquiry & Report Seminar I & II* with instructor _____. I understand that no real names will be used and that the identity of (**name of child**) will not be revealed in any other way.

During the course of this case study, the following procedures will be used to learn more about **(name of child).**

{Note to 296C/D student: List each item here: for example - samples of school work, interviews with the subject, interviews with the parents/teachers, and observations of the person in interaction with peers or family members may be used. Interviews, samples of work, and observations must be documented with dates and times of data collection.}

I and my child understand that the course instructor will be given copies of assessments; however, a fictitious name will be used to protect the **confidentiality** of my child's name.

I and my child understand that participation is **voluntary**, that my child or I can choose not to participate in part or all of the project, and that my child or I can withdraw at any stage of the project without being penalized or disadvantaged in any way.

I and my child understand that any data that the teacher-candidate obtains from interviews or assessments for use in reports **will not**, under any circumstances, contain names or identifying characteristics of the child. Upon completion of the case study project, any interviews, assessments (excluding state tests or IEPs) or other data collected by the teacher-candidate will be shredded.

I and my child understand that any information I provide is **confidential** and that no information that could lead to the identification of any individual will be disclosed in any reports on the project, or to any other party.

Name and Address:

_____

_____

Relation to participant: _____

Phone:

_____

Additional Remarks:

_____

_____ _____

(Parent's Signature) (Date)

Special Permission Signature:

If the study is being conducted by a teacher-candidate who is working as a student teacher in the classroom of their cooperating teacher:

I and my child give permission for the results of the case study to be shared with the teacher of record.

_____ _____

(Parent's Signature) (Date)

By signing this form, I declare that I am the legal parent/guardian of the minor child listed above and authorized to grant such permission.

This gives basic information and/or language you can include in your informed consent using the required template. This example should not be used in place of the required template.

Appendix I
Another consent sample from the
University of Wisconsin – Milwaukee

Consent to Participate in Online Research

Study Title:

Person Responsible for Research:

Study Description: The purpose of this research study is to … (add study specific information). Approximately (number of subjects) subjects will participate in this study. If you agree to participate, you will be asked to complete a survey that will take approximately (length of time) minutes to complete. The questions will ask … (brief description of survey questions).

Risks / Benefits: Risks to participants are considered minimal. There will be no costs for participating, nor will you benefit from participating other than to further research.

Confidentiality: Your responses are completely confidential and no individual participant will ever be identified with his/her answers. Data from this study will be saved on a password protected computer for (length of time data will be retained). Only (PI, study staff, etc. – list who will have access to the data) will have access to the information.

Voluntary Participation: Your participation in this study is voluntary. You may choose to not answer any of the questions or withdraw from this study at any time without penalty. Your decision will not change any present or future relationship with the University of Wisconsin Milwaukee.

Who do I contact for questions about the study: For more information about the study or study procedures, contact (name) at (email and/or phone number).

Who do I contact for questions about my rights or complaints towards my treatment as a research subject? Contact the UWM IRB at 414-229-3173 or irbinfo@uwm.edu

Research Subject's Consent to Participate in Research:
By completing and submitting the attached survey, you are voluntarily agreeing to take part in this study. Completing the survey indicates that you have read this consent form and have had all of your questions answered, and that you are 18 years of age or older.

Thank you!

APPENDIX I continued: Additional Sample Language for Consent Documents

- "Your confidentiality will be kept to the degree permitted by the technology being used. No guarantees can be made regarding the interception of data sent via the Internet by any third parties." (Penn State)
- Address uncertainty in data longevity in more open-ended terms: "Data may exist on back ups or server logs beyond the timeframe of this research project."
- "Your confidentiality will be kept to the degree permitted by the technology being used. No guarantees can be made regarding the interception of data sent via the Internet by any third parties." (Penn State)
- Address uncertainty in data longevity in more open-ended terms: "Data may exist on back ups or server logs beyond the timeframe of this research project."
- (with mobile device research): "Remote data deletion will be performed in the event of a lost or stolen phone"

NOTE: If you are using a third party to hold your data or to collect data such as Survey Monkey, iCloud, etc. you MUST add this information to your consent! Then you may also use this statement:

"Although every reasonable effort has been taken, confidentiality during actual Internet communication procedures cannot be guaranteed."

OR

"Please note that the online survey is hosted by Company ABC which is a web survey company located in the USA. All responses to the survey will be stored and accessed in the USA. This company is subject to U.S. Laws, in particular, to the US Patriot Act/Domestic Security Enhancement Act that allows authorities access to the records that your responses to the questions will be stored and accessed in the USA. The security and private policy for Company ABC can be viewed at http://..."

You can use this in the confidentiality section above.