



Version 2.7  
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Protocol Packet

For

The Institutional Review Board (IRB)

For

The Protection of Human Participants

Milwaukee School of Engineering

# Table Of Contents

MSOE Requirement for Investigator Education .....	2
MSOE Policy Statement for Research Involving Human Participants.....	3
Definition of Research .....	3
Research Conducted at Another Facility with NIH Assurance .....	3
List of Exemptions.....	4
IRB Review Process	
Exempt Projects .....	5
Minimal Risk Projects .....	5
Risk or Deception Projects .....	6
Modifications .....	7
Renewals of Protocols .....	7
Cover Sheet to Protocol <i>Part One</i> .....	8
Abstract to Protocol <i>Part One</i> .....	9
Instructions for Preparing Protocol <i>Part Two</i> (Outline Format)	
I. Participants .....	10
II. Procedures .....	10
III. Risk/Deception.....	11
IV. Safeguarding Participants' Identity .....	11
V. Informed Consent .....	11
VI. Cooperating Institutions .....	14
Sample Affiliation Letter .....	15
IRB Membership List .....	16
IRB Meeting Dates and Protocol Submission Dates .....	17

## Investigator Education For The Protection Of Human Research Participants

The Milwaukee School of Engineering's Institutional Review Board requires all research personnel to complete education in the use of human research participants prior to submission of the IRB Protocol Packet. All persons working on a project that includes the use of human research participants must complete training. *This includes the principal investigator, co-investigators, senior personnel, advisors and supervisors. Completed education certificates must accompany the submitted protocol packet. Research projects will not be reviewed nor approved without the accompanying investigator education certificate.*

This education program is designed to provide investigators with a background in the ethics of research and the protection of human research participants. A primary focus is on Department of Health and Human Services (DHHS) regulations as they pertain to projects funded by the National Institutes of Health. However, the principles as they apply to human participant research are universal. The program consists of:

1. A web-based educational tutorial in a question and answer format
2. An interactive test
3. A printed certificate of completion.

The investigator education tutorial is available at <http://ethics.jaeb.org/>. Follow these instructions for completing the tutorial.

1. Go to website <http://ethics.jaeb.org/>. Click on continue.
2. Read overview page. Click on continue
3. Click on "I am a new user". Click on continue.
4. Enter first name, last name and user e-mail address. Click on continue.
5. Select Education Tutorial. Complete tutorial. Return to main menu.
6. Select Documents. Review all sections under documents. Return to main menu.
7. Select Interactive Test. Complete test. Return to main menu.
8. Select Reprint Certificate. Print certificate. Return to main menu and exit from program.
9. Attach investigator education certificate to your completed IRB protocol packet.
10. Submit protocol packet and certificate(s) to the MSOE IRB Committee for review.

**Questions?? Contact:** Ann Bloor  
IRB Administrator  
MSOE  
1025 N. Broadway  
Milwaukee, WI 53202-3109  
  
414-277-7237 (phone)  
414-277-7470 (fax)  
[bloor@msoe.edu](mailto:bloor@msoe.edu)

# PROTOCOL PACKET

## Institutional Review Board For The Protection Of Human Participants

### *MSOE Policy Statement for Research Involving Human Participants*

Since your research will involve human participants, your project will require review to determine if adequate measures are employed to protect those individuals involved in your study. The Milwaukee School of Engineering reviews all research proposals involving human participants regardless of the funding source.

The box below reflects MSOE's policy statement for implementation of federal regulations concerning Institutional Review Board (IRB) governance of research involving human participants.

#### ***Definition of Research***

The Office for Protection from Research Risks (OPRR) has published regulations governing Institutional Review Board (IRB) policies for reviewing research involving human subjects [*Federal Register* (June 18, 1991, Vol. 56, No. 117)]. MSOE adheres to these regulations and has adopted the *Belmont Report* [April 18, 1979, (which provides ethical principles and guidelines for the protection of human subjects of research)]. Anyone intending to use human subjects in research should read these two publications. These publications are available in the IRB Office.

For the purpose of IRB review, ***research is defined*** in the *Federal Register* [June 18, 1991, Vol. 56, No. 117] as:

**“a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program, which is considered research for other purposes. For example, some 'demonstration' and 'service' programs may include research activities.”**

The attached pages include guidelines and instructions to assist you in preparing a protocol to be submitted to the IRB. The brief synopses on pages 4-7 will help you to determine which parts of the protocol to complete and will explain the review process.

#### ***Federal Wide Assurance (FWA)***

**If your research will be done at another facility that has FWA Assurance for IRB review, please have the other facility's IRB approve your protocol *before* bringing it before the MSOE Institutional Review Board for review. Once you have approval from the other facility, please submit to the IRB office a copy of your approved protocol, MSOE's Cover Sheet, and a copy of the letter stating that your protocol has been approved by that facility's IRB, which includes their assurance number. There will be no need to revise your protocol packet, as long as the original protocol covers all the points that must be addressed under MSOE's protocol review. Any additional information that is required should be submitted with your original protocol.**

If you have any additional questions regarding completion of the protocol or the federal regulations, please contact Ann Bloor (414) 277-7237.

### **RESEARCH EXEMPT from REVIEW**

***Even though an individual researcher may determine that an investigation falls within the categories of exempt research, IT IS NECESSARY TO FILE THE COVER SHEET AND A ONE-PAGE DESCRIPTION OF THE PROJECT WITH THE IRB.*** The one-page description of the project must include the reason for exemption and be written in layperson's terminology.

**THESE EXEMPTIONS DO NOT APPLY TO RESEARCH INVOLVING PRISONERS, FETUSES, PREGNANT WOMEN, OR HUMAN IN VITRO FERTILIZATION.**

Unless otherwise required by department or agency heads, research activities in which the only involvement of human participants will be in one or more of the following categories are exempt from IRB review:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. **(Applies to research with minors.)**
  2. Research involving the use of educational tests<sup>1</sup> (cognitive, diagnostic, aptitude, achievement), survey procedures,<sup>2</sup> interview procedures<sup>2</sup> or observation of public behavior<sup>3</sup> **unless:**
    - (i) Information obtained is recorded in such a manner that human participants can be identified, directly or through identifiers linked to the participants; **and** (ii) Any disclosure of the human participants' responses outside the research could reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, or reputation.
- <sup>1</sup>**Applies to minors**  
<sup>2</sup>**Does not apply to research with minors**  
<sup>3</sup>**Applies to research with minors *only* when the investigator(s) *does not* participate in the activities observed**
3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not already exempt under #2, if:
    - (i) The human participants are elected or appointed officials or candidates for public office; *or* (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
  4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that participants cannot be identified, directly or through identifiers linked to the participants. **(Applies to research with minors.)**
  5. Research and demonstration projects which are conducted by or subject to the approval of [federal] department or agency heads *and* which are designed to study, evaluate, or otherwise examine:
    - (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under these programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.
  6. Taste and food quality evaluation and consumer acceptance studies,
    - (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or 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 of the Food Safety and Inspection Service of the U.S. department of Agriculture.

## IRB Review Process

### ***SUBMISSION of EXEMPT PROJECT PROTOCOLS***

#### **Determination of Exempt Status and Submission Materials**

Read through the exempt categories 1 - 6 on page 4. Note: *these exemptions do not apply to research involving prisoners, fetuses, pregnant women, of human in vitro fertilization.* If it is exempt, your protocol packet should consist of:

1. A Cover Sheet that is provided in the protocol packet (page 8). ***Be sure to indicate the appropriate exemption number(s).***
2. A one-page project summary/abstract in layperson's terminology that includes the reason(s) your project qualifies to exempt status.
3. Any instruments used for your research project.
4. An affiliation letter -- if applicable (see instructions for this form on pages 14-15).
5. **OPTIONAL:** An informed consent form. (For exempt protocols questionnaires, surveys, etc., you may wish instead to include a Cover Sheet explaining all elements of the study and state at the top of the questionnaire, survey, etc., **“By filling out this [questionnaire, survey, etc.] you are giving your informed consent.”**)

#### **Review of Exempt Research**

Send the above-mentioned materials to the IRB Administrative Office and reviewed at the next monthly IRB meeting. The project will be discussed and approved, disapproved or tabled (e.g., due to insufficient information, concern about the protocol, etc.) at this meeting.

After the meeting, you will receive a letter indicating the status of your protocol. If your protocol is determined to be exempt, no further review of your protocol will be needed unless you make any modifications (see *Modifications*, page 7). If the Board determines that your protocol is not exempt, you will be notified and given instructions on how to proceed.

### ***SUBMISSION of MINIMAL RISK PROJECTS***

#### **Determination of Minimal Risk Status and Submission Materials**

If your project is not “exempt” and the risk of harm anticipated in the research is **not** greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests, your project is **minimal risk** and your protocol packet should consist of:

1. A Cover Sheet that is provided in the protocol packet (page 8).
2. A one-page project summary/abstract in layperson's terminology that includes the reason(s) your project qualifies for minimal risk status.
3. A summary of your project using the outline format in Part Two of the protocol packet (pages 10-11).
4. An informed consent form (see instructions for this form on pages 11-13).
5. An affiliation letter -- if applicable (see instructions for this form on pages 14-15).
6. Any instruments (surveys, interview questions, etc.) used for your research project.

## Review of Minimal Risk Research

Send the above-mentioned materials to the IRB Administrative Office. Your protocol will be reviewed at the next monthly IRB meeting. The project will be approved, conditionally approved, disapproved or tabled (e.g., due to insufficient information, concern about the protocol, etc.) at this meeting.

After the meeting, you will receive a letter indicating the status of your protocol. If conditions need to be fulfilled, you must submit materials to fulfill the conditions in order to receive a one-year approval. Once you have met these conditions, you will receive a condition fulfillment letter indicating an approval period. **NOTE: An approval letter will not be sent to funding agencies until all conditions are met and the protocol is approved.** A request for renewal will be sent to you two months before the approval period expires.

If there are *any modifications* to the protocol during the approval period, these must be submitted to the IRB for further review and approval.

## ***SUBMISSION of RISK or DECEPTION PROJECTS***

### **Determination of Risk or Deception Status and Submission Materials**

If your project involves *more* than a minimal risk to participants (e.g., risk of harm anticipated in the research is *greater*, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examination of tests) or utilizes deception, your project is categorized as **risk or deception** and your protocol packet should consist of:

1. A Cover Sheet that is provided in the protocol packet (page 8).
2. A one-page project summary/abstract in layperson's terminology that includes the reason(s) your project qualified for risk or deception status.
3. A summary of your project, using the outline format in Part Two of the protocol packet (pages 9-10).
4. An informed consent form (see instructions for this form on pages 11-13).
5. An Affiliation letter - if applicable (see instructions for this form on pages 14-15).
6. Any instruments used for your research project.
7. A debriefing statement if deception is used.

### **Review of Risk or Deception Research**

Send the above-mentioned materials to the IRB Administrative Office, where your protocol will be reviewed at the next IRB meeting. The project will be approved, conditionally approved, disapproved or tabled (e.g., due to insufficient information, concern about the protocol, etc.) at this meeting.

After the meeting, you will receive a letter indicating the status of your protocol. If conditions need to be fulfilled, you must submit materials to fulfill the conditions in order to receive a one-year approval. Once you have met these conditions, you will receive a condition fulfillment letter indicating an approval period. **NOTE: An approval letter will not be sent to funding agencies until all conditions are met and the protocol is approved.** A request for renewal will be sent to you two months before the approval period expires.

If there are *any modifications* to the protocol during the approval period, these must be submitted to the IRB for further review and approval.

## ***MODIFICATIONS***

If you make changes to your protocol, you must submit a copy of the modified protocol to the IRB Administrative Office, highlighting the areas that have been changed. If the changes are minor, a copy of the changes will be sent to the Chair for approval. If the changes are major, the protocol will need to go before the full IRB for review.

## ***RENEWALS***

Two months before renewal, you will be sent a one-page Annual Progress Report form to be completed. If there are no changes to your protocol, you should submit the Annual Progress Report form for review by the Chair and approval by the Board. If there are changes to your protocol, you will need to attach your revised protocol to the Annual Progress Report form with your changes highlighted, and return to the IRB Administrative Office for review.

If your project extends to a third year, you will need to resubmit the protocol, with any changes, for full Board review.

Human Participants Review Protocol

Protocol # \_\_\_\_\_

PART ONE - Cover Sheet

ORIGINAL SUBMISSION       PROTOCOL MODIFICATION       RENEWAL

(If **Renewal** or **Modification**, See Protocol # \_\_\_\_). If there are changes, *submit a complete copy, highlighting the changes.*

I. **PROJECT TITLE** (Please print) \_\_\_\_\_

Principal Investigator \_\_\_\_\_ Title \_\_\_\_\_ Dept. \_\_\_\_\_  
Co-Investigator \_\_\_\_\_ Title \_\_\_\_\_ Dept. \_\_\_\_\_  
MSOE Proposal Name and Proposal No. (If applicable) \_\_\_\_\_

Total Project Period: From \_\_\_\_\_ To \_\_\_\_\_

- A. Is this project **EXTRAMURALLY FUNDED**? Circle: **No Yes** Funding Source \_\_\_\_\_
- B. Should we notify your funding source when you have IRB approval? Circle: **No Yes** (Provide address to IRB Office)
- C. Is this project **INTERNALLY FUNDED**? Circle: **No Yes** Funding source \_\_\_\_\_
- D. Is this project **THESIS OR DISSERTATION** Research? Circle: **No Yes**
- E. Is this project a **STUDENT CLASS PROJECT**? Circle: **No Yes** What class? \_\_\_\_\_

II. **DETERMINATION of RISK: EXEMPT:** See page 4 for list of exemptions. These exemptions *do not* apply to research involving prisoners, fetuses, pregnant women, or human in vitro fertilization. See page 5 for instructions and an explanation of the review process. **MINIMAL RISK, and RISK OR DECEPTION:** See pages 5-7 for definitions, instructions, and an explanation of the review process.

EXEMPT NO(S). \_\_\_\_\_  MINIMAL RISK       RISK OR DECEPTION

III. Check *all* of the following descriptors that apply to your research:

- Minors                       Fetuses                       Pregnant Women                       Prisoners
- Test Participants for new drugs or clinical devices       Abortions       Illegal Behavior       Mentally Disabled or Handicapped

IV. Principal Investigator Assurance:  
I have read the statement of MSOE research ethics, including the responsibility to obtain Informed Consent from participant(s) and will comply.

Principal Investigator (Print)	Faculty Advisor (Print) Required for Students
Principal Investigator (Signature & Date)	Faculty Advisor Signature( Required for Students) (Date)
Street Address      City      State      Zip	Faculty Phone
( )      ( )      ( )	Faculty e-mail address
Home Phone      Work Phone      Fax Number	
e-mail address	

**Human Participants Review Protocol**

**PART ONE - ABSTRACT**

*All protocols must include a one-page abstract. You may use this page or insert your own.*

## Human Participants Review Protocol

### PART TWO - INSTRUCTIONS

*Part Two should be limited to four pages with an additional one or two pages for your proposed “Informed Consent” documentation.* The Principal Investigator (PI) must supply all appended materials (e.g., questionnaires, and other support materials).

Describe the participant population and summarize procedures to be used according to the following outline. It is requested that the entire project design be included and the procedures involving human participants be fully described. More detail is required for any procedure that could potentially be harmful, such as the use of electric shock, hypnosis, unusual stress, drugs, or the imposition of demeaning and dehumanizing conditions.

#### **NOTE: USE THIS OUTLINE FORMAT**

#### **I. PARTICIPANTS**

- A. Describe the pool(s) of human participants you will be using:
  - 1. Sex, race or ethnic group, age range, etc.;
  - 2. Affiliation of participants, e.g., institutions, hospitals, general public;
  - 3. Participants' general state of health (mental and physical).
    - a. If a requirement of the research is that participants be in good mental or physical health, indicate how good mental/physical health will be determined and who will determine that mental/physical health.
  - 4. List approximate number of participants involved in the study.
- B. If human participants are minors, mentally incompetent, or legally restricted groups, give explanation as to the necessity for using these particular groups.
- C. If the participants are minors, and if parents are not allowed to see the results of their child's participation, the parents should be notified of that fact ahead of time. In most situations, parental consent is required for research with minors. The **IRB may alter** the consent process or waive the requirement for you to obtain a signed consent form for some or all participants if you meet the requirements set forth in the *Federal Register*, June 18, 1991, Vol. 56, No. 117.

#### **II. PROCEDURES**

- A. Describe procedures used for contacting and enrolling participants, e.g., who contacts them and enrolls them in the study, and how this is done. Use nontechnical language.
- B. Describe information to be gathered, and the means for collection and recording it.
- C. Describe personnel interacting with the participant.
- D. At what location will the human participant involvement occur? Will research occur where hazardous or radioactive materials are stored?
- E. State the duration of the project, amount of time required of each participant (if more than one instrument is being used, indicate the amount of time required for each instrument).

### III. RISK/DECEPTION

- A. Describe in detail any physical, psychological, social, legal, economic or other risks you can foresee, both immediate and long range:
1. Immediate risks;
  2. Long range;
  3. Rationale for the necessity of such risks;
  4. Alternatives that were or will be considered;
  5. Why alternatives may not be feasible.
- B. A Non-Beneficial Research is designed as research involving investigations of a person, his or her body, life, or surroundings, which is devoid of benefit to that person. If you plan to conduct this type of research and feel that there are no other methods available for obtaining the information needed, please justify and describe:
1. The extent of the risks (physical, psychological, social, legal, and other);
  2. The importance of the knowledge to be gained;
  3. Why you feel that the value of the information to be gained outweighs the risks.
- C. If deception is to be utilized in gathering data, you must:
1. Justify and support the use of deception in the project;
  2. Provide a detailed written description of the debriefing process, which includes a complete explanation of the study.
  3. Certify that each individual has been debriefed.

### IV. SAFEGUARDING PARTICIPANTS' IDENTITY

- A. What uses will be made of the information obtained from the participants? What elements of your project might be openly accessible to other agencies or appear in publications?
- B. What precautions will be taken to safeguard identifiable records or individuals? These questions also apply to secondary sources of data.
1. Long-range use of data (by you and others);
  2. Immediate use of data (by you and others);
  3. Describe specific procedures to be used to provide confidentiality of data. (e.g., the data and master list will be kept in a locked cabinet);
  4. State whether or not human participants can be identified directly or through identifiers linked to the participants.

### V. INFORMED CONSENT

Obtaining the informed consent of a potential human participant for participation in an experiment or demonstration is a safeguard for protecting the well being of that person. It adheres to the basic ethical principal of voluntariness. Permitting the participant to make a fully informed decision to participate in an activity averts potentially inequitable or coercive conditions of human participant use and assures the voluntary nature of participant involvement. The **IRB may alter** the consent process or waive the requirement for you to obtain a signed consent form for some or all participants if you meet the requirements set forth in the *Federal Register*, June 18, 1991, Vol. 56, No. 117.

When seeking informed consent be sure you give a sufficient amount of time for the participant to consider whether or not to participate. This will minimize the possibility of coercion or undue influence. Consent is given or revoked orally; this Informed Consent form only documents that you informed the participant of the risks and benefits and

that the participant consented *at that time* to participate. The participant may *at any time* revoke that consent orally and, therefore, you must continually monitor the participant's consent.

For exempt protocol questionnaires, informed consent may be obtained by including a cover page explaining all the elements of the study at the beginning, followed by a statement that completion of the questionnaire constitutes informed consent.

The following is a sample format of an informed consent form to be used in a research study. Modify this sample to fit your particular needs. All informed consent forms should be in language understandable to the potential participant. **A copy of the Informed Consent form must be given to each participant (or legal representative) and you must keep a copy of the signed Informed Consent form for a period of three years after the completion of gathering of data.**

(Introduction: should include explanation of purpose of research)

(SAMPLE) Informed Consent Form  
(PROJECT TITLE) **Patient-Professional Relationships**

I am Professor \_\_\_\_\_, of the General Studies Department at MSOE.  
My student, William Jones, and I are conducting a study of how medical professionals relate to patients. We would appreciate your participation in this study, as it will assist us in making recommendations for improving the teaching of health professionals and the way they treat you.

(Explanation of Procedures)

A full explanation of procedures that should include the following:

- 1. Number of questionnaires, interviews, etc.**
- 2. Amount of time required for each questionnaire, interviews, etc.**
- 3. Duration of project**
- 4. Total amount of participation time for participants**
- 5. Identification of any experimental procedures**
- 6. Approximate number of participants involved in study**

(Alternative Procedures)

Although we could study this question by just interviewing your doctor and the office staff, we feel that speaking with patients is the best way to find out if they are receiving good medical treatment.

(Risks and Benefits)

A full explanation of the risks and benefits of the study should include the following:

- 1. Any foreseeable risks or discomforts such as inconvenience of time requirements, anxiety regarding sensitive questions, additional costs that may result from participation by the participant**
- 2. Any benefits to the participant or others, such as compensation - If compensation will be given, indicate amount, when compensation will be given, and what happens to compensation if the participant withdraws from the study**
- 3. Where medical treatments are available if injury occurs (if applicable)**

(Safeguards)

This section should include information addressing the following areas:

- 1. Whether or not human participants can be identified directly or through identifiers linked to the participants**
- 2. Agencies or groups to whom the data will be released**
- 3. Published data will be in aggregate form (if applicable)**

(Freedom to Withdraw)

This section should indicate the following:

1. Participation is *completely* voluntary
2. Decision not to participate will involve *no penalty or loss of benefits* to which the participant is otherwise entitled; if a participant withdraws, indicate what will happen to information gathered from the participant (e.g., quality of care and/or services they are otherwise entitled to will not diminish)
3. An explanation about the circumstances under which the participant's participation may be terminated by the research investigator without regard to the participant's consent, (if appropriate)

(Offer to Answer Inquiries)

This section should state the following:

**Once the study is completed, we will be glad to give the results to you. In the meantime, if you have any questions, please ask us or contact:**

**Your Contact Person  
MSOE  
Milwaukee, WI 53202  
Phone Number Where Person Can Be Reached**

(Third Party Referral)

The bolded information below *must* be included in every Informed Consent form:

**If you have any complaints about your treatment as a participant in this study, please call or write:**

**Ann Bloor  
Institutional Review Board  
Applied Research and Grants  
Milwaukee School of Engineering  
1025 North Broadway  
Milwaukee, WI 53202**

**414-277-7237, bloor@msoe.edu**

**All complaints will be maintained in confidence.**

(Closing)

The following two paragraphs and signature/date line must be inserted:\*

**I have received an explanation of the study and agree to participate. I understand that my participation in this study is strictly voluntary.**

**Name \_\_\_\_\_ Date \_\_\_\_\_**

**This research project has been approved by MSOE Institutional Review Board for the Protection of Human Participants for a one-year period.**

\* If the participants are minors, the informed consent must be obtained from the parents of the participants and a *second* signature line should be added for the assent of the minor participant.

**VI. COOPERATING INSTITUTIONS** (Use the Sample "Affiliation Letter")

Protocols for projects involving cooperating institutions must be accompanied by evidence of an affiliation letter with each cooperating institution, which (1) specifies the assignment of responsibility for the activities to be performed and (2) identifies the supervisory personnel in the agency. ***Original signed affiliation letters must be submitted to the IRB Office before data collection or participant recruitment may begin.***

The sample "Affiliation Letter" (See page 15) may be rephrased so that it pertains to specific situations. ***It is the researcher's responsibility to obtain the signature of his/her Department Chair and the signature of the individual with authority from the cooperating institution.*** The original "Affiliation Letter" will be returned to the researcher and a copy will be retained in the IRB files.

# Sample Affiliation Letter

Date

Name  
Street  
City, State, Zip

Dear \_\_\_\_\_:

The Milwaukee School of Engineering wishes to express its appreciation to you and your organization for allowing \_\_\_\_\_ (name of researcher, title), to perform scholarly research on your premises.

**[in accordance with Wis. Stats sec. 146.82(2)(a)6]** *(Add this bracketed language if a health care provider is allowing you access to patient medical records.)*

**[as an unpaid student investigator.]** *(Add this bracketed language if you are a student.)*

1. The researcher/student will require access to data (and other resources if listed below) necessary to conduct research for a project entitled  
\_\_\_\_\_  
\_\_\_\_\_
2. We understand that the contact person at your organization with whom the researcher/student is to communicate with in regard to such access is \_\_\_\_\_ (name) \_\_\_\_\_ (title), who may be reached at (telephone), (office address) \_\_\_\_\_.
3. The researcher/student has agreed [and been instructed] *(Add bracketed language if you are a student.)* to protect confidentiality of data collected so that no participant will be individually identifiable.
4. The researcher/student will share a copy of a final report with your organization upon request.
5. If any problems and/or concerns arise regarding this project, we would appreciate you notify Ann Bloor, IRB Administrator at 414-277-7237 or [bloor@msore.edu](mailto:bloor@msore.edu) or at 1025 N. Broadway, Milwaukee, WI 53202.
6. The following must be inserted:

Please sign a copy of this letter to acknowledge receipt and your understanding of the scope of the researcher's/student's proposed activity. Return it to \_\_\_\_\_ (your name) at the address listed above.

Thank you for your cooperation.

Sincerely,

Your Name  
Your Title  
Your Department

MSOE

For: (Participating Organization) \_\_\_\_\_  
By: (Authorized Signature) \_\_\_\_\_  
\_\_\_\_\_  
(Title) \_\_\_\_\_  
\_\_\_\_\_  
(Date) \_\_\_\_\_

\_\_\_\_\_  
(Signature)  
\_\_\_\_\_  
(Title)  
\_\_\_\_\_  
(Date)