

**UNIVERSITY OF WISCONSIN-WHITewater**  
**INSTITUTIONAL REVIEW BOARD (IRB) FOR THE PROTECTION OF HUMAN SUBJECTS**

**RESEARCH PROTOCOL POLICIES AND PROCEDURES**

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The University of Wisconsin-Whitewater (UWW) encourages and supports free and responsible investigation by faculty, staff, and students. University of Wisconsin-Whitewater policies and procedures for the protection of human subjects have been developed to protect the rights and welfare of human subjects. This GUIDE contains guidelines and instructions to assist you in the preparation of a protocol for submission to the Institutional Review Board for the Protection of Human Subjects (IRB).

Research projects that involve human subjects will require review by the UWW IRB to determine if you have employed adequate measures to protect the participants involved in your study. Additional campus policies regarding drawing blood and stress testing can be found in the University Handbook or on-line at <http://uwwcwis.uww.edu/uwwhdbk>.

**UWW POLICY STATEMENT REGARDING FEDERAL REGULATIONS  
AND IRB GOVERNANCE OF RESEARCH**

The Office for Human Research Protection (OHRP) has published regulations for IRB governance of research involving human subjects [Federal Register (June 18, 1991, 45CFR46) Revised June 23, 2005 and Effective June 23, 2005]. The University of Wisconsin-Whitewater adheres to these regulations. Faculty, staff, and students intending to use human subjects in research should read this publication (available from Research and Sponsored Programs) or available on the Web at:

<http://www.nihtraining.com/ohrsite/guidelines/45cfr46.html>

For the purpose of IRB review, Federal Register [June 23, 2005, 45CFR46] defines research 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 that is considered research for other purposes. For example, some demonstration and service programs may include research activities.***



**ADDITIONAL QUESTIONS**

If you have any additional questions regarding the completion of the protocol or the Federal Regulations, contact: Denise Ehlen, IRB Administrator, Research and Sponsored Programs Telephone: 472-5212, E-Mail: [ehlend@uww.edu](mailto:ehlend@uww.edu), Web: [www.uwworsp.org](http://www.uwworsp.org).

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| <b>COURSE RESEARCH CERTIFICATION</b> |
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INTRODUCTION/DEFINITION

The UWW IRB recognizes that many projects conducted to fulfill course requirements involve research with human subjects. Such research occasionally entails certain risks to the participants involved. As students vary in expertise regarding research procedures designed to protect the rights of human subjects, the IRB has developed the following guidelines regarding classroom-based research projects. These guidelines are intended to provide clarification and simplify the process for obtaining IRB approval.

EXEMPT CATEGORIES

Students who wish to collect data from human subjects as part of the requirements for a specific class may conduct research as long as the informants are not identifiable by name or description. The key factor is that they do not require participants to reveal anything about sensitive personal experiences, behaviors, and/or identity. This would guarantee that participants are not considered to be placed at risk by their participation. In these cases, IRB approval of each individual project is not required. Instructors must submit an ORSP/IRB Cover Sheet for Research with Human Subjects AND the appropriate IRB Protocol to the Office Research and Sponsored Programs certifying that students will conduct research that qualifies as "exempt" from further oversight as defined by 45CFR46 and outlined below.

These exemptions do NOT apply to research involving prisoners, fetuses, pregnant women, or human in vitro fertilization.

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education 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 (cognitive, diagnostic, aptitude, achievement) [*applies to research with minors*], survey procedures [*does NOT apply to research with minors*], interview procedures [*does NOT apply to research with minors*], or observation of public behavior [*applies to research with minors only when the investigator(s) does(do) NOT participate in the activities observed*] **UNLESS**

(i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects, **and** (ii) Any disclosure of the human subjects' responses outside the research could

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reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation<sup>1</sup>.

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 subjects are elected or appointed public officials or candidates for public office, **or** (ii) Federal statute(s) require(s) without exception that confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

3. Research involving the collection or study of existing data, documents, records, or pathological or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified directly or through identifiers linked to the subjects. [*Applies to research with minors.*]

4. 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) payment for benefits or services under those programs.

5. 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 or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

EXPEDITED AND FULL PROCESS

Instructors must complete and submit an *ORSP/IRB Cover Sheet for Research with Human Subjects* AND the appropriate IRB Protocol for all projects that meet the following criteria:

1. Participants will be identified either by direct correlation or by the responses to specific questions and/or behaviors; or

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<sup>1</sup> Applies to minimal risk student integrated/practicum projects.

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2. Participants will be systematically selected from a potentially vulnerable or sensitive group and asked questions regarding their opinion, behavior or experiences, e.g., gifted children, alcoholics, homosexuals, etc.; or
3. Any other types of projects eligible for expedited review, student integrated projects, or practicum projects that do not qualify as exempt from further IRB oversight, or projects that require FULL BOARD review as defined by 45CFR46.

**COLLABORATIVE RESEARCH**

If you are submitting a collaborative protocol with another facility and/or faculty/staff employed by another institution, that institution's IRB must approve the protocol before submission to UWW's IRB. Once you have obtained approval from the collaborating institution, submit a copy of the approved protocol and all attachments, the ORSP/IRB Cover Sheet, and the document stating that the collaborating facility's IRB has approved your protocol.

If you are managing the project and the project participants are UWW students, the protocol should only be submitted to UWW's IRB.

FULL BOARD protocols for projects involving cooperating institutions (hospitals, prisons, social welfare agencies, for example) must be accompanied by evidence of an affiliation letter with each cooperating institution, which specifies the assignment of responsibility for the activities to be performed and identifies the supervisory personnel in the agency. You may not begin subject recruitment or data collection until you have submitted the original signed affiliation letter(s) to Research and Sponsored Programs.

Projects which have been approved by another institution's Review Board will be ratified by UWW's IRB during our full Board meeting or electronically. Any Board member may call for a full review if significant deviations from federal regulations are identified in the approved protocol.

You may modify the sample "**Affiliation Letter**" so it pertains to the specific situation of your protocol, but it must contain all the pertinent information in the sample. It is your responsibility, as the researcher, to obtain the signature of the individual with authority from the cooperating institution and your department chair.

Research and Sponsored Programs will obtain the signature of the University of Wisconsin-Whitewater authorized institutional representative. The original "Affiliation Letter" will be returned to you and a copy will be retained in the IRB files.

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**COOPERATING INSTITUTIONS**

Protocols for projects involving cooperating institutions (hospitals, prisons, social welfare agencies, etc.) must be accompanied by evidence of an affiliation by a letter, which specifies the assignment of responsibility for the activities to be performed. The "**Affiliation Letter**" must also identify the supervisory personnel at the cooperating institution. You may not begin subject recruitment or data collection until you have submitted a copy of the signed affiliation letter(s) to the Research and Sponsored Programs office.

You may modify the sample "**Affiliation Letter**" so it is relevant to the specific situation of your protocol. The letter must contain all pertinent information provided in the sample. It is your responsibility, as the researcher, to obtain the signature of the individual with authority from the cooperating institution(s) and your department chair.

The Research and Sponsored Programs office will obtain the signature of the University of Wisconsin-Whitewater authorized institutional representative. The original "**Affiliation Letter**" will be returned to you and a copy will be retained in the IRB files.

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**SAMPLE AFFILIATION LETTER**

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*(suitable for cut, paste, and print on campus letterhead)*

University of Wisconsin-Whitewater  
800 West Main Street, Whitewater WI 53190

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

The University of Wisconsin-Whitewater wishes to express their appreciation to you and your organization for allowing \_\_\_\_\_ to perform scholarly research on your premises.

The researcher will require access to data (and other resources if listed below) necessary to conduct research for a project titled \_\_\_\_\_ with University of Wisconsin-Whitewater Institutional Review Board for the Protection of Human Subjects Protocol # \_\_\_\_\_. The researcher has agreed to safeguard all data from unauthorized access and protect confidentiality to the extent possible under the law. The researcher will conduct the following study:

I understand that the contact person at your organization with whom the researcher is to communicate with regarding the research project is \_\_\_\_\_ who may be reached at \_\_\_\_\_. If any problems and/or concerns arise concerning this project, please notify Denise Ehlen in the University of Wisconsin-Whitewater Office of Research and Sponsored Programs, 800 West Main Street, Whitewater, WI 53190, E-mail: [ehlend@uww.edu](mailto:ehlend@uww.edu), Telephone: 262.472.5212,

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

Thank you for your cooperation.

Principal Investigator / UW-Whitewater

Collaborating Institution

\_\_\_\_\_  
By

\_\_\_\_\_  
By

\_\_\_\_\_  
Name and Title

\_\_\_\_\_  
Name and Title

\_\_\_\_\_  
Date

\_\_\_\_\_  
Date