

**UNIVERSITY OF WISCONSIN-WHITEWATER
INSTITUTIONAL REVIEW BOARD (IRB) FOR THE PROTECTION OF HUMAN SUBJECTS
INSTRUCTIONS FOR PROTOCOL PREPARATION AND SUBMISSION
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Using the following outline format, describe the subject population and summarize the procedures you will use. You must fully describe the procedures involving human subjects.

1. RESEARCH PARTICIPANTS

- a. Outline gender, race or ethnic group, age range, and other participant characteristics.
- b. Describe subject affiliation (institutions, general public, students, etc.) and your relationship to the cooperating institution, if any (employee, member, volunteer, etc.).
- c. Describe participants' general state of health (mental and physical). If the research design dictates that participants be in good mental and/or physical health, indicate who will determine and how.
- d. If participants are minors, mentally incompetent, or legally restricted groups, explain the necessity/rationale for including these particular groups.
- e. If the participants are minors, and if parent(s)/guardian(s) are not allowed to see the results of their child's participation, the parent(s)/guardian(s) should be notified of that fact ahead of time. Address this here in your protocol. Written parental consent is required for research with minors unless specifically waived by the IRB. The IRB may alter the consent process or waive the requirement for you to obtain a signed consent form for participants if you meet the requirements set forth in the Federal Register, June 23, 2005, 45CFR46, §46.116 and §46.117. If this applies to your research, state the CFR citation (either 45CFR46, §46.116 or §46.117) and why it applies. The Board will discuss and vote on the consent procedure modification at the FULL BOARD meeting.

2. RESEARCH DESIGN/PROCEDURES

Please pay particular attention to procedures and research design. If the IRB determines that the protocol involves only minimal risk BUT the design is so flawed as to result in no/minimal benefit, the protocol may be rejected or returned for modification and resubmission.

- a. State the specific hypothesis(es) to be tested.

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- b. Outline possible benefits or advantages the proposed study may provide to an individual subject, group of subjects, or society. If there are no direct benefits to individuals, clearly state this.
- c. Outline the inclusion and/or exclusion criteria for participants, explaining the rationale for the involvement of any special groups.
- d. Explain how you will recruit participants or sampling procedure(s). Include who will contact participants, how the contact will be made, how names will be obtained as potential candidates for the project, and how participants will be enrolled in the study.

You must attach a copy of all recruitment materials (posters, telephone scripts, etc.).

If you will recruit participants from UWW classes (NOTE: faculty and staff may refuse access to their students as participants despite IRB approval), you must provide *a copy of the complete approved protocol and attachments* to the instructor(s).

- e. Provide a detailed description of the research procedures and methodologies to be used. (Explain the information you will be gathering along with the means for collecting, recording, and analyzing the data.) Describe where and for how long you will store the data during the study and after the study is complete.
- f. Indicate personnel (including students) who will interact with the subject(s) or who will be present during a subject's(s') participation. State the qualifications and roles of all personnel. (You may attach curriculum vitae or resumés establishing investigator qualifications in lieu of text. If you choose to provide attachments, please reference the appropriate appendix number(s) here.) Clarify that the co-investigator's and/or student's presence will not jeopardize data safeguards.
- g. State the location(s) where you will work with participants.
- h. State the duration of the project and the total amount of time required of each participant. If you will be using multiple instruments, state the amount of time required for each instrument.
- i. If you will pay (or otherwise "reward") participants, indicate the type of payment (cash, money order, extra credit, etc.), the amount of payment, when the participants will receive the payment, and whether or not your participants will receive the payment if they drop out of the study.

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- j. If the project involves invasive medical procedures and/or stress testing, please state the qualifications of the person(s) performing the procedure.
 - k. If the project involves Internet research, address items one through eleven of the University of Wisconsin-Whitewater policy outlined in this GUIDE.
3. SAFEGUARDING THE IDENTITY OF PARTICIPANTS
- a. Describe which elements of your project might be openly accessible to other agencies or appear in publications.
 - b. Describe the precautions you will employ to safeguard identifiable records or individuals. These questions also apply to secondary sources of data.
 - i. Describe the immediate use of the data by yourself and others.
 - ii. Describe the long-range use of data by yourself and others.
 - iii. State whether or not participants will be identifiable directly or through identifying information linked to the participants. If applicable, state how you will link the data to participants during your study. Describe specific procedures you will use to safeguard participants' data from unauthorized access.
4. RISK
- a. Describe in detail any physical, psychological, social, legal, economic, or any other risks you foresee, the rationale for the necessity of such risks, and why alternatives may not be feasible.
 - b. If you plan to conduct "non-beneficial research" (i.e. research involving investigations of a person, life, or surroundings, which has no benefit to that person) and you feel that there are no other methods available for obtaining the information needed, justify:
 - i. Extent of the risks,
 - ii. The importance of the knowledge you will gain, and
 - iii. Why you feel that the value of the information to be gained outweighs the risk involved.

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5. DECEPTION

- a. If you will utilize deception in gathering your data, you must do the following:
 - i. Justify and support the use of deception,
 - ii. State that each individual will be debriefed, and
 - iii. Provide a detailed written description of the debriefing process, which includes a complete explanation of the deception (the participants should receive a written explanation of the need for deception if possible). You must attach a copy of all recruitment and debriefing materials (posters, telephone scripts, etc.).

6. INFORMED CONSENT / CHILD ASSENT

Obtaining informed consent/child assent adheres to the basic ethical principle of voluntariness. This is a safeguard for protecting the well being of participants. Permitting the subject to make a fully informed decision to participate in an activity averts potentially coercive conditions and assures the voluntary nature of participant involvement. The IRB may alter the consent/assent process or waive the requirement for you to obtain a signed consent for participants if you meet the requirements set forth in the Federal Register, June 23, 2005, 45CFR46, §46.116 and §46.117.

When seeking informed consent, allow a sufficient amount of time for subjects to consider whether to participate. This will minimize the possibility of coercion or undue influence. Consent may be given or revoked orally. "Informed Consent" only documents that you informed the subject of the risks and benefits and that the subject gave consent, at that time, to participate. The subject may revoke that consent orally at any time for any reason. Therefore, you must continually monitor the subject's consent.

FORMAL (SIGNED) CONSENT/ASSENT

Informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject and/or the subject's legally authorized representative, when appropriate. A copy shall be given to the person signing the form and the researcher shall retain a copy. Consent may take either of two forms:

A written consent statement may be used which is read to or read by the subject or the subject's legally authorized representative. All legal minors or persons assigned legal guardians must assent to participate in a study. Investigators must also obtain the written consent of the parent or guardian.

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A "short form" written consent statement, which states that the elements of informed consent have been presented orally to the subject/legally, authorized representative. When the "short form" method is used, there must be a witness to the oral presentation. Only the "short form" itself must be signed by the subject/legally authorized representative. However, the witness must sign both the "short form" and a copy of the summary.

WAIVER OF FORMAL (SIGNED) CONSENT/ASSENT

For protocols where written consent may not be feasible and/or will substantially delay project progress (for example, mailed surveys, telephone surveys, etc.) you may obtain informed consent by including an informational cover page or paragraph (at the beginning of the survey, questionnaire, etc.) explaining the study and including all basic elements of informed consent. The following additional statement must appear on the cover page or at the top of the first page of your survey or questionnaire.

Completing this (survey, etc.) indicates that I am at least eighteen years of age and give my informed consent to participate in this study.

You may also read a consent statement, containing all basic elements of informed consent, to the respondents and obtain oral consent. If you will read a consent statement to your participants, you must provide the IRB with a copy of the consent script for review.

- a. Provide a rationale for the selected method of obtaining participants' informed consent, child assent, and/or parental consent.
- b. Provide a copy of the informed consent and/or assent document(s) that includes the following BASIC ELEMENTS OF INFORMED CONSENT. If you plan to conduct Internet research, you must also address items one through eleven of the University of Wisconsin-Whitewater policy outlined in this GUIDE.
 - i. A statement that the study involves research, an explanation of the purpose of the research, the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.
 - ii. A description of any reasonably foreseeable risks or discomforts to the participants.
 - iii. A description of any benefits to the participants or to others, which may reasonably be expected from the research.

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- iv. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject (if applicable).
- v. A statement describing how the records identifying the subject will be safeguarded. For example:
 - A. Every effort will be made to safeguard your identity and any information you provide from unauthorized access. Participants' names will not be used in any reports or presentations derived from this study.
 - B. All information you provide will be kept confidential to the extent provided by the law.⁴
- vi. For research involving more than minimal risk, an explanation as to whether any compensation is to be given.
- vii. For research involving more than minimal risk, an explanation as to whether any medical treatments for injuries or counseling/psychological services for mental stress are available and, if so, a description of services and where further information may be obtained. Student participants should be directed to contact UWW's University Health and Counseling Services in the event of research-related injury/distress. You must provide a name and telephone number at minimum.

Non-student participants should be provided with a research-specific and appropriate referral in the event of physical injury/emotional distress.
- viii. An explanation of whom to contact for answers to pertinent questions about the research. (Include the principal

⁴ The term confidential is restricted for use only in certain circumstances (attorney/client privilege, doctor/patient confidentiality, etc.) Participant data may be shared as follows WITHOUT express participant consent: 1) The Institutional Review Board for the Protection of Human Subjects, the researcher's supervisor, and the Chancellor will have access to all data upon request. 2) If the researcher has reason to believe that you or someone else may be in danger of physical harm, state law and professional ethics require the researcher to take steps to protect you and/or other persons involved. This may include notification of appropriate social service agencies, legal agencies, and legal guardians (in the case of a subject under the age of 18). 3) In the event that the data is subpoenaed by the court.

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investigator/faculty advisor's⁵ name, address, and telephone number.)

- ix. An explanation of whom to contact for answers to pertinent questions about the research subject's rights/treatment. You may direct participants to contact:

Denise Ehlen, IRB Administrator
Office of Research and Sponsored Programs
University of Wisconsin-Whitewater
800 West Main Street
Whitewater, WI 53190
Telephone: 262-472-5212
Fax: 262-472-5214
E-Mail: ehlehd@uww.edu

- x. A statement that participation is voluntary and that refusal to participate will involve NO penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

7. ADDITIONAL ELEMENTS OF INFORMED CONSENT

- a. When appropriate, one or more of the following elements of information shall also be provided to each subject:
 - i. 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.
 - ii. A statement of anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.
 - iii. A description of any additional costs to the subject that may result from participation in the research.

⁵ Campus policy dictates that ALL research be directed by a faculty or staff member. Student research projects must be coordinated under the directed supervision of an appropriate faculty or staff advisor. Both advisor and student investigator contact information should be included in consent document associated with student research.

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- iv. An explanation of the consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.
- v. 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.
- vi. A description of the approximate number of participants involved in the study.