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Institutional Research Board
for the Protection of Human Subjects

IRB GUIDE



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OVERVIEW

The fundamental principle of human subject protection (National Science Foundation, <http://www.nsf.gov/bfa/dias/policy/human.jsp>) is that “people should not be involved in research without their informed consent, and that subjects should not incur increased risk of harm from their research involvement, beyond the normal risks inherent in everyday life. The regulations are designed mainly to pertain to biomedical research, based on the philosophical principles contained in a key document, "The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research" (<http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html>)

EXEMPT RESEARCH, EXPEDITED, AND FULL BOARD REVIEW

Social and behavioral scientists are subject to the same regulations as their biomedical colleagues, but the Common Rule gives discretion to institutions and IRBs to match the severity of the review to the potential risk of harm to subjects. IRBs have two forms of reviewing proposals:

1. Full (the entire IRB reviews the proposal) and
2. Expedited (the IRB Chair or a designee reviews the proposal for the committee).

In addition, the Common Rule specifies broad classes of research involving human subjects as Exempt from further oversight.

“All research proposals must be inspected by the IRB, which decides whether the research is exempt or qualifies for expedited or full board review. Researchers or department chairs should not have the authority to make this designation themselves.”

At the University of Wisconsin-Whitewater, only the IRB may determine if a study is exempt.

OVERVIEW OF IRB POLICIES AND PROCEDURES

The U.S. Department of Health and Human Services’ (HHS) Office for Human Resource Protections (OHRP), provides leadership in the protection of the rights, welfare, and wellbeing of subjects involved in research. OHRP provides clarification and guidance, develops educational programs and materials, maintains regulatory oversight, and provides advice on ethical and regulatory issues in biomedical and social-behavioral research. Visit <http://www.hhs.gov/ohrp/index.html> to learn more.

HUMAN SUBJECT REGULATIONS DECISION CHARTS (AKA DECISION TREES)

The Office for Human Research Protections (OHRP) provides graphic aids as a guide for IRBs and investigator to facilitate a determination of whether or not an activity is research involving human subjects that must be reviewed by an IRB under the requirements of the U.S. Department of Health and Human Services (HHS) regulations at 45 CFR part 46. The charts address decisions whether an activity is research that must be reviewed by an IRB; whether the review may be performed by expedited procedures; whether informed consent or its documentation may be waived. See <http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html> to access this valuable resource.

The charts are intended to assist IRBs and investigators in their decision-making process and should not be used as substitutes for consulting the regulations. OHRP cautions that the full text of applicable regulatory provisions should be considered in making final decisions. The charts are necessarily generalizations and may not be specific

enough for particular situations. The charts do not address requirements that may be imposed by other organizations, such as the Food and Drug Administration, National Institutes of Health, other sponsors, or state or local governments.

MEETING INFORMATION AND PROTOCOL SUBMISSION DATES

All meetings will be held at the Office of Research and Sponsored Programs, Andersen Library Suite 2243 at the University of Wisconsin-Whitewater. The Board meets in closed session. Investigators are invited to participate in protocol discussion only. Investigators will be notified of date and time of review. Meeting dates and locations are posted on our website at <http://www.uww.edu/orsp>.

Investigators must submit protocols requiring Full Board Review during the academic school year. At this time we do not accept Full Board protocols for review during the summer (25 May to 25 August) session.

Faculty, staff, and students may submit anytime those protocols that qualify as EXEMPT from further oversight or are eligible for review under the EXPEDITED process.

Protocols requiring FULL BOARD REVIEW must be submitted to Research and Sponsored Programs by 4:30 p.m. on the first of the month to ensure consideration that month (September to May). FULL BOARD protocols submitted after the first of the month may not be reviewed until the next regularly scheduled meeting. (If the first of the month falls on a weekend, you will have until 4:30 p.m. on the following Monday, to submit your protocol.)

You must submit your protocol using the online documents and submission process located on our website. We WILL NO LONGER accept protocols in hard copy, or using any previous versions of our departmental forms or outlines. Full Board review protocols will also require review and signature approval of your department Chair.

IRB MEMBERSHIP AND PERSONNEL

IRB MEMBERS

NAME DEPARTMENT	OFFICE LOCATION TELEPHONE NUMBER	COLLEGE / REPRESENTATION E-MAIL
Robin Fox <i>Curriculum and Instruction</i>	Winther 2035 x5821	Education & Professional Studies / Research with Minors foxr@uww.edu
Lynn Gilbertson (Chair) <i>Communication Sciences & Disorders</i>	Roseman 1016 x5202	Education & Professional Studies / Hearing Science gilbertl@uww.edu
Maxwell Hsu <i>Marketing</i>	Hyland 3434 X5471	Business & Economics / Marketing hsum@uww.edu

IRB MEMBERS (continued)

Margo Kleinfeld <i>Geography & Geology</i>	Upham 113 X1087	Letters & Sciences / Geography & Geology kleinfem@uww.edu
Giuliana Miolo <i>Communication Sciences & Disorders</i>	Roseman 1022 X1485	Education & Professional Studies / Phonetic & Linguistic Communication miolog@uww.edu
Christine Neddenriep <i>Psychology</i>	Winther 5040 x1850	Letters & Sciences / Health & Counseling neddenrc@uww.edu
Doug Parker <i>Community Representative</i>	Whitewater Unified School District 262-472-8700	Non-Affiliated Community Representative / Nonscientific dparker@wwusd.org
Stanislav Vysotsky <i>Sociology, Criminology & Anthropology</i>	Laurentide 2132 X4121	Letters & Sciences / Sociology, Criminology & Anthropology vysotsks@uww.edu
S-A Welch <i>Communication</i>	Heide 450 x5722	Arts & Communication / Social Sciences welchs@uww.edu

ADMINISTRATIVE SUPPORT PERSONNEL

All protocol questions should be directed to:

NAME DEPARTMENT	OFFICE LOCATION TELEPHONE NUMBER	E-MAIL
Carol Katch, IRB Administrator & Compliance Manager <i>Research & Sponsored Programs</i>	Andersen 2245 x5288	katchc@uww.edu
Ashley Wellnitz, Compliance Associate <i>Research & Sponsored Programs</i>	Andersen 2249 x5286	rsp-research@uww.edu

RESEARCH PROTOCOL POLICY AND PROCEDURES

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://www.uww.edu/uwwhdbk/>.

All staff and student researchers submitting or renewing protocols are required to have completed and passed the CITI Program SBE Human Research Course prior to approval of the new or renewing protocol. Registration and the course are free, and can be found at <https://www.citiprogram.org>. Instructions for registration and required course(s) can be found at <http://www.uww.edu/orsp/compliance/human-research> under the **RESOURCE** tab.

Upon completion of this training a copy of your completion the Office of Research and Sponsored Programs will be notified of your training certification, this certification expires every four years. If you entered UW-Whitewater as your institution with CITI, you will receive a reminder approximately 60 days prior certification expiration. We will also accept a training certificate from the NIH Protecting Human Research Participants course that has been completed within the last four years.

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 Carol Katch, Compliance Manager, Research and Sponsored Programs Telephone: 262/472-5288, E-Mail: katchc@uww.edu, Web: <http://www.uww.edu/orsp>.

COURSE RESEARCH

INTRODUCTION / DEFINITION

In accordance with federal regulations, the University of Wisconsin-Whitewater requires that all research involving human participants be prospectively reviewed by IRB. Capstone projects and creative components that involve human participants require IRB review if the results will be disseminated beyond the course instructor or committee, and/or the specific client for which the project is conducted. Honors capstone projects that involve human participants require review if results will be disseminated beyond the project advisor(s), Honors Program poster presentations, Undergraduate Research Day(s)/conferences, or at the Posters in the Rotunda event. Presentations given in the latter setting are considered a continuation of the education process or professional training (e.g., experience in public speaking).

UW-Whitewater recognizes that some student projects conducted to fulfill course requirements involve activities (e.g., data collection procedures) that, in a different context, might be viewed as research. As a general rule, when those activities are conducted solely to fulfill a course requirement, an element of the definition of research—the intent to develop or contribute to generalizable knowledge—is lacking. The University considers classroom assignments involving research activities to be educational in nature and not subject to IRB review when the results of the classroom assignment, including audio/video recordings, photographs, etc., are only used and shared as follows:

1. In the classroom; and/or,
2. If the project involves gathering data from or about a company, agency, or organization, the data/results are shared only with that company, agency, or organization; and/or
3. Project results are presented at departmental or interdepartmental seminars designed to exhibit coursework or to continue the learning process related to presentations.

PLEASE NOTE:

Research using protected subjects such as Minors, Pregnant Women, Fetuses, Prisoners, the Mentally Impaired, etc. or sensitive subjects such as substance abuse and research referencing sexual issues/preference must be submitted individually by each student for IRB review.

In addition, If data will be shared beyond the circumstances described above (e.g., for publication, presentation at academic conferences, in a thesis/dissertation, etc.), then the project must receive IRB approval prior to initiation. The IRB cannot retroactively approve a protocol once data has been collected.

FACULTY/STAFF RESPONSIBILITIES

It is the responsibility of the course instructor to determine whether an assigned project involving human participants can be classified as a course-related student project. Faculty/staff should contact the Office of Research and Sponsored Programs if assistance in making this determination is needed.

It is also the responsibility of the course instructor or project advisor to ensure that the rights and welfare of participants in student projects are protected. This responsibility includes discussing the principles of ethical research with human subjects with the class prior to the initiation of the project. It also includes reviewing student research plans and monitoring research activities to ensure that human participants are protected. At a minimum,

best practices include informing participants of the voluntary nature of participation and employing measures to protect privacy and confidentiality.

Finally, instructors/advisors must convey to students that the data may not be used or shared beyond the circumstances described above.

DISCLOSURE TO PARTICIPANTS

All projects conducted under this policy involving human participants must be preceded by a disclosure of the following information to the respondent. If an Informed Consent Document is used, these points must be included in that document:

1. The student identifies him/herself as a UW-Whitewater student who is performing the activity to fulfill a course requirement, and the course is specifically identified.
2. The name and contact information for the supervising faculty/staff member to contact for questions is provided.
3. The persons who have access to the individual data and/or summarized results are specified (e.g., instructor only, company/organization/agency).
4. Participants are informed that their participation is completely voluntary, that they can skip any questions they do not wish to answer (e.g., for surveys, interviews, focus groups, etc.), and that they can stop participating at any time.
5. The disclosure should not state that the project has been approved by the IRB.

RETROACTIVE APPROVAL

It is very important that careful consideration be given to the possibility of an eventual desire to publish, present the material, or use any collected data in future studies, etc. Retroactive approval cannot be given for studies conducted without IRB approval. For example, if a class project was conducted without IRB approval and resulted in unexpected but important findings or data, those findings or data may not be presented at a national meeting or used in a future project or research study.

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, using our online submission process, and the document stating that the collaborating facility's IRB has approved your protocol. You must complete our online form and then you may attach electronic copies of the other institution's documentation.

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 (schools, 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 is relevant 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.

COOPERATING INSTITUTIONS

Protocols for projects involving cooperating institutions (schools, 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. See Addendum F.

INTERNET RESEARCH

Researchers utilizing the Internet as a research tool must address the following issues (unless considered "not applicable") and include information on each issue in their protocol and informed consent. A copy of our Internet Research Form is available on our website and an example is included at Addendum H.

PLEASE NOTE: Use of an online survey tool IS considered Internet Research. The UW-Whitewater IRB will no longer authorize the use of any other survey tool other than the approved application being used at UW-Whitewater. Currently this application is Qualtrics. Additional information is available at: <http://www.uww.edu/irp/qualtrics>. If your research is being done collaboratively with another institution and they have approved another survey application, it will be approved by the UW-Whitewater IRB. There are no other exceptions.

1. State whether the Internet site is considered public or private space. State whether you have obtained (or how you attempted to obtain) permission from the list owner or administrator (if applicable) to recruit subjects from, or post messages on, the site. If no list owner or administrator can be contacted, researchers should post a message of interest to conduct research to the list participants for their discussion and consideration before informed consent documents are provided to participants. Researchers shall also obtain permission to use archived data from a list or site. (Permission may be verified by an e-mail from the list owner or administrator, and a copy should be included in your protocol.)

Inform the subjects that online communications, in general, are considered public in nature.

Electronic records of such communications may therefore be subject to open records requests.

2. Inform the subjects that there is no completely secure interaction online. The following statement must be inserted into the informed consent document: "While the investigator(s) have taken measures to maintain confidentiality, as an online participant in this research, there is always the risk of intrusion by outside agents, i.e., hacking, and therefore the possibility of being identified." Such a statement highlights concerns related to data confidentiality and the risk/benefit of participation in the study.
3. State that subjects provided with an online e-mail account are allowed and encouraged to change passwords at regular intervals.
4. If the researcher uses encryption software, a thorough set of instructions shall be included in the protocol and provided to the subjects.
5. The protocol will describe how subjects will be identified in written reports, whether by use of their screen names or by pseudonyms (if applicable).
6. The researcher will state that the data and identifiers shall be kept on different servers/computers.
7. Researchers shall provide a forum for participants to ask questions online (e.g., the researchers' e-mail address) before consenting to participate in a research project.
8. Researchers shall identify how participant identity will be safeguarded on a forum where some participants consent while others do not.
9. The researcher will provide a yes/no statement or checkbox in the online format to substitute for a signature on the consent form.
10. Online research with minors is strongly discouraged. If minors are recruited for online research, a written, signed informed consent by a parent or guardian is required and a consent form using verbiage suitable for the age of the minor is encouraged.

DETERMINATION OF STATUS

DETERMINATION OF "EXEMPT" STATUS

EXEMPT (from further IRB oversight) research is a category of research, defined by Title 45 Code of Federal Regulations Part 46 (aka the Common Rule) that does not require FULL BOARD review and approval. Unless otherwise required by department or agency policies, research activities, which only incorporate human subject involvement as described below, will qualify for one or more of the following EXEMPT categories.

EXEMPT CATEGORIES

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

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 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.

4. 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.]
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) 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 or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

DETERMINATION OF "EXPEDITED" STATUS

If your project is not classified as EXEMPT and the risk of harm anticipated in the research is not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests, your project may qualify for EXPEDITED review (involves minimal risk).

DETERMINATION OF "FULL BOARD REVIEW" STATUS

If your project involves more than "minimal risk" to participants as defined previously, your project requires a FULL BOARD review. Protocols involving any of the following will also require FULL BOARD review (unless your project qualifies as EXEMPT as described in that section):

- Including minor subjects (children 17 years of age or younger)
- Targeting special populations (prisoners, pregnant women, individuals with disabilities)
- Using of video- or audiotape to record participants
- Asking questions that may be highly embarrassing or compromising (e.g., sexual behavior, sexual orientation, alcohol consumption, illegal drug use, medical conditions, violations of the law, personal finances, problems in the workplace, etc.)
- Exposing participants to graphically violent or pornographic materials
- Inflicting physical pain upon, attaching electrodes to, or injecting any substance into participants
- Creating high levels of stress, fear, discomfort, or tension
- Threatening participants in any way
- Causing participants to violate laws or official university regulations
- Providing some participants with benefits denied to others (this includes payments or rewards for participation, e.g., exclusively offering extra credit to research participants, etc.)

- Causing physical or mental exhaustion or engaging participants in intense (maximal) exercise
- Placing individuals in confining physical settings or attaching other devices
- Exposing participants to extreme conditions (e.g., bright lights, loud noise, intense pressure, strong odors, complete darkness, extreme heat or cold, sudden movement, etc.)
- Leaving participants alone for periods of time longer than 20 minutes
- Taking hair samples or nail clippings from participants
- Taking human tissue samples or sampling any other bodily fluid

PROTOCOL REVIEW PROCEDURES

REVIEW OF EXEMPT RESEARCH

Completed protocols should be submitted to the Research and Sponsored Programs office for review by the IRB Chair or designee. Research and Sponsored Programs will notify you when your protocol is approved as EXEMPT. You may NOT begin your research until you receive the approval notification from that office.

Once approved, you will not need additional review of your protocol unless you make modifications to your original protocol submission.

If the IRB Chair or designee determines that your protocol is not EXEMPT, needs clarification/modification, or requires FULL BOARD review, you will be notified and given instructions on how to proceed.

The IRB requires a minimum of ten business days to complete review of EXEMPT protocols.

REVIEW OF EXPEDITED RESEARCH

If your project is classified as minimal risk and qualifies for EXPEDITED review, you must submit your protocol to Research and Sponsored Programs for review by the IRB Chair or designee. Research and Sponsored Programs will notify you when your protocol is approved. You may not begin your research until you receive the approval notification from that office.

If the IRB places a conditional approval on your protocol, you will not receive official approval until the IRB Chair reviews and approves the required modifications. Once you have met those conditions, you will receive notification of condition fulfillment approving your protocol for one year. (Instructions for submission of Condition Fulfillment are presented later in this GUIDE.)

The IRB will NOT provide approval letters to funding agencies until all the conditions necessary to approve the protocol have been met.

If the IRB Chair or designee determines that your protocol does NOT qualify for EXPEDITED review and requires FULL BOARD review, you will be notified and given instructions on how to proceed.

If at any time you modify your expedited protocol, you must submit those changes to Research and Sponsored Programs for review and approval by the IRB. Instructions to submit protocol Modification presented later in this GUIDE.

The IRB requires a minimum of ten business days to complete review of EXPEDITED research.

REVIEW OF FULL BOARD PROTOCOLS

If your project requires FULL BOARD review, you must submit your protocol to Research and Sponsored Programs for review by the IRB Chair or designee by the appropriate deadline. The Board meets in closed session. You will receive documentation providing an approximate time the Board will discuss your protocol. The IRB encourages you to attend the FULL BOARD review to provide any clarification the Board may need. At the meeting, the IRB may approve, conditionally approve, reject, or table (e.g. due to insufficient information) your protocol.

After the meeting, Research and Sponsored Programs will notify you of the status of your protocol. If the IRB places a conditional approval on your protocol, you will not receive official approval until the IRB Chair or the Full Board reviews and approves the required modifications. Once you have met those conditions, you will receive notification of condition fulfillment approving your protocol for one year. The IRB will NOT provide approval letters to funding agencies until all the conditions necessary to approve the protocol have been met.

If at any time you modify your protocol, you must submit those changes to Research and Sponsored Programs for further review by the IRB.

PROTOCOL CHANGES

CONDITION FULFILLMENT

If the IRB places a conditional approval on your protocol, you will not receive official approval until the IRB Chair reviews and approves the required modifications. You must submit a Modified Protocol Submission Form (with the “Condition Fulfillment” box checked) through our electronic submission system along with any documents to which modifications were required. If the required modifications are minor (i.e., title change, agency change, addition of data collection sites, etc.) the IRB Chair or designee will review and approve the changes (policy applies to EXEMPT, EXPEDITED, and FULL protocols). If major modifications are required for a protocol reviewed under the FULL BOARD process, the condition fulfillment must also be included on the next IRB agenda for FULL BOARD review UNLESS the Board specifically vests the Chair (during initial review) with the authority to review and approve the required condition fulfillment modifications. A copy of the Modified Protocol Submission Form is available as Addendum I. No other forms of conditional fulfillment modification will be accepted.

MODIFICATIONS

If you make any changes to your protocol, you must submit a Modified Protocol Submission Form (with the “Modified Protocol” box checked) through our electronic submission system along with any documents or recruitment materials you may have modified. If the modifications are minor (i.e., title change, agency change, addition of data collection sites, etc.) the IRB Chair or designee will review and approve the changes (policy applies to EXEMPT, EXPEDITED, and FULL protocols). If major modifications are made to a protocol originally requiring FULL BOARD review, the modified protocol will be included on the next IRB agenda for another FULL BOARD review. A link to the Modified Protocol Submission Form is available on our website at www.uww.edu/orsp

(Human Research). An example is attached as Addendum I. No other forms of protocol modification will be accepted.

INSTRUCTIONS FOR PROTOCOL PREPARATION AND SUBMISSION

INSTRUCTIONS FOR PROTOCOL PREPARATION AND SUBMISSION [FORMAT]

You are required to use the University of Wisconsin – Whitewater online protocol submission process (which will offer the most current versions of our protocol documents). You will be required to complete the entire online submission form and, if all research is being done only with UWW IRB approval, you will also be required to use our templates for Signed Informed Consent, Waiver of Signed Consent Request, Implied Consent, Affiliation Letter and Permission to Audio or Video Tape. The only exceptions to these forms that will be considered are if you are collaborating with another institution, and they have provided the original approval for the research. In this case you must fill out the online protocol submission form but all additional documentation may be in the form required by the approving institution.

Our online submission form uses the following outline format, please use this as a general guideline when you prepare your protocol. You will use your own verbiage to describe the subject population and summarize the procedures you will use. You must also fully describe the procedures involving human subjects. You will need to complete this information in the online form. A copy of the online protocol submission form is located at Addendum A.

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.
- 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 résumé's 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.

- 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.

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 wellbeing 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.

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

You must complete a Request for Waiver of Signed Formal Consent in order to either completely wave consent OR to use Implied Consent (see next paragraph). If you are requesting to completely wave consent (no consent document will be presented to the participant), your protocol WILL require full board review. If you are requesting the use of Implied Consent, (a consent document will be provided but not signed by the participant), your protocol may be eligible for expedited review if no other special conditions apply. Protocols involving minors or the mentally ill are not eligible for a Waiver of Formal Consent/Assent or Implied Consent, you will be required to provide a signed consent form for the Parent or Guar

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 or Implied Consent (at the beginning of the survey, questionnaire, etc.) explaining the study and including all basic elements of informed consent.

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.

The UW-Whitewater IRB requires the use of the Signed or Implied Consent forms designed by our IRB. IF you are choosing a complete waiver of consent OR Implied consent, then you must complete and submit a Request for Waiver of Signed Formal Consent. These electronic forms are available on our office web site.

1. 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.
 - 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.

REQUIRED DOCUMENTS FOR SUBMISSION:

1. Online Protocol Submission document.
2. **Waiver of Signed Consent Request** (Included with Implied Consent Document or as a complete Waiver of Consent).
3. **Implied Consent**, if applicable.
4. **Informed Consent** / Child Assent document(s).

5. Any Instruments used for your research project (including recruitment scripts and/or documents, survey questions, interview scripts, etc.).
6. An **Internet Research Form**, if any data will be collected on-line. (Internet Surveys ARE considered Internet Research). An Example is available as Addendum H.
7. A **Cooperating Institution Letter (Affiliation Letter)**, if applicable. (A copy signed by an authorized representative of the cooperating institution must be received by ORSP prior to data collection.)
8. **Permission to Audio or Video Tape**, if applicable.
9. A **Debriefing Statement**, if you will use deception.

PLEASE NOTE: If you wish to 'save' and return to your protocol application, you will need to complete each section (with N/A if necessary), and submit the document. Please then email a request to katchc@uww.edu requesting a link to your document to complete the submission process. Please include the P.I. name and complete protocol title in your request.

ADDENDUM A: SAMPLE OF ONLINE PROTOCOL SUBMISSION FORM



UNIVERSITY OF WISCONSIN-WHITEWATER

Office of Research and Sponsored
Programs Institutional Review Board
for the Protection of Human Subjects (IRB)

IRB PROTOCOL SUBMISSION

PLEASE NOTE:

All research participants are required to complete the CITI (Collaborative Institutional Training Initiative) Human Research "Social, Behavioral, & Educational (SBE) Sciences – All Researchers" training. This training must be completed every four years. YOUR RESEARCH APPLICATION WILL NOT BE REVIEWED UNTIL ALL INVESTIGATORS ON YOUR PROTOCOL HAVE COMPLETED THE REQUIRED TRAINING. (Completing the NIH Office of Extramural Research Protecting Human Research Participants Course within four years is also acceptable.) The link for CITI Training is available at <https://www.citiprogram.org>. Instructions for registration are available at www.uww.edu/orsp on the bottom right hand page. The Office of Research and Sponsored Programs will be notified upon successful completion of the training module.

Project Title: *

Submission Type: *

Projected Start Date: *

Projected End Date: *

Principal Investigator: *

Last Name, First Name

Department: *

P.I. Phone Number: *

P.I. Email Address: *

Co-Investigator(s) [Faculty/Staff]:

Last Name, First Name

Co-Investigator(s) Phone Number:

Co-Investigator(s) E-mail:

Student Investigator(s):

Last Name, First Name

Student Investigator(s) Phone:

Student Investigator(s) E-mail:

Brief Summary of Protocol: *

(200 words or less)

Protected Populations & Other Review Determinants: *

Please select any of the following descriptors that apply to your research.

**PRINCIPAL INVESTIGATOR FACULTY/STAFF
SUPERVISOR CERTIFICATION**

I have read the University of Wisconsin-Whitewater IRB Guide and certify that this research conforms to campus and federal regulations; policies, and procedures; is theoretically justified by sound research design; will adhere to ethical principles of research; and is compatible with the goals and/or objectives of my department/unit and college/division.

I further certify that if supervising student or course research, I will train all students in federal and institutional policies and procedures governing the use of human subjects in research. I understand that I am responsible for research conducted by my students.

Principal Investigator's Name: *

Principal Investigator's Electronic Signature: *

P.I. Signature Date: *

 

STUDENT INVESTIGATOR CERTIFICATION

I have read the University of Wisconsin-Whitewater IRB Guide and certify that I am familiar with campus policies and procedures related to the protection of participants and will uphold high ethical principles in all research using human subjects.

Student Investigator's Name:

Student Investigator's Signature:

Student Signature Date:

 

DEPARTMENT CHAIR/UNIT DIRECTOR ACKNOWLEDGEMENT (mandatory for any protocols requiring review by the Full Convened Board):

I acknowledge receipt and review of the attached protocol.

Department Chair/Unit Director Name:

Department Chair/Unit Director Signature:

Chair/Director Signature Date:

 

PROTOCOL SUMMARY

Using the following outline format, describe, in layman's terms, the subject population and the procedures you will use. You must fully describe the procedures involving human subjects.

*NOTE: All fields marked with an asterisk must be completed, use N/A if not applicable to your research.

1. RESEARCH PARTICIPANTS

a. Participant Characteristics: *

Outline gender, race or ethnic group, age range, and other participant characteristics

b. Participant Affiliation: *

Describe subject affiliation (institutions, general public, students, etc.) and your relationship to the cooperating institution, if any (employee, member, volunteer, etc.).

c. Participant Health: *

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. Use of Participants from Protected Populations: *

e. Parent's Awareness of Child's Participation

If the participants are minors, and if parent(s)/guardian(s) will not be 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 CONVENE BOARD meeting.

2. RESEARCH DESIGN AND 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 re-submission.

a. Hypothesis(es):*

State the specific hypothesis(es) to be tested.

b. Benefits or Advantages:*

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. Inclusion and/or Exclusion of Participants:*

Outline the inclusion and/or exclusion criteria for participants, explaining the rationale for the involvement of any special groups.

d. Recruitment of Participants*

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).

e. Research Procedures and Methodologies: *

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 after the study and after the study is complete.

f. Research Personnel: *

Indicate personnel (including students) who will interact with the subject(s) or who will be present during the a subject(s) participation. State the qualifications and roles of all personnel. (You may attach curriculum vitae or resumes establishing investigator qualifications in lieu of text. If you choose to provide attachments, please reference appropriate appendix number(s) here.) Clarify that the co-investigator's and/or students presence will not jeopardize data safeguards.

g. Location of Research *

State the location(s) where you will work with participants.

h. Project Duration: *

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. Compensation for Participation:*

If you will pay (or otherwise "reward") participants, indicate the type of payment (cash, gift card, extra credit, etc.) the amount of payment, when the participant will receive the payment, and whether or not your participants will receive payment if they drop out of the study.

j. Qualifications of Staff for Invasive Medical Procedures:*

If the project involves invasive medical procedures and/or stress testing, please state the qualifications of the person(s) performing the procedure.

k. Does Your Protocol Involve Internet Research?:*

(Online surveys are considered Internet Research.)

▼

NOTE: If you answered yes to the previous question, you MUST fill out an Internet Research Form or your submission will be considered INCOMPLETE.

3. SAFEGUARDING THE IDENTITY OF PARTICIPANTS

a. Publication or Accessibility of Research:*

Describe which elements of your project might be opening accessible to other agencies or appear in publications.

b. Safeguarding Individuals and their Records: *

Describe the precautions you will employ to safeguard identifiable records or individuals. These questions also apply to secondary source 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 participants. If applicable, state how you will link the data to participants during your study. Describe the specific procedures you will use to safeguard participants' data from unauthorized access.

4. RISK

a. Risk Description: *

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. Reasoning for "Non-beneficial Research": *

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 there are no other methods available for obtaining the information needed, justify:

- i. Extent of 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.

5. DECEPTION

a. Procedures for Use of Deception in Data Collection: *

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 the deception if possible). You must attach a copy of all recruitment and debriefing materials (Posters, telephone scripts, etc.)

6. INFORMED CONSENT:

What type of informed consent are you planning to use?

Signed consent is used in situations where the participant is available to give a physical signature and anonymity of the participant is not relevant.

Implied Consent does not require a signature, and is typically used for an online survey where there is no document to physically sign or anonymity of the participant is a part of the protocol. You MUST fill out a Waiver of Signed Consent Request to use Implied Consent, however this alone will not justify a Full Convened IRB review.

If you would like to receive a COMPLETE Waiver of Consent (no consent form will be given/available for the participant), you will be required to fill out a Waiver of Consent Request, AND the protocol must go through Full Convened IRB review.

Fillable Electronic Signed and Implied Consent forms are available on our website and must be included with your protocol submission.

Informed Consent Type: *

▼

7. ADDITIONAL DOCUMENTATION

Your complete protocol submission will include the following additional documentation (please check all that apply and attach in the next section):

Internet Research Form
Informed Consent Document
Waiver of Signed Consent Request (Included with Implied Consent Document or as a complete Waiver of Consent)
Recruiting Script or Document(s)
Survey or Other Instruments
Affiliation Letter
Permission to Audio or Video Tape
Debriefing Statement (if you will use deception).

File Attachments

Upload...

PLEASE NOTE:

If you should make any changes in the protocol involving 1) method, 2) participants, 3) informed consent, and/or 4) subject identification, you must resubmit the protocol.

You are responsible for submission of the annual Continuing Review/Closing Report and for maintaining all records related to this project for at least three years after completion of the research project. Upon completion of research, your annual report is due within 10 business days.

Thank you for your submission!

The project referenced above has been received by the University of Wisconsin-Whitewater Institutional Review Board for the Protection of Human Subjects (IRB) Administrator and is being processed. It typically takes a minimum of 10 BUSINESS DAYS for review by the IRB. If we anticipate a delay, or if we require additional information, we will notify you as soon as possible.

If you have questions or require additional information, please do not hesitate to contact the IRB Administrator at (rsp-compliance@uww.edu, 262-472-5288).

If you wish to have a copy of your protocol immediately emailed to you, please select "SEND ME A COPY OF MY RESPONSES" in the next section, and supply your email address when indicated.

Send me a copy of my responses

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[Privacy Policy](#) | [Report Abuse](#)

ADDENDUM B: SAMPLE OF REQUEST OF WAIVER OF SIGNED CONSENT FORM

**University of Wisconsin-Whitewater
Request for Waiver of Signed Informed Consent**

Title: *Place project title here*

Investigator:

Place your name and contact information (phone number, office location).

Research Sponsor:

If appropriate, place your faculty advisor's name and contact information here. If you are a faculty researcher, this may be removed.

- Request for waiver of Signed Consent only. An Implied Consent form will be provided for the participant including all elements of Informed Consent.
 Yes No: Would the only record linking the subject and the research be the signed consent document?
 Yes No: Would the principal risk be the potential harm resulting from a breach in confidentiality?
 Yes No: The research involves no greater than minimal risk?
- Request for complete waiver of consent. No consent form will be provided for the participant because it is prohibitive or potentially dangerous. (COMPLETE WAIVER OF CONSENT REQUIRES FULL CONVENEED BOARD REVIEW.)

Please explain the reason(s) for your request:

Principle Investigator Signature

Date

ADDENDUM C: SAMPLE OF SIGNED CONSENT DOCUMENT

The process of obtaining informed consent must comply with the requirements of US Department of Health and Human Services, Office for Human Research Protections title 45 Code of Federal Regulations 46.116 (45 CFR 46.116). The documentation of informed consent must comply with 45 CFR 46.117. For further clarification of informed consent refer to the UW-Whitewater IRB GUIDE or contact the University of Wisconsin-Whitewater IRB Administrator, Carol Katch (katchc@uww.edu, 262-472-5288).

DO NOT USE THIS DOCUMENT AS IS.

Researchers should print the consent on University, College/Division, Department/Unit, or Center letterhead. All sections need to be addressed unless otherwise noted.

Delete all text in red and replace all italicized text with your information.

University of Wisconsin-Whitewater
SAMPLE
Signed Consent Form for Research Involving Human Subjects

Consent to Participate in University of Wisconsin-Whitewater Approved Research

Title: *Place project title here*

Investigator:

Place your name and contact information (phone number, office location).

Research Sponsor:

If appropriate, place your faculty advisor's name and contact information here. If you are a faculty researcher, this may be removed.

Description:

Include a description of the research you intend to perform. This description should contain enough detail that your subjects can make an intelligent, informed decision about their participation in your project. This will be similar to the section you filled out on the IRB protocol form.

Risks and Benefits:

Every situation comes with risks. Explain the benefits, otherwise there is no reason for subjects to participate. While the benefits may not be to the subject directly, the general benefits need to be outlined. This will be similar to the section you filled out on the IRB protocol form.

Special Populations:

If your project requires the use of minors or other special populations, then the informed consent must reflect this. Any research involving minors must have informed consent addressed to the parent or guardian and include a signature line for them (see below). This section may be omitted if the service of any special population is not being requested.

Time Commitment and Payment:

Provide each subject with a general expectation of the commitment for completing the research. Each subject will receive compensation for their time and effort, which should be explicitly stated.

Safeguarding the Identity of Participants:

Describe which elements of your project might be openly accessible to other agencies or appear in publications and the precautions you will employ to safeguard identifiable records or individuals. These questions also apply to secondary sources of data. Additionally, explain the immediate use of the data by yourself and others and the long-range use of data by yourself and others. Furthermore, 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.

Right to Withdraw:

No one should ever feel obligated to participate or continue participation in a project with which they are uncomfortable. A typical right to withdraw statement would read, "Your participation in this study is entirely voluntary. You may choose not to participate without any adverse consequences to you. Should you choose to participate and later wish to withdraw from the study, you may discontinue your participation at this time without incurring adverse consequences."

IRB Approval:

The following must be included on every informed consent:

This study has been reviewed and approved by The University of Wisconsin-Whitewater's Institutional Review Board (IRB). The IRB has determined that this study meets the ethical obligations required by federal law and University policies. If you have questions or concerns regarding this study please contact the Investigator or Advisor. If you have any questions, concerns, or reports regarding your rights as a research subject, please contact the IRB Administrator.

Principal Investigator (Faculty/Staff):

Place your name, phone number, and email address here.

Co-Investigator: Place your name, phone number, and email address here.

Student Investigator: Place your name, phone number, and email address here.

IRB Administrator:

Carol Katch
Compliance Manager
UW-Whitewater
Office of Research and Sponsored Programs
800 West Main St., Andersen Library 2245
Whitewater, WI 53190
262-472-5288
katchc@uww.edu

Statement of Consent:

This section must include the language, "By signing this consent form you certify you are at least 18 years of age and agree to participate in the project entitled, **(INSERT YOUR TITLE HERE)**."

Signature

Date

Signature of parent or guardian
(if minors are involved)

Date

ADDENDUM D: SAMPLE OF IMPLIED CONSENT DOCUMENT

University of Wisconsin Whitewater
SAMPLE
Implied Consent Statement for Research Involving Human Subjects

DO NOT USE THIS DOCUMENT AS IS.

Many surveys use implied consent when the only way to identify a person's involvement in the research is through a signature on an informed consent document. In these cases, consent is implied when the subject completes the document/survey/form. It is necessary to include specific information in the implied consent statement. Each of the following sections must be addressed in the informed consent statement.

Delete all text in red and replace all italicized text with your information.

Consent to Participate In UW-Whitewater Approved Research

Title: *Place project title here*

Investigator(s):
Place your name and contact information (phone number, office location).

Research Sponsor:
If appropriate, place your faculty advisor's name and contact information here. If you are a faculty researcher, this may be removed.

Description:
Include a description of the research you intend to perform. This description should contain enough detail that your subjects can make an intelligent, informed decision about their participation in your project. This will be similar to the section you filled out on the IRB protocol form.

Risks and Benefits:
Every situation comes with risks. You also need to explain the benefits; otherwise there is no reason for them to participate. While the benefits may not be to the subject directly, the general benefits need to be outlined. This will be similar to the section you filled out on the IRB protocol form.

Special Populations:
If your project requires the use of minors or other special populations, then implied consent MAY NOT be used. Any research involving minors must have informed consent addressed to the parent or guardian and include a signature line for them (see sample informed consent).

Time Commitment and Payment:
Provide each subject with a general expectation of the commitment for completing the research. If subjects are to receive compensation for their time and effort, that should also be explicitly stated. If compensation is to be provided, it is suggested that a signed consent be obtained as a record of receipt.

Safeguarding the Identity of Participants:
Describe which elements of your project might be openly accessible to other agencies or appear in publications and the precautions you will employ to safeguard identifiable records or individuals. These questions also apply to secondary sources of data. Additionally, explain the immediate use of the data by yourself and others and the long-range use of data by yourself and others. Furthermore, 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. If you are using Internet Research (which includes Web Survey Tools), you must include the following verbiage;

Right to Withdraw:

No one should ever feel obligated to participate or continue participation in a project with which they are uncomfortable. A typical right to withdraw statement would read, "Your participation in this study is entirely voluntary. You may choose not to participate without any adverse consequences to you. However, should you choose to participate and later wish to withdraw from the study, there is no way to identify your anonymous document after it has been turned into the investigator."

IRB Approval:

The following must be included on every informed consent:

This study has been reviewed and approved by The University of Wisconsin-Whitewater's Institutional Review Board (IRB). The IRB has determined that this study meets the ethical obligations required by federal law and University policies. If you have questions or concerns regarding this study please contact the Investigator or Advisor. If you have any questions, concerns, or reports regarding your rights as a research subject, please contact the IRB Administrator.

Principal Investigator (Faculty/Staff):

Place your name, phone number, and email address here.

Co-Investigator(s): *Place your name, phone number, and email address here.*

IRB Administrator:

Carol Katch
Compliance Manager
UW-Whitewater
800 West Main St.,
Andersen Library 2245
Whitewater, WI 53190
262-472-5288
katchc@uww.edu

Statement of Consent:

*This section must include the language, "By completing the following survey (**or other document as appropriate**) certify that you are at least 18 years of age, and you agree to participate in the project entitled, (**INSERT YOUR TITLE HERE**)."*

ADDENDUM E: SAMPLE OF CHILD ASSENT DOCUMENT

University of Wisconsin Whitewater
SAMPLE
Assent of Minor for Research Involving Human Subjects

DO NOT USE THIS DOCUMENT AS IS.

Delete all text in red and replace all italicized text with your information.

Title of Research: *Place project title here*

Investigator(s):
Place your name here

Research Sponsor:
If appropriate, place your faculty advisor's name here. If you are a faculty researcher, this may be removed.

These are some things we want you to know about research studies:
We are asking you to be in a research study. Research is a way to test new ideas and find new answers to questions or problems.

Whether or not to be in this research is your choice. You can say Yes or No. Whatever you decide is OK.

Why am I being asked to be in this research study?:
Explain in age appropriate language why they or their group/class/etc. has been selected to participate.

What is the study about?:
Explain in age appropriate language what you are trying to accomplish with your research.

What will happen during this study?:
If you agree to be in this study, you will...

Would you like to be a part of our research study?
Please check one.

Yes No

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 Carol Katch, IRB Administrator in the University of Wisconsin-Whitewater Office of Research and Sponsored Programs, 800 West Main Street, Whitewater, WI 53190, E-mail: katchc@uww.edu, Telephone: 262.472.5288,

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

ADDENDUM H: SAMPLE OF INTERNET RESEARCH FORM

University of Wisconsin-Whitewater
SAMPLE
Internet Research Form for Research Involving Human Subjects

DO NOT USE THIS DOCUMENT AS IS.

This document needs to be completed for any research being done via the Internet. This includes Internet Surveys. Protocols that include Internet Research will be considered incomplete if this document is not included.

Delete all text in red and replace all italicized text with your information.

Internet Research Summary for IRB Protocol

Title: *Place project title here*

Primary Investigator:

Staff/Faculty Investigator(s):

Student Investigator(s):

Researchers utilizing the Internet as a research tool may only use the UW-Whitewater Qualtrics Survey Software¹ for Internet Surveys, and must address the following issues (unless considered "not applicable"). This information must also be included with the informed consent documentation provided to your participants.

1. State whether the Internet site is considered public or private space:

State whether you have obtained (or how you attempted to obtain) permission from the list owner or administrator (if applicable) to recruit subjects from, or post messages on, the site. If no list owner or administrator can be contacted, researchers should post a message of interest to conduct research to the list participants for their discussion and consideration before informed consent documents are provided to participants. Researchers shall also obtain permission to use archived data from a list or site. (Permission may be verified by an e-mail from the list owner or administrator, and a copy should be included in your protocol.)

2. Open records information:

How will you inform the subjects that online communications, in general, are considered public in nature? Electronic records of such communications may therefore be subject to open records requests.

3. Inform the subjects that there is no completely secure interaction online:

The following statement must be inserted into the informed consent document: As an online participant in this research, there is always the risk of intrusion by outside agents, i.e., hacking, and therefore the possibility of being identified. Such a statement highlights concerns related to data confidentiality and the risk/benefit of participation in the study.

4. Using online email accounts:

State that subjects provided with an online e-mail account are allowed and encouraged to change passwords at regular intervals.

5. Use of encryption software:

If the researcher uses encryption software, a thorough set of instructions shall be included in the protocol and provided to the subjects.

6. Identification of participants in research documentation:

The protocol will describe how subjects will be identified in written reports, whether by use of their screen names or by pseudonyms (if applicable).

7. Storage of data:

The researcher will state that the data and identifiers shall be kept on different servers/computers which are secured within the UW-Whitewater network or via UW-Whitewater Google Driveⁱ. Storage via personal computers, flash/thumb drives and other cloud services (including personal Google Drive access) are not considered secure, and therefore are not permitted.

8. Ability to ask questions:

Researchers shall provide a forum for participants to ask questions online (e.g., the researchers' e-mail address) before consenting to participate in a research project.

9. Safeguarding identity during participation:

Researchers shall identify how participant identity will be safeguarded in a forum where some participants consent while others do not.

ⁱ For information regarding [Qualtrics Survey Software](#)

ⁱⁱ For information regarding [UW-Whitewater Google Drive Access](#)

ADDENDUM I: SAMPLE OF IRB PROTOCOL MODIFICATION FORM



IRB Protocol Modification Request

Protocol Number: *

Project Title: *

Principal Investigator: *

Last Name, First Name

Co-Investigator(s) [Faculty/Staff]:

Last Name, First Name

Student Investigator(s):

Last Name, First Name

Modification Type: *

Modification Summary: *

Describe below or attach a separate document



File Attachments

file name Upload...

NOTE: You may not make changes to your protocol until the modifications have been reviewed and formally approved by the IRB.

Send me a copy of my responses

Submit

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