OVERVIEW

The fundamental principle of human subject protection 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). For more see the National Science Foundation: http://www.nsf.gov/bfa/dias/policy/human.jsp).

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.

WHY MUST HUMAN RESEARCH BE APPROVED BY THE IRB?

The University of Wisconsin – Whitewater maintains Federalwide Assurance (FWA) for the Protection of Human Subjects. In short, we have agreed that if we accept federal funding for our institution, we will agree to adhere to federal rules. In this agreement, UW – Whitewater has agreed to follow a Statement of Principles when providing guidance for human research on our campus.

These principles and policies must have the oversight of the IRB according to federal regulations. In addition, these principles and policies must conform to laws, regulations, policies and guidelines referenced in the U.S. Code of Federal Regulations and the Common Rule.

The consequences of not adhering to these rules to compromise all federal funding to University of Wisconsin – Whitewater.

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 virtual (e.g., via WebEx). 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.

Investigators must submit protocols requiring Full Board Review during the academic school year and not during the summer (25 May to 25 August).

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 the Research Compliance Officer on the first of the month to ensure consideration that month. 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, investigators may submit a protocol following Monday.

Full Board review protocols will require review and signature approval of the investigator's department chair.

David Beyea	Communication beyead@uww.edu
Jolly Emrey	Political Science emreyj@uww.edu
John Frye	Geography, Geology, and Environmental Sci. Associate Director, Undergraduate Research fryej@uww.edu
Michael Hammer	Communication Sci & Disorders hammerm@uww.edu
Angela Harlan	Mathematics/Asst. Dean, Grad Studies harrisak@uww.edu
David Havas	Psychology havasd@uww.edu
Donna Kempf	Research Compliance kempf@uww.edu
Margo Kleinfeld	Geography & Geology kleinfem@uww.edu
Eric Loepp	Politics, Government, and Law/ICIT loeppe@uww.edu
Ana Caballero Mengibar	Integrated Studies/Director, UG Research caballea@uww.edu
Carrie Merino	Counselor Education merinoc@uww.edu
Charles Tayor	Community Member seetaylor@centurytel.net
Dan Zamzow	Integrated Studies zamzow@uww.edu

ADMINISTRATION

All protocol questions should be directed to:

Donna Kempf Kempfd@uww.edu
IRB Administrator &
Research Compliance Officer

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 document contains guidelines and instructions for protocol preparation and 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 the study employs adequate measures to protect the participants involved. 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 training, investigator certificates are directed to UW-W's Research Compliance Officer. The certification expires after 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

Additional questions regarding protocol completion or submission, CITI training, or the Federal Regulations, contact the UW-W Research Compliance Officer, Donna Kempf - Telephone: 262/472-5288; E-Mail: kempfd@uww.edu; Website: https://www.uww.edu/orsp/research-compliance/human-research

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 are only used and shared:

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 by each student individually 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 Research Compliance if assistance in making this determination is needed.

It is the 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 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 the Research Compliance Officer.

Projects which have been approved by another institution's Review Board will be ratified by UWW's IRB. 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.

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 Compliance Officer.

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 original "Affiliation Letter" will be returned to you and a copy will be retained in the IRB files.

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 Compliance Officer for review. The Research Compliance Officer 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 Research Compliance Officer 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 the Research Compliance Officer for review by the IRB Chair or designee. The Research Compliance Officer 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 the Research Compliance Officer 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 the Research Compliance Officer 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, the Research Compliance Officer 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 the Research Compliance Officer 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.

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.).

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

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 Human Research web page.

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 <u>Signed</u> 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 kempfd@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.