

POLICIES AND PROCEDURES FOR RESEARCH INVOLVING HUMAN SUBJECTS

University of Wisconsin-River Falls

Adopted by the UW-RF Institutional Review Board for the
Protection of Human Subjects on November 10, 1994;
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Administered by the Office of Grants & Research
104 North Hall, UW-RF, River Falls, WI 54022
Phone: 715/425-3195 FAX: 715/425-0649
Email: wm.e.campbell@uwrf.edu

The components of this manual are also available at
<http://www.uwrf.edu/grants/irb.htm>

POLICIES AND PROCEDURES FOR RESEARCH INVOLVING HUMAN SUBJECTS

The University of Wisconsin-River Falls is committed to protecting the rights and welfare of persons involved as subjects in research. In accord with federal regulations we have established an Institutional Review Board for the Protection of Human Subjects (IRB) and a set of policies and procedures to protect research subjects. The IRB and its policies and procedures are based on, and are consistent with, the Code of Federal Regulations, 45 CFR 46 (March 8, 1983) and the Federal Policy for the Protection of Human Subjects: Notices and Rules (June 18, 1991).

Research involving human subjects cannot be initiated by UW-RF faculty, staff, or students before it is reviewed and approved in writing by the IRB.

Research, in this context, means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute “research” for the purposes of these regulations, whether or not they are supported or funded under a program which is considered research for other purposes. For example, some “instructional,” “demonstration,” and “service” programs may include research activities.

Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, including both physical procedures by which data are gathered and manipulations of the subject or subject’s environment that are performed for research purposes; or (2) identifiable private information, including information about behavior that occurs in a context in which an individual can reasonably expect that no observation recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public. Private information must be individually identifiable (i.e. the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

Research protocols for any projects involving human subjects, as defined above, must be reviewed and approved by the IRB to assure that the rights and welfare of human subjects are protected and that appropriate methods of obtaining informed consent will be utilized. If it is unclear whether or not a project needs IRB approval, please contact the Director of Grants and Research or the IRB chair using the contact information listed on the cover of this manual or at the UW-RF IRB website (<http://www.uwrf.edu/grants/irb.htm>).

The IRB review will determine whether:

- The potential risks to the subject are clearly identified.
- The risks to the subject are so outweighed by the sum of the benefit to the subject and the importance of the knowledge to be gained as to warrant approval of the research project.
- The rights and welfare of all subjects will be adequately protected.

- Adequate explanation of the potential risks and safeguards, as well as benefits, is given to the subjects; subjects will give legally informed consent to the research procedures.
- Any exceptions are consistent with federal and university guidelines.

Engaging in research involving human subjects without the approval of the IRB violates UW-River Falls policy. Data on human subjects must not be collected until the IRB approves the project in writing.

PREPARING A PROTOCOL FOR RESEARCH INVOLVING HUMAN SUBJECTS

To help researchers fulfill their responsibilities towards the human subjects of their research, the IRB has developed the following procedures. These procedures are intended to help researchers move from an initial research request to final approval of the research protocol as quickly and efficiently as possible. If questions arise before or during this process, researchers should consult with the Director of Grants & Research or any member of the IRB, all of whom will facilitate the process insofar as possible. For the names and contact information of those individuals, see the UW-RF website (<http://www.uwrf.edu/grants/irb.htm>).

1. Researchers who have not filed protocols before should **consult** with the Director of Grants and Research or the Chair, IRB, about the nature and scope of the research project and the procedures which must be followed. Student initiated research must be overseen by a faculty or staff research sponsor; either the sponsor or the student may consult with the Director of Grants and Research or Chair, IRB, about the research project.

If students are conducting research projects in the context of a course, the instructor has the option of requesting certification for the entire course rather than requiring each student to file a protocol for individual projects. Psychology and sociology courses, for example, frequently require all students to engage in research projects involving human subjects; a course certification can yield approval for all of those research topics, thereby relieving students from filing protocols for each study. On the other hand, other courses that include student research projects require student-researchers to submit protocols during the course as part of the learning experience.

2. **Determine** the level of review. Research involving human subjects will be reviewed at either the exempted, expedited, or full board level. Exempted protocols are reviewed by the Director of Grants and Research; expedited protocols are reviewed by the Director of Grants and Research and Chair, IRB; all other protocols are reviewed by the full board. To determine a protocol's appropriate review level, refer to Appendix A.

3. **Prepare** your protocol. Each protocol consists of three parts; many require attachments. *Part I, Cover Sheet* provides the IRB with the project's title, name(s) of researchers, contact information, and level of review. It also carries the signature of researcher and sponsor, if any. The IRB takes these signatures very seriously; they certify that the researchers understand and accept the principles UW-RF has adopted to protect human subjects, including the requirement to obtain informed consent of subjects. Research protocols should use the form provided in Appendix B. Course certification protocols should use the form provided in Appendix C. These forms are also available at <http://www.uwrf.edu/grants/irb.htm>. Researchers should download the appropriate form, fill it out onscreen, and print it for signature(s).

Part II, Description of Study, summarizes the research project (or, in the case of a Course Certification protocol, research projects) and procedures the researcher(s) will follow. Most protocols provide all the information that is needed in a page or two of narrative. Researchers should use the outline provided in Appendix B (<http://www.uwrf.edu/grants/descr%7E1.htm>), addressing each issue in turn.

Part III, Protection of Human Subjects, summarizes the steps the researcher will take to protect his/her subjects during the study. Again, researchers should use the outline provided in Appendix B (<http://www.uwrf.edu/grants/humans%7E1.htm>), addressing each issue in turn.

4. **Submit** your proposal to the Director of Grants and Research or Chair, IRB. Student researchers should submit their protocols to their faculty/staff sponsors for signature; the sponsor will submit the protocol to the Director of Grants and Research or Chair, IRB.

The Director of Grants and Research or Chair, IRB, will review the protocol for completeness and clarity; if it is incomplete or needs clarification, s/he will return it to the proposer with suggestions. If it is complete and clear, your protocol will be reviewed in one of three ways:

Exempted protocols will be reviewed by the Director of Grants and Research **or** the Chair, IRB. Under normal circumstances, s/he should respond to the proposer within three days.

Expedited protocols will be reviewed and approved/disapproved by the Director of Grants and Research **and** the Chair, IRB. Expedited protocols are normally reviewed within seven days.

Full Review protocols will be reviewed by the entire IRB. The proposer (and faculty/staff sponsor, if there is one) will be invited to attend the IRB meeting to summarize the project, answer any questions that might arise, and (if required) suggest modifications to meet the objections or concerns of IRB members. The IRB meets irregularly and members must have at least one full week to read protocols before they meet. Therefore, proposals requiring full review may take up to three weeks to gain a verdict. Researchers who suspect that their protocols will require full review should

consult with the Director of Grants and Research or Chair, IRB, about submission dates long before they plan to begin collecting data.

If the protocol is approved, the Director of Grants and Research or Chair, IRB, will Email the researcher with the verdict and send a copy of Part I, Cover Sheet, with signature certifying approval, via campus or US mail.

APPENDIX A DETERMINATION OF REVIEW LEVEL

The initial step in the preparation of your research protocol involves determining the appropriate level of review: exempted, expedited, or full. The researcher (and the faculty/staff sponsor if the researcher is a student) should determine which level of review is to be requested; if uncertain, consult with the Director of Grants and Research or Chair of the IRB.

The following sections describe the categories of research which qualify for exempted, expedited, or full review. Beginning with exempted research, please read the description and complete the checklist. Continue through the descriptions until you reach the level of review for which your project qualifies.

I. EXEMPTED RESEARCH

In general, research which does not propose to disrupt or manipulate subjects' normal life experiences, or incorporate any form of intrusive procedures, may be declared exempted from expedited or full IRB review. Major considerations when determining if an exempted level of review is appropriate include level of risk and the presence or absence of deceptive procedures.

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examination or tests.

Projects involving more than minimal risk must be presented for full IRB review. Further, any degree of deception disqualifies a protocol from exempted review.

A. Research Activities Eligible for Exempted Review

1. **Exemption for education.** Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods is exempted. Individuals under the age of 18 constitute a protected class. Consequently, many projects involving minors will require expedited or full board review. However, some of these exemptions are applicable to research with minors, including this one.

2. **Exemption for research involving educational tests.** research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement) is exempted, 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 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. This exemption applies to research using minors.

3. **Exemption for survey or interview procedures.** research involving survey or interview procedures is exempted 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 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. This exemption does **not** apply to research using minors.
4. **Exemption for research involving observation of public behavior.** Research involving observation is exempted 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 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. This exemption applies to research with minors only when the investigator(s) does not participate in the activities observed.
5. **Exemption for research involving elected or appointed public officials or candidates for public office.** Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempted under exemption #2, #3, and #4 above is exempted 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 the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
6. **Exemption for collection or study of existing data.** Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens is exempted, 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.
7. **Exemption for research and demonstration projects conducted by or subject to approval of federal departments or agencies.** Research and demonstration projects which are conducted by or subject to the approval of department or agency heads are exempted if they are designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs, (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.
8. **Exemption for taste and food quality evaluation and consumer acceptance studies.** Taste and food quality evaluation and consumer acceptance studies are exempted if, (i) wholesome foods without additives are consumed; or (ii) 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 containment 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 US Department of Agriculture.

B. Checklist for Exempted Review Level

	YES	NO
1. It is clear that the nature of the proposed research fits one of the categories listed in section I.B. of this appendix.	_____	_____
2. No implications for criminal or civil liability, employability, or damage to subject’s financial standing or reputation would exist if data were known outside the study.	_____	_____
3. The research does not use a protected group as subjects (e.g. fetuses, pregnant women, prisoners, mentally handicapped, minors) in a survey or interview study, or minors in a participant observation study.	_____	_____
4. The study does not present more than a MINIMAL RISK to subjects.	_____	_____
5. The study does not involve DECEPTION.	_____	_____
6. Appropriate informed consent procedures will be followed.	_____	_____

“Yes” answers to all of the above are required to qualify for a recommendation for exempted review. If the answer to one of these questions is “no”, then expedited or full IRB review is required.

II. RESEARCH ELIGIBLE FOR EXPEDITED REVIEW

In general, research may qualify for expedited review if it is judged to involve no more than minimal risk, does not include deception, and includes appropriate informed consent procedures. Protocols for expedited review may use members of protected classes as long as they are not subject to more than minimal risk.

In studies qualifying for expedited review, the description of subjects’ performance should not be misleading or untruthful. However, there are times when full disclosure would jeopardize the procedure. For example, subjects might not be informed of the actual purpose of certain procedures.

No more than such mild deception can be tolerated in an experiment or research study submitted for expedited review. Any intentional deception involving misleading or untruthful information provided to the subjects must be considered in a full IRB review.

A. Research Activities Eligible for Expedited Review

The following sections present examples of research activities that may be reviewed through expedited review procedures. This list was established by the Secretary of Health and Human Services.

1. Collection of: hair and nail clippings, in a nondisfiguring manner; deciduous teeth; and permanent teeth if patient care indicates a need for extraction.
2. Collection of excreta and external secretions including sweat, uncannulated saliva, placenta removed at delivery, and amniotic fluid at the time of rupture of the membrane prior to or during labor.
3. Recording of data from subjects 18 years of age or older using noninvasive procedures routinely employed in clinical practice. This includes the use of physical sensors that are applied either to the surface of the body or at a distance and do not involve input of matter or significant amounts of energy into the subject or an invasion of the subject's privacy. It also includes such procedures as weighing, testing, sensory acuity, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, diagnostic echography, and electroretinography. It does not include exposure to electromagnetic radiation outside the visible range (for example, x-rays, microwaves).
4. Collection of blood samples by venipuncture, in amounts not exceeding 450 milliliters in an eight-week period and no more often than two times per week, from subjects 18 years of age or older and who are in good health and not pregnant.
5. Collection of both supra- and subgingival dental plaque and calculus, provided the procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques.
6. Voice recordings made for research purposes such as investigations of speech defects.
7. Moderate exercise by healthy volunteers.
8. The study of existing data, documents, records, pathological specimens, or diagnostic specimens.
9. Research on individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory, or test development, where the investigator does not manipulate subjects' behavior and the research is not designed to induce stress in the subjects.

10. Research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required.

B. Checklist for Expedited Review Level

	YES	NO
1. It is clear that the nature of the proposed research fits among the examples listed in section II.B. of this appendix.	_____	_____
2. No implications for criminal or civil liability, employability, or damage to subjects’ financial standing or reputation would exist if data were known outside of the study.	_____	_____
3. The study does not present more than a MINIMAL RISK to subjects.	_____	_____
4. The research does not use a protected group as subjects (e.g. fetuses, pregnant women, prisoners, mentally handicapped, minors) in a survey or interview study, or minors in a participant observation study.	_____	_____
5. The study does not involve INTENTIONAL DECEPTION such that misleading or untruthful information is provided to subjects.	_____	_____
6. Appropriate informed consent procedures will be followed.	_____	_____

“Yes” answers to all of the above are required to qualify for a recommendation for expedited review. If the answer to one or more of these questions is “no”, then full IRB review is required.

III. RESEARCH REQUIRING FULL BOARD REVIEW

The following categories of research require full IRB review.

1. Projects for which the level of risk is greater than minimal. (*Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in*

and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examination or tests.)

2. Projects which involve the intentional deception of subjects, such that misleading or untruthful information has been provided.
3. Projects which involve sensitive or protected populations; e.g. minors, prisoners, fetuses, mentally retarded, mentally disabled, test subjects for new drugs or clinical devices, pregnant women, illegal behavior, or legally incompetent persons, except for survey or interview studies, or a participant observation study using minors.

IV. DECEPTION POLICY

Intentionally misleading or providing untruthful information to subjects is not considered to be a desirable procedure. All other possible alternative research strategies should be explored and eliminated before settling on a deceptive approach. Should a researcher choose to implement a deceptive strategy, s/he must provide a clear and compelling justification of the procedure to the IRB as well as additional measures to protect subjects.

Justification must address:

1. Consideration of alternative research methods that would not require the adoption of deceptive practices (e.g. role playing, gaming approaches, simulation strategies, etc.)
2. The social value of the research being conducted. Though social value is not a total justification, it is necessary to demonstrate increased benefit to offset the increased subject risk where deception is involved.
3. Steps taken to further insure subject safety. Deception exploits the subjects' willingness to participate and thus renders the unwary subject vulnerable to increased psychological or physical harm. Steps must be taken, and be clearly explained in the justification, to protect against harm to the subjects.
4. Debriefing: where deception is used, thorough debriefing of the subjects is essential. Upon completion of participation, the deceptive practice must be disclosed to the subjects and reasons for the deception provided. The experimenter should insure that the subjects are able to complete their participation in a similar emotional, physical, and cognitive state as when they started. Therefore, deceptions with potential long-term negative implications for subjects should be avoided.

APPENDIX B
IRB RESEARCH PROTOCOL

University of Wisconsin-River Falls
IRB HUMAN SUBJECTS RESEARCH REVIEW PROTOCOL
PART I. Cover Sheet.

Original Submission _____ Proposal Modification _____ Renewal _____

IRB USE ONLY		
Date Received: _____	Approval Date: _____	Protocol Number: _____
Signed _____	Reapproval Date: _____	
Review: Exempted <input type="checkbox"/> Expedited <input type="checkbox"/> Full Board <input type="checkbox"/> Board Members present: _____		

This application is to be submitted to and approved in writing by the IRB prior to the initiation of any investigation involving human subjects, data or material.

A. Principal Investigator:

Department/Program: _____ US Mail address: _____
 Telephone: _____ Email address: _____
 Sponsor (if PI is a student: _____
 Project Title: _____
 Beginning Date: _____ Ending Date: _____

B. Is extramural funding being sought? _____ Potential Supporting Agency: _____

C. Requested Review Level: See Appendix A for instructions on determining the appropriate level of review. Be aware that the IRB may require a level of review different from your recommendation.

Exempted review _____ Expedited review _____ Full Board Review _____

A complete protocol consists of Part I, this *Cover Sheet*, and a brief narrative consisting of Part II, *Description of Study*, and Part III, *Human Subjects Protection*. Follow the outlines for Parts II and III beginning on the next page, addressing each item. Attach a copy of the informed consent form you will use and any instruments or questionnaires you will use. If your study will collect data at a school, institution, or place of business other than UW-RF, or if you will use data that belongs to another entity, attach a letter (on the organization's letterhead) from an official responsible for the testing site or data certifying that you have the organization's approval for the study.

Submit protocols to Bill Campbell, UW-RF Director of Grants & Research, 104 North Hall, 410 S. 3rd St., River Falls, WI 54022. If your protocol qualifies for exempted or expedited review, provide the original and one copy. If it requires full board review, provide the original and six copies.

D. Statement of assurance: I/We have read the UW-River Falls Policies and Procedures for Research Involving Human Subjects, and will comply with them, including the informed consent requirement. Furthermore, I/we will inform the IRB if significant changes are made in the proposed study.

Signature of PI *Date* *Signature of Sponsor* *Date*

PART II

DESCRIPTION OF STUDY

- A. **Research question.** Provide a brief statement of the question(s) being asked and the supporting rationale. For example: “The study is designed to determine if conformity is related to perceptions of group strength. This project is based on the social impact theory of group influence which suggests that social influence will increase as a function of perceived ‘strength’ among the group members. Perceived strength in this study is being defined by the expertise of the members.”

Notice that the statement is brief and expresses not only the research question but the theoretical rationale behind the question. Some projects will undoubtedly require a bit more explanation, but a complete literature review is not necessary for IRB review purposes.

If you have a hypothesis or hypotheses, explain them briefly. Hypotheses are encouraged but not required; preliminary studies that are designed to help the researcher form hypotheses are sometimes acceptable.

B. Subject Selection.

1. Number of subjects:
2. Human subject pool:
 - a. Describe relevant features of the subjects you will be using (e.g. sex, race, or ethnic group; age range; general state of mental and physical health; etc.).
 - b. Note the relevant affiliations of your subjects (e.g. institutions, hospitals, general public, etc.).
3. If human subjects are children, mentally incompetent, or other legally restricted groups:
 - a. Explain the necessity of using these particular groups.
 - b. Describe any special arrangements to protect their safety.

C. Procedures.

1. Describe your recruitment procedures and any material inducements given for participation.
2. Note the location of the study. Be as specific as possible.
3. Describe all personnel, including names and affiliation with UW-River Falls (and any other relevant affiliations).

4. Describe the information to be gathered and the means for collecting and recording data.

If previously collected data is to be used, describe both the previous and proposed uses of these data.

5. Provide a step by step description of everything subjects will be asked to do in your study.
6. Note the title and source of instruments (i.e. personality scales, questionnaires, evaluation blanks, etc.). Include copies of original instruments.

PART III HUMAN SUBJECTS PROTECTION

A. Potential Risks you can anticipate for subjects.

1. Describe immediate risks, long term risks, rationale for the necessity of such risks, alternatives that were or will be considered, and why alternatives may not be feasible.
2. Describe any potential legal, financial, social or personal effects on subjects of accidental data disclosure. Though the potential for disclosure may be extremely remote, if a fire or bombing exposed your data, how would it affect subjects?

B. Expected benefits for subjects (if any) and/or society:

The IRB is required to insure that the potential risks to subjects (however minimal) are clearly justified by the potential benefits of the research both to the subjects and to the current state of theoretical knowledge on the topic. You can assist this process by providing a statement clarifying the potential for new knowledge resulting from the study as well as any benefits directly to the subjects. Stating that “more research is needed on this topic” will be of little help. Please explain why more research will be a benefit.

C. Deception used in gathering data.

Justify and support the use of deception in the project, particularly if subjects are being provided with any untruthful or misleading information. Realize that not providing complete information is minimally deceptive. Provide a detailed written description of the debriefing process.

D. Safeguarding Subjects’ Identity.

1. What uses will be made of the information obtained from the subjects? What elements of your project might be openly accessible to other agencies or appear in publications?

2. What precautions will be taken to safeguard identifiable records or individuals? How will confidentiality of data be protected?

E. **Informed consent.**

Please refer to Appendix D for guidelines with respect to informed consent and sample consent forms. Submit a copy of the consent form and all materials used in the recruitment and selection of subjects.

If the study involves children, the informed consent form must be signed by the child's parent or guardian. The IRB usually requires the child to sign a consent form as well so that s/he understands as completely as possible the research which is being performed. Older children can sign the same consent form as the parent/guardian. For younger children, a separate form in simpler language may be required.

When a signed consent form is required, a copy must be made available to the subjects. At the very least--e.g. when completion of the instrument serves as giving consent--subjects must be given a form identifying the researcher by name, address, and phone number, and including these statements:

If you have concerns about how you were treated in this study, please contact: Dr. William Campbell, Director of Grants and Research, 104 North Hall, UW-RF, 715/425-3195.

This project has been approved by the UW-River Falls Institutional Research Board for the Protection of Human Subjects, protocol # _____.

Some researchers might meet this requirement by detaching the signature portion of the consent form and giving the rest to the subject. Others might print a separate card or sheet with the required information for distributing to subjects.

Studies that maintain the anonymity of subjects should not require subjects to sign informed consent forms, since that would violate their anonymity. Researchers can obtain their consent by providing a statement such as:

I am researching [brief description of study]. I ask you to participate by completing the following questionnaire. Please do not write your name on the questionnaire; this study is meant to be anonymous. It is completely voluntary; if you are willing to participate, please answer the questions to the best of your ability. If you choose not to participate, please return the questionnaire to the researcher. [name of researcher, contact information.]

Attachments

If your study employs an instrument—survey, questionnaire, test, etc.—please include a copy. If the instrument is a commercial product that you cannot attach because of copyright or expense, reference the instrument in your narrative so that reviewers can research it.

If your study will take place at an off-campus, non-public site, please attach a letter from an official with appropriate authority giving you permission to perform your research on his/her site. For instance, protocols for studies involving school children must include a letter from the school's principal or other responsible official certifying that the researcher has the school's permission to perform the research. Such letters should be written on school letterhead and should mention the researcher by name and the project by title.

APPENDIX C
COURSE CERTIFICATION PROTOCOL FORM

University of Wisconsin-River Falls
IRB HUMAN SUBJECTS COURSE CERTIFICATION PROTOCOL

PART I. Cover Sheet.

Original Submission _____ Proposal Modification _____ Renewal _____

Instructors teaching courses in which students may utilize human subjects in their research projects may use this form to certify the entire course, rather than having students file research protocols for each experiment. The form and any attachments must be completed and submitted to the IRB chair or Director of Grants and Research prior to the collection of data. **Note: Approval of this protocol expires after one year.**

IRB USE ONLY			
Date Received: _____	Approval Date: _____	Protocol Number: _____	
Signed _____	Reapproval Date: _____		Exempted _____
____ Expedited _____	Full Board _____	Board Members present: _____	

A. Course Instructor:

Dept:

Course No.:

Course Title:

B. Requested Review Level: See Appendix A for instructions on determining the appropriate level of review. Be aware that the IRB may require a level of review different from your recommendation.

Exempted review _____ Expedited review _____ Full Board Review _____

If exempted or expedited review is requested, please submit two copies of the protocol. If the protocol will require full board review, please submit seven copies.

Include this cover sheet and a narrative addressing C, D, and E, below.

C. Description of Study: Describe, briefly, the experiments that students will be conducting.

D. Use of Human Subjects: Describe the nature of human subject involvement in the course.

E. Protection of Human Subjects: Describe how you will ensure that the UW-RF guidelines for using human subjects will not be violated.

F. Course Instructor Assurance: *I have read the UW-RF "Policies and Procedures for Research Involving Human Subjects," including the section on the responsibility to obtain informed consent from subjects; the students in my course and I will comply.*

Signature

Date

APPENDIX D

INFORMED CONSENT
SAMPLE CONSENT FORMS

INFORMED CONSENT

I. General Requirements.

No investigator may involve a human being as a subject in research unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

A. Basic elements of informed consent. Except as provided in paragraph (c) or (d) of this section, in seeking informed consent the following information shall be provided to each subject:

1. Name, affiliation, and contact information for the researcher.
2. A statement that the study involves research, an explanation of the purpose(s) of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures that are experimental;
3. A description of any reasonably foreseeable risks or discomforts to the subject;
4. A description of any benefits to the subject or to others which may reasonably be expected from the research;
5. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
6. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
7. For research involving more than minimal risk, an explanation as to whether any compensation is provided and an explanation as to whether any medical or non-medical treatments are available if injury or damage occurs and, if so, what they consist of, or where further information may be obtained;
8. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and
9. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled to receive for participation up to point of their termination.

B. Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:

1. 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.
 2. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subjects' consent.
 3. Any additional costs to the subject that may result from participation in the research.
 4. The consequences of the subject's decision to withdraw from the research, and procedures for orderly termination of participation by the subject.
 5. A statement that significant new findings developed during the course of the research which may relate to the subjects' willingness to continue participation will be provided to the subject.
 6. The approximate number of subjects involved in the study.
- C. The IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirements to obtain informed consent provided the IRB finds and documents that:
1. The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:
 - (i) programs under the Social Security Act, or other public benefit or service programs;
 - (ii) procedures for obtaining benefits or services under those programs;
 - (iii) possible changes in or alternatives to those programs or procedures; **or**
 - (iv) possible changes in methods or levels of payment for benefits or services under those programs; **and**
 2. The research could not practicably be carried out without the waiver or alteration.
- D. The IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirements to obtain informed consent provided the IRB finds and documents that:
1. The research involves no more than minimal risk to the subjects;
 2. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
 3. The research could not practicably be carried out without the waiver or alteration; **and**
 4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.
- E. The informed consent requirements in these regulations are not intended to preempt any applicable federal, state, or local laws which require additional information to be disclosed in order for informed consent to be

legally effective.

- F. Nothing in these regulations is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable federal, state, or local law.

II. Documentation of Informed Consent.

- A. Except as provided in paragraph C of this section (below), informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative.
- B. Except as provided in paragraph C of this section (below), the consent form may be either of the following:
 - 1. A written consent document that embodies the elements of informed consent required by the Code of Federal Regulations. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed; or
 - 2. A "short form" written consent document stating that the elements of informed consent required by the Code of Federal Regulations have been presented orally to the subject or representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the "short form."
- C. The IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:
 - 1. That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or
 - 2. That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

In documentation where the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research. Please see the following sample consent forms. Each contains the basic required elements for informed consent.

**Subject Consent Form for Participation of Human Subjects in Research
University of Wisconsin-River Falls**

Project Title: Social Influence in Group Decisions

Researcher: Jane A. Doe, Dept. of Psychology, 1234 CSH, UW-RF, 715/425-0000

Description: The purpose of this experiment is to examine the social interaction patterns that develop within the small groups. If you volunteer for this research study, you will be asked to participate in a series of group discussions and decisions. Groups will vary from 3 to 9 persons and the topics discussed will relate to issues of common concern to young adults and college students. All other participants in the study will be fellow students completing the research requirement for their psychology course. The topics are neither embarrassing nor intended to be upsetting. You will first be asked to complete a questionnaire and then will discuss one to six of the topics related to items on the questionnaire with other group members. You may be asked to attempt to reach total agreement among group members on the topics. A second response will then be requested to each question discussed. The total time for your participation will be *one hour*.

The results of each individual's participation will be strictly confidential. The results of your participation will be recorded by group only. No names or individual identifying information will be maintained. With the exception of the researchers involved in running this study, nobody will be allowed to see or discuss any of the individual responses. Your responses will be combined with many others and reported in group form in a professional journal article.

The risks to you are minimal though you may encounter other individuals attempting to change your mind on some issues during the group discussions. Though all participants will be asked to keep their comments constructive, the researchers are trained to step in to protect individuals from hostile or inappropriate comments made during discussions. The discussions will be discontinued if any of the group members cannot refrain from inappropriate remarks to others.

The overall nature of the study will be explained as soon as you have completed your session. A summary report and explanation of the results will be made available to you when the study is completed if you so request.

Authorization: I have read the above and understand the nature of this study and agree to participate. I understand that by agreeing to participate in this study I have not waived any legal or human rights. I also understand that I have the **right to refuse to participate** and that **my right to withdraw from participation at any time during the study will be respected with no coercion or prejudice**.

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

Wm. E. Campbell
Director, Grants and Research, UW-River Falls
River Falls, WI 54022 telephone: 715/425-3195

This research project has been approved by the UW-River Falls Institutional Review Board for the Protection of Human Subjects, protocol # _____.

Participant signature

Date

1. Purpose:

The purpose of this experiment is to study how people remember lists of items. The results are intended to provide insights into memory processes.

2. Procedure:

You will be shown some lists of words one word at a time. After a given list has been presented, you will be asked to write down as many of those words as you can remember.

3. Time required:

Your participation will involve one session lasting approximately 45 minutes.

4. Risks:

It is not anticipated that this study will present any risk to you other than the inconvenience of the time taken to participate.

5. Your rights as a subject:

- (i) The information gathered will be recorded in anonymous form. Data or summarized results will not be released in any way that could identify you.
- (ii) If you want to withdraw from the study at any time, you may do so without penalty. The information collected from you up to that point would be destroyed if you so desire.
- (iii) At the end of the session, you have the right to a complete explanation (“debriefing”) of what this experiment was all about. If you have questions afterward, please ask your experimenter or contact:

Dr. John Doe (or faculty sponsor’s name, for students)
Dept of Psychology, CSH, UW-RF, 715/425-0001

Also, once the study is completed, you may request a summary of the results.

6. If you have any concerns about your treatment as a participant in this study, please call or write:

Wm. E. Campbell, Director, Grants & Research, UW-RF,
River Falls, WI 54022 telephone: 715/425-3195

This research project has been approved by the UW-River Falls Institutional Review Board for the Protection of Human Subjects, protocol # _____.

I have read the above information and willingly consent to participate in this experiment.

Signed: _____

Date: _____

(Sample #3)*

**Subject Consent Form for Participation of Human Subjects in Research
University of Wisconsin-River Falls**

PLEASE DO NOT PUT YOUR NAME ANYWHERE ON THIS SURVEY. There is no need to identify yourself.

You are being asked to complete this survey to help researchers better understand some of the behaviors and attitudes of college students in the Midwest. Many of the questions ask about your plans and activities with respect to career and family. Thus, for some respondents these may be current activities and for others they may require either a look into the past or into the future. Please be as honest with us as possible and answer all questions to the best of your knowledge. You should be able to complete the questionnaire in about 25 minutes.

Once the study is completed, a summary of the results will be made available through the Sociology Department office.

Your participation in this survey is entirely voluntary. By completing this survey you are giving your consent to be involved in the research. If any point you decide that you do not want to complete the questionnaire, please return it and inform the administrator. Your course grades will not be affected if you decide not to participate.

Please feel free to ask any questions you may have of the person who is giving you this survey, especially if there is a word or phrase you do not understand. Feel free to write in the margins if you feel you need room to express or explain an answer.

Thank you for your cooperation and the time that you have put into the project.

If you should have concerns about your treatment as a participant in this study, please call or write:

Wm. E. Campbell, Director, Grants and Research, UW-River Falls
104 North Hall, River Falls, WI 54022 Telephone: 715/425-3195

This research project has been approved by the UW-River Falls Institutional Review Board for the Protection of Human Subjects, protocol # _____.

Again, **please do not put your name anywhere on this survey.**

Thank you,
Dr. Jane Doe, 715/425-0000

*Appropriate for questionnaire/survey research where data are recorded in an anonymous fashion, the study does not address sensitive or illegal behaviors, and the participants are at least 18 years of age.