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A. INTRODUCTION
It is legally, morally and ethically imperative that the rights and welfare of research participants be protected. In accordance with federal, as well as state and UW-System regulations, UW-Platteville has established the Institutional Review Board for the Protection of Human Participants (IRB) and the following policies and procedures for research involving human participants, or data or materials derived from humans. Safeguarding the rights and welfare of human participants protects not only the participant, but also the researcher and the institution sponsoring the research project.

B. IRB STATEMENT OF PURPOSE
The IRB has been charged with implementing these policies and procedures, which are applicable to any research project, funded or unfunded, originated at or supported by UW-Platteville, that involves humans as participants, or data or materials derived from humans. This would include all research involving UW-Platteville students, personnel, or facilities and research involving human participants, human tissues, or human records. All research projects will be held to the standards for federally funded projects set by the Code of Federal Regulations, 45 CFR 46 (June 23, 2005), and the Federal Policy for the Protection of Human Subjects: Notices and Rules (June 18, 1991).

Researchers are legally and ethically obligated to protect their participants. Regardless of perceived risk, faculty, staff, and students cannot initiate research involving human participants (including data or materials derived from human participants) before it is reviewed and approved in writing by the IRB.

C. IRB DUTIES
The IRB reviews submitted protocols of research involving human participants. The review will ascertain if participants will be placed at risk, if adequate safeguards are implemented, and if participants’ rights are protected. The review shall ascertain whether:

1. Potential risks to the participant are clearly identified;
2. Risks to the participant are outweighed by the benefits to the participant and the importance of the knowledge to be gained as to warrant approval of the research project;
3. Rights and welfare of all participants will be adequately protected;
4. Adequate explanations of the potential risks and safeguards, as well as benefits, are given to the participants, and legally informed consent will be obtained by adequate methods in accordance with the provisions outlined in Section VI; and
5. Any exceptions are consistent with federal and university guidelines.

In addition to reviewing research protocols, the IRB also:

1. Publishes the IRB Manual of Policies and Procedures, which contains the protocol form and the procedures for submitting and reviewing proposals. This manual is reviewed annually and revised as needed;
2. Helps faculty understand the federal regulations and prepare protocols;
3. Coordinates findings with the Office of Sponsored Programs when the research involves extramural funding;
4. Maintains a file of IRB documents for a period of at least three years as required by federal regulations; and

5. Complies with the Federalwide Assurance statement from the U.S. Department of Health and Human Services (HHS).

D. COMPOSITION OF IRB

- Nine (9) faculty with three-year staggered terms, and attention to racial and cultural diversity and gender equity in membership, including one faculty member from each college and one member of the Academic & Institutional Research Committee, with the requirement that there be a member from Psychology and the School of Education;

- One (1) academic staff with a three-year term, with the recommendation that he/she be from an area with an interest in human research (instructional academic staff, Health Services, Counseling Services, and/or Student Support Services);

- One (1) community representative with three-year term, appointed by the IRB; and

- Ex-Officio: Director of Sponsored Programs.

- The IRB committee members are officially appointed by the Provost/Vice Chancellor.

- A list of current members is available on the IRB web site at http://www.uwplatt.edu/committees/irbhsr/index.html.

E. PRINCIPLES OF THE BELMONT REPORT

All investigators engaged in research involving human participants, human tissues, or human records must adhere to the principles of Respect for Persons, Beneficence, and Justice embodied in the Belmont Report, which was approved by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, on April 18, 1979. The principles in this report continue to form the basis of current federal regulations. For a complete text of the Belmont Report, see http://ohsr.od.nih.gov/guidelines/belmont.html.

The three principles outlined in that report, and the related IRB review criteria, are summarized on the following page. The IRB is required to consider the three principles to be equally important. Some researchers tend to focus almost exclusively on Beneficence, arguing that if no participants are being put at risk in their projects (beyond minimal risk, as defined in the federal guidelines) then the IRB should not have to approve their projects. Such projects do require review and approval. Some researchers wish the IRB to give less weight to Respect for Persons than to Beneficence, because they do not wish to secure informed consent from their participants. We have found that researchers are particularly reluctant to secure documented (signed) informed consent. The IRB has discretion with regard to securing and documenting informed consent. The IRB is required to give greater consideration to the participant’s right to act as an autonomous agent than to a researcher’s convenience or needs. Students are particularly at risk of exploitation (bringing in the third principle, Justice), given their easy availability to faculty as possible participants.
Principle 1: *Respect for Persons*
Individuals should be treated as autonomous agents; persons with diminished autonomy are entitled to protection.

Criteria for IRB Approval
- Informed consent is sought from each participant.
- Informed consent is appropriately documented.
- Privacy and confidentiality of participants are protected.
- Additional safeguards are included for vulnerable populations.

The federal regulations identify children, prisoners, and pregnant women (with regard to projects which might be harmful to the woman or fetus) as vulnerable populations.

Students are considered a vulnerable population, given the power differential between professors and students.

Principle 2: *Beneficence*
Do no harm; Maximize benefits and minimize harm.

Criteria for IRB Approval
- Risks to participants are minimized.
- Risks are reasonable in relation to anticipated benefits.
- Data collection is monitored to ensure participant safety and welfare.

Principle 3: *Justice*
There is an equitable distribution of research costs and benefits; populations should not be overly selected because of their easy availability, compromised position, or manipulability.

Criteria for IRB Approval
- Selection of participants is equitable.

Students are often disproportionately selected as research participants, given their easy availability. Consequently, students should be included as participants only when students will benefit from the research experience and/or results.
A. DEFINING RESEARCH
The first step for a potential researcher is to determine if his/her project is considered research. Research protocols for projects involving human participants must be reviewed and approved by the IRB to assure that the rights and welfare of human participants are protected and that appropriate methods of obtaining informed consent will be utilized. If it is unclear whether or not a project needs IRB review and approval, contact the IRB Chair. In-house surveys, designed and used solely for program improvement and future planning, do not qualify as research (as defined below).

RESEARCH, as defined in the Code of Federal Regulations, means a systematic investigation, including development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

GENERALIZABLE KNOWLEDGE is knowledge made public through formal presentation or publication in paper or electronic format. In the Belmont Report, it is referred to as knowledge “expressed in theories, principles, and statements of relationships” that can be widely applied to the public.

HUMAN PARTICIPANT (also referred to as “human subject”), as defined in the Code of Federal Regulations, means a living individual about whom an investigator—whether professional or student—conducting research obtains: (1) Data through intervention or interaction with the individual; or (2) Identifiable private information.

B. DOES YOUR PROJECT QUALIFY AS RESEARCH INVOLVING HUMAN PARTICIPANTS?
The attached Chart 1, adapted from the department of HHS at http://www.hhs.gov/ohrp/humansubjects/guidance/decisioncharts.htm, could be useful in determining whether a project involving human participants requires IRB approval. This is a starting point to determine whether your project requires IRB approval. If your project qualifies as research with human participants, then see sections C and D below to determine whether UW-Platteville IRB approval is needed.

C. DOES MY PROJECT REQUIRE A UW-PLATTEVILLE IRB PROTOCOL?
1. UW-Platteville Researchers:
After determining if a project qualifies as research involving human participants, there are three categories that UW-Platteville researchers could fall into, for IRB purposes. Whether or not a UW-Platteville IRB protocol needs to be submitted depends on the primary investigator’s role in the research project:

a. A primary investigator is involved in a UW-Platteville associated research project that is either conducted on campus using campus resources or conducted elsewhere.
   - Go through UW-Platteville’s IRB process
b. A faculty member or student is involved as a consultant in a research project for a company where the project is done as a class project or uses campus resources.

- Go through UW-Platteville’s IRB process (may also go through the company’s process). Also see section D below.

c. A primary investigator is a consultant for a project not associated with UW-Platteville.

- If the following are all true, then UW-Platteville’s IRB process is not required (however, another entity’s IRB process may need to be followed). If any one of the following is not true, then the project must go through UW-Platteville’s IRB:
  1. The researcher consults or is hired on his or her own time;
  2. The researcher holds no rights in the work; and
  3. Neither the researcher nor UW-Platteville retains any rights to the data.

2. Non UW-Platteville Researchers:
If a researcher, who is not currently associated with UW-Platteville, wishes to conduct a study involving human subjects at UW-Platteville then they will need to go through the IRB process at UW-Platteville. If they are going to conduct research at UW-Platteville and are associated with another university then that university’s IRB process should be gone through first, if required. Upon approval, they will need to submit that IRB’s documents, including the approval, to the current UW-Platteville IRB chair. The IRB chair will then determine whether any further requirements for our IRB need to be met. If the researcher is not required to submit to their home university’s IRB, then they will be required to complete UW-Platteville’s IRB process.

D. CLASS ASSIGNMENTS
There are situations when a class assignment will require IRB approval. However, if any of the following are not true, then IRB approval is needed:

- The activity is a class assignment designed for learning purposes only and is not designed to develop or contribute to generalizable knowledge.

- Results of the class assignment are viewed within the classroom for teaching and learning purposes.

- Results of the class assignment are not presented in a public forum nor published in paper or electronic format for distribution outside UW-Platteville.

- Procedures present no more than minimal risk.

- Vulnerable populations are not targeted (e.g., children under age 18, prisoners, persons who are cognitively impaired).

- When appropriate, an informed consent process is in place.

If you have any questions about whether a project requires an IRB protocol, please contact the IRB Chair. If a class project or assignment does not require UW-Platteville IRB approval, the instructor is still responsible for communicating to the students the ethics of research involving human participants.
CHART 1:
IS MY PROJECT CONSIDERED RESEARCH INVOLVING HUMAN PARTICIPANTS?

Start here

Is the activity a systematic investigation designed to develop or contribute to generalizable knowledge?

NO

The activity is research.

NO

The research does not require IRB review.

BUT

NO

Is the research involving obtaining information about living individuals?

YES

The activity is research.

NO

Does the research involve intervention or interaction with the individuals?

YES

The activity is research involving human participants and must be reviewed by the IRB.

NO

Is the information individually identifiable (the identity of the subject is or may readily be determined by the investigator associated with the information)?

YES

Is the information private? (Concerning behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, or provided for specific purposes by an individual and which the individual can reasonably expect will not be made public.)

YES

AND

Other local, state, and federal laws and/or regulations may still apply.

NO

BUT

NO

BUT

YES

YES
Preparation of your research protocol involves determining the appropriate level of review. Assistance may be obtained from the IRB Chair. The principal investigator (PI), and the sponsor if the PI is a student, is asked to make an initial recommendation as to the appropriate level of review; however, the IRB Chair may require a level of review different from your recommendation.

What follows are descriptions of the categories of research which qualify for expedited and for full board review, and definitions which should be applied to both.

**SECTION III: DETERMINING THE APPROPRIATE LEVEL OF REVIEW**

Preparation of your research protocol involves determining the appropriate level of review. Assistance may be obtained from the IRB Chair. The principal investigator (PI), and the sponsor if the PI is a student, is asked to make an initial recommendation as to the appropriate level of review; however, the IRB Chair may require a level of review different from your recommendation.

What follows are descriptions of the categories of research which qualify for expedited and for full board review, and definitions which should be applied to both.

**A. LEVELS OF REVIEW**

The UW-Platteville IRB requires all protocols be submitted for either expedited review or full board review.

**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 examinations or tests.

**INTENTIONAL DECEPTION** involves providing misleading or untruthful information. Not revealing one’s hypotheses, and/or not revealing the activities in which other participants will engage, do not constitute intentional deception.

**B. 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 intentional deception, does not employ sensitive populations or topics, and includes appropriate informed consent procedures. The expedited review procedure may not be used where identification of the participants and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the participants’ financial standing, employability, insurability, or reputation, or would be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

The greater the probability of harm or discomfort, the greater the responsibility the researcher has to provide safeguards for the protection of participants’ safety and well-being.

In studies qualifying for expedited review, the description of the participants’ performance should not be misleading or untruthful. However, there are times when full disclosure would jeopardize the procedure. For example, participants 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. It is the UW-Platteville IRB’s policy that any intentional deception involving misleading or untruthful information provided to the participants must be considered in a full board review.
The following are examples of research activities that may be reviewed through expedited review procedures. (Additional examples are available in Appendix C of this document. This list was established by the Secretary of HHS and will be amended as appropriate through periodic publication in the Federal Register.)

1. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior);

2. Research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies;

3. Research conducted in established or commonly accepted educational settings and which involves normal educational practices, such as research on regular or special education instructional strategies or research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods;

4. Research involving the use of educational tests;

5. Research on public behavior;

6. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens;

7. Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine public benefit or service programs;

8. Taste and food quality evaluation and consumer acceptance studies; and

9. Collection of data for research purposes from previously recorded voice, video, digital, or image recordings.

C. RESEARCH REQUIRING FULL BOARD REVIEW
The IRB schedules meetings to accommodate requests for full board review, as well as to conduct other business. The following categories of research require full IRB approval:

1. Projects for which the level of risk is determined by the PI, IRB Chair, or IRB reviewer to be greater than minimal;

2. Projects that involve the intentional deception of participants, 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 participants for new drugs or clinical devices, pregnant women (in any study which could have health implications for the mother or fetus), legally incompetent persons; and

4. Projects in which identification of the participants and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.
Please refer to the checklist for help in determining review level:

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<th>TRUE</th>
<th>FALSE</th>
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<td>It is clear that the nature of the proposed research fits one of the categories listed in either Section III B or Appendix C.</td>
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<td>No implications for criminal or civil liability, for damage to participants’ financial standing, employability, insurability, or reputation, or for stigmatization would exist if data were known outside of the study, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.</td>
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<tr>
<td>The research does not employ a protected group as participants (e.g. fetuses, pregnant women in any study which could have health implications for the mother or her fetus, prisoners, mentally handicapped, or minors).</td>
<td></td>
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<tr>
<td>The study does not present more than a MINIMAL RISK to participants.</td>
<td></td>
</tr>
<tr>
<td>The study does not involve INTENTIONAL DECEPTION such that misleading or untruthful information is provided to participants.</td>
<td></td>
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<tr>
<td>Appropriate informed consent procedures are followed.</td>
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Answers of “true” to all of the above are required to qualify for expedited review. If any are answered “false,” submit for full board review.
SECTION IV: PREPARING A PROTOCOL

Engaging in research involving human participants (or data or material derived from human participants) without the approval of the IRB violates UW-Platteville policy. Data on human participants must not be collected until the IRB approves the project in writing.

A. DETERMINING LEVEL OF REVIEW
Research involving human participants (or data or material derived from human participants) will be reviewed at either the expedited or full board level. To determine a protocol’s review level, see Section III, pages 10-12. If this is a protocol revision, see section V.

B. PREPARING YOUR PROTOCOL
After you have determined your protocol’s review level, begin preparing the IRB review protocol, described in Appendix A, pages 20-27. (The templates for the protocols are available at http://www.uwplatt.edu/committees/irbhsr/index.html.)

C. SUBMITTING THE PROTOCOL
The procedure for submitting the protocol to the IRB depends on the role of the principal investigator (PI).

UW-Platteville Faculty/staff: Submit the typed protocol to your department/program Human Subjects Review (HSR) committee (if one exists) or your department/program IRB Chair. Once you have obtained the required signatures, submit the final copies of your protocol to the IRB Chair. The Chair will review the materials and either returns the protocol to the researcher with suggestions for clarification or change, or sends the protocol on to the IRB reviewers.

UW-Platteville Students: Submit your typed protocol to your faculty/staff sponsor for corrections and/or editing. Once approved by your sponsor, submit the protocol to the Chair of your department/program HSR committee (if one exists) or your department/program Chair. Once you have obtained the required signatures, have your sponsor submit the final copies to the IRB Chair. From this point on, the procedure will be the same as for faculty/staff research, except that all IRB communication will be directed to the student and the student’s sponsor.

Non UW-Platteville Researchers: If required to submit a UW-Platteville IRB Protocol (see Section II.C.2), then the protocol should be submitted to the on campus department, the researcher is working with for their departmental approval. If not working with a specific department, then the protocol should be submitted to the UW-Platteville Provost’s office for approval. Once you have obtained the required signatures, submit the final copies of your protocol to the IRB Chair. The Chair will review the materials and either return the protocol to the researcher with suggestions for clarification or change, or send the protocol on to the IRB reviewers.

The IRB will not accept protocols without the required signatures.

Requests for expedited review will be reviewed by at least two IRB members. Requests for full board review must be considered during a scheduled meeting of the IRB, with the PI and faculty sponsor (if applicable) in attendance. Please see Chart 2 on page 14 for a summary of the review process.

Continuations or modifications of previously approved projects are reviewed and approved by the IRB Chair. See section V for further information on continuations and modifications.

D. RESULTS FROM THE IRB REVIEW
The IRB has the authority to either approve, require modifications needed to secure approval, or disapprove research projects. It is anticipated that most protocols will be approved with only minor or no modifications. However, if a project is disapproved, you will be notified in writing and given reasons for the decision. PIs then have an opportunity to respond to the IRB in writing. Some projects approved by the IRB may be subject to further review by University administrators.

**CHART 2: SUMMARY OF THE REVIEW PROCESS**

**Determine Review Level:**
1. Complete the Checklist for Review Level on page 12.
2. If further assistance is needed to determine whether your project needs IRB review, or the appropriate review level, contact the IRB Chair.

**Prepare Protocol:**
1. Complete the Cover Page and Parts I and II (templates are available at [http://www.uwplatt.edu/committees/irbhsr/index.html](http://www.uwplatt.edu/committees/irbhsr/index.html))
2. Attach consent form and copies of materials.
3. Obtain department/program assurance.

**Expedited Review:**
1. E-mail the protocol to the IRB Chair, for review by at least two board members.
2. Results will be provided to the PI (or student’s sponsor) within 10 business days of submission.

**Full Board Review:**
1. E-mail the protocol to the IRB Chair, at least 10 business days prior to the meeting at which they will be reviewed.
2. The PI (and faculty sponsor, if applicable) must attend that meeting.
3. Results of the review will be provided to the PI (or faculty sponsor) within five business days of the IRB decision.

**Results:**
1. If approved, proceed with the project.
2. If modifications are requested, copies of the new materials (approved by the faculty sponsor, if applicable) should be re-submitted to the IRB Chair. Feedback will be provided as soon as reasonably possible.
3. If not approved, you may appeal to the IRB in writing.
SECTION V: REQUESTING A CONTINUATION, MODIFICATION OR TERMINATION OF A PROTOCOL

A. CONTINUATION
Approval of a protocol lasts for one year. If a research project will last longer than one year, then it is the responsibility of the principal investigator to file a request for continuation at least 10 days before the original approval expires. If the 10 day deadline is not met, a new protocol must be submitted that will cover the remainder of the project. Federal guidelines do not allow for any exceptions to this rule.

B. MODIFICATION
Occasionally a research project will need to be changed from what was submitted in the original protocol. If this happens, the principal investigator will need to inform the IRB Chair by filing a request for modification before the change is implemented. Copies of all instruments and consent forms that are changed will need to be included with the request.

C. TERMINATION
If a research project is terminated by the researchers before it is completed, the principal investigator needs to inform the IRB chair.

A single form located at http://www.uwplatt.edu/committees/irbhsr/files/RequestContinuation.pdf can be used to take care of all three of the above situations.

SECTION VI: USE OF INTENTIONALLY DECEPTIVE PRACTICES

Intentionally misleading or providing untruthful information to participants is not a desirable procedure. Intentional deception takes advantage of the participant’s willingness to participate and thus renders the unwary participant vulnerable to increased psychological or physical harm. 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, it will be necessary to provide a clear justification of the procedure to the reviewers as well as additional measures to protect participants.

Justification must address:

1. Alternative research methods that would not require the adoption of deceptive practices (e.g. role playing, gaming approaches, simulation strategies);

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 participant risk where deception is involved;

3. Additional steps taken to ensure participant safety. Steps must be taken, and clearly explained, to protect against harm to the participants; and
4. Disclosure of the deception to participants. Upon completion of participation, the deceptive practice must be disclosed to the participants and reasons for the deception provided.

It is necessary to ensure that participants have every opportunity 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 participants should be avoided.

SECTION VII: INFORMED CONSENT

Except as provided in Section C below, no investigator may involve a participant in research unless the investigator has obtained the legally effective informed consent of the participant or the participant’s legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective participant 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 participant or the representative shall be in language understandable to the participant or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the participant or the representative is made to waive or appear to waive any of the participant’s legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Signed consent forms should be kept by the PI for at least one year after completion of the study.

A. BASIC ELEMENTS OF INFORMED CONSENT
   Except as provided in C or D of this section, when seeking informed consent, the following information shall be provided to each participant:

   1. A statement that the study involves research, an explanation of the purpose(s) of the research, the expected duration of the participant’s involvement, a description of the procedures to be followed, and identification of any procedures which are experimental;

   2. A description of any reasonably foreseeable risks or discomforts to the participant;

   3. A description of any benefits to the participant or to others, which may reasonably be expected from the research;

   4. A disclosure of appropriate alternative procedures or courses of treatment and conduct, if any, which might be advantageous to the participant;

   5. A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained;

   6. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any health-related treatments are available if injury occurs, and if so, what they consist of, or where further information may be obtained;

   7. An explanation of whom to contact for answers to pertinent questions about the research and participants’ rights, and who to contact in the event of any research-related harm to the participant. At UW-Platteville, that statement should read:
“If you have concerns about how you were treated in this study, please contact: Barb Barnet, IRB Chair, (342-1942; barnetb@uwplatt.edu).”

8. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled to receive for participation up to the point of their withdrawal or termination from the research.

B. ADDITIONAL ELEMENTS OF INFORMED CONSENT
When appropriate, one or more of the following elements of information shall also be provided to each participant:

1. A statement that the particular treatment or procedure may involve risks to the participant (or to the embryo or fetus, if the participant is or may become pregnant), which are currently unforeseeable;

2. Anticipated circumstances under which the participant’s participation may be terminated by the investigator without regard to the participant’s consent;

3. Any additional costs to the participant that may result from participation in the research;

4. The consequences of a participant’s decision to withdraw from the research, and procedures for orderly termination of participation by the participant;

5. A statement that significant new findings developed during the course of the research which may relate to the participant’s willingness to continue participation; and

6. The approximate number of participants involved in the study.

C. EXCEPTIONS TO CONSENT REQUIREMENTS
The IRB may approve a consent procedure which does not include some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent, provided the researcher documents and the IRB finds that:

1. The research could not practicably be carried out without the waiver or alteration; and

   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:

   a. programs under the Social Security Act, or other public benefit or service programs;
   b. procedures for obtaining benefits or services under those programs;
   c. possible changes in or alternatives to those programs or procedures; or
   d. possible changes in methods or levels of payment for benefits or services under those programs.

OR

2. The research could not practicably be carried out without the waiver or alteration;

   The research involves no more than minimal risk to the participants;

   The waiver or alteration will not adversely affect the rights and welfare of the participants; and

   Whenever appropriate, the participants will be provided with additional pertinent information after participation.
D. DISCLAIMERS

1. 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.

2. Nothing in these regulations is intended to limit the authority of a health-care professional and facility to provide emergency medical care; to the extent the health-care professional and facility are permitted to do so under applicable federal, state, or local law.

E. DOCUMENTATION OF INFORMED CONSENT

Except as provided in 2 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 participant or the participant’s legally authorized representative.

If individually identifiable student grades, GPA, or other confidential/protected information provided by any source other than the respondent are part of your data set, then written/signed consent is required; to include this information without signed permission would be a violation of the FERPA regulations. (See sample consent forms #1 and #2 on pages 29-30) When signed consent is required, participants must be given a copy of the consent form for their records.

1. Except as provided in 2 of this section (below), the consent form may be either of the following:

   a. A written consent document that embodies the elements of informed consent required by the CFR. This form may be read to the participant or the participant’s legally authorized representative, but in any event, the investigator shall give either the participant or the representative adequate opportunity to read it before it is signed; or

   b. A “short form” written consent document stating that the elements of informed consent required by the CFR have been presented orally to the participant or the participant’s legally authorized 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 participant or the representative. Only the short form itself is to be signed by the participant 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 participant or the representative, in addition to a copy of the “short form.”

2. The IRB may waive the requirement for the investigator to obtain a signed consent form for some or all participants if it finds either:

   a. That the only record linking the participant and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Participants will be given a copy of the consent form if requested; or

   b. That the research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context.
In cases where the documentation requirement is waived, the IRB requires the investigator to provide participants with a written statement regarding the research. That form must identify the research and include the statement on page 17 regarding how to contact the IRB Chair.
Two IRB Review Protocol forms are available.

The Standard Form is appropriate for the majority of research projects. A sample cover page is provided on page 21 of this manual. Pages 22-24 provide detailed instructions on how to complete the protocol.

The Teaching Improvement Form is appropriate for many teaching improvement projects and was designed to simplify the IRB process for research which:

- Is conducted in established or commonly accepted educational settings;
- Involves normal educational practices, such as research on regular or special education instructional strategies or research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

A sample cover page is provided on page 25 of this manual. Pages 26-27 provide detailed instructions on how to complete the protocol.

Templates for the protocol forms are available at http://www.uwplatt.edu/committees/irbhsr/index.html. Your submission should be typed directly into the appropriate online form and then a signed original should be submitted to the IRB Chair. **All required signatures must be secured prior to submission.**
This protocol is to be submitted to and approved in writing by the IRB prior to the initiation of any investigation involving human participants, data, or material. Approval is valid for one year unless otherwise noted.

Indicate Status of Protocol:  □ Original Submission  □ Protocol Modification

Indicate Requested Review Level:  □ Expedited  □ Full Board

See Section III, pages 10-12, of the IRB Manual for instructions to determine the appropriate review level. Be aware that the IRB may require a level of review different from your request.

Principal Investigator(s)

Name(s):
Department/Program:
Rank/Title(s):
Email:
Phone #:

Sponsor(s) (if PI is a student)

Name(s):
Department/Program:
Rank/Title(s):
Email:
Phone #:

Project Title:
Start Date for Data Collection:  End Date for Data Collection:

Is federal or other extramural funding being sought?  □ Yes  □ No

Name of potential supporting agency:

Assurance of Departmental/Program Review:

If a departmental/program HSR exists, the signature of the HSR Chair assures the IRB that the protocol has been approved and a copy is on file in the department. If no HSR exists, the signature of the Department Chair assures the IRB that s/he has been informed of the project and a copy is on file in the department.

Signature/Date:  ___________________________  /  ______________________

Indicate Title:  □ HSR Chair  □ Department Chair

Assurance to IRB: I/we have read the UW-Platteville IRB Manual of Policies and Procedures for Research Involving Human Participants and will comply with the informed consent requirement and conditions. Further, I/we will inform the IRB if significant changes are made in the proposed study.

Signature of PI(s)/Date:  ___________________________  /  ______________________

Signature of Sponsor(s)/Date:  ___________________________  /  ______________________
Note: Your submission should be typed directly into the online Standard Form template and then e-mailed to the IRB Chair. All required signatures must be secured prior to submission.

PART I: DESCRIPTION OF STUDY

A. RESEARCH QUESTION

Provide a brief statement of the question(s) being asked and the supporting rationale. 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. Include appropriate citations. References for those citations must be provided in Section E, below.

B. HYPOTHESIS(ES)

Provide a clear statement of the research hypothesis(es) as related to the rationale and theory behind the study.

For example: “Higher levels of conformity will be observed for groups that have undergone a preliminary cohesion enhancement procedure than control groups with no systematic history of cohesion enhancement.”

C. PARTICIPANT SELECTION

1. Number of Participants:

2. Human participant pool:
   a. Describe relevant features of the participants you will be using (e.g., sex, race or ethnic group, age range/group, general state of mental and physical health).
   b. Note the relevant affiliations of your participants (e.g., institutions, hospitals, schools, clubs, and organizations).

3. If participants are children, mentally incompetent, or other legally restricted groups:
   a. Explain the necessity of using these particular groups of individuals as participants.
   b. Describe any special arrangements to protect their safety, rights, and well-being.

D. PROCEDURES

1. Describe recruitment procedures and any material inducements given for participation. Recruitment materials should be included for review, as those materials cannot be overly enticing to participants.

2. Note the location of the study. Be as specific as possible.

3. Describe all personnel, including name and affiliation with UW-Platteville (and other relevant affiliations).

4. Describe the information to be gathered and the means for collecting and recording data. If previously collected data are to be used, describe both the previous and proposed uses of those
data. Include citations for previously published materials/instruments (e.g., personality scales, questionnaires, evaluation blanks). References for those citations must be provided in Section E, below. Attach copies of all materials/instruments presented to the participants. The IRB must have an opportunity to review all materials that will go to participants.

5. Provide a step-by-step description of your procedure. Include everything participants will be asked to do in your study, what the PIs will do in conducting the research, and any follow-up procedures. Please include a description of any materials used in the study, which have not been described in section D.4 above.

6. Very concisely, describe the design of your study and the proposed statistical analysis.

E. REFERENCES

Include references for above citations.

PART II: HUMAN PARTICIPANT PROTECTION

A. POTENTIAL RISKS YOU CAN ANTICIPATE FOR PARTICIPANTS

1. Describe immediate risks, long-term risks, and 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 participants of unintentional data disclosure. If any breach of security or privacy measures were to occur, how would it affect your participants?

B. SAFEGUARDING PARTICIPANTS’ IDENTITY

1. What uses will be made of the information obtained from the participants? What elements of your project might be openly accessible to other agencies or appear in publications, internet resources, written documents, or any other type of public record?

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

C. EXPECTED BENEFITS FOR PARTICIPANTS (IF ANY) AND/OR SOCIETY

1. The IRB is required to ensure that the potential risks to participants (however minimal) are clearly justified by the potential benefits of the research both to the participants and to the current state of knowledge and information on the topic of research and investigation. 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 participants. Stating, “more research is needed on this topic” will be of little help. Please explain why more research will be a benefit.

2. The debriefing should provide a reasonable understanding of the project and its goals to the participant. Clarify when the debriefing will occur and what information will be provided.

D. DECEPTION USED IN GATHERING DATA
Justify and support the use of deception in the project, particularly if participants 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.

E. INFORMED CONSENT

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

Under very limited circumstances, the requirement for informed consent can be waived; however, these exceptions are rare and must be justified by the PI(s) and then approved by the IRB. If you are proposing to not secure informed consent (signed or unsigned), please refer to Section VII, page 16, of the IRB Manual and then provide sufficient justification within your protocol. Convenience of the investigator is never considered sufficient justification.
University of Wisconsin-Platteville
IRB HUMAN PARTICIPANTS RESEARCH REVIEW PROTOCOL: TEACHING IMPROVEMENT FORM

This protocol is to be submitted to and approved by the IRB prior to the initiation of any data collection. Approval is valid for one year unless otherwise noted.

Principal Investigator(s)

Name(s): Rank/Title(s):
Department/Program(s): Email:
Phone #:

Sponsor(s) (if PI is a student)

Name(s): Rank/Title(s):
Department/Program: Email:
Phone #:

Project Title:

Start Date for Data Collection: End Date for Data Collection:

Is federal or other extramural funding being sought? Yes No

Name of potential supporting agency:

Assurance of Departmental/Program Review:

If a departmental/program HSR exists, the signature of the HSR Chair assures the IRB that the protocol has been approved and a copy is on file in the department. If no HSR exists, the signature of the Department Chair assures the IRB that s/he has been informed of the project and a copy is on file in the department.

Signature/Date: ________________________________/__________________
Indicate Title: □ HSR Chair □ Department Chair

Assurance to IRB: I/we have read the UW-Platteville IRB Manual Policies and Procedures for Research Involving Human Participants and will comply with the informed consent requirement and conditions. Further, I/we will inform the IRB if significant changes are made in the proposed study.

Signature(s) of PI(s)/Date: ________________________________/__________________
Signature of Sponsor(s)/Date: ________________________________/__________________
Template for Teaching Improvement Projects

Note: Your submission should be typed directly into the online Teaching Improvement Form and then a signed original (plus two copies) should be submitted to the IRB Chair. All required signatures must be secured prior to submission.

This template was designed to be as efficient as possible. Many questions can be answered with a simple check of a box. However, in the online template, room for additional explanation is often provided. It is extremely important that you provide the requested attachments (e.g., surveys, appropriate class materials, consent forms), since we will be working from a very minimal description of your project.

A. PERSONNEL:

Identify any personnel involved in your project who were not already identified on the cover page. Also, indicate if and how they are affiliated with UW-Platteville (e.g., faculty member, graduate student). For those not affiliated with, indicate their relevant affiliations (e.g., Platteville Public Schools, UW-Extension).

B. RESEARCH QUESTION:

1. Describe your project and its overall goal(s). If a survey or questionnaire is used, please attach a copy. (Note: A concise step-by-step outline of your method provides a good overview of the project.)

2. What do you expect to find?

3. Where might you present or publish your findings? Will any formal papers or reports result from your project and with whom will they be shared? (Note: Indicating the nature of the forums to which you plan to submit is sufficient.)

C. PARTICIPANT SELECTION:

1. Number of participants:

2. Human participant pool: (Note: Federal regulations require higher levels of review for protected populations. Such groups include individuals who, for various reasons, cannot give informed consent. The following questions allow us to determine if you would be working with a protected group and if a more complete protocol will be needed.)

   a. Will all participants be members of the UW-PLATTEVILLE student body?  □ No  □ Yes
      If not, who will serve as your participants?

   b. Will all participants be at least 18 years of age?  □ No*  □ Yes

   c. Will any participants come from protected groups (e.g., fetuses or people who are minors, prisoners, developmentally disabled, or psychologically impaired)?  □ No  □ Yes*

D. PROTECTION OF THE RESPONDENTS AND THEIR RIGHTS:

1. If your participants are students and will be given course credit for participating, is there an alternative option for earning that credit?

   □ No  □ Yes  □ Not applicable
2. Is any of the information that you will be collecting of a confidential/protected nature (grades, GPA, medical information, etc)?
   - ☐ No  ☐ Yes

3. Would there be any negative effects for your participants (legal, financial, social, or personal) if the information contained in your data set or in your project files was somehow exposed to the public? (Note: If yes, describe that information in the space provided.)
   - ☐ No  ☐ Yes

4. How will the information be recorded and/or secured so as to protect the participants' identities?

5. Informed consent: (Note: Generally informed consent is required, as the autonomy of the respondent should always be protected. However, a signed consent form is often not required. The following questions help us determine what type of consent is needed for a given project.)
   a. If individually identifiable student grades, GPA, or other confidential/protected information provided by any source other than the respondent are part of your data set, then written/signed consent is required. Does your data set include student grades, GPA, or other confidential/protected information provided by any source other than the respondent?
      - ☐ No  ☐ Yes
      If yes to 5a, attach a copy of your written/signed consent form.
      (See Appendix B, pages 29-34 of the IRB Manual for sample consent forms.)
   b. If written/signed consent is not required, is informed consent still secured?  ☐ No  ☐ Yes
      If yes to 5b, attach a copy of your informational/unsigned consent form.
      (See Appendix B, pages 29-34 of the IRB Manual for sample consent forms.)
   c. Under very rare circumstances the requirement for informed consent can be waived. (Convenience of the investigator is never sufficient reason.) If you believe informed consent should be waived for your project, write a justification for your recommendation based on the Federal criteria given in Section VII, page 16, of this Manual. Realize that the IRB must agree with your recommendation before the requirement for informed consent is waived.

6. Are participants given any untruthful or misleading information?  ☐ No  ☐ Yes
   If yes to 6, at what point are the participants debriefed? Explain the inaccurate information which will be provided to the participants, and how the debriefing will correct the inaccurate information and explain why it was necessary.

7. Does the project present any more risk to participants than would normally be encountered in daily life or during the performance of routine physical or psychological examinations or tests?
   - ☐ No  ☐ Yes*

Notes: If you checked any of the response options marked with an asterisk (*), a standard protocol is automatically required for full board review. Further, depending on your responses to the preceding questions, it may be necessary for you to complete our standard protocol; we will contact you if that is necessary for your project.
APPENDIX B: SAMPLE CONSENT FORMS

Samples 1 and 2 are examples of signed consent forms, and Samples 3 and 4 are examples of unsigned consent forms. Sample 5 is an example of a parental consent form, while sample 6 is an example of a child assent form – these two should be both used in studies involving children. In all cases, participants should be given either a copy of the consent form or the written statement as described on page 18.
CONSENT FORM FOR PARTICIPATION OF HUMAN PARTICIPANTS IN RESEARCH
UNIVERSITY OF WISCONSIN - PLATTEVILLE

1. Purpose: The purpose of this study is to determine different predictors of academic performance.

2. Procedure: You will be given a questionnaire to fill out and return. Your cumulative grade point average and ACT score will be confidentially obtained by Dr. Jane Doe and assigned a code. The student researchers will at no time see your name attached to your ACT score or grade point average.

3. Time Required: Participation is expected to take approximately 30 minutes.

4. Risks: There will be no immediate risks to participants other than the time and effort required to participate in the study. No long term risks are foreseen.

Benefits: Understanding which factors better predict academic success is of value to universities, instructors, and students. For example, such information could help us better identify which students will need additional assistance during their college career.

5. Your rights as a participant: The information gathered in this study will be used in a confidential form. Data or summarized results will not be released in any way that could identify you. If you want to withdraw from the study at any time, you may do so without penalty or repercussions. The information collected from you up to that point would be destroyed if you so desire.

At the end of the study, participants will be given a debriefing detailing the exact purpose of the study. If you have any questions afterward, please ask your experimenter or contact:

Sue Student, Researcher
Dr. Jane Doe, Faculty Sponsor
Department of XXXX
University of Wisconsin-Platteville
(608) 342-XXXX

Once the study is completed, you may request a summary of the results by contacting the above researcher or faculty sponsor.

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

Barb Barnet
Chair, UW-Platteville IRB
(608) 342-1942
barnetb@uwplatt.edu

I have read the above information and willingly consent to participate in this experiment. In doing so, I am giving Dr. Jane Doe permission to obtain my cumulative ACT score and my GPA, and then to provide that information (coded by a confidential ID number) to the researchers.

Please print your full name (First, Middle, Last):

______________________________________________________________

Signature: ___________________________ Date: _________________
CONSENT FORM FOR PARTICIPATION OF HUMAN PARTICIPANTS IN RESEARCH
UNIVERSITY OF WISCONSIN - PLATTEVILLE

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 approx. 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.

   Benefits:
   Your participation in this study will provide you with a look at how psychologists answer questions about our memory functions. Understanding memory functions in normal individuals could help psychologists better assist those who have deficits in this area.

5. Your rights as a participant:
   The information gathered will be recorded in anonymous form. Data or summarized results will not be released in any way that could identify you. If you want to withdraw from the study at any time, you may do so without penalty or repercussions. The information collected from you up to that point would be destroyed if you so desire.

   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:

   Sue Student, Researcher
   Dr. Jane Doe, Faculty Sponsor
   Department of XXXX
   University of Wisconsin-Platteville
   (608) 342-XXXX

   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:

   Barb Barnet, Chair, UW-Platteville IRB
   (608) 342-1942
   barnetb@uwplatt.edu

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

Signed _______________________________ Date ___________________
CONSENT FORM FOR PARTICIPATION OF HUMAN PARTICIPANTS IN RESEARCH
UNIVERSITY OF WISCONSIN - PLATTEVILLE

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 approximately twenty-five minutes.

Once the study is completed, a summary of the results will be made available through the Psychology 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 at any point you decide that you do not want to complete the questionnaire, please return it and inform the administrator. Your course grade and evaluation will not be affected if you decide not to participate.

Your participation should present you with no risks, other than the time and effort involved in completing the materials. Further, you may benefit from your participation by learning about the research methods employed in the social sciences.

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 more space to express or explain an answer.

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

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

Barb Barnet, Chair, UW-Platteville IRB
(608) 342-1942
barnetb@uwplatt.edu

Again, PLEASE DO NOT PUT YOUR NAME ANYWHERE ON THIS SURVEY.

Thank You,
Sue Student, Researcher
Dr. Jane Doe, Faculty Sponsor
Department of XXXX
University of Wisconsin-Platteville
(608) 342-XXXX
CONSENT FORM FOR PARTICIPATION OF HUMAN PARTICIPANTS IN RESEARCH
UNIVERSITY OF WISCONSIN – PLATTEVILLE

PLEASE DO NOT PUT YOUR NAME ANYWHERE ON THE MATERIALS USED IN THIS PROJECT.
There is no need to identify yourself.

1. Purpose: The purpose of this experiment is to determine what factors influence the employment selection process.

2. Procedure: You will be shown a picture of a hypothetical applicant. We will then distribute that applicant’s resume and a questionnaire. Please complete the questionnaire to the best of your ability. After you have completed the questionnaire, please turn it face down, put your writing utensil down, and then wait for the debriefing.

3. Time Required: Participation is expected to take approximately 15 minutes.

4. Risks: There will be no immediate risks to participants other than the time and effort required to participate in the study. No long term risks are foreseen.

   Benefits: Your participation in this study will teach you about the research methods used in psychological studies. The knowledge gained from this study could, potentially, contribute to the development of better employment selection procedures.

5. Your rights as a participant: Your participation is completely voluntary. If you want to withdraw from the study at any time, you may do so without penalty or repercussions. The information collected from you up to that point would be destroyed if you so desire.

   The information gathered will be recorded in an anonymous form. Data or summarized results will not be released in any way that could identify you.

   At the end of the study, you have the right to a complete explanation (“debriefing”) of the study. If you have questions afterward, please ask your experimenter or contact:

   Sue Student, Researcher
   Dr. Jane Doe, Faculty Sponsor
   Department of XXXX
   University of Wisconsin-Platteville
   (608) 342-XXXX

   At the end of the semester, you may request a summary of the results by contacting the above researcher or faculty sponsor.

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

   Barb Barnet, Chair, UW-Platteville IRB
   (608) 342-1942
   barnetb@uwplatt.edu

Again, PLEASE DO NOT PUT YOUR NAME ANYWHERE ON THE PROJECT MATERIALS.
PARENT/GUARDIAN CONSENT FORM FOR PARTICIPATION OF HUMAN PARTICIPANTS IN RESEARCH
UNIVERSITY OF WISCONSIN-PLATTEVILLE & Name of Child’s School/Organization

1. **Purpose:** The purpose of this research is to determine the quality of teacher/student relationships at Name of Child’s School/Organization.

2. **Procedure:** Your child will be asked to complete a brief survey. PARTICIPATION IS VOLUNTARY AND HE/SHE WILL BE ASKED TO GIVE HIS/HER ASSENT. YOUR CHILD’S NAME WILL NOT BE RECORDED ON THE RESEARCH MATERIALS AND IT WILL NOT BE INCLUDED IN OUR DATA SET OR IN ANY REPORTS ABOUT THE PROJECT.

3. **Time Required:** Participation is expected to take approximately 10 minutes.

4. **Risks:** No short-term or long-term risks are foreseen. The only “cost” to the participants will be the time and effort required to participate in the study.

   **Benefits:** Understanding what factors better predict good relationships is of value to our school. For example, such information could help us know what we as faculty, staff, administration, or members of the UW-Platteville’s Teacher Education Program can do to relate better to our students.

5. **Your Rights as the Parent of a Student Participant:** The information gathered in this study will be confidential. Data or summarized results will not be released in any way that could identify you or your child. If your child would like to withdraw from the study at any time, he/she may do so without penalty or repercussions. The information collected from your child up to that point would be destroyed if you or he/she so desire.

   At the end of the study participants will be given a debriefing detailing the exact purpose of the research. If you have any questions afterward, please ask:

   
   Name of Researcher, Title of Researcher  
   Department of Researcher, University of Wisconsin-Platteville  
   Phone number of researcher  
   Email of researcher

   Once the study is completed, you may request a summary of the results by contacting the above researcher or Name of Onsite Supervisor/Administrator.

6. If you have any questions about your child’s treatment as a participant in this study, please call or write

   Barb Barnet  
   Chair of the UW-Platteville IRB  
   (608) 342-1942  
   barnetb@uwplatt.edu

   Name of Onsite Supervisor/Administrator  
   Title of Onsite Supervisor/Administrator  
   Phone of Onsite Supervisor/Administrator  
   Email of Onsite Supervisor/Administrator

---

I have read the above information and (check one):

___  DO give consent for my child to participate in the research.

___  DO NOT give consent for my child to participate in the research.

Please print your child’s name (First, Middle, Last): ____________________________________________

Please print your full name (First, Middle, Last): ____________________________________________

Signature: ____________________________________________  Date: ______________________

Then return this completed form to __________________________ by ______________________

(Sample #5, Parental Consent Form)
STUDENT ASSENT FORM FOR PARTICIPATION IN RESEARCH
UNIVERSITY OF WISCONSIN-PLATTEVILLE & Name of Child’s School/Organization

Dear Student,

We want to provide the best education possible to you and to future students. Therefore, we are conducting this research project. You are invited to participate in our survey on relationships.

The purpose of our survey is to explore what relationships are strong at NAME OF SCHOOL and how we can strengthen those relationships. You are being asked to participate in this survey because you, as a student at NAME OF SCHOOL, know what works for you.

Participation in this survey will have absolutely no impact on your grades. The information gathered in this survey will be used to help make NAME OF SCHOOL a better, more welcoming place for you and your classmates.

Your parents have already given permission for you to participate in our research project and we are hoping that you will agree to participate. Your voluntary completion of the survey constitutes your agreement/assent to participate.

Thank you for helping us to better help you.

Sincerely,
Name of Researcher, Title of Researcher Department of Researcher, University of Wisconsin-Platteville Phone number of researcher Email of researcher

Name of Onsite Supervisor/Administrator Title of Onsite Supervisor/Administrator Phone of Onsite Supervisor/Administrator Email of Onsite Supervisor/Administrator

If you have any questions about your treatment as a participant in this study, please call or write either of us or contact:

Barb Barnet
Chair of the UW-Platteville IRB
(608) 342-1942
barnetb@uwplatt.edu
1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
   (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
   (b) Research on medical devices for which
      (i) an investigational device exemption application (21 CFR Part 812) is not required; or
      (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
   (a) from healthy, non-pregnant adults who weigh at least 110 pounds. For these participants, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
   (b) from other adults and children, considering the age, weight, and health of the participants, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these participants, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8-week period and collection may not occur more frequently than 2 times per week.

3. Prospective collection of biological specimens for research purposes by noninvasive means.
   (Examples: hair and nail clippings in a non-disfiguring manner; permanent teeth if routine patient care indicates a need for extraction)

4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis).

6. Continuing review of research previously approved by the convened IRB as follows:
   (a) where
      (i) the research is permanently closed to the enrollment of new participants;
      (ii) all participants have completed all research-related interventions; and
      (iii) the research remains active only for long-term follow-up of participants; or
   (b) where no participants have been enrolled and no additional risks have been identified; or
   (c) where the remaining research activities are limited to data analysis.

APPENDIX C: ADDITIONAL EXAMPLES OF RESEARCH ACTIVITIES ELIGIBLE FOR EXPEDITED REVIEW
Belmont Report: Approved by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, on April 18, 1979. The principles in this report continue to form the basis of current federal regulations. For a complete text of the Belmont Report, see http://ohsr.od.nih.gov/guidelines/belmont.html.


Common Rule: Used to refer to the Federal Policy for the Protection of Human Subjects, 45 CFR 46, Subpart A. Its basic policy has been endorsed by at least 15 different federal agencies. See http://ori.hhs.gov/education/products/ucla/chapter2/page04b.htm.

Exempt review level: Does not mean exempted from IRB review but rather from some specific federal regulations; UW-Platteville does not have an exempted review level, as all IRB protocols are reviewed at the expedited or full board review level.

Expedited review level: Research involves no more than minimal risk, does not include intentional deception, does not employ sensitive populations or topics and includes appropriate informed consent procedures.

Federalwide Assurance: The Federalwide Assurance (FWA) is the only type of new assurance of compliance accepted and approved by OHRP for institutions engaged in non-exempt human subjects research conducted or supported by HHS. Under an FWA, an institution commits to HHS that it will comply with the requirements set forth in 45 CFR part 46, as well as the Terms of Assurance. See http://www.hhs.gov/ohrp/humansubjects/assurance/filasurt.htm.

Formal presentation: See generalizable knowledge. Formal presentations do not include presentations given in class or to UW-Platteville departments/committees. Examples of formal presentations include: 1) Presentations at conferences, 2) Community presentations (e.g. Lions Club, etc.), and 3) On-campus presentations to the UW-Platteville community at large (e.g. Research/Poster Day, faculty forums, etc.).

Full-board review level: Research where one of the following are true: 1) level of risk is determined to be greater than minimal, 2) involve the intentional deception of participants, such that misleading or untruthful information has been provided, 3) involves sensitive or protected populations or 4) identification of the participants and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the participants’ financial standing, employability, insurability, reputation or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

Generalizable knowledge: Made public through formal presentation or publication in paper or electronic format. In the Belmont Report, it is referred to as knowledge “expressed in theories, principles, and statements of relationships” that can be widely applied to the public.

Human participants: Also known as “human subjects.” As defined in the Code of Federal Regulations, means a living individual about whom an investigator—whether professional or student—conducting research obtains: (1) Data through intervention or interaction with the individual; or (2) Identifiable private information. See [http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.102](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.102).

HSR committee: Human Subjects Review committee for a department/program

Informed consent: Agreement by a participant to take part in research after being informed of and having understood the risks involved.

Intentional deception: Involves providing misleading or untruthful information. Not revealing one’s hypothesis, and/or not revealing the activities in which other participants will engage, do not constitute intentional deception.


Minimal risk: 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 examinations or tests. See [http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.102](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.102).


PI: Principal Investigator; the individual(s) conducting the research project

Protected populations: Populations that are at risk of exploitation including minors, prisoners, fetuses, mentally retarded, mentally disabled, test participants for new drugs or clinical devices, pregnant women or legally incompetent persons. See sensitive populations.

Protocol: The form submitted to the IRB for review of research involving human participants

Research: A systematic investigation, including development, testing and evaluation, designed to develop or contribute to generalizable knowledge; in-house surveys designed and used solely for program improvement and future planning, do not qualify as research. See [http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.102](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.102).

Sensitive populations: Populations that are at risk of exploitation including minors, prisoners, fetuses, mentally retarded, mentally disabled, test participants for new drugs or clinical devices, pregnant women or legally incompetent persons. See protected populations.

Sponsor: Faculty member responsible for research being conducted by undergraduate or graduate students

Systematic: Carried out in a methodical and organized manner

Voluntary: The participant has the right to refuse to participate

Vulnerable populations: Populations that are at risk of exploitation including minors, prisoners, fetuses, mentally retarded, mentally disabled, test participants for new drugs or clinical devices, pregnant women or legally incompetent persons. See protected populations.