University of Wisconsin-Stevens Point
Institutional Review Board – Human Subjects Research Protocol Application

Application Directions

- *This protocol must be approved prior to conducting research.*
- *Complete the applicable sections of the form and include all necessary appendices. (Review Protocol Submission Checklist below.)*
- *All research personnel must complete the appropriate CITI training on Human Subjects Research and submit certificates with this protocol. For further guidance on CITI courses related to IRB, visit IRB Training.*
- ***Submit the application and appendices, with signatures, via the submission portal link found on the IRB website.***
- *If you are uncertain if your project requires IRB review, or if you have a class project and are uncertain if IRB review is required, please contact irb@uwsp.edu*

The IRB will examine the information provided in the application documents to determine whether an approval can be granted, and under what conditions. If the IRB cannot determine the status based on the information provided, the application will be returned to the investigator with a request for additional information. The IRB may request revisions to protocol documents to secure approval. Investigators will be notified in writing of the IRB determination.

*Please allow up to two (2) weeks to initially review an application. Protocols which require Full Board Review are reviewed at monthly committee meetings and may take longer to review than exempt or expedited protocols. Protocols requiring Full Board Review must be submitted to the IRB **no later than 1 week prior** to the committee meeting. Committee meetings are scheduled prior to the start of each semester, and are posted on the IRB Committee page.*

Protocol Submission Checklist

Required:

- ☐ Submit application and appendices, with signatures, electronically via the submission portal link found on the IRB website.
- ☐ CITI Training Certificates
- ☐ Survey Instruments or other data collection systems
- ☐ Outlines for Interviews
- ☐ Informed Consent Documentation
- ☐ Other:

Optional:

- ☐ Abstract of the proposed project
- ☐ Demographic Forms, if demographic information will be collected
- ☐ Debriefing Statement (deception only)
- ☐ Letter(s) of approval from an authorized official if collecting data on sites outside of UWSP
- ☐ Other:

Cover Sheet

Project Title:
Funding Source:
Is this an externally funded project? ☐ Yes ☐ No

Principal Investigator Name:
Department:
Email: Phone:

Is there a Co-Principal Investigator? ☐ Yes ☐ No
Name(s) of Co-Principal Investigator(s):
Department(s):
Email(s): Phone(s):

Project Type:
☐ Research
☐ Student Research Project: ☐ Field Study ☐ Thesis ☐ Dissertation ☐ Honors
Student Name(s):
☐ Class Project
Name of Class:
Name of Student(s): A class roster may be attached
Project Title:
☐ Other (If collaborating with another institution, contact the IRB for assistance early in the process to determine which IRB(s) will be the record holder):

Individual Research Roles in Project:

Please include PI, Co-PI(s), and all research personnel who will work on the project.
For status, please indicate if the individual is faculty, academic staff, undergraduate student, graduate student, doctoral student, or volunteer.
Indicate each person's role in the project using the following number *key: 1) research design, 2) recruitment, 3) informed consent, 4) data collection, 5) data analysis, 6) Other (indicate role).

Name	Institution/Affiliation	Status	Role in Project (see above)	Email
		Select one		
		Select one		
		Select one		
		Select one		
		Select one		

If more space is needed, please attach additional names and their signatures as an appendix with this application submission.

Principal Investigator Certification:

By signing this form, the **I, the Principal Investigator,** certifies that:

1. the information provided in this application is correct
2. I have read and understand UW Stevens Point policies regarding protection of human participants in research;
3. I have completed and submitted HIPAA training documentation if working with private health information (PHI) under a covered entity and has HIPAA authorization if applicable
4. I will not begin research (including recruitment of research participants) until notification of approval is received
5. I take responsibility for the research design, and will make best efforts to ensure all personnel engaged in the research are compliant with the requirements of the UW Stevens Point IRB;
6. **For ALL student projects, students have thoroughly reviewed the application, received training and guidance in research design, provided signatory testimony that the application exhibits clarity and completeness. Adequate supervision from the PI will be provided to students conducting research.**
   6.1. Doctoral committees must approve student's research proposals prior to IRB submission.
7. I will be available to answer questions from the IRB regarding the application and am willing to attend convened IRB meetings to answer questions about the application, if requested to do so;
8. I will report in writing any significant new findings which develop during the course of the study which may affect the risks and benefits to participation
9. I will seek approval from the IRB in advance of implementation of any changes (*IRB Protocol Modification Form*);
10. I will immediately inform the IRB of any adverse events, unanticipated problems or other negative consequences incurred by participants in this research (*IRB Forms-Unanticipated Problem or Event Report Form*);
11. I agree to update the IRB on the status of the research at least annually for non-exempt projects as required by federal regulations (*IRB Continuing Review Form*)

Please use Adobe Digital Signature below, DocuSign, or ink signature when application is complete. Note Adobe E-Sign will lock the fillable boxes from further additions and edits.

PI Signature:_____ Date: _____

Print Name:

Date: _____

Co-PI Signature:_____

Print Name:

Date: _____

Student Signature*:_____

Print Name:

**if applicable*

If more space is needed (ex. multiple students), please attach additional names and their signatures as an appendix with this application submission.

Part 1: Project Description

1. What is the purpose of the research?

    a. What question(s) do you hope to answer?

    b. How will the results of the study be disseminated?
    NOTE: *Projects lacking valid research questions and method are not approvable. Ethical and regulatory standards do not permit investigators to expose participants to research risks when the work lacks scientific merit.*

2. Briefly describe research that has already been done in this area.

    a. How will your study contribute to the knowledge of this topic?

    b. Please cite one or two scholarly references where appropriate.

3. Describe your data collection method. (Example: observations, survey, experimental manipulation, psychological test, interview, etc.) If you are using published surveys or instruments, name them. Copies of all instruments must be attached as an appendix to this application, and links provided. If you are requesting to analyze existing human subjects data only, please complete an IRB Existing Human Subjects Data Application Form.

4. Explain why you have selected this particular data collection method.

5. Will the research be conducted at a location/site other than UW Stevens Point? ☐ Yes ☐ No
   If yes, please attach a signed letter of administrative approval/permission from an authorizing individual at the off-site location as an appendix
   a. Describe the location in which the research will be conducted.

   b. What is your relationship to the site(s)? (Example: place of employment, campus/class where you are instructor or student)

Continue to Part 2 on the next page

Part 2: Participants

1. Do participants belong to a vulnerable population requiring special protections? Check all that apply:
   - ☐ No/Not Applicable
   - ☐ Human Fetuses/Neonates
   - ☐ Minors
   - ☐ Prisoners
   - ☐ Pregnant Women
   - ☐ Non-English Speaking
   - ☐ Other (Ex: Cognitively Impaired, Diminished Capacity, Institutionalized, Economically/Educationally Disadvantaged)

2. Briefly describe your participant pool in terms of
   a. Sex, race or ethnic group, age range, etc:

   b. Affiliation of participants (ex: institutions, hospitals, general public, etc):

   c. Participants general state of mental and physical health:

   d. Number of participants or sample size:

3. Explain why you have chosen this particular group to study. *Justification is especially important for special groups.*

4. What is your relationship to the participants? (Ex: Classroom instructor, nurse in a clinic, etc)

5. If there is an authority relationship between you and the participants, describe the measures you will take to ensure that participation is voluntary.

6. Will participants be recruited? ☐ Yes ☐ No
   If not, please explain. (Recruitment may not be involved in some types of record review and/or research.)

7. Identify the people who will approach potential participants. If these people have dual or authority relationship with potential participants, please describe. (Ex: caregiver, teacher, employer, service provider, etc)

8. Describe the process that will be used to approach participants. If the approach will be verbal, provide a script; if by advertisement, letter, poster, or email please provide a copy as an appendix.

9. If you will exclude certain classes of individuals from your recruitment, describe and justify the criteria for exclusion. Describe the method you will use to identify and exclude those individuals from the study.

Continue to Part 3 on the next page

Part 3: Procedures

1. Describe the setting in which the participants' involvement will take place.

    a. Where will they be?

    b. Will they be alone or in a group?

    c. Will there be any specific conditions such as darkness, specific background noises or music?

2. Describe the instructions that will be given to participants about the procedures. (Hold consent for later section)

3. What will they do or what will be done to them?

4. Will you be administering the procedure, or will someone else? If so, describe how they will be involved.

5. How long will the procedure take?

    a. How many times will the procedure be done and over what time span?

6. Will participants experience any discomfort (physical or mental)? ☐ Yes ☐ No
   If yes, please explain:

Continue to Part 4 on the next page

Part 4: Deception

NOTE: *Deception is defined as the deliberate attempt to fabricate and/or manipulate in any way, factual and/or emotional information. The use of deception is common in studies that evaluate fundamental aspects of human behavior. Because the use of deception in experimental procedures requires a modification of the required informed consent, the use of such procedures may trigger the requirement for Full Board IRB review. Student researchers are discouraged from employing deception in their experimental procedures except with specific training in those techniques under close faculty supervision.*

1. Will deception be used in your experimental procedures? ☐ Yes ☐ No
   If No, skip to Part 5: Risk/Benefit Analysis
   If Yes, answer the following question and attach a copy of the study Debriefing Form as an appendix.

   a. Explain why deception is necessary to conduct this study.

   b. Describe how you will debrief participants, and procedures you will follow if a participant decides to withdraw their consent.

Continue to Part 5 on the next page

Part 5: Benefit/Risk Analysis

NOTE: *Research that lacks benefit is not approvable. Ethical and regulatory standards require that the benefits of research outweigh the risks, which is impossible if there are no benefits. All researchers are expected to carefully consider the benefits and risks to participants in designing their study. Participants should be asked to assume no more risk than what is absolutely necessary to accomplish the research objective. For projects in which risks exceed the regulatory definition of minimal risk, researchers are expected to take all possible measure to minimize risks and/or minimize the consequences of such risks.*

Benefits

1. Will the participants benefit from being part of your study? If yes, explain.

2. What are the benefits to knowledge or society at-large that will accrue as a result of this research?

3. Are there other benefits? Describe.

4. Will you offer incentives, reimbursement costs, or other compensation to participants? ***NOTE:*** *Prizes, awards and gifts must follow UW System Policy. UW Stevens Point adheres to an additional policy as it relates to payments to research participants and is available on the IRB website.* ☐ Yes ☐ No
   If yes, answer the following:
   a. What will you offer as incentive, reimbursement, or compensation?

   b. What conditions must a participant meet to receive these benefits?

   c. Justify this benefit as necessary to the research, adequate to meet your research purposes, and explain why it will not contribute to perceived or actual coercion of participants.

Risks

NOTE: *Risks most commonly encountered in research may be physical, social, psychological, legal, or risks to employment or economic well-being. All risks must be fully disclosed to participants, even if they are no greater than minimal risks. 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*

5. Describe all risks, perceived and actual, that participants might encounter during this study. (A response of N/A is not acceptable for this answer.)

6. Do you believe those risks to be no greater than minimal? If so, explain why.

7. If risks are greater than minimal, describe the following:
   a. What have you done to minimize risks to the extent possible without compromising your research objectives?

   b. What protections have you put in place to minimize the consequences of risks if they were to be realized?

   c. What procedures have you established for reporting adverse events, if they occur?

   d. Explain why these risks are essential to conduct your study.

Continue to Part 6 on the next page

Part 6: Confidentiality/Anonymity

NOTE: *In much social/behavioral research, the primary risk to participants is breach of confidentiality. Risks to reputation, financial well-being, or social standing can be minimized with appropriate protections for privacy and confidentiality of data.*

When possible, complete ***anonymity*** *(participants identity is unknown to researcher and the researcher does not have any codes to the data that could potentially re-identify participants) is the most desirable protection against such risks. Preserving anonymity may be used as a justification for requesting a waiver of documented consent for minimal risk research. When anonymity is not possible (researcher may know the identity of participants or the data contains identifiable information), data shall be kept confidential.* ***Confidentiality*** *refers to how the subject's identifiable data will be handled, managed, stored, and, if applicable, disseminated. The researcher is responsible for safeguarding the identities, responses, and other private information of all research participants. For example, to protect confidentiality, codes may be assigned to participants and the researcher keeps the codes and the master list and/or signed consent forms separate from the data and results, and all results are shared in aggregate or group form. The safeguards used to protect confidentiality should be disclosed in the informed consent process, as they may impact a prospective participant's willingness to engage in the research.*

1. Will the data collected in your research be anonymous?
   ☐ **Yes, the data collected will be anonymous.**
   a. Explain how you will create and preserve anonymity of data. Attach an information sheet or script that will be presented to participants as an appendix.

   b. Where will the data be stored?

   c. How will the data be access, after collection and during analysis?

   ☐ **No, the data collected will not be anonymous.**
   a. What information collected can be linked to participants, either directly or indirectly?
      ☐ Name ☐ Personal ID number ☐ Birth Date ☐ Phone Number ☐ Email ☐ Address
      ☐ Photographs ☐ Audio/Video ☐ IP or MAC Address ☐ PHI
      ☐ Other:

   b. Explain the procedures and safeguards you will use to protect the confidentiality of your data:
      1. During the data collection process,

2. While results are being analyzed,

3. In publication or other reporting of results,

4. In storage after research is complete and results are reported.

c. At each phase of the project, explain who will have access to the data and whether that access will be with or without identifiable information:
   1. During the data collection process,

   2. While results are being analyzed,

   3. In publication or other reporting of results,

   4. In storage after research is complete and results are reported

d. Where will raw data, transcripts, consent forms and other materials that may contain identifiers be stored upon completion of the project? *(**NOTE:** all materials must be retained and available for inspection by the faculty advisor [if student research], the IRB, and/or an IRB audit for a minimum of seven years following completion and closure of the research project. The research project must maintain IRB approval status during data analysis if data has identifiers.)*

e. How will data be accessed, after collection and during analysis?

Continue to Part 7 on the next page

Part 7: Consent

NOTE: *Legally effective, voluntary, and prospectively obtained informed consent is required from all research participants or their legal representative. Consent to participate in research is a process. The informed consent process involves three key features: (1) disclosing information needed to make an informed decision to potential research subjects; (2) facilitating the understanding of what has been disclosed; and (3) promoting the voluntariness of the decision about whether or not to participate in the research. The circumstances under which consent is sought must allow the prospective participant or their representative (in the case of minors or others legally incapacitated) sufficient opportunity to consider whether or not to participate, including an opportunity to seek explanations and have questions answered. A signature on a consent form does not necessarily mean that full consent has been obtained. A signed consent form constitutes documentation of consent, not consent per se. In some circumstances, the IRB may waive or modify the requirement for documentation of informed consent.*

1. Describe how you will obtain informed consent from your participants. Consent must be obtained in a setting that minimizes the possibility of real or perceived coercion or undue influence.

    a. In what setting?

    b. Who will be present?

    c. What information will be provided and by whom?

    d. Will there be an opportunity for questions to be asked and answered?

2. Describe the precautions you have taken to ensure that consent is freely and voluntarily obtained.

3. Do you wish to request a **waiver of documentation of informed consent**? (Select Yes if you do not wish to obtain participant signatures but will provide participants information about the study which contains all required elements of consent.) 45 CFR 46.117(f)

☐ Yes (answer questions on next page and attach information sheet or script that will be presented to participants)

☐ No (skip to Question 4)

Provide justification as to how the research meets at least one of the appropriate regulatory categories below, check all that apply:

☐ The only record linking the participant and research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality:

☐ The research presents no more than minimal risk to the participant and does not involve procedures for which written consent is normally required outside the research context:

☐ Participants are members of a distinct cultural group or community in which signing forms is not the norm, the research presents no more than minimal risk of harm, and an alternative mechanism for documenting consent is available:

☐ Please provide participants with a statement regarding the research and attach with application submission:

4. Do you wish to request a Waiver or Alteration of the Informed Consent Process? 45 CFR 46.116(f)(3)

☐ **No (move on to Question 5)**

☐ **Waiver of Informed Consent Process (waive entire consent process)**

☐ **Alteration of Informed Consent Process (withhold some required elements of consent)**

Provide Justification as to how the research meets all four of the appropriate regulatory categories below:

a. The research involves no more than minimal risk to all subjects

b. The waiver will not adversely affect the rights and welfare of the subjects

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

i. If the research involves using identifiable private information or identifiable biospecimens, and the research could not practicably be carried out without using such information or biospecimens in an identifiable format:

d. When appropriate, the subjects will be provided with additional pertinent information after participation

5. Attach the following forms with submission, if applicable, as an appendix. Check all that apply. Samples can be found on the IRB website
   - ☐ Consent form that will be used to document the informed consent for participants
   - ☐ For participants younger than 18 years old, please attach parental consent and minor assent form (*School district personnel cannot give permission or consent on behalf of minor children.*)
   - ☐ Information sheet that will be provided in writing or verbally if a waiver of documentation of consent is requested
   - ☐ Debriefing script or other pertinent information that will be provided to subjects, if applicable.

NOTE: *Informed consent must not include any exculpatory language by which the participant or their representative is made to waive, or appear to waive, any of the subject's legal rights. Informed consent must also not release, or appear to release, the investigator, the sponsor, the institution, or its agents from liability for negligence. The IRB will review your consent scripts, documents, and procedures to ensure that this is the case. Example Informed Consent Documents are available online.*

NOTE: *Projects employing deception (and therefore requiring approval or a modified consent process) must address the specific requirements outlined in Part 4 above.*

ATTACH AND LABEL ALL ABSTRACTS AND APPENDICES WITH APPLICATION SUBMISSION.