***Application Directions***

* *This form is to be used when individually identifiable data (containing direct or indirect identifiers) about human subjects will be obtained by the investigator for secondary analysis. The data must be in existence at the time the research is proposed. Data may be in the form of existing data sets, interview notes, medical records, or audio/video recordings.*
* *Note: Existing data sets without individually identifiable data may not require IRB review.*
* *This protocol must be approved prior to conducting research.*
* *Complete the applicable sections of the form and include all necessary appendices. A checklist can be found at the back of the application.*
* *All research personnel must complete the appropriate* [*CITI*](http://www.citiprogram.org) *training on Human Subjects Research and submit certificates with this protocol.*
* *Submit the application and appendices, with signatures, electronically to* [*irb@uwsp.edu*](mailto:irb@uwsp.edu)*.*
  + *Signature page can also be mailed to ORSP Old Main 208.*

*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 website*](https://www3.uwsp.edu/acadaff/orsp/irb/Pages/default.aspx)*.*

**Cover Sheet**

Project Title:

Funding Source:

Is this an externally funded project?  Yes  No \*If yes, be sure you have completed the [Transmittal Form and Compliance Worksheet](https://www3.uwsp.edu/acadaff/orsp/Pages/submission-of-grants.aspx).

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):

\*\*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 the ORSP office.

**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). Please attach an appendix if additional room is needed.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Name** | **Institution/Affiliation** | **Status** | **Role in Project** | **Email** |
|  |  |  |  |  |
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**Principal Investigator Certification:**

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

1. the information provided in this application is correct
2. s/he has read and understands UW Stevens Point policies regarding the protection of human participants in research;
3. s/he has completed and submitted HIPAA training documentation if working with private health information (PHI) under a covered entity and has HIPAA authorization if applicable
4. s/he will not begin research (including recruitment of research participants) until formal notification of IRB approval is received
5. s/he takes responsibility for the research design, and will make best efforts to ensure all personnel engaged in the research are in compliance with the requirements of the UW Stevens Point IRB;
6. for student projects, s/he has thoroughly reviewed the application, has provided training and guidance in research design, and is providing signatory testimony that the application exhibits clarity and completeness. Adequate supervision will be provided to students conducting research.
7. s/he agrees to be available to answer questions from the IRB regarding the application and is willing to attend fully-convened meetings of the IRB to answer questions about the application, if requested to do so;
8. s/he 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. s/he will seek approval from the IRB in advance of implementation of any changes (*Modification Request Form*);
10. s/he will immediately inform the IRB of any adverse events, unanticipated problems or other negative consequences incurred by participants in this research (*Adverse Event Form or Unanticipated Problem Form*);
11. s/he agrees 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*)

PI Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_

Print Name:

Co-PI Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_

Print Name:

Student Signature\*: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_

Print Name:

\**if applicable*

**Part 1: Project Description**

1. What is the purpose of the research? What question(s) do you hope to answer?

***NOTE:*** *Projects lacking a 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.*

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

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

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

1. Describe the process of obtaining the existing data (including the source, participant population and purpose for which they were originally collected). If data are from a previous research study, please attach a copy of the original consent form as an appendix.

1. Describe the method or list of variables that will be extracted from the records. Provide copy as appendix if applicable.

1. Is the existing data set publicly available?  Yes  No
2. Will you have access to private health information (PHI) from a covered entity?  Yes  No
3. Will you have access to private identifiable information or a key to identifying the information?  Yes  No
4. Will information be recorded WITHOUT identifier or linkage codes?  Yes  No
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. If a written agreement with the Data Supplier is required by the supplier, please provide a copy of the data use agreement.*

1. Describe the location in which the research will be conducted.

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

**Part 2: 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.*

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

1. Are their other benefits? Describe.

1. Describe all risks, perceived or actual, that might occur during this study. (Note: A response of “not applicable” is not an acceptable answer.)

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

**Part 3: 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.*

1. Will the data be recorded in a manner that subjects cannot be identified, directly or through linked identifiers? (i.e. medical chart review-no identifiers are recorded in research records)

Yes No If yes, explain:

1. If identifiers will be recorded or kept in your research records, what information can be linked to specific individuals either directly or indirectly?

Name  Personal ID number  Birth Date  Phone Number  Email  Address

Photographs  Audio/Video  IP or MAC Address  PHI  Other:

* 1. Explain the procedures and safeguards you will use to protect the confidentiality of your data:

1. During the data collection process,

1. While results are being analyzed,

1. In publication or other reporting of results,

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

1. 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:
2. During the data collection process,

1. While results are being analyzed,

1. In publication or other reporting of results,

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

1. 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.)*

**Part 4: Consent**

***NOTE:*** *Researchers using data previously collected under another study should consider whether the currently proposed research is a “compatible use” with what subjects agreed to in the original consent form. For non-exempt studies, a consent process description or justification for a waiver must be included in the research protocol. The IRB may require that informed consent for secondary analysis be obtained from subjects whose data will be accessed. Alternatively, the IRB can consider a request for a waiver of one or more elements of informed consent under 45 CFR 46.116(f).*

1. Was informed consent documented for the original use of the data?  Yes No

If Yes, did participants agree to have their data used for further research studies?  Yes No

1. Will informed consent be documented for secondary use of data?  Yes No

If Yes, please describe how you will obtain informed consent from your participants: In what setting? Who will be present? What information will be provided? By whom? Will there be an opportunity for questions to be asked and answered? Consent must be obtained in a setting that minimizes the possibility of real or perceived coercion or undue influence.

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

1. 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)](https://www.ecfr.gov/cgi-bin/text-idx?m=12&d=31&y=2018&cd=20181220&submit=GO&SID=83cd09e1c0f5c6937cd9d7513160fc3f&node=pt45.1.46&pd=20180719#se45.1.46_1117)

Yes (answer below questions 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:

1. 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:

1. 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:

1. 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:

1. Please provide participants with a statement regarding the research and attach here:

1. Do you wish to request a **Waiver or Alteration of the Informed Consent Process**? [45 CFR 46.116(d)](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.116)

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

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

**No** (skip to question 4)

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

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

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

1. The research could not practicably be carried out without the waiver

1. 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:
2. When appropriate, the subjects will be provided with additional pertinent information after participation

1. Attach the following forms, if applicable, as an appendix. Examples can be found on the [IRB website](https://www3.uwsp.edu/acadaff/orsp/irb/Pages/default.aspx).

* 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 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.*

**Protocol Submission Checklist**

Submit application and appendices, with signatures, electronically to [irb@uwsp.edu](mailto:irb@uwsp.edu).

* + Signature page can also be mailed to ORSP Old Main 208.

CITI Training Certificates

Abstract of the proposed project (optional)

Chart of data to be collected

Informed consent document(s) if applicable (Note: If participants are minors, an Assent Document may be required in addition to Parental Consent.)

Letters of approval from an authorizing if collecting data on sites outside of UWSP

Other:

**INSERT AND LABEL ALL ABSTRACTS AND APPENDICES ON THE FOLLOWING PAGES**