***Application Directions***

*This form was created to assist UWSP Campus in determining whether quality improvement, quality assessment or student learning projects meet the definition of human subjects research as defined by the Department of Health and Human Services. Review SOP 1: Determination of Human Subjects Research, complete the form below and submit to the link provided on the* [*IRB website*](https://www3.uwsp.edu/acadaff/orsp/Pages/What-is-IRB.aspx)*. IRB will determine if your project will require submission of an IRB Protocol Application.*

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 this a student project?  Yes  No

If Yes, a faculty or staff member must be listed as the Principal Investigator, and is responsible for signing this document and oversight of the project.

Doctoral Student

Graduate Student

Undergraduate Student

**Part 1: Project Description**

Provide an abstract of the project. Describe the reasons for conducting the proposed project; describe the proposed activities of the project; provide a brief description of the project including objectives.

Provide the name of the organization or agency and location in which the project will be conducted. Attach a letter of authorization to conduct activities that will occur outside of UW-Stevens Point.

Provide contact information for the organization or entity, if applicable.

**Part 2: Determination of Research**

Note: The following four activities are determined to not meet the definition of research, per 45 CFR 46.102, do not require IRB review and oversight:

1. Scholarly or journalistic activities
2. Public health surveillance activities
3. Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes
4. Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions
5. Do the proposed activities involve a systematic investigation? *A systematic investigation involves a predetermined method or plan for studying a specific topic, answering a specific question, testing a specific hypothesis, or developing theory. It incorporates collection of data and/or specimens. To be considered a systematic investigation, the research concept must meet all of the following:*

* *Attempt to answer research questions*
* *Is methodologically driven; collects data or information in an organized and consistent way*
* *Data or information is analyzed, either qualitatively or quantitatively*
* *Conclusions are drawn from the results*

YES  NO

If NO, please explain why the proposed activities do not involve a systematic approach:

1. Is the primary intent of the proposed activities to develop or contribute to generalizable knowledge? *Is the primary intent of the project to generalize results outside UWSP, organization, or agency to inform the field of study AND has the project been designed so that the findings will be generalizable (i.e. randomization of subjects, comparison of cases vs. control groups)? Generalizable knowledge includes one or more of the following statements:*

* *Knowledge contributes to a theoretical framework of an established body of knowledge*
* *Primary beneficiaries of the research are other researchers, scholars and practitioners in the field of study*
* *Publication, presentation or other distribution of results is intended to inform the field of study*
* *Results are expected to be generalized to a larger population beyond the site of data collection or population specified*
* *Results are intended to be replicated in other settings*

☐ YES ☐ NO

If NO, please explain the intent of the proposed activities and explain how they are not intended to contribute to generalizable knowledge:

*For IRB Use: If Yes to 1 and 2, the activities constitute research.*

**Part 3: Determination of Human Subjects**

1. Does the activity involve obtaining information about living individuals through intervention or interaction? *Intervention includes both physical procedures information is gathered and manipulations of the subject(s’) environment that are performed for research purposes. Interaction includes communication or interpersonal contact between the investigator and subject. NOTE: If you are asking questions about a program, product or policy and NO questions specifically about an individual, answer NO.*

☐ YES ☐ NO

1. Will the activity involve obtaining private identifiable information about living individuals? *View the IRB Identifiers Chart to determine what qualifies as protected health information or personally identifiable information.*

☐ YES ☐ NO

If Yes, answer below:

1. Will the data be protected health information?

☐ YES ☐ NO

If Yes, answer below:

1. Is HIPAA Authorization required?

☐ YES ☐ NO

View the HIPAA Quick Reference Guide and attach a letter/email from the HIPAA covered entity giving permission for access to PHI for this project and detailing any special requirements that need to be followed.

1. Attach a copy of the HIPAA training verification completed. Training can be completed through the CITI Program course titled: CITI Health Information Privacy and Security.
2. Does the activity involve the use of coded private information or specimens?

☐ YES ☐ NO

If yes, answer below:

1. The release of the key to investigators is prohibited (attach agreement or documentation form a repository or data management center)

☐ YES ☐ NO

*For IRB Use: If Yes to 1 OR 2, activities involve human subjects. If Yes to 3 AND No to 3a, activities involve human subjects.*

**Part 4: Quality Improvement OR Program Evaluation Checklist**

*If you think your project may be considered a Quality Improvement or Program Evaluation ONLY and WILL NOT contribute to generalizable knowledge, confirm by answering either the Quality Improvement/Quality Assessment or Program Evaluation questions below.*

**Quality Improvement/Professional Development**

1. The project is intended to improve or evaluate a practice or process within a particular institution, classroom or program. ☐ YES ☐ NO
2. The primary intent of the projects is NOT designed to expand knowledge of a scientific discipline or scholarly field of study. ☐ YES ☐ NO
3. All activities are “best practices”, “routine care” or “standard practice” and conducted by staff where the project will take place. Untested methods and/or interventions are NOT being evaluated. ☐ YES ☐ NO
4. The project does NOT involve a control group or randomization of subjects or blinded interventions.

☐ YES ☐ NO

1. The project is NOT funded externally as a human subjects research project. ☐ YES ☐ NO
2. The project will NOT involve testing an experimental drug, device, or biologic. ☐ YES ☐ NO

**Program Evaluation Project**

1. The evaluation is being initiated based on the request and needs of a partner organization or department for internal purposes only. ☐ YES ☐ NO
2. The intent of the evaluation is to improve a specific program and/or to meet funding agency requirements.

☐ YES ☐ NO

1. The program or intervention being evaluated has been tested and is evidence based.

☐ YES ☐ NO

1. The evaluation does NOT involve randomization of participants, but may involve comparisons of variations in programs. ☐ YES ☐ NO

**If No was selected for any of the above questions, please explain:**

*For IRB Use: If No to any QA/QI/Program Evaluation Questions, activities may constitute research, but further explanation may be required for clarification.*