# **Institutional Review Board (IRB) Application Form**

|  |  |
| --- | --- |
| **Part I: Project Details****Instructions:**  [**IRB Process**](https://uwosh.edu/sponsoredprograms/irb/process/)**Title of Research Project:** |       |
| **Funding Source:** |        |
| Is this a federally funded project? [ ]  Yes\* [ ]  No \*If yes, FCOI Disclosure Date:       Grant ID:       |
| **Name of Principal Investigator:**      **College:**       **Department:**      **E-mail:**       **Phone:**      **Affiliation:** [ ]  UWO Oshkosh Campus [ ]  UWO Fox Cities Campus [ ]  UWO Fond du Lac Campus [ ]  External      **Principal Investigator (PI) Status:** Select one of the following eligible categories below for PI status. For student projects, a faculty or staff mentor must be listed as PI. Student projects/ student name can be indicated under Project Type below. For further details, please see [**IRB SOP #6 for Principal Investigator Status Requirements**](http://grants.uwosh.edu/sample-page/research-compliance/institutional-review-board-irb/irb-sops/). [ ]  Faculty or Instructional Academic Staff [ ]  Professional Academic Staff [ ]  Visiting Faculty/Scientist**Co-Principal Investigator(s) on Project?** [ ]  Yes [ ]  No**Name(s) of Co-Principal Investigator(s):**       **College:**       **Department:**      **E-mail(s):**       **Phone:**      **Affiliation:** [ ]  UWO Oshkosh Campus [ ]  UWO Fox Cities Campus [ ]  UWO Fond du Lac Campus [ ] External      **Co-Principal Investigator Status: (check all that apply)** [ ]  Faculty or Instructional Academic Staff [ ]  Professional Academic Staff [ ]  Visiting Faculty/Scientist [ ]  Post-Doctoral Student [ ]  University Staff  [ ]  Other (explain):       **Project Type:** [ ]  **Faculty or Staff** **Research** [ ]  **Student Research Project:** [ ]  Field Study [ ]  Thesis [ ]  Dissertation [ ]  Honors [ ]  McNair  **Student Name:**        [ ]  **Class Project**\*   **(\*See** [**SOP #7: Student Research and Class Projects**](https://uwosh.edu/sponsoredprograms/irb/sops/) **to determine if IRB review is required)**  Name of Class:        Name of Student(s): a class roster may be attached as an appendix:        [ ]  **Other**\*\* (please specify:       **Expected Duration to Complete Study**:      **International/Multisite Research (Please contact the IRB for assistance early in the process)**International research: [ ]  Yes\* [ ]  No \*If yes, list travel dates and country/countries to be visited:       Multi-site collaborative research: [ ]  Yes\* [ ]  No \*If yes, list institution(s):              Request for UWO IRB serve as the single IRB of record: [ ]  Yes\* [ ]  No  \*If yes, please provide IRB/Ethics contact information:        Is collaborator’s IRB part of the SMART IRB Agreement? [ ]  Yes [ ]  No **Project Abstract:**     **Part II: Research Roles and Training in Human Subjects Research****Individual Research Roles in Project:** Pleaseinclude PI, Co-PI(s), and all research personnel who will work on the project. For status, please indicate if the individual is faculty, instructional or professional 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. Please note that individuals not affiliated with an institution of higher education must complete UW Oshkosh [Hiring a Volunteer Paperwork](https://uwosh.edu/hr/policies-procedures/supervisors-toolkit/) with Human Resources prior to working on a UW Oshkosh led project.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Name** | **Institution/Affiliation** | **Status** | **Role in Project (see key above)** | **Email** |
|       |       |       |       |       |
|       |       |       |       |       |
|       |       |       |       |       |
|       |       |       |       |       |
|       |       |       |       |       |
|       |       |       |       |       |
|       |       |       |       |       |
|       |       |       |       |       |
|       |       |       |       |       |
|       |       |       |       |       |
|       |       |       |       |       |
|       |       |       |       |       |

 |
|
|  |

## **Training in Human Subjects Research**

## **Include PI, Co-PI(s), and all research personnel.** **Training Requirements:** [**https://uwosh.edu/sponsoredprograms/irb/training/**](https://uwosh.edu/sponsoredprograms/irb/training/)

## All individuals listed on the protocol must complete CITI Training in Human Subjects Research.

## Note: Some research activities involve additional training courses: 1) Research involving the collection of Private Health Information (PHI) from a HIPAA covered, requires completion of the CITI Information Privacy and Security (IPS) Course; 2) Research involving student records covered by FERPA, requires completion of the CITI FERPA Course; and 3) Research meeting the clinical trial definition also requires training in Good Clinical Practices (GCP) through CITI Program. Please attach a training appendix if additional space is needed.

|  |  |  |  |
| --- | --- | --- | --- |
| **Name** | **CITI Training Course Title(s)**  | **CITI Training Completion Date(s)** | **CITI Completion Report URL(s)**  |
|       |       |       |       |
|       |       |       |       |
|       |       |       |       |
|       |       |       |       |
|       |       |       |       |
|       |       |       |       |
|       |       |       |       |
|       |       |       |       |
|       |       |       |       |
|       |       |       |       |
|       |       |       |       |
|       |       |       |       |

## **Part III: Project Description**

|  |  |  |  |
| --- | --- | --- | --- |
| 1. **What is the purpose of the research?**

|  |
| --- |
|  |

* 1. **What question(s) do you hope to answer? (Note: Projects lacking a valid research question and a method likely to produce meaningful results are not approvable. Ethical and regulatory standards do not permit investigators to expose participants to research risks when the work lacks scientific merit.)**

|  |
| --- |
|  |

* 1. **How will the results of the study be disseminated or shared?**

|  |
| --- |
|  |

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

|  |
| --- |
|        |

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

|  |
| --- |
|       |

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

|  |
| --- |
|       |

1. **The data that will be collected/used include (check all that apply):**

 [ ]  Personal Identifiable Information ([PII](https://uwosh.edu/sponsoredprograms/wp-content/uploads/sites/29/2019/03/Identifiers-Guidance-3-26-19.pdf)) *(e.g. names, email, contact information, UWO NetID, etc.)* [ ]  Protected Health Information ([PHI](https://uwosh.edu/sponsoredprograms/wp-content/uploads/sites/29/2019/03/Identifiers-Guidance-3-26-19.pdf)) from a HIPAA covered entity *(e.g. medical records)* [ ]  Education Records *(e.g. grades, student records, etc)* [**See SOP#10: Guidance on FERPA**](https://uwosh.edu/sponsoredprograms/irb/sops/)  [ ]  Other:      1. **Describe your data collection method.** *(Example: observations, survey, experimental manipulation, psychological test, interview, etc. If you are using published surveys or instruments, please name them. Copies of all instruments must be attached as an appendix to this application. If you are requesting to analyze existing identifiable data or conduct research on biospecimens, please complete an* [*IRB Existing Human Subjects Data Application Form*](https://uwosh.edu/sponsoredprograms/irb/forms/)*.)*
 |
|  |       |
| 1. **Explain why you have selected this particular data collection method.**
 |
|  |       |
| 1. **Will the research be conducted at a location/site other than UW Oshkosh?** [ ]  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. Note: If the research is internet based, site permission is not required.*1. **Describe the location in which the research will be conducted.**
 |
|  |       |

## **What is your relationship to that site/location?** *(For example, is it your place of employment? A campus/ class where you are a student or instructor?)*

|  |
| --- |
|       |

## **Part IV: Participants**

|  |
| --- |
| 1. **Do participants belong to a vulnerable population for which special protections may be required? Check all that apply:**

[ ]  No/Not applicable[ ]  Pregnant Women/Human Fetuses/Neonates (Subpart B Applies)[ ]  Prisoners (Subpart C Applies)[ ]  Minor Children under the age of 18 (Subpart D Applies)[ ]  Non-English Speaking (Please submit IRB Supplemental Form: [Non-English Speaking Participants Form](https://uwosh.edu/sponsoredprograms/irb/forms/) as an Appendix)[ ]  Participants Residing/Traveling in EAA Country (See [SOP #11: Guidance on General Data Protections Regulation](https://uwosh.edu/sponsoredprograms/irb/sops/))[ ]  Other (Ex: Cognitively Impaired, Diminished Consent Capacity, Institutionalized, Economically/Educationally Disadvantaged) Please explain:       |
| 1. **In one to two sentences, describe your participant pool in terms of:**
 |
| * 1. **Sex, race or ethnic group, age range, etc.:**
 |
|  |  |       |
| * 1. **Affiliation of participants (e.g., institutions, hospitals, general public, UWO students, faculty/staff, etc.):**
 |
|  |  |       |
| * 1. **Participants’ general state of health (mental):**
 |
|  |  |       |
| * 1. **Participants’ general state of health (physical):**
 |
|  |  |       |
| * 1. **Number of participants or sample size:**
 |
|  |  |       |
| 1. **Explain why you have chosen this particular group to study:** *(Justification is especially important for vulnerable populations)*
 |
|  |       |
| 1. **What is your relationship to the participants?** *(e.g., are you their classroom instructor, a nurse in a clinic where participants are seeking medical care, etc.?)*
 |
|  |       |
| 1. **If there is an authority relationship between you and the participants, describe the measures you will take to ensure that participation is voluntary.**
 |
|  |       |

**Part V: Participant Recruitment**

|  |
| --- |
| 1. **Will participants be recruited?** [ ]  **Yes** [ ]  **No**

 **If no, please explain.** *(Recruitment may not be involved when studying existing data/reviewing charts)* |
|  |       |
| 1. **Identify the people who will approach/contact potential participants to recruit them for the study. If these people have a dual or authority relationship with potential participants, please describe.** (e.g., caregiver, teacher, employer, service provider, etc.)
 |
|  |       |
| 1. **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 of the recruitment as an appendix.**
 |
|  |       |
| 1. **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.**
 |
|  |       |

## **Part VI: 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?**

|  |
| --- |
|       |

1. **Describe the instructions that will be given to participants about the procedures.** *(Please reserve discussion of consent information for the section on consent below.)*
 |
|  |       |
| 1. **Describe procedures and interventions that will be performed for this project.**
 |
|  |       |
| 1. **Will you be the one administering the procedure, or will someone else do it for you? If someone else, describe how they will be involved.**

      \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

|  |
| --- |
| 1. **How long will the procedure take?**
 |
|  |       |

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

|  |
| --- |
|       |

**COVID-19 Safety Information for In-Person Research:** **Please review UW Oshkosh’s Titans Return webpage for the current COVID-19 response plans and expectations:** [**https://uwosh.edu/titans-return/home/**](https://uwosh.edu/titans-return/home/) **COVID-19 information to be provided to participants prior to study:** **Please provide a copy of the IRB-approved** [**COVID-19 Information Packet for In-Person Human Subjects Research**](https://uwosh.edu/sponsoredprograms/irb/forms/) **to all in-person research participants via email or postal mail *prior* to them participating in the study. If you wish to provide additional study-specific materials about COVID-19, please include that information in the appendices of this application.** |

## **Part VII: 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. 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 procedures?** [ ]  Yes [ ]  No |  |  |  |  |
| *If no, skip this section and proceed to Part VII.**If you answered yes to this question, you must answer the following questions and attach a copy of the study Debriefing Form as an appendix.* |
| * 1. **Explain why deception is necessary for the conduct of this study.**
 |
|  |  |       |
| * 1. **Is the intervention or the methods used to collect data benign (defined as not expected to cause physical or emotional harm, persistent discomfort, be embarrassing, or offensive)?** [ ]  Yes [ ]  No
	2. **Is the intervention brief in duration (defined as a few minutes to a few hours)?** [ ]  Yes [ ]  No
	3. **Does the deception only involve participation by adults?** [ ]  Yes [ ]  No
	4. **Does the participant have adequate decision-making capacity?** [ ]  Yes [ ]  No
	5. **Will the subjects be made aware in advance (in consent process) that they will be misled regarding the nature or purpose of the study?**

 [ ]  Yes [ ]  No* 1. **Describe how you will debrief participants, and procedures you will follow if a participant decides to withdraw his/her consent.**
 |
|  |  |       |

## **Part VIII: Risk/Benefit 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. **Will the participants benefit from being a part of your study? If yes, explain.**
 |
|  |       |
| 1. **What are the benefits to knowledge or to society at large that will accrue as a result of this research?**
 |
|  |       |
| 1. **Are there other benefits? Describe.**
 |
|  |       |
| 1. **Will you offer incentives, reimbursement of costs, or other compensation to participants? Prizes, awards, and gifts must follow** [**UW System Policy**](https://www.wisconsin.edu/uw-policies/uw-system-administrative-policies/prizes-awards-and-gifts/)**. Please also see the** [**UWO Policy on Participant Payments for Research**](https://grants.uwosh.edu/wp-content/uploads/2018/01/ParticipantCompensationPolicy-3.pdf)**.** *(Note: Questions regarding payments should be directed to the Office of Finance and Administration Accounts Payable.)*
 |
|  | [ ]  | Yes  | [ ]  | No, proceed to question 5. |
| If yes, please answer the following: |
| * 1. **What will you offer as incentive, reimbursement or compensation?**
 |
|  |  |       |
| * 1. **What conditions must a participant meet to receive these benefits?**
 |
|  |  |       |
| * 1. **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 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.*

|  |
| --- |
| 1. **Describe all risks, perceived and actual, that participants might encounter during this study.** *(NOTE: a response of “not applicable” is unacceptable for this answer.)*
 |
|  |       |
| 1. **Do you believe those risks to be no greater than minimal? If so, explain why you believe that to be the case?**
 |
|  |       |
| 1. **If risks are greater than minimal, describe the following:**
 |
| 1. **What have you done to minimize risks to the extent possible without compromising your research objectives?**
 |
|  |  |       |
| 1. **What protections have you put in place to minimize the consequences of risks if they should become realized?**
 |
|  |  |       |
| 1. **What procedures have you established for reporting adverse events should they occur?**
 |
|  |  |       |
| 1. **Explain why these risks are essential to the conduct of your study.**
 |
|  |  |       |

## **Part IX: Consent**

*The goals of 46.116 (consent requirements) and 46.117 (documentation of consent) in the 2018 Final Rule are to facilitate a prospective subject’s or legally authorized representative’s understanding of the reasons why an individual might or might not want to participate in the research and the consent process. The information must be presented in a language understandable to the subject or legally authorized representative. The investigator has the responsibility to make sufficient time and opportunity to discuss the research, provide additional information upon request, and answer any questions during the consent process. A new approach to consent is requiring that the “key information” essential to decision making receive priority by appearing at the beginning of the consent form and being presented first in the consent discussion. The key information should be organized and presented in a way that facilitates comprehension. Informed consent shall be documented by the use of a written informed consent form approved by the IRB and signed (physical signature or electronic format allowed) by the subject or legally authorized representative. A written copy must be given to the person signing the informed consent form. UW Oshkosh has developed a NEW* [***Consent Template***](https://uwosh.edu/sponsoredprograms/irb/forms/) *to encompass the key information and required elements of consent. For further details, please see* [***SOP#3 Informed Consent Process***](https://uwosh.edu/sponsoredprograms/irb/sops/)*.*

|  |
| --- |
| 1. **Describe how you will obtain informed consent from your participants.** (Note: Consent must be conducted in a setting that minimizes the possibility of real or perceived coercion or undue influence.)
 |
|  |       |
|  |
| **a. In what setting will consent take place?**

|  |
| --- |
|  |

* 1. **Who will be present?**

|  |
| --- |
|  |

* 1. **What information will be provided and by whom?**

|  |
| --- |
|  |

* 1. **Describe the precautions you will take to ensure that consent is freely and voluntarily obtained.** (Note: Consent must be conducted in a setting that minimizes the possibility of real or perceived coercion or undue influence.)

|  |
| --- |
|  |

* 1. **Will there be an opportunity for questions to be asked and answered and for participants to obtain a copy of the consent document?**

|  |
| --- |
|  |

 |
| 1. **Do you wish to request a Waiver of Documentation of Informed Consent?** *(Select yes if you do not wish to obtain participant signatures physically or electronically, but will provide participants information about the study including all elements of consent verbally and/or in writing)*[45 CFR 46.117(c)](http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/#46.117(c))

 **Select one:** [ ]  **Yes.** *Provide justification below and attach information sheet or verbal script that will be presented to participants as Appendix*[ ]  **No.** Skip to Question #3**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 the 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 involves no procedures for which written consent is normally required outside of the research setting**

|  |
| --- |
|  |

1. **It is not the cultural norm for subjects to sign such documents, and the IRB determines, 1) the research is no more than minimal risk and an alternative documentation mechanism is used for documenting informed consent.**

|  |
| --- |
|  |

1. **Do you wish to request a** **Waiver or Alteration of Informed Consent Process?**

*Note: A waiver of the consent process applies in special circumstances when the IRB determines that it is not necessary to obtain the participants’ consent to conduct the research (i.e., retrospective chart review study). An alteration of the consent process may be requested if the research design requires that participants be left unaware of the particular purpose of the research (i.e., deception research), because the participants’ responses might be biased if they know in advance what the investigators are seeking. Such research designs do not preclude offering potential participants partial or general information about the research. No misleading or false information can be given to participants on the consent form.***Select One:**[ ]  **Yes.** *Select type of waiver request below 46.116(e), 46.116(f), 46.116 (g),*46.408 *and provide justification for request.*  [ ]  **No.** *Skip to Question #4*[ ]  **Waiver or Alteration of Consent in Research Involving Public Benefit and Service Programs** [**46.116 (e)**](https://www.ecfr.gov/cgi-bin/text-idx?SID=fb9243dbcf0ae51bbf765e5da725a0b7&mc=true&node=se45.1.46_1116&rgn=div8)**:***Note: This research must be conducted by or subject to the approval of state or local officials.* Provide justification as to how the research meets **All** of the appropriate regulatory categories below:* 1. **The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (a) 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; AND**

|  |
| --- |
|       |

* 1. **The research could not practicably be carried out without the waiver or alteration. Note: subjects may be vulnerable, economically disadvantaged, elderly, or decisionally impaired.**

|  |
| --- |
|       |

[ ]  **General Waiver or Alteration of Consent** [**46.116 (f)**](https://www.ecfr.gov/cgi-bin/text-idx?SID=fb9243dbcf0ae51bbf765e5da725a0b7&mc=true&node=se45.1.46_1116&rgn=div8)**:**Provide justification as to how the research meets **All** of the appropriate regulatory categories below for waiver or alteration of informed consent process: |
| 1. **The research involves no more than minimal risk to the 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. **When appropriate, the subjects will be provided with additional information after participation.**

|  |
| --- |
|       |

 **e. If the research involves using identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format.**

|  |
| --- |
|       |

[ ]  **Waiver of Consent Process for Screening, Recruiting or Determining Eligibility** [**46.116 (g)**](https://www.ecfr.gov/cgi-bin/text-idx?SID=fb9243dbcf0ae51bbf765e5da725a0b7&mc=true&node=se45.1.46_1116&rgn=div8)**:**An investigator may request a waiver of consent to obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective subjects without the informed consent of the prospective subject or the subject’s legally authorized representative. Provide justification as to how **(1)** of the following conditions will be met:1. **The investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative, or**

|  |
| --- |
|       |

1. **The investigator will obtain private information or identifiable biospecimens be accessing records or stored identifiable biospecimens**

|  |
| --- |
|       |

[ ]  **Waiver of Child Assent or Parental Permission for Research with Children** [**46.408**](https://www.law.cornell.edu/cfr/text/45/46.408)Subpart D allows for various conditions in which a waiver may be requested. The IRB may waive the requirements for obtaining parental or guardian permission if it determines and documents that **1)** the research is minimal risk and fits into Category 1 Research with Children ([45 CFR 46.404](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/special-protections-for-children/index.html)) and meet the criteria under either [45 CFR 46.116(c) or (d)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.116). **2)** In addition to the provisions for waiver contained in [46.116(c) and (d)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.116), if the IRB determines that a research protocol is designed to study conditions in children or a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children), it may waive the parental permission requirements provided that an appropriate mechanism is in place to protect the children, and provided that the waiver is not inconsistent with federal, state, or local law ([45 CFR 46.408(c)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.408)). The choice of an appropriate substitute mechanism (for example, appointing a child advocate or an assent monitor) for protecting children participating in research would depend on the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and the child’s age, maturity, status, and condition ([45 CFR 46.408(c)](https://www.law.cornell.edu/cfr/text/45/46.408)1. **Please provide justification for your request to waive parental permission for minor children in the study:**

|  |
| --- |
|       |

 |

1. **Is your study NIH funded AND does it meet the definition of clinical research?** *(Clinical study is defined by NIH as a study in which one or more human subjects are prospectively assigned to one or more interventions, which may include placebo or other control, to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes. See NIH Decision Tool for additional information, training requirements, and new consent posting requirements:* [*https://grants.nih.gov/ct-decision/index.htm*](https://grants.nih.gov/ct-decision/index.htm)*).*

 [ ]  **Yes** [ ]  **No**

## **Part X: Privacy of Subjects/Confidentiality of Data**

*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 of subjects and confidentiality of data.*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|

|  |
| --- |
| 1. **Will the research involve the access, collection, use, or disclosure of personally identifiable information (PII) and/or protected health information (PHI) (**[**See IRB Identifiers Guidance**](https://uwosh.edu/sponsoredprograms/wp-content/uploads/sites/29/2019/03/Identifiers-Guidance-3-26-19.pdf)**)?** [ ]  Yes [ ]  No, proceed to Question 6
 |

 **If yes, which of following types of personally identifiable information are being collected?**[ ]  Name [ ]  Personal ID numbers [ ]  Date of Birth [ ]  Telephone number [ ]  Email [ ]  Postal Address[ ]  Photographs [ ]  Video/Audio [ ]  Asset Information (IP) or (MAC) address [ ]  Private Health Information[ ]  Other:      1. **For each box checked above in question 1, explain why collecting that information is necessary for conducting the research** (collection of identifiable private information about a subject should be limited to the amount necessary to conduct the research).

|  |
| --- |
|       |

1. **How will subjects be identified in the research records?**

|  |
| --- |
|       |

1. **What individuals or entities will have access to the identifiable information?**

|  |
| --- |
|       |

**5. Describe measures which will be taken to protect the privacy of subjects and confidentiality of data:** 1. **During data collection:** (e.g., research will be conducted in a private room to protect privacy, pseudonyms will be used, include data storage protections, sensitive data will be locked in storage/encrypted if stored electronically)

|  |
| --- |
|       |

1. **While results are being analyzed,** (e.g., how will confidential data be shared with those who need access, indicate if/when identifiable information will be destroyed and how)

|  |
| --- |
|       |

1. **In publication or other reporting of results,** (e.g., will any identifiable information be reported, will information be aggregated)

|  |
| --- |
|       |

1. **­­­­­­­­­­­­­­­­­­­­­How will survey/interview data, transcripts, consent forms, audio/video files, photographs, or other study materials be handled or stored upon completion of the study?** (Note: All materials must be retained and available for inspection by the IRB, and/or an IRB audit for a minimum of 3 years following the closure of the study. Identifiable data should be destroyed at the earliest opportunity. Sometimes, special circumstances for retention of identifiable information exists which should be explained here).

|  |
| --- |
|  |

**Part XI. Principal Investigator Certification:**By signing this form, the **Principal Investigator** certifies that:1. information provided in this application is accurate;
2. s/he has read and understands [UW Oshkosh policies and standard operating procedures](https://uwosh.edu/sponsoredprograms/irb/sops/) regarding the protection of human participants in research;
3. s/he has completed required CITI training in human subjects research and will conduct the research in accordance with the principles of the Belmont Report (respect for persons, beneficence, and justice)
4. s/he will not begin research (including recruitment of research participants) until formal notification of IRB approval is received;
5. 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
6. s/he will seek approval from the IRB in advance of implementation of any changes ([*Modification Request Form*](https://uwosh.edu/sponsoredprograms/irb/forms/));
7. 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*](https://uwosh.edu/sponsoredprograms/irb/forms/));
8. s/he agrees to update the IRB on the status of the research at least annually for non-exempt research deemed by the IRB to need annual continuing review ([*IRB Continuing Review Form*](https://uwosh.edu/sponsoredprograms/irb/forms/))
9. s/he will maintain records of this research according to federal and state regulations, including maintaining documents for at least 3 years after the completion of the project, or longer if required.
10. for student research projects, the faculty PI 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 must be provided to students conducting research.

|  |  |  |  |
| --- | --- | --- | --- |
| **PI Signature:** |       |  **Date:** |       |
| **Co-PI Signature:** |       |  **Date:** |       |
| **Student Project/ Student Signature:** |       | **Date:** |       |

Signatures may be inserted as an image or by typing your name if the application is submitted from the PI’s university email account in order to verify identity. Alternatively, you may physically sign and scan the application package as a pdf for submission. Students must copy their faculty mentor when submitting the form.**IRB Application Submission Checklist:**1. **One (1) signed electronic copy of the protocol, CITI training for PI and all research personnel, and all applicable appendices as a single word document or pdf submitted to** **irb@uwosh.edu** **on the following date:**
2. **Appendices Checklist:** Check all that pertain to your project and attach on the following page as part of your application. Appendices that do not pertain to your project may be omitted when submitting your application.

|  |  |
| --- | --- |
| [ ]  | CITI Training Certificate(s) (Required) |
| [ ]  | Abstract (1/2 page) |  |
| [ ]  | Recruitment Materials (emails, flyers, verbal scripts, etc) |
| [ ]  | Demographic Forms if demographic information will be collected |
| [ ]  | Survey Instruments or other data collection systems (forms, tools, questionnaires, observation list, chart, etc.) |
| [ ]  | Outlines for Interviews |
| [ ]  | Informed Consent Document(s) Note: If participants are minors, an Assent Document may be required (if age appropriate) in addition to Parental Consent. If a waiver of documentation of consent is requested, please provide an Information Sheet that will be given to participants about the study (verbally and/or in writing). See [IRB website](https://uwosh.edu/sponsoredprograms/irb/forms/) for consent templates. |
| [ ]  | Debriefing statement or form (Required if deception is used) |
| [ ]  | Letters of administrative approval/permission from an authorizing official is required for any off-campus site(s) where data collection will occur |
| [ ]  | Other Pertinent Information: Explain:       |

 |

**PLEASE LABEL AND ATTACH ALL APPENDICES ON THE FOLLOWING PAGES TO SUBMIT THE APPLICATION AS A SINGLE WORD or PDF PACKAGE. SUBMIT TO IRB@UWOSH. EDU UPON COMPLETION.**