

**Iowa Western Community College**

**INSTITUTIONAL REVIEW BOARD (IRB)**

**APPLICATION FOR APPROVAL TO USE HUMAN SUBJECTS IN RESEARCH**

1. Project Title: Click here to enter text.

**PRINCIPAL INVESTIGATOR INFORMATION**

1. Principal Investigator: Click here to enter text.

Department: Click here to enter text. Phone: Click here to enter text.

Fax: Click here to enter text.

Email: Click here to enter text.

 *(Required)*

1. Co-Principal lnvestigator (if any): Click here to enter text.

Department: Click here to enter text. Phone: Click here to enter text.

Fax: Click here to enter text.

Email: Click here to enter text.

 *(Required)*

1. Status (check one): [ ] IWCC Faculty/Staff [ ] IWCC Student

 [ ] Other (please explain) Click here to enter text.

For student and non-IWCC researchers *only*, please give your home address and phone number:

Click here to enter text.

**PROTOCOL INFORMATION**

1. Does your study involve individually identifiable protected health or mental health information (PHI), including demographic information and biological specimens identified to an individual, created or maintained by, or received from, a person or an entity covered by the Privacy Rule issued under the Health Insurance Portability and Accountability Act (HIPAA) (e.g., a hospital; a physician, or a practice in psychology, psychotherapy, or social work; a health insurer, HMO, or health plan; or a community clinic, or a social service or mental health agency)?

 [ ] Yes [ ] No

1. If your answer to question (5) is Yes, please list below or on a separate sheet the PHI that is necessary for your research and that you intend to use in your research.

Click here to enter text.

1. If your answer to question (5) is Yes, please list below or on a separate sheet the name and address of each person or entity that is creating, maintaining or providing the PHI for your research.

Click here to enter text.

1. Does your study involve the collection of data from a vulnerable population?

 [ ]  Yes [ ]  No

If yes, please specify type of population:

[ ]  Children/Minors

[ ]  Prisoners

[ ]  Fetuses

[ ]  Pregnant Women

[ ]  Cognitively Impaired Persons

[ ]  Other Click here to enter text.

1. Does this study involve deception (research in which the subject is purposely led to have false beliefs or assumptions)?

 [ ]  Yes [ ]  No

1. If the study involves risk to subjects, is the risk greater than that incurred in ordinary life or tasks?

 [ ]  Yes [ ]  No

1. Has this study ever been previously approved by this IRB?

 [ ]  Yes [ ]  No

1. Is this proposal new or revised in response to previous IRB review?

 [ ]  New [ ]  Revised

1. Is funding being sought for this study?

 [ ]  Yes [ ]  No

If yes, through what sponsoring agency?

Agency: Click here to enter text.

**I certify that the research plan and safeguards to human subjects described in this application conform to that which has been submitted/will be submitted to an external funding source.**

⮊ Principal Investigator:

 Principal Investigator signature

 Co-Principal Investigator signature

Date: Click here to enter text.

1. Is this study being reviewed by an IRB at another institution?

[ ]  Yes [ ]  No

 If yes, please list the institutions below.

 Click here to enter text.

Documentation of IRB reviews of this study conducted at other institutions must be provided when it becomes available. **Research may not begin until IRB review has been concluded at all institutions involved.**

**Please answer the following questions on a separate sheet.**

1. State the purpose of the research. Include major hypotheses and research design. If the study is part of a larger study, briefly describe that larger study and indicate whether it has received IRB approval from another institution. **Please keep in mind that the IRB is composed of individuals from many disciplines and thus the description of your research should be written in terms readily comprehensible by non-experts.**
2. Describe the source(s) of subjects and the selection criteria. Selection of subjects must be equitable and, in the case of protected populations such as children, prisoners, pregnant women, the mentally disabled, etc. should address their special needs. Include the number of subjects. The text of any advertisement, letter, flier, oral script or brochure used to solicit potential subjects **must be attached**.
3. Provide a description of the procedures to be followed. If available, include copies of questionnaires and/or interview protocol, or a sufficiently detailed description of the measures to allow the IRB to understand the nature of subjects’ involvement.
4. Describe any potential harms or benefits to be derived by subjects, with a discussion of the risk/benefit ratio. For approval of any study with more than minimal risk, the benefits must clearly be shown to outweigh the risk. Describe how the study may expose participants to stress, physical, psychological or interpersonal hazard, including the possibility of pain, injury, disease, discomfort, embarrassment, worry or anxiety.
5. Describe the specific methods by which confidentiality and anonymity will be protected, including the use of data coding systems, how and where data will be stored and who will have access to it, and what will happen to data after the study has been completed.
6. If applicable, provide the following: 1) a description of the debriefing procedures to be used in cases where deception has occurred; 2) a statement describing what actions you will take should the research reveal the possibility of a medical or other potentially troubling condition.
7. Describe the oral and written consent processes and attach all consent documents. When the consent form to be used will be in a language other than English, an English translation must be provided. **Unless one or more of the required elements described below is explicitly waived by the IRB, informed consent documents should contain:**
8. A fair explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
9. A description of any possible discomforts and risks reasonably expected. This includes any potential financial risks that could ensue;
10. A description of any benefits reasonably expected;
11. A disclosure of any appropriate alternative procedures;
12. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled;
13. An offer to answer any inquiries concerning the goals of the research or the research procedures and to provide a summary of results upon request and an explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject;
14. An instruction that the subject is free to withdraw or discontinue participation at any time without prejudice.
15. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained; and
16. Provisions for parent or guardian approval for participation of minors or for subjects from vulnerable populations when appropriate.
17. Please provide a form from issuing institution stating it holds IWCC harmless for breaches in protocol.
18. Please provide documentation from issuing institution that all participants have signed a consent form.
19. Please provide any other information that might be pertinent to the IRB’s decision.

Upon approval of the study, the consent document will be stamped with an expiration date. **Only this document may be used when enrolling subjects.** Studies extending beyond the expiration date must be submitted for a continuation review. **Any changes in the consent form must be approved by the IRB.**