**Dickinson State University**

**Institutional Review Board (IRB) for the Protection of Human Subjects in Research**

**PROTOCOL APPLICATION FOR THE USE OF HUMAN SUBJECTS IN RESEARCH.**

**I. The Research Team**

1. **Principal Investigator/Researcher**

The Principal Investigator/s (PI) conducts and directs the study. S/he acts as the main contact person for the IRB, and carries full responsibility for the study and must provide documentation of completed Human Subject training.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Name: |  | Title: | |  | | |
|  |  |  | |  | | |
| Department: |  | Email: | |  | | |
|  |  |  | |  | | |
| Address: |  | Phone: | |  | | |
|  |  |  | |  | | |
| Is documentation of Human Subjects training attached? | |  | Yes | |  | No |

1. **Co-Investigators**

Co-investigators are those other than the Principal Investigator who conduct, direct, and are responsibility for the study. Co-Investigators must provide documentation of completed Human Subject training. If more than one co-investigator is involved in the study, please list them in “Other,” below.

\_\_\_\_\_\_ I have co-investigators for this project. \_\_\_\_\_\_ I have no co-investigators for this project.

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Name: | |  | Title: |  | | | | | |
|  | |  |  |  | | | | | |
| Department: | |  | Email: |  | | | | | |
|  | |  |  |  | | | | | |
| Address: | |  | Phone: |  | | | | | |
|  | |  |  |  | | | | | |
| Other co-investigators: | |  | | | | | | | |
|  |  | | | |  |  | | | | |
| Is documentation of Human Subjects training attached for each individual? | | | | |  | | Yes |  | No |

1. **Other personnel**

Other personnel include all team members other than the principal investigator and co-investigator/s who assist in the execution of the study. This may include students. Please indicate in “Role” if this person is a student, employee, or has another relationship with the campus.

\_\_\_\_\_\_ I have other personnel for this project. \_\_\_\_\_\_ I have no other personnel for this project.

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Name: |  | | Role: | |  | | | | | |
|  |  | |  | |  | | | | | |
| Name: |  | | Role: | |  | | | | | |
|  |  | |  | |  | | | | | |
| Name: |  | | Role: | |  | | | | | |
|  |  | |  | |  | | | | | |
| Others: |  | | | | | | | | | |
|  | |  | |  | |  | | | | |
| Is documentation of Human Subjects training attached for each individual? | | | | | | |  | Yes |  | No |

**II. The Research Project**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1. **Project Title:** | |  | | |
|  |  |  |  |  |
| 1. **Objectives:** | | List your research objectives, including the purpose of the study and research questions. | | |
|  | |  | | |
| 1. **Procedure:** | | Provide a detailed description of the research design including (a) a step-by-step description of what will happen to the subjects, (b) a timeline for the project, (c) and a description of the materials used. | | |
|  | |  | | |
| 1. **Subjects:** | | Provide a detailed description of the desired subjects including (a) the population of interest, (b) the number of subjects that will be used to represent that population, and (c) a description of the desired demographic of the subject pool including age, sex, race, or any other specific characteristics. | | |
|  | |  | | |

1. **Special Populations:** Please check all of the following that apply and complete the appropriate Section if indicated.

Adults, Non-students (No additional forms) Minors under 18 (Complete Section D

DSU students (Complete Section B) Cognitively Impaired (Complete Section E)

Prisoners (Complete Section C) Other (Please explain below)

|  |  |
| --- | --- |
| 1. **Recruitment:** | Provide a detailed description of (a) all sources of potential subjects, (b) all the mechanisms through which subjects will be recruited, (c) the exclusion and inclusion criteria. All recruitment documents must be included as attachments. |
|  |  |
| 1. **Risks:** | Provide a detailed description of (a) any potential risks to subjects even if minimal, (b) procedures that will be used to minimize the risks, and (c) procedures that will be followed if any harm comes to a subject. |
|  |  |
| 1. **Benefits:** | Provide a detailed description of (a) any benefits to the subjects themselves for participating in the research, including compensation of any sort, (b) benefits to the researchers, if any, and (c) benefits to the greater knowledge base. |
|  |  |
| 1. **Confidentiality** | Provide a detailed description of (a) how confidentiality of subjects will be protected during data collection, (c) how confidentiality of subjects will be protected during data analysis, (c) how data will be safeguarded and stored after the study is complete, (d) how and when data will be destroyed or archived, and (e) who will have access to the data at each stage of the study. |
|  |  |

**FUNDING**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Does this project have an outside funding source? |  | Yes\* |  | No |

*\*If you answered “Yes” to the question above, you must complete Section A – Funding Source*

**III. Informed Consent**

Unless waived by the IRB, informed consent is necessary for all research involving human subjects and must be documented in some manner. The investigator may determine which method would best serve the interest of the subject population, but the IRB reserves the right to require alternative or more stringent means of securing consent. Use of subjects unable to give personal consent for reasons of age, mental state, legal or other such status requires that consent be secured from parents or a legal guardian.

The traditional informed consent process may be waived under particular conditions. Please review the conditions at this link <http://answers.hhs.gov/ohrp/questions/7268> if you believe your project qualified for waiver of informed consent. If you would like to apply for a waiver of Informed Consent, please complete the waiver form in Section F.

**\_\_\_\_\_\_ Waiver of consent is requested**. If checked, please complete the waiver form in Section F

**\_\_\_\_\_\_ Waiver of consent is NOT requested.** If checked, please continue below.

**INFORMED CONSENT FOR ADULT SUBJECTS**

This section is for adult subjects only. If you plan to work with minors, please complete the informed consent information in Section D.

|  |  |
| --- | --- |
| 1. **Process:** | Please describe the procedures used to obtain informed consent including (a) how informed consent will be obtained, (b) where consent will be obtained, and (c) who will obtain the consent. |
|  |  |
| 1. **Understanding:** | Please describe how you will ensure that the subjects understand the information presented. If English is not the native language, how will translation be provided? |
|  |  |

|  |  |
| --- | --- |
| 1. **Competence:** | Will all adult subjects be competent to give consent? If not, how will competency be assessed and how will proxy consent be obtained? |
|  |  |

|  |  |
| --- | --- |
| 1. **Documentation:** | Please indicate all of the ways in which informed consent will be documented. A copy of the consent form must be attached to this document. |
|  |  |