Dickinson State University

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

All research with human subjects conducted at DSU must be approved by the IRB. If you believe your research is exempt from IRB approval, please review and complete the exemption form.

I. THE RESEARCH TEAM

A. 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

B. Co-Investigators

Co-investigators are those other than the Principal Investigator who conduct, direct, and are responsible 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

C. 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

A. Project Title:

B. Objectives: List your research objectives, including the purpose of the study and research questions or hypotheses.

C. 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.

D. 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.

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

- ☐ Adults, Non-students (No additional forms)
- ☐ DSU students (Complete Section B)
- ☐ Prisoners (Complete Section C)
- ☐ Minors under 18 (Complete Section D
- ☐ Cognitively Impaired (Complete Section E)
- ☐ Other (Please explain below)

F. 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.

G. 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. Every study has some potential risk, so "no potential risk" is not an acceptable statement.

H. 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.

I. 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 qualifies 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 competent adult subjects only. If you plan to work with minors or with another special population, please complete the appropriate form in Section C through E.

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.

2. **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?

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

4. **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.

IV. ASSURANCES AND RESPONSIBILITIES

As principal investigator(s)/researcher(s), I hereby offer assurance of each of the following:

☐ I will follow procedures to safeguard and protect the rights and welfare of the subjects of my research.

☐ I will not begin data collection until I receive a written approval from the IRB.

☐ I will use a third party to solicit participation, administer the study, and collect data when subjects are either students in a course for which I am the instructor or under my direct supervision.

☐ I acknowledge responsibility for each of the following:

- ☐ Protecting the rights and welfare of human subjects
- ☐ Complying with all applicable federal and IRB regulations
- ☐ Conducting the research according to the IRB expedited or full board protocol
- ☐ Reporting any changes in previously approved protocols to the IRB prior to implementation
- ☐ Reporting unanticipated injuries or problems involving risks to human subjects to the IRB
- ☐ Maintaining all approved protocol documents and notifications for three years after completion of the protocol
- ☐ Supervising all research conducted by students
- ☐ Obtaining approval for continuation protocols.

Checklist: For each of the following, please indicate whether the forms are attached or not applicable.

• Section A – Funding Source	☐ Attached	☐ Not Applicable
• Section B – DSU Students as Subjects	☐ Attached	☐ Not Applicable
• Section C – Prisoners as Subjects	☐ Attached	☐ Not Applicable
• Section D – Minors Under 18 as Subjects	☐ Attached	☐ Not Applicable
• Section E – Cognitively Impaired People as Subjects	☐ Attached	☐ Not Applicable
• Section F – Consent Waiver Form	☐ Attached	☐ Not Applicable
• Informed Consent Form	☐ Attached	☐ Not Applicable
• Child Assent Form	☐ Attached	☐ Not Applicable
• Materials to be used in the study such as surveys, questionnaire, tests, etc.	☐ Attached	☐ Not Applicable
• Recruitment materials	☐ Attached	☐ Not Applicable
• Documentation of Human Subjects Training for all Researchers	☐ Attached	☐ Not Applicable

Please submit the completed IRB Form as signed and scanned PDF attachments or as paper copies to the chair of the IRB. Contact information for the chair may be found at http://www.dickinsonstate.edu/academics/academic_resources/academic_affairs/forms/irbforms.aspx

As principal investigator, I agree with all of the researcher assurances and responsibilities above.

_____ _____

Signature of Principal Investigator/Researcher **Date**

As faculty advisor, I hereby accept responsibility for the conduct of this project.

_____ _____

Signature of Faculty Advisor if a student is the principal investigator **Date**

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Date received: _____ **Protocol Review Number:** _____

Review completed: _____ **Notification sent:** _____

IRB members present to review the application:

_____ _____

Signature of Chair of IRB committee **Date**