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

REQUEST FOR EXEMPTION FROM FEDERAL REGULATIONS

In accordance with federal regulations, the IRB determines whether research protocols involving human subjects may be exempted. Even though the research may qualify as exempt from federal regulations, the committee still has a responsibility to decide whether the protocol represents ethical research.

Principal Investigator(s)/Principal Researcher(s) Information: The Principal Investigator(s) (PI) conducts and directs the study. She/he acts as the main contact person for the IRB, and carries full responsibility for the study. **Principal Investigator(s)/Principal Researcher(s) must provide documentation of completed Human Subjects training.**			
Name:		Title:	
Department:		E-Mail:	
Campus Address:		Phone:	

Title of Research Project: (If internal or external funding will be requested, the title of the research project must be the same as the proposal title.)	
Title:	

Funding Source/Agency: (Provide name of funding source/agency and indicate if funds are internal or external. If funding will not be requested, mark N/A.)					
Name:					
Internal: ☐		External: ☐		N/A: ☐	

Period of Project:	**From:**	**To:**

Co-Investigators: Co-investigators are those other than the Principal Investigator(s) who conduct, direct, and are responsible for the study. Please list the name, degree, department, telephone number, and e-mail address of each co-investigator. **Co-Investigators listed here must provide documentation of completed Human Subjects training.**

Other Personnel: Other Personnel includes all team members other than the Principal Investigator(s) or Co-Investigator(s) who assist in the execution of the study, especially those who have subject contact. This may include students or graduate assistants. Please provide the names of any person who will have contact with subjects in connection with this study. **Other Personnel listed here must provide documentation of completed Human Subjects training.**

For the categories of research listed below, researchers may request that the IRB exempt their protocols from federal regulations. If you believe your research protocol may be eligible for consideration as exempt from the federal regulations, consider which of the categories from the list below applies and check all that apply.

	EXEMPT CATEGORIES – 46.101(b)
☐	1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as: (i) research on regular and special education instructional strategies; or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
☐	2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
☐	3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
☐	4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
☐	5. Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.
☐	6. Taste and food quality evaluation and consumer acceptance studies: (i) if wholesome foods without additives are consumed; or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

The exemptions at 45 CFR 46.101 (b) do not apply to research involving prisoners, Subpart C. The exemption at 45 CFR 46.101 (b)(2), for research involving survey or interview procedures or observation of public behavior, does not apply to research with minors, Subpart D, except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.

Justification: Please provide a justification for why this research meets the exempt category (i.e., explain how the research you are proposing belongs to the selected categories above): (Boxes will expand, or if necessary, attach additional pages.)

PROJECT DESCRIPTION

Abstract: Provide an abstract of the proposed research ***in language that can be understood by a lay person***. The abstract should summarize the objectives of this project and the procedures to be used, with an emphasis on what will happen to the subjects. Feel free to use as much space as needed to provide a thorough abstract. (Boxes will expand, or if necessary, attach additional pages.)

Subjects: Describe and quantify the subject population for this study, including the number of subjects expected to be enrolled, and describe how the subjects will be recruited for participation. Note inclusion and exclusion criteria. (Boxes will expand, or if necessary, attach additional pages.)

Consent: Describe the process by which consent will be obtained and documented from subjects. If consent or documentation of consent is not being obtained, you must formally request a waiver from the IRB and fully justify why the informed consent and/or signed informed consent requirement(s) should be waived. (Boxes will expand, or if necessary, attach additional pages.)

Are DSU student subjects being recruited? ☐ **YES** ☐ **NO**

If you answered yes, clearly address all items in the "DSU STUDENTS AS SUBJECTS" section before submitting your protocol application. If you answered no, simply indicate that the items are not applicable to your research.

DSU STUDENTS AS SUBJECTS

The following sections must be completed if applicable to your research. (Note: The information also must be included in the informed consent documents as required by federal and IRB regulations.)

Clearly address all items below before proceeding to the next question or if you answered no, simply indicate that the items are not applicable to your research.

Instructor (not subject) Safeguards:

Describe how permission to use subjects will be obtained. (Boxes will expand or, if necessary, attach additional pages.)

If DSU students are recruited as subjects in an instructor's class, explain how you will inform instructors that they can refuse to allow the research to be conducted in their class. (Boxes will expand or, if necessary, attach additional pages.)

Additional Information:

Clearly indicate whether participation as a research subject in this study fulfills a course requirement (i.e., all students are expected to participate in exchange for course credit) or will be conducted without fulfilling a course requirement (i.e., students may choose whether or not to participate without considering course requirements). If participation will fulfill a course requirement, clearly indicate that the instructors for the courses involved will establish appropriate alternative assignments that students may complete if they choose not to be a subject in this research. (Boxes will expand or, if necessary, attach additional pages.)

Clearly indicate how the students will be informed that no penalty will be incurred for non-participation in the research. (Boxes will expand or, if necessary, attach additional pages.)

Are any of the DSU student subjects in the researcher's class or under her/his direct supervision?

☐ **YES** ☐ **NO**

NOTE: **Researcher must use a third party to solicit participation, administer the study, and collect data from subjects when they are students in the researcher's class or when they are employees or supervisees of the researcher.**

If you answered yes, clearly address all items in the subject safeguards section below before proceeding. If you answered no, simply indicate that the items are not applicable to your research.

Subject Safeguards:

Identify third party who will solicit subjects, administer and collect informed consent and all instruments, and retain documents until final grades are submitted. (Boxes will expand or, if necessary, attach additional pages.)

Identify third party as a contact for subjects to notify if they wish to withdraw from the research project. (Boxes will expand or, if necessary, attach additional pages.)

Online training in the protection of human subjects in research is required for all researchers. Once you have completed your online training, please attach a copy of your Certificate of Completion to your completed protocol application.

After you have completed all other parts of your protocol application, read the information below and sign if you agree with the researcher assurances and responsibilities.

Researcher Assurances and Responsibilities:

As principal investigator(s)/researcher(s), I hereby assure that 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.

If data are to be collected from students and/or other DSU employees, I will use a third party to solicit participation, administer the study, or collect data when subjects are either students in a course for which I am the instructor or under my direct supervision.

As principal investigator(s)/researcher(s), I acknowledge responsibility for protecting the rights and welfare of human subjects; complying with all applicable federal and IRB regulations; conducting the research according to the IRB *exempt* 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; and supervising research conducted by students.

If your study is determined to be exempt by the IRB committee, you are not required to complete continuation or final review reports. However, if any revisions are made to a project or if any unexpected risks arise during an investigation, it is your responsibility to notify the IRB by submitting a Part H (Change of Status) fully explaining all changes or unexpected risks, prior to making any changes to the study. Please note that changes made to an exempt protocol may disqualify it from exempt status and may require an expedited or full-board review.

After your application is approved, The Office of Academic Affairs will hold your exemption application for six years, after which your protocol will be closed. If your project is still ongoing, you will need to contact the Office of Academic Affairs and complete a new exemption application.

It should be noted that research involving minors may not qualify for exemption.

Please submit two (2) copies of the completed DSU Request for Exemption From Federal Regulations, Human Subject Training Documentation, Consent Documents (if applicable), Questionnaires/Surveys etc., (if applicable), Support Letters or any other documentation that would be useful in reviewing the protocol application to the Administrative Assistant in the Office of Academic Affairs.

Signature of Principal Investigator(s)/Researcher(s)	Date

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

Signature of Faculty Advisor	Date

Do not write below this line

Date Received:	Protocol Review Number:
Review Completed:	Notification Sent: