Exemption - Application for Approval of Investigations Involving the Use of Human Subjects Northwestern State University

The Principal Investigator must complete this application and electronically sign and date it before forwarding the document to others who also need to electronically sign and date it. Then the Investigator should email the application along with all supporting documents to irb@nsula.edu

All supporting documents must be saved as separate digital files (i.e. Word or PDF documents) and emailed together as one complete packet in one email to irb@nsula.edu

Please check below all the documents that are being submitted in your application.

Office	PI	
☐	☐	Informed consent form
☐	☐	Assent form
☐	☐	Debriefing form
☐	☐	Ethics Training Certificate (if your certificate is on file with the IRB and was earned in the last 5 years, then it does not need to be included in this packet.)
☐	☐	Site permission letter
☐	☐	Appendices of surveys/questionnaires/other materials that will be used in the study
☐	☐	Permission to use above mentioned surveys/questionnaires/other materials that will be used in the Study
☐	☐	Statement about maintaining and storing data for at least 5 years.
☐	☐	Statement about submitting a final report to the IRB within 6 weeks of project completion.
☐	☐	Faculty Advisor checklist (only if the PI is a student)
☐	☐	Other: _____

For Office Use Only

IRB Proposal ID#: _____

Date of Submission: _____

Ethics Training Certificate PI: _____

Ethics Training Certificate FA: _____

Exempt Category: _____

Approval Date: _____

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This application must be completed by the Investigator and sent to the Office of Sponsored Programs by email to irb@nsula.edu All correspondence will be sent to the principal investigator and sponsor unless otherwise specified.

1. Investigator(s) Names(s):_____

2. Local Address of Principal Investigator:
   _____

3. Campus and Local Phone Number:_____ Email address:_____

4. If you are a student, complete the following:
Faculty sponsor & rank: _____ College/Department: _____

   Phone: _____ Email address: _____

5. Project Title:_____

6. Expected Starting Date: _____ Expected Completion Date: _____

7. Where is the study taking place? (Please indicate the location from which the participants will be recruited, and where data collection will be conducted. Note that site permission letters will be required if the location is anywhere other than an NSU campus.)
   _____

8. Number and age level of human subjects: Number: _____ Age:_____

9. Indicate the categories of subjects and controls to be included in the study. Check ALL that apply:

☐ Students ☐ Normal Volunteers ☐ Minors (17 yrs or less) ☐ Prisoners ☐ Abortuses/Fetuses

☐ Decisionally Impaired ☐ Decisionally Impaired (Institutionalized) ☐ Pregnant Women ☐ Patients

10. Is this project: (Check all that apply) A graduate thesis? ☐ A Case study? ☐ A Class project ? ☐
Publishable research? ☐ Being conducted in a foreign country? ☐ Undergraduate Thesis? ☐

11. Has this project previously been considered by the IRB and a formal decision was made?
☐ Yes ☐ No If yes, give approximate date of review _____

12. Is this proposal being submitted to a sponsor for financial support? ☐ Yes ☐ No
Is notification of human subject approval required to a granting agency? ☐ Yes ☐ No
What agency? _____

****** If submitted externally, a complete copy of the proposal must be submitted to the IRB.******

13. Identify other KEY personnel assisting in research project (attach additional sheets if necessary):

(Indicate all personnel authorized by the principal investigator to obtain informed consent.)

Name, Rank/Degree_____

Responsibility in Project _____ Authorized to Obtain Consent: ☐ Yes ☐ No

Name, Rank/Degree_____

Responsibility in Project _____ Authorized to Obtain Consent: ☐ Yes ☐ No **Complete the following information about your study.**

14. What is (are) the purpose(s) or objectives of the research project?

15. What are the benefits to (1) study subjects and (2) institution?

16. Who are the study subjects?

17. Briefly describe the methodology of the study. Be sure to specify the procedure and what data will be collected, and how it will be collected?

18. How will confidentiality of subject information and data be maintained?

19. Will subject anonymity be assured? ☐ Yes ☐ No If yes, how will anonymity be assured?

20. How will results be disseminated?

21. Include an explanation of a conflict of interest. If no conflict of interest is present, please provide a statement that says, "No conflict of interest."

IMPORTANT NOTE: Please attach copies of and permission to use all instruments, copies of Informed Consent. Also include statements that records will be maintained for five years and that a final summary report will be submitted to the IRB within 6 weeks of the project's completion.

Check all of the following exempt categories where you believe your proposal fits.

22. Research activities are exempt from the federal policy for the Protection of Human Subjects when the ONLY involvement of human subjects falls within one or more of the categories below. Check the appropriate categories that apply to your research project:

☐ 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.

☐ Research only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), surveys, interviews, public observation if at least ONE of the following criteria is met:

(i) recorded information cannot readily identify the subject (directly or indirectly/linked); OR
(ii) any disclosure of responses outside of the research would reasonably place subject at risk (criminal, civil liability, financial, employability, educational advancement, reputation); OR
(iii) information is recorded with identifiers or code linked to identifiers & IRB conducts Limited Review

☐ Research involving benign behavioral interventions (BBI) through verbal, written responses, (Including data entry or audiovisual recording) from adult subject who prospectively agrees and ONE of the following met: :

(A) recorded information cannot readily identify the subject (directly or indirectly/linked); OR
(B) any disclosure of responses outside of the research would NOT reasonably place subject at risk (criminal, civil liability, financial, employability, educational advancement, reputation); OR
(C) information is recorded with identifiers & IRB conducts Limited Review.

☐ Secondary research for which consent is not required: use of identifiable information or identifiable biospecimen that have been or will be collected for some other "primary" or "initial" activity, if ONE of the following criteria met:

(i) biospecimens or information is publicly available; OR
(ii) information is recorded so subject cannot be readily identified (directly or indirectly/linked); investigator does not contact subjects and will not re-identify the subjects; OR
(iii) Collection and analysis involving investigators use of identifiable health information when use is regulated by HIPAA "health care operations" or "research" or "public health activities and purposes"; OR
(iv) Research information collected by or on behalf of federal government using government generated or collected information obtained for non-research activities

☐ 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:

(v) public benefit or service programs;
(vi) procedures for obtaining benefits or services under those programs;
(vii)possible changes in or alternatives to those programs or procedures; or
(viii) possible changes in methods or levels of payment for benefits or services under those programs.

☐ 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 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.

Certification and Approval Certification by Investigator: I agree to accept responsibility for the scientific and ethical conduct of this research study; to obtain prior approval from the Institutional Review Board before amending or altering the research protocol or implementing changes in the approved consent form; to immediately report to the IRB any serious adverse reactions and/or unanticipated effects on subjects which may occur as a result of this study; to submit a written continuance request to the IRB, if needed; and to submit a final report to the IRB within six weeks of the conclusion of the project.

_____

Signature of Investigator Date

Faculty Sponsor: If the Investigator is a student, his/her Faculty Sponsor must approve this form. I certify that this project is under my direct supervision and that I have reviewed this research protocol and that I attest to the scientific merit of this study and the competency of the investigator(s) to conduct the project.

_____

Signature of Faculty Sponsor Date

Approving Agent/Budget or Unit Head: I have reviewed the design of the proposed study and certify that the safeguards utilized do adequately protect the rights and welfare of the human subjects involved. I also attest to the scientific merit of this study and the competency of the investigator(s) and give my permission to conduct the project.

_____

Signature of Approving Agent/Budget or Unit Head Date

Chairperson of IRB: I have reviewed the design of the proposed study and certify that the safeguards utilized do adequately protect the rights and welfare of the human subjects involved. The principal investigator and a faculty sponsor (if applicable) also certify that the study will be monitored to assure compliance with the design.

_____

Signature of Chairperson of IRB Date