Expedited 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: _____

Risk Designation: _____

Approval Date: _____

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

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: _____

   Campus and Local Phone Number:_____

   Email address:_____

3. If you are a student, complete the following:

   Faculty sponsor & rank: _____ College/Department: _____

   Phone: _____ Email address: _____

4. Research Project Title:_____

5. Expected Starting Date: _____ Expected Completion Date: _____

6. 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.)

   _____

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

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

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

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

9. Is this project: (Check all that apply) A graduate thesis? ☐ A field study? ☐

   A Case study? ☐ A Class project ? ☐ Publishable research? ☐

   Being conducted in a foreign country? ☐ Undergraduate Thesis? ☐

10. Has this project previously been considered by the IRB and a formal decision was made?

    ☐ Yes ☐ No If yes, give approximate date of review _____

11. 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.******

12. Indicate which of the categories listed below accurately describes this protocol (This does not constitute expedited or exempt):

☐ Not greater than minimal risk

☐ Greater than minimal risk, but presenting the prospect of direct benefit to individual subjects

☐ Greater than minimal risk, no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.

☐ Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of subjects

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

14. Will data be collected from individuals through intervention or interaction with the individuals?
☐ Yes ☐ No

15. Will identifiable private information be collected from other sources (e.g. medical records)?
☐ Yes ☐ No

16. Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.
    a. The categories in this list apply regardless of the age of subjects, except as noted.
    b. The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.
    c. The expedited review procedure may not be used for classified research involving human subjects.
    d. IRBs are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review - expedited or convened - utilized by the IRB.

17. Check the one that best applies to your project.

☐ Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
    (a) Research on drugs for which an investigational new drug application is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
    (b) Research on medical devices for which (i) an investigational device exemption application is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

☐ Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

(a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or

(b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

☐ Prospective collection of biological specimens for research purposes by noninvasive means. Examples:

(a) hair and nail clippings in a nondisfiguring manner;
(b) deciduous teeth at time of exfoliation or if rountine patient care indicates a need for extraction;
(c) permanent teeth if routine patient care indicates a need for extraction;
(d) excreta and external secretions (including sweat);
(e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue;
(f) placenta removed at delivery;
(g) amniotic fluid obtained at the time or rupture of the membrane prior to or during labor;
(h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;
(i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;
(j) sputum collected after saline mist nebulization.

☐ Collect of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples:

(a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy;
(b) weighing or testing sensory acuity;
(c) magnetic resonance imaging;
(d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;
(e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

☐ Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. This listing refers only to research that is not exempt.)

☐ Collection of data from voice, video, digital, or image recordings made for research purposes.

☐ Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. This listing refers only to research that is not exempt.)

18. Explain why you believe this project should be expedited.

19. Complete the rest of the application to explain your project. The chairperson of the IRB retains final judgment as to whether this project meets the expedited criteria.

I. Purpose and Objectives of the Project

What is (are) the purpose(s) and objectives of the study?

II. Design of the Project:

Describe the project design (e.g., control and experimental groups, etc.). Indicate whether or not the subjects will be randomized for this project. Address whether deception will be involved.

III. Description of the Subject Population(s)

Describe the characteristics of the subject populations, such as anticipated number, age range, gender, ethnic background and health status. **If advertising for subjects, include a copy of the proposed advertisement.**

A. Who are the subject groups and how are they being recruited? Explain how sign-up will occur.

B. Approximately how many subjects are in each group? _____

C. What are the criteria for selection and/or exclusion of subjects?

D. If a special or vulnerable population is being used, please explain why they must be in the study and how their special rights and welfare will be protected. (Vulnerable populations include such groups as children under 18, minority groups, pregnant women or fetuses, prisoners, and those with mental impairment. Other populations may qualify, depending on the project.)

IV. Recruitment Methods

A. Describe plans for the recruitment of subjects and the consent procedures to be followed, including how the population will be accessed, the circumstances under which consent will be sought and obtained, who will seek it and the method of documenting consent.

B. Describe alternative procedures (treatment, care) that might be available to subjects who choose not to participate in the study which offer the subject equal or greater advantages. For example, if extra credit is awarded to students recruited from classes for participation, indicate that alternate and equivalent options are available; if experimental treatment is provided in study and a control group is employed, the control group must have the eventual option of receiving the experimental treatment.

V. Activities Involving Human Subjects

A. Describe in detail the activities and procedures involving each subject group. Include the expected amount of time subjects will be involved in each activity and when and where the activities will be conducted. (Attach additional sheets as needed.)

B. How will the data be collected?

☐ questionnaires (Submit a copy. If the questionnaire was developed by the investigator, state it. Otherwise, provide evidence that the questionnaire is in the public domain or provide copyright holder and author permission statements if the questionnaire is copyrighted.)

☐ interviews (Submit sample of questions.)

☐ observations (Briefly describe below.)

☐ standardized tests (If yes, list names.)

☐ other (Describe below.)

VI. Treatment of Data

A. How will the data be recorded (notes, video or audio tapes, computer files, completed questionnaires, tests, etc.)?

B. Who will have access to the gathered data during the study and after the study?

C. How will confidentiality be maintained during the study, after the study and in reporting the results?

D. What are the plans for the data after completion of the study, and how and when will data be maintained or destroyed? Include special measures used to secure data (e.g. locked file cabinet, limited access, location of archival data, stored for at least five years)

VII. Benefits, Risks, Costs

A. What are the potential benefits to the subjects, to the field or discipline, and to the university? Discuss why the risks to subjects are reasonable in relation to the anticipated benefit to subjects and in relation to the importance of the knowledge that may reasonably be expected to result.

B. What compensation (money, extra credit, etc.) will be offered to the subjects, and how will it be dispersed? If monetary compensation is offered, indicate how much the subjects will be paid and describe the terms of payment.

C. What risks to the subjects are most likely to be encountered?

- ☐ social (employability, financial/personal reputation, etc.)
- ☐ psychological (emotional, behavioral, etc.)
- ☐ physical
- ☐ loss of confidentiality
- ☐ criminal or civil liability
- ☐ deception (benevolent misdirection)
- ☐ financial (any expense including travel)
- ☐ other (explain below)

D. Explain any of the risks identified above.

What safeguards will you use to eliminate or minimize these risks, including risks to confidentiality? If subjects experience adverse reactions, how will these reactions be managed or where can they seek help and at whose cost? Also, where appropriate, describe the provisions for maintaining the data collected to ensure the safety of subjects' anonymity.

VIII. Off-Site Research

A. If the research project receives federal funds from an agency, each study site will need to negotiate a Federal Wide Assurance with the Office for Human Research Protections (OHRP). Guidance may be found at OHRP's web site, **http://ohrp.osophs.dhhs.gov/irbasur.htm**.

B. If the research project will receive no federal funds, a letter from the appropriate administrator of each facility should be submitted on the facility's letterhead stationary and should contain the following information: agreement for the study to be conducted; identification of someone at the site who will provide information about appropriateness for its population; assurance of adequate capabilities to perform the research as approved by the IRB; and, if applicable, assurance that facility personnel involved in data collection have appropriate expertise and will follow IRB approved procedures.

IX. Follow-up Procedures

All approved projects will submit a final report (e.g., abstract of thesis or article) to the IRB within six weeks of the conclusion of the project. If the project will continue past the reported completion date, the investigator will provide to the IRB chairperson a written continuance request with an explanation of why more time is needed for the project. The IRB chairperson must approve the request before the project will be allowed to continue.

X. Informed Consent

Attach all the informed consent form(s), permission letters, sample documents and (if applicable) release forms you will use in this study.

A. How will the study be explained to the subjects and by whom?

B. Does the consent form include the following information? Answer "yes" or "no" in each blank.

_____ The title, the principal investigator's name, and purpose of the project.

_____ A statement that explains what the participant will have to do.

_____ A statement that participation in this project is voluntary.

_____ A statement that explains the cost, if any, to the subject to participate.

_____ A statement that the subject's name will not be revealed or linked in any way to the data that is collected **OR** request to waive this requirement is explained below. Conditions for waiver usually include written consent of the subject and justification that the need to use the subject's name is integral to the study.

_____ A statement that explains who will have access to the requested information.

_____ A statement that the participant may withdraw from the study at any time without penalty.

_____ The name and phone number of a specific person to contact if the participant has questions or concerns about the project.

_____ The name and phone number of counseling or treatment center should subjects experience any adverse effects as a result of the project. Include who will pay for treatment if treatment is sought.

_____ A statement that neither participation nor non-participation will effect a student's grade in any institution

_____ If participants receive extra credit points, non-participants must have an opportunity to earn equivalent points.

_____ A statement that explains benefits to subjects and/or department.

_____ A statement or space for participants to receive the summary of results (if applicable).

_____ A conflict of interest statement.

C. Explain "no" answers or request for waiver (above), or other special conditions relating to informed consent.

D. If subjects are less than the age of legal consent, or are mentally incapacitated, indicate how consent of parents, guardians, or other qualified representatives will be obtained.

E. If the project involves minors, the informed consent form must also include the following information:

☐ The consent form must be clearly identified as a consent form of a minor.

☐ At least one parent or guardian must sign the consent form

☐ Minors six (6) years of age or older should be involved in the decision to participate.

XI. Debriefing Form

A. The debriefing form should be a past-tense form of the informed consent form.
B. The subject must be allowed to keep the debriefing form.

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