IRB Application for Expedited or Full Review

Version: 2.4 Date: 01/26/2019

The North Park University IRB is required to review and approve all research involving human subjects. This application is intended for studies which require expedited or full review by IRB. If you believe your research is exempt, please complete the exempt application first to see if the IRB assesses your project to be exempt. If you require written documentation from the IRB, complete the entire form, and email the signed form and any relevant supporting documents (i.e., grant, protocol, consent forms) to IRBChair@northpark.edu. You should receive an IRB response within 10 business days.

Expedited or Full Review
E-mail the signed form and any relevant supporting documents (i.e., grant, protocol, consent forms, surveys) to IRBChair@northpark.edu.

Section 1: Project Information
Project Title
Name of Funding Source (i.e., Department, NIH, Foundation)
Grant Number (if applicable)
Project Description and Methodology 1. Describe the aims of the study and any activities involving interaction, intervention with human subjects, and/or their information or specimens. You should describe the research design and methods in lay language. Please include attachments including instruments, and consent forms. You should include everything the subjects will hear or see.

2. Provide the research question or hypothesis and briefly (1/2 page maximum) discuss relevant background information and literature reviewed to provide the rationale for the proposed research. Please cite references in text, as appropriate, to justify background and hypothesis(es). State the relevance of this research to and potential for contribution to the field of study.

Investigator Information	
Name (Last, First)	
Department	
E-mail	Phone Number
Address:	
Co-investigator(s):	
Faculty Sponsor (if applicable):	
Department	
E-mail	Phone Number
Address:	
Proposed Project Starting and Ending Dates:	
Has this research been reviewed by another IRB: ☐ Yes	(Please indicate organization and date):

Training Certificate
A certificate of training for Protecting Human Subject Research Participants is necessary. It can be obtained by going to the CITI (Collaborative Institutional Training Initiative) training site (https://about.citiprogram.org/en/homepage/) and taking an on-line course. Please see the CITI account access document on the IRB website. CITI is a consortium of mainly research institutions which offers approved training. North Park is a member of this consortium.

☐ The certificate is attached.

Informed Consent:	☐ **The consent form is attached**
Describe the procedures for obtaining informed consent, including timetables.	

Vulnerable Subjects

☐ Yes	Are any subjects under 18 years of age[1]?
☐ Yes	Are any subjects confined in a correctional or detention facility?
☐ Yes	Will a person with a supervisory or teaching relationship to the research participant perform data collection?
☐ Yes	Are all subjects presumed to be legally competent?
☐ Yes	Are fetuses in utero subjects in this research?
☐ Yes	Is pregnancy a prerequisite for serving as a subject?

Briefly describe how you will make sure to protect these vulnerable subjects. This may include protections above and beyond what you would do for subjects not in this category.

[1] Who is a child?

Privacy	
☐ Yes	Are personal records (medical, academic, etc.) used without written consent?
☐ Yes	Are data from subjects (responses, information, specimens) directly or indirectly identifiable?
☐ Yes	Are data potentially damaging to subjects' financial standing, employment, or reputation?
What personal identifying information will be collected? *(name, address, phone #, student ID#, hospital ID#, Social Security #):*	
How will these personal identifiers be linked to data, and for what period of time?	

Briefly describe how confidentiality of the subjects or data will be maintained if the data can be linked to subjects (including plans for data storage and destruction.)

Will anyone other than the research team have access to the data? ☐ Yes ☐ No

If yes, please explain:

Data Gathering:

How will the data be gathered and what instruments will be used in this study **(please list all instruments and protocols here and include copies of all instruments and protocols with this application)**:

What will be number of subjects (sample size)?	_____

How will subjects be recruited and selected? ***(attach letters and advertisements)***

Is compensation being offered?	☐ Yes ☐ No

If yes, indicate type and amount of compensation. If compensation is in kind, estimate the dollar value of the services or goods being offered.

Will existing data be used? ☐ Yes ☐ No

If the answer to the above question was yes (e.g.,archived tissue samples), please provide a brief explanation:

Risk	
What are the potential risks to the Research Subject?	**Explain:**
Physical ☐ None ☐ Minimal ☐ Moderate ☐ Severe	
Psychological/emotional ☐ None ☐ Minimal ☐ Moderate ☐ Severe	
Social ☐ None ☐ Minimal ☐ Moderate ☐ Severe	
Economic ☐ None ☐ Minimal ☐ Moderate ☐ Severe	
Privacy/confidentiality ☐ None ☐ Minimal ☐ Moderate ☐ Severe	
Other ☐ None ☐ Minimal ☐ Moderate ☐ Severe	
Describe the precautions that will be taken to minimize risks.	
How will adverse effects be handled? (In the event of physical or emotional risk, please indicate emergency action plan if applicable)	
Who will be *financially* responsible for adverse impacts or injuries resulting from study participation?	

Benefits: Describe potential benefits to Study subjects and Society.

Signature of Investigator: _____

Date: _____

SECTION VII: IRB Determination (to be completed by IRB)*

The activities are as described in the ☐ submitted protocol and/or ☐ materials and description of activities provided by the investigator.

☐ The proposal meets the criteria of expedited compliance in accordance with 45 CFR 46 and 21 CFR 50 & 56.

- ☐ It was approved.
- ☐ It was rejected.

☐ The proposal requires a convened IRB meeting, which met on _____

- ☐ It was approved.
- ☐ It was rejected.

☐ For activities involving decedents and their Protected Health Information (PHI), the conditions as set forth in the Privacy Rule at 45 CFR 164.512(i)(I)(iii), have been met.

- the use or disclosure sought is solely for research on the protected health information of decedents;
- documentation can be provided, at the request of the covered entity, of the death of such individuals; and
- the protected health information for which use or disclosure is sought is necessary for the research purposes.

Authorized IRB Personnel Printed Name: _____

Authorized IRB Personnel Signature: _____

Title: _____

Date: _____

*If any activities completed were or possibly were not in compliance with federal regulations regarding prior IRB review, please forward the form to the IRB Compliance Manager for review. For example, the investigator reports activities which are already completed but initially required IRB approval.

This form was adapted with permission from a Northwestern U. application.