NORTH PARK UNIVERSITY
CHICAGO

IRB Exempt Application

Version: 2.2 Date: 1/31/2019

The North Park University IRB is required to review and approve all research involving human subjects. This application is intended to help you determine if your project requires IRB approval. 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.

Section I: Project Information	
Principal Investigator	Date of IRB submission:
Project Title	
E-Mail address:	Phone:
Address:	
Name of Funding Source (i.e., Department, NIH, Foundation) if applicable	
Grant Number (if applicable)	
Project Description (describe the aims of the study and any activities involving interaction, intervention with human subjects, and/or their information or specimens). Please include attachments, instruments, and consent forms as needed.	

Current Status of the Project

Has the project already been conducted (i.e., data has already been collected and analyzed)?

☐ Yes ☐ No

SECTION II: Activities Determined by the NPU IRB Not to Represent Human Subjects Research

A. ☐ **Case Report / Case Study**: The project consists of a case report, case study or series which describes an interesting treatment, presentation or outcome. A critical component is that nothing was done to the patient(s) with prior "research" intent.

NOTE: For case reports, HIPAA requires that the disclosure of an individual's protected health information must be authorized by that individual. If a case report contains any of the 18 protected health information identifiers as defined by the HIPAA regulations, a signed authorization to disclose this information must be obtained from the individual(s) whose information is being disclosed.

B. ☐ **Course-Related Activities**: The project is limited to course-related activities designed specifically for educational or teaching purposes where data are collected from and about students as part of a routine class exercise or assignment and is not intended for use outside of the classroom.

NOTE: IRB approval is required if a student is involved in an activity designed to teach research methodologies and the instructor or student wishes to conduct further investigation and analyses in order to contribute to scholarly knowledge. If the research is only to be used and presented only in the course please complete the *Classroom research IRB form*.

C. ☐ **Journalism/Documentary Activities**: The activities are limited to investigations and interviews that focus on specific events, views, etc., and that lead to publication in any medium (including electronic), documentary production, or are part of training that is explicitly linked to journalism. There is no intent to test a hypothesis.

NOTE: IRB approval may be required when journalists conduct activities normally considered scientific research intended to produce generalizable knowledge (e.g., systematic research, surveys, and/or interviews that are intended to test theories or develop models).

D. ☐ **Oral History:** The project is limited to oral history activities, such as open ended interviews, that only document a specific historical event or the experiences of individuals without the intent to draw conclusions or generalize findings.

NOTE: IRB approval is required when the oral history activities are intended to produce generalizable

E. ☐ **Program evaluation /Quality Improvement/Quality Assurance Activities**: The project is limited to program evaluation, quality improvement or quality assurance activities designed specifically to assess or improve performance within the department, hospital or classroom setting. The intention of the project is not to generate conclusions that can be applied universally, outside of the immediate environment where the project occurred.

F. ☐ **Public Use Datasets:** The project is limited to analyzing de-identified data contained within a publicly available dataset. Below are examples of data sources that qualify as not-human subjects research (unless the researcher has received the restricted use data):

☐ Data files downloaded from the ICPSR (Interuniversity Consortium for Political and Social Research): http://www.icpsr.umich.edu/icpsrweb/ICPSR/ or the Roper Center for Public Opinion Research http://www.ropercenter.uconn.edu.

☐ American National Election Studies, (ANES) 1948-2010 http://www.electionstudies.org/

☐ Bureau of Economic Analysis: http://www.bea.gov/

☐ Bureau of Labor Statistics (BLS): http://www.b1s.gov/

☐ Center for Disease Control (CDC): http://www.cdc.gov/

☐ Consumer expenditure Survey: http://www.bls.gov/cex/

☐ Current Population Survey: http://www.bls.gov/cps/ n General Social Survey: http://www3.norc.org/GSS+Website/

☐ National Center for Education Statistics (NCES): http://nces.ed.gov/

☐ National Longitudinal Surveys (NLS): http://www.bls.gov/nls/

☐ Government sites that bring data files together: Data.gov (http://www.data.gov/); FedStats (http://www.fedstats.gov/); and USA.gov (http://www.usa.gov/Topics/Reference_Shelf/Data.shtml)

☐ Other _____

NOTE: IRB review is required if the publicly available data set contains identifiers, or if the merging of multiple data sets might result in identification of the subjects. In both cases, Exempt Category #4 may apply.

Instructions: If your activity did not fall into the categories described in Section II, continue to Section III to assess if you are engaged in human subjects research per the regulations set forth by the Department of Health and Human Services (HHS) and the Food and Drug Administration (FDA).

Nota bene: We welcome your opinion as to the status of your research, but It is the responsibility and prerogative of the IRB to determine which human subject research qualifies as exempt, and which does not. Even if the investigator proposes that his or her research is exempt this must still be affirmed by the IRB.

Section III. Activities subject to HHS human subject research regulations (45 CFR 46)

1. Is the activity RESEARCH a systematic investigation designed to contribute to generalizable knowledge?

TIP: If the investigation characterized by order, planning, and methodology and the intention of the investigation is to generate conclusions that can be applied universally, outside of the immediate environment where the investigation occurred (i.e., the classroom, hospital, department), then the activity meets the definition of research**.**

☐ Yes, IRB review required ☐ No, IRB review is not required

2. Will the research lead to a publication or a presentation that is designed to contribute to the generalized knowledge in a field?

☐ Yes, IRB review required ☐ No, IRB review is not required

3. Does the research involve obtaining information about LIVING individuals?

☐ Yes, IRB review required ☐ No, IRB review is not required

4. Does the research involve collecting data through intervention (i.e., physical procedures or manipulation of the environment) or interaction (i.e., communication or interpersonal contact between investigator and person) with the individuals?

☐ Yes, IRB review required ☐ No, IRB review is not required

5. Does the research involve collecting identifiable information (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information)?

☐ Yes, IRB review required ☐ No, IRB review is not required

6. Is the information private? (About behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, or provided for specific purposes by an individual and which the individual can reasonably expect will not be made public)

☐ Yes, IRB review required ☐ No, IRB review is not required

Section IV: Complete this section if you or the IRB have determined that your activities do not constitute human subjects research and you require written confirmation of this determination from the IRB. E-mail the signed form and any relevant supporting documents (i.e., grant, protocol, surveys, consent forms) to IRBChair@northpark.edu	
Investigator Information	
Name (Last, First)	
Department	
E-mail	Phone Number
Address	

Signature of Investigator: _____

Date: _____

SECTION V: 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.

☐ They do not constitute research with human subjects in accordance with 45 CFR 46 and 21 CFR 50 & 56. IRB approval is not required.

☐ 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: _____

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