NORTH PARK UNIVERSITY
CHICAGO

IRB APPLICATION FOR HUMAN SUBJECT RESEARCH

1. PROJECT TITLE

2. PROJECT DATES:

to

NOTE: Project may not start before IRB approval.

3. TYPE OF REVIEW: (See Exempt and Expedited Categories Lists) Investigator's best estimate of the anticipated level of review:

Exempt ☐ Expedited ☐ Full ☐

*The IRB will make final determination.

a. For an exempt review, please check the appropriate exempt review category below.

- ☐ Category 1 Educational Practices
- ☐ Category 2 Educational Tests, Surveys, Interviews, or Observation of Public Behavior
- ☐ Category 3 Benign Behavioral Interventions with Adults
- ☐ Category 4 Secondary Research for Which Consent is Not Required
- ☐ Category 5 Public Benefit or Service Programs
- ☐ Category 6 Taste and Food Quality Evaluation
- ☐ Category 7 Storage or Maintenance for Secondary Research Using Broad Consent
- ☐ Category 8 Secondary Research Using Broad Consent

b. For an expedited review, please check the appropriate expedited review category below.

- ☐ Category 1 Clinical Studies of Drugs and Medical Devices
- ☐ Category 2 Blood Sample Collection
- ☐ Category 3 Prospective Collection of Biological Specimens
- ☐ Category 4 Noninvasive Collection of Clinical Data
- ☐ Category 5 Research Using Existing Materials
- ☐ Category 6 Data from Recordings
- ☐ Category 7 Individual or Group Characteristics or Behavior
- ☐ Category 8 Continuing Review of Previously Approved Research
- ☐ Category 9 Continuing Review of Minimal Risk Research

c. Full Board Review

- Does not fit one of the exempt or expedited categories.
- Presents greater than minimal risk.
- Research involving invasive procedures or with significant psychological, legal, or economic risks.
- Research involving vulnerable populations when the procedures or risks exceed what is allowed under exempt or expedited review.

3. Type of Study

New ☐ Current Study Modification ☐ Continuing/Renewal ☐ Denied Resubmission ☐

Is this project expected to recur annually? ☐ Yes ☐ No

If yes, please describe the anticipated frequency or schedule:

4. PRINCIPAL INVESTIGATOR INFORMATION

Principal Investigator	
Co-Investigators	
Department or Affiliation	
Telephone	Email:
Name of chair/supervisor	
Email of chair/supervisor	

5. IRB Training and Certification

Have you completed the required online IRB training program appropriate to your study? ☐ Yes Date _____

Course(s) Completed: _____

_____

***Proof of completion must be submitted along with this application.**

6. Student / Outside Researcher Information

If you are a student, please provide the following as applicable:

Type of Project: Thesis/Dissertation: ☐ Independent Study: ☐ Class Project: ☐ Other: ☐

Course # & Name: _____

Faculty Sponsor:		Dept:	
Faculty Email:		Phone:	

Students and outside researchers must provide their current address:

NOTE: An application by a student researcher must have the following statement signed by a university sponsor:

I have examined this completed form, and I am satisfied with the adequacy of the proposed research design and the measures proposed for the protection of human subjects. For student projects, I will take responsibility for informing the student of the need to keep all raw data (e.g., test protocols, tapes, questionnaires, interview notes, etc.) safe.

Signature of University/Faculty Sponsor _____ Date _____

If you are an outside researcher, please provide the following as applicable:

Investigator Name:			
Name of Home Institution:			
Investigator email:		Phone:	
Home Institution IRB Contact:		Dept:	
Date of IRB Approval: (Please include copy of approval)		FWA Number	

NOTE: An application by an outside researcher must have the following statement signed by a university sponsor:

I have examined this completed form, and I am satisfied with the adequacy of the proposed research design and the measures proposed for the protection of human subjects. I will take responsibility for informing the above-mentioned investigator of the need to safeguard all raw data (e.g., test protocols, tapes, questionnaires, interview notes, etc.).

Signature of University/Faculty Sponsor _____ Date _____

5. FUNDING

Is this project being funded? ☐ Yes ☐ No

If yes, list the funding source and/or grant number:

Please provide additional details as relevant (pending, externally/internally funded, Federal):

6. **RESEARCH STATEMENT:** Give a short justification for the study:

7. **PARTICIPANTS**

a. Indicate the population to be studied (see HHS Regulations for the Protection of Human Subjects):

Indicate which, if any, of the following groups will be research subjects (check all that apply):
OHRP designated vulnerable populations:

- ☐ Children
- ☐ Pregnant women/fetuses/neonates
- ☐ Prisoners
- ☐ Individuals with cognitive impairments

Populations requiring additional consent/accessibility considerations:

- Non-English Speakers
- ☐ Economically or Educationally Disadvantaged
- ☐ Single Subject Populations (by Sex and Race and/or Ethnicity)
- ☐ Residents of institutional or residential settings who may be vulnerable to coercion or undue influence
- ☐ Subjects that have been abused
- ☐ People with chronic illness, debilitating medical conditions, degenerative diseases, or other physical, mental, or emotional disabilities
- ☐ Terminally ill subjects
- ☐ Research in emergency settings
- ☐ Veterans
- ☐ North Park Employees and Students
- ☐ No special groups
- ☐ Other (specify):

c. If your group is considered a vulnerable population or one that requires additional consideration, state the rationale for their use as research subjects.

d. What is the approximate number of subjects to be recruited?

e. How will the subjects be solicited (check all that apply)?

☐ Advertisements ☐ Letters ☐ Random Calls
☐ Telephone Lists ☐ Notices ☐ Direct Solicitation

Other (specify):

8. INCENTIVES

f. Will subjects be compensated and/or are incentives being offered? ☐ **Yes** ☐ **No**

- **The Office for Human Research Protections offers guidance on incentives and informed consent. You can find that information here.**

g. If incentives are being offered, please explain, including type of compensation, amount/value, purpose, payment schedule, withdrawal provisions, recruitment disclosure, and justification:

9. INFORMED CONSENT.

OHRP guidance on informed consent can be found here. Information on consent and assent forms, the required consent elements, and sample consent forms can be found here.

a. Type of Consent/Minor Assent Requested (check all that apply):

(i) ☐	Adult Consent

(ii)	Use of Minors (under 18 years of age)	
☐	Parent/Guardian Consent	
☐	Child/Minor Assent (Non-readers): Not able to read or not proficient at reading)	
☐	Child/Minor Assent (Proficient readers: Can read & understand a simple assent form)	

(iii) In certain circumstances, a waiver of informed consent/minor assent may be requested. In this case, subjects are not informed, or are only partially informed, about a study. To request that informed consent or assent be waived, indicate the category below (check all that apply).

☐	Informed consent will not be obtained.
☐	Parental consent will not be obtained.
☐	Child/minor assent will not be obtained.
☐	Partial Consent/Assent: This study involves deception

Justify why informed consent will not be obtained or why deception is necessary for this study. For studies that involve deception, please include plans for how and when subjects will be debriefed. If a debriefing statement will not be used, explain why.

b. Method to obtain consent/minor assent.

☐ Written Consent/Assent (written signature will be obtained from subjects)
☐ Oral Consent
☐ Electronic Consent
☐ No Written Consent/Assent Obtained (a written signature will not be obtained from subjects. Documentation of a signature is waived.)

Provide a rationale below for the method of consent:

10. DATA & CONSENT COLLECTION

a. Data collection methods (check all that apply):

☐ Questionnaire or Survey
☐ Web or Internet
☐ Interview
☐ Observation
☐ Video or Audio Taping
☐ Computer Collected Task Data
☐ Other:
☐ Archival Data
☐ Intervention
☐ Focus Groups
☐ Testing/Evaluation
☐ Instruction/Curriculum
☐ Physical Tasks

b. Will the data be collected with identifiers? ☐ Yes ☐ No

If yes, will the data be rendered anonymous for analysis? ☐ Yes ☐ No

Will the data be rendered anonymous for reporting? ☐ Yes ☐ No

c. Describe how consent forms and other study material (e.g., data instruments, interview questions) will be distributed and collected and how confidentiality/anonymity will be maintained throughout both the consent and data collection process.

d. Describe security of the data, including where the consent forms and other study material will be stored, who will have access, and how and when the material will be destroyed. Note that signed consent forms must be retained for **three years** after the end of the study. State who will maintain the consent forms for the specified three years. (Note: faculty/staff sponsors may retain the original or a copy of signed consent forms, including those collected from student projects.) Please address cloud storage, encryption, and related topics.

11. METHODOLOGY: Describe in detail how the research will be conducted making sure to address (1) how subjects will be identified and the process of contacting, selecting and excluding subjects; (2) how consent will be obtained, and if children will be used, describe how parental consent and child assent will be obtained; and (3) how data will be collected, including how data instruments, if used, will be distributed and collected, and the location where the study will take place.

12. RISK FACTORS: A research participant is considered to be at risk if they may be exposed through the procedures of the planned experiment to the possibility of physical or mental harm, coercion, deceit, or loss of privacy. The most obvious examples of placing participants at risk of harm include administration of unusual physical exertion, deceit, and public embarrassment or humiliation. Coercion may be present when potential participants are unable to exercise their right to decline participation, particularly when the researcher holds greater power over them.

a. Risk Criteria **CHECK ONE**

Deceit, coercion, or possible embarrassment/humiliation	☐ Yes	☐ No
Experimental drugs will be used.	☐ Yes	☐ No
Potential for medical problems exists.	☐ Yes	☐ No
Participants may experience physical discomfort.	☐ Yes	☐ No
Participants may experience mental discomfort.	☐ Yes	☐ No
Electrical equipment will be used.	☐ Yes	☐ No
Participants will be tape recorded, photographed, or videotaped.	☐ Yes	☐ No

b. Does any part of this activity have the potential for coercion of the subject? If yes, explain and describe the proposed safeguards. ☐ Yes ☐ No

c. Assess the likelihood and seriousness of risks (physical, mental, or other) to the subjects. Describe alternative methods that would not entail comparable risks and why these were not used.

d. Description of the anticipated benefits to subjects and contributions to general knowledge in the field of inquiry:

e. If the research subjects will be compensated or rewarded, indicate the type and amount of compensation and the milestone for each payment. If subjects are being recruited from NPU classes, indicate whether students are receiving course credit (regular or extra credit) and, if so, what alternatives are offered to those students who do not wish to participate in the research.

13. Is Artificial Intelligence being used? ☐ **Yes** ☐ **No**

a. If AI is being used, which AI platform?

b. Will identifiable information be entered?

14. SUBMISSION MATERIAL

The IRB must review copies of all final material presented to subjects. The IRB cannot approve a project without a complete and accurate application and final copies of all supporting materials. Please indicate below what materials have been attached to this application (check all that apply):

- ☐ Recruitment material (flyer, announcement, oral script, email, letter, etc.)
- ☐ Data instruments (surveys, interview questions, tests, web-survey, etc.)
- ☐ Informed consent
- ☐ Debriefing statement
- ☐ Video clips, music CDs, photos, etc.
- ☐ Other: (specify) _____

15. CERTIFICATION STATEMENT

Investigator Certification and Assurance

In submitting this application, I certify that I have read and understand North Park University's policies and procedures governing research involving human participants, including those described in the North Park University Institutional Review Board Policy. I agree to conduct this research in accordance with the approved protocol, applicable University policies, and applicable federal regulations governing the protection of human research participants.

I further certify and agree that:

1. ***IRB Approval/Determination:*** *I will not initiate research activities involving human participants until I have received the required IRB approval or determination and have satisfied any other applicable institutional requirements.*
2. ***Approved Protocol:*** *I will conduct the research in accordance with the IRB-approved protocol and supporting materials. I will obtain IRB approval before implementing changes to the approved research, except when a change is necessary to eliminate an apparent immediate hazard to participants. Any such change will be reported promptly to the IRB.*
3. ***Informed Consent:*** *I will obtain and document legally effective informed consent, and assent when applicable, in accordance with the IRB-approved protocol unless the IRB has approved a waiver or alteration of these requirements.*
4. ***Privacy and Confidentiality:*** *I will protect the privacy of research participants and maintain the confidentiality and security of identifiable private information and identifiable biospecimens in accordance with the approved protocol, applicable University policies, and applicable legal and regulatory requirements.*
5. ***Research Personnel:*** *I will ensure that all individuals engaged in the conduct of this research are appropriately qualified, have completed required human-subjects research training, and understand their responsibilities under the approved protocol before participating in research activities.*
6. ***Reporting:*** *I will promptly report to the IRB any unanticipated problems involving risks to participants or others, reportable adverse events, serious or continuing noncompliance, or other matters requiring reporting under University IRB policy.*
7. ***Continuing IRB Requirements:*** *I will comply with any applicable requirements for continuing review, progress reports, amendments, and study closure and will maintain IRB approval when required for ongoing research activities.*
8. ***Records:*** *I will maintain research and IRB records as required by University policy, the approved protocol, and applicable law and regulation.*
9. ***Departmental or Other Requirements:*** *I understand that individual departments, programs, collaborating institutions, funding agencies, or research sites may impose additional requirements, and I am responsible for identifying and complying with those requirements when applicable.*

By signing or electronically certifying this application, I acknowledge my responsibility for the ethical conduct of this research and for the protection of the rights, safety, privacy, and welfare of research participants.

X _____

Principal Investigator/Project Director

X _____

Supervisor/Dean/Chair/Director

16. CHAIR APPROVAL

X _____

IRB Chair Signature

17. SUBMISSION INFORMATION

An electronic copy of the completed application and all required supporting documents should be submitted HERE.

Submitting incomplete packets may significantly delay the review process.

For questions, comments, or assistance in completing the form, contact Pauline Lipscomb at plipscomb@northpark.edu.

Additional information on IRB federal policy can be found here.