# Institutional Review Board
# Research Proposal

**PROJECT TITLE:** _____

## INVESTIGATOR INFORMATION

Principal Investigator Name, Degree(s): _____

Affiliation: _____

Contact phone: _____

Institutional Email: _____

## ADVISOR CONTACT INFORMATION (REQUIRED FOR ALL STUDENTS

Name, Degree(s): _____

Contact phone: _____

University Email: _____

## ALTERNATE/COORDINATOR CONTACT INFORMATION

Name: _____

Contact phone: _____

University Email: _____

Office Use Only:
Application v 2023-02

## SECTION 1: REQUIRED SIGNATURES (This page may be a separate PDF document)

### 1. PRINCIPAL INVESTIGATOR

I will conduct my study according to the requirements of the Winnebago Tribe of Nebraska procedures for research with human subjects.

| Signature | Date | Print Name |
|---|---|---|

### 2. ADVISOR

I will oversee the student researcher according to the Winnebago Tribe of Nebraska procedures for research with human subjects.

| Signature | Date | Print Name |
|---|---|---|

## SECTION 2: GENERAL INFORMATION

**1.** What is the expected length of this project?

**2.** Is the project funded? ☐ No ☐ Yes- Complete required below:
Provide name of funder:

**3.** List all personnel working on the study:

| Name | Research Role | Consenting Individuals (Y/N) | Affiliation |
|---|---|---|---|
| | | | |
| | | | |

## SECTION 3. SPECIFIC QUESTIONS FOR RESEARCH WITH THE TRIBE

*1)* Describe the process the researcher used to consult with the Tribe:

*2)* Describe the specific local laws or customs that the researcher will follow to complete the proposed research activity:

*3)* Describe any specific recruitment, consent, and additional risk factors that the IRB needs to take into consideration:

*4)* Describe how results will be shared with participants, and families, and the Tribe:

*5)* Will the data or information remain with the researcher once the study is complete:

☐ *No* ☐ *Yes* - explain:

*6)* Will biological specimens be collected
☐ No ☐ Yes - *explain:*

*7)* Will biological specimens be placed in a repository?
☐ No ☐ Yes - *explain:*

## SECTION 4. PROJECT NARRATIVE

***Delete the red text prior to submitting this form to the IRB. A lay summary is required for all items below.***

**1) Background**

Provide the scientific or scholarly background for the proposed Human Research. Discuss relevant prior experience or preliminary data (e.g., existing literature).

## 2) Purpose

This section should describe the purpose, specific aims, objectives, questions to be answered, hypotheses, and/or primary and secondary study endpoints of the Human Research.

## 3) Lay Summary (approximately 400 words)

Provide a brief description of the proposed research using terms that someone who is not familiar with the science or discipline can understand.

## 4) Setting of the Human Research

This section should discuss the setting in which the Human Research is to be conducted.

Describe site-specific regulations or customs affecting the research.

## 5) Resources available to conduct the Human Research

Describe the resources (personnel, facilities, time, emergency resources, etc.) available to recruit, consent, conduct study procedures, and analyze data.

Describe your process to ensure that all persons assisting with the study (e.g., school teachers or community members) will receive appropriate training for their study-related duties and functions.

## 6) Study Population

Provide a general description of who is in the study and how many individuals are anticipated to complete the proposed study. The populations described here should reflect all the populations being recruited and asked to consent.

## 7) Recruitment Methods and Consenting Process

**a.** Recruitment Process: Describe how potential participants will be identified, where recruitment will take place, when recruitment will occur, and the methods that will be used to recruit.

Provide copies of any materials used to recruit participants directly (e.g. recruitment scripts, emails, print/audio/visual advertisements, or online notices).

**b.** Informed Consent: Describe the consent process, setting, time to discuss and ask questions, and who will be involved. Include oral and written processes for people who do not speak and/or read English.

Include how consent will be documented (e.g. written, oral, online, or waived). Describe procedures that minimize the potential for coercion or undue influence. When children are participants or where participants are unable to consent, include procedures to protect these populations (e.g. parental permission or Legally Authorized Representative).

## 8) Research procedures involved in the Human Research

This section should explain the research **in lay language.** Include how long participant participation is expected to last.

Discuss all research procedures involved in the Human Research for each participant population participating in the study. Research procedures may be direct interactions or interventions, like surveys, questionnaires, recordings, photographs, blood draws, or medical exams. Procedures may also include indirect interactions, such as records review and data analysis.

Describe what information will be collected, including screening and long-term follow-up. If records will be accessed to collect information about participants, discuss to whom the records belong and how the records will be made accessible to the researcher.

## 9) Cost to participants

Describe any costs, monetary and non-monetary, that participants may incur. Include how much time it takes participants to complete research activities. The information in this section should match what appears in the consent documents.

## 10) Risks to participants

Risks may be physical, psychological, social, legal, and or economic. Risks should be 'reasonably foreseeable risks of the research.' If known, discuss their probability, magnitude and expected duration. If applicable, discuss what steps have been taken to minimize risk to participants.

## 11) Potential benefits to participants and/or Tribe

Benefits may be educational, psychological, physical, and/or medical. If applicable, indicate the probability, magnitude, and duration of the benefit, including benefit to the Tribe.

## 12) Provisions to protect the privacy of participants and the confidentiality of data

a. **Protection of participant privacy:** Describe steps to protect the privacy of the participants throughout their participation in the Human Research (e.g. during the recruitment process, consent process, and/or research procedures).

b. **Protection of data confidentiality:** Describe steps to protect information obtained from participants. Discuss the process for storing, securing access (including who may have access to the information), what security measures are in place, and how long the information will be stored.

   If using video or audio recording, discuss when the recording will be transcribed.

## 13) Future use and long-term storage of data or specimens

Describe if data or specimens will be kept for future research, including unspecified future research.

**14) Access to Private Information**

a. **Access to medical records (HIPAA)**: Describe what information will be accessed, who will access the information, and how the information will be recorded and stored. Written authorization is required unless waived. Provide a description of the data elements that will be reviewed or abstracted from the medical record.

b. **Access to educational records (FERPA):** Describe what records will be accessed, who will access the information, and how the information will be recorded and stored. Written authorization is required in most instances.

**15) Participant compensation**

Discuss the amount and timing of any compensation (monetary and/or non-monetary). Describe if compensation will be prorated.

**16) Monitoring for participant safety**

If the Human Research involves more than minimal risk to participants, provide a brief lay discussion of the plan to monitor for participant safety. Describe how the data will be evaluated, include a timeline of when the review(s) will occur, who will review the information, and what information will be reviewed.

**17) Withdrawal of participants**

Discuss how, when and why participants may be removed from the study. If abrupt withdrawal is necessary, discuss how participants will be withdrawn so that they are not put at increased risk.

Discuss what happens if a participant is withdrawn from one part of the study but asked to continue with other parts, such as ongoing follow-up.

| **SECTION 4: LIST OF ATTACHMENTS FOR THIS SUBMISSION (REQUIRED)** | |
|---|---|
| **Document Name** | **Version Date** |
| **1.** | **1.** |

**Items needed for approval:**

- Word Versions of Application, Consents, Recruitment and Data Collection
- **Informed Consent/Permission/Assent Form(s)** – If consent will not be documented in writing, a script of information to be provided orally to participants
- **Recruitment Materials** – telephone scripts, flyers, brochures, websites, email texts, radio/television spots, newspaper advertisements, press releases, etc.

- **Participant Materials** – written materials to be provided to or meant to be seen or heard by participants (e.g. study newsletter, incentive items, holiday/birthday cards, certificates, instructional videos/written guides, calendars, certification of achievement, etc.)
- **Copies of other approvals** – approval from home institution and all supporting documents

**Instructions for Submission:**

Submit a completed copy of this application and required attachments to the Winnebago Tribe of Nebraska Institutional Review Board at irb@winnebagotribe.com.