

Appendix A

Dated Received: _____

File Number: _____



CMN Institutional Review Board
Application to Conduct Human Subjects Research

Type of application: Initial _____ Resubmission _____ Continuing _____

Principal Investigator: _____

Title of Research Project: _____

Address: _____

Phone: _____ Email: _____

Co-Investigator(s): _____

Phone: _____ Email: _____

Co-Investigator(s): _____

Phone: _____ Email: _____

Faculty Sponsor: _____

Department: _____ Title: _____

Phone: _____ Email: _____

Funding: Verified _____ Anticipated _____ None _____
(Identify the funding source if Verified or Anticipated)

Funding Source: _____

Projected Duration of Research: _____ Projected Starting Date: _____

Other organizations and/or agencies, if any, involved in the study: _____

Study Overview

Please provide the following narrative, abstract/background. Provide a short description of the problem, objectives, and the importance of the research.

Study Procedures

Location of the research: _____

Study duration (hours): _____ Number of study visits required of research participants: _____

Data collection:

Tests _____

Surveys _____

Interviews _____

Observations _____

Existing data _____

Other _____

Expected number of participants: Minimum _____ Maximum _____

Expected duration of participation for each subject: _____

Describe how you will recruit potential participants: _____

Inclusion/Exclusion Criteria, if any: _____

Subjects

Age ranges: youngest _____ oldest _____

Will the study involve any of the following participants? (Please check all that apply if your study specifically targets these populations.)

Children (under 18) _____

Pregnant women _____

Prisoners or detainees _____

Medical patients _____

Mentally impaired _____

Elderly _____

Non-English speakers _____

Native Americans _____

Physically handicapped _____

If any of the above categories have been checked, please state how you will protect the rights and privacy of these individuals. _____

Please provide the rationale for the inclusion of these subjects. _____

Does the proposed research require that you deceive participants in any way? Yes_____ No____
If your response is yes, describe the type of deception you will use, indicate why it is necessary for this study.

What are the potential risks of the research? Include physical harm, psychological harm, privacy, and employability. _____

What steps will be taken to reduce the risks? _____

Will any type of compensation be used? (e.g., money, gift) Yes_____ No____
If your response is yes, describe the type of compensation you will use. _____

Describe the probable benefits. How will participating in this study benefit the individual and society?

Describe the procedures you will use to obtain and document informed consent and/or assent.

Describe the steps you will take to ensure the confidentiality of the participants and data. _____

Where will the data be stored? _____

Attachments:

1. Provide a copy of consent/assent forms
2. Surveys
3. Interview questions
4. Recruitment script
5. Any handouts or materials you will use to conduct this research
6. Applicants conducting research in cooperation with an outside institution or agency must submit documentation of approval from their home institution or agency.

Responsibilities of the Principal Investigator:

1. Any additions or changes in procedures in the protocol will be submitted to the IRB for written approval prior to these changes being implemented.
2. Any problems connected with the use of human subjects once the project has begun must be communicated to the IRB Chair.
3. The principal investigator is responsible for retaining informed consent documents and all research data for a period of three years after the project.

Signature:

Principal Investigator _____ Date _____

Co-Investigator(s) _____ Date _____

Co-Investigator(s) _____ Date _____

Faculty Co-Investigator _____ Date _____

IRB USE ONLY

Level of Review	Exempt	Expedited	Full Review	Continuation
IRB Chair (Check 1 Box)	Approved	Resubmit with corrections		Not Approved
Signature IRB Chair:				Date:

**College of the Muscogee Nation
Institutional Review Board
Informed Consent to Participate in a Research Study**

Principal Investigator:_____
Title of Research Project:_____

Please read this form and ask any questions that you may have before agreeing to take part in this study. You are being asked to volunteer for this research study. This study is being conducted at (enter the study site).

Purpose of the Research Study

The purpose of this study is: (Briefly explain the research question and its purpose in lay language.)

Number of Participants

About (insert number of study participants) people will take part in this study.

Procedures

If you agree to be in this study, you will be asked to do the following: (Explain the tasks/procedures involved in the study. Identify assignments to study groups, frequency of procedures, etc. Describe any procedures that are experimental. If there are none, this may be omitted.)

Length of Participation

(Indicate the length of time of participation such as 30 minutes, 1 hour, 4 visits for a total of 2 weeks. If applicable, also include anticipated circumstances under which the participant's participation may be terminated by the investigator without regard to the participant's consent.)

This study has the following risks:

(In order of severity, list any possible risks--physical, psychological, economical, etc. Include the likelihood of each and under what conditions the researcher will terminate the study.)

Benefits of being in the study are

(If no benefits, enter "None." Do not include compensation as a benefit)

Confidentiality

There will be no information included that will make it possible to identify you without your permission. Research records will be stored securely and only approved researchers will have access to the records.

Compensation

You (will/will not) be reimbursed for your time and participation in this study. (Include payment, reimbursement, class credit, etc. Explain when disbursement will occur and conditions of payment (e.g., if compensation will be reduced for early withdrawal).)

Voluntary Nature of the Study

Participation in this study is voluntary. If you withdraw or decline participation, you will not be penalized or lose benefits or services unrelated to the study. If you decide to participate, you may decline to answer any question and may choose to withdraw at any time.

Audio/ video Recording of Study Activities (Delete this section if not applicable.)

To assist with accurate recording of participant responses, interviews may be recorded on an audio recording device. You have the right to refuse to allow such recording without penalty. Please select one of the following options.

I consent to audio/video recording. ☐ Yes ☐ No.

Contacts and Questions

If you have concerns or complaints about the research, the researcher(s) conducting this study can be contacted at (Provide phone number and email address. If the researcher is a student, include the advisor's name, telephone number, and email address here.)

Statement of Consent

I have read the above information. I have asked questions and have received satisfactory answers. I consent to participate in the study.

Signature

Date