



Cherokee Nation Institutional Review Board

Federal Wide Assurance #00000447

Research Approval Application

Date: _____

*CN IRB meetings occur on the **2nd Thursday of every month**.*

*Applications for consideration must be submitted no less than **10 business days prior** to the date of the meeting.*

Basic Information

Principle Investigator Name: _____

Co-Principle Investigator Name: _____

Proposal Title:

Project Start Date: _____ Project End Date: _____ Assigned IRB # (if applicable): _____

Type of Submission: **New Research** ☐ **Revision** ☐ (Revision # _____) **Continuation/Renewal** ☐

PI Phone: _____ Email: _____

Co-PI Phone: _____ Email: _____

Other Contact Name: _____

Other Phone: _____ Email: _____

Signatures

The CN IRB will make the final determination whether your application is appropriate for full, expedited, or exempt review. The CN IRB may request additional information or revision of materials or procedures before approval.

The CN IRB has the authority to approve, disapprove, modify, conduct continuing review, observe/verify changes, suspend, terminate or take any action deemed appropriate on research when it occurs within the Cherokee Nation, over which the Cherokee Nation has jurisdiction. (Cherokee Nation Bylaws, Article III, Section 1:45 - Code of Federal Regulations, CFR, 46.109).

The Cherokee Nation Institutional Review Board has been delegated the authority for final approval of research papers intended for presentation or publication. No publications/presentations are allowed on projects that did not submit final dissemination material for review and receive proper CN IRB approval.

Principle Investigator

Signature: _____ Date: _____

Co- Principle Investigator

Signature: _____ Date: _____

This above application page and all documents can be submitted via email, to the CN IRB at:

review-board@cherokee.org

Continuation/Renewal Checklist

The following section is a checklist of all the material that should be completed and submitted with your renewal application. Please follow the instructions for each item.

☐	Renewal Protocol:	All pages of a protocol should include project name in the upper left hand corner, investigator's last name in the upper right hand corner, and consecutive pages numbers in the lower right hand corner. The font type and size should be consistent throughout the document. We encourage you to use Times New Roman (12 point), Arial (11 point) or Calibri (11 point) and margins set at 1 inch. Single spacing, bold, italics, and underlining are acceptable. Renewal Proposals should include: 1- Summary aims and goals, with a list of key personal. 2- Update on all competed research activity 3- Any interim findings or a summary of any risks or benefits discovered, 4- the remaining activities which are being, or will be, completed, 5- A list of any changes (approved or not approved by CN IRB) to the research study protocol or study materials, 6- a table of all subjects withdrawn (voluntarily or non-voluntarily), with a description of any known reasons for each subject, 7- Any complaints about the research project, describing the number and nature of the complaints, and 8- Any adverse events.
☐	Supporting Appendix:	(if applicable) If you there has been any interim findings reported in your renewal protocol, please submit the charts, graphs, or tables of the interim findings here . Please be sure to appropriate label your visuals to match your renewal protocol summary.
☐	IRB Letter of Approval:	(if applicable) If you are not a Cherokee Nation employee/volunteer, you must submit a current IRB approval letter from the Principal Investigator's Institution, OR a current IRB approval letter from the Indian Health Service (IHS), OR a short statement of pending IRB approval from either listed locations.
☐	Personal CVs:	Please submit any additions/changes to Key Personnel's CV/Resumes.
☐	CITI Certifications:	Please submit current Principal Investigator and Key Personnel CITI Certifications.
☐	Consent:	Please submit the most current version of any consent forms. Please also included any HIPPA forms, Confidentiality Certificates, and Waivers.
☐	Lay Summary:	The CN IRB requires each study (regardless of review type) to provide an annual brief summary of a research project goals, activities, and findings. This document will be provided to the tribe to promote transparency on complex scientific research. Please see "Lay summary Guidance" on our <u>website for a template and more information</u> .

Please submit as one Word or PDF Document