Cherokee Nation
Institutional Review Board

Federal Wide Assurance #00000447

Research Approval Application

Date:_____

*CN IRB meetings occur on the **2nd Wednesday 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:

irb@cherokee.org

However if you wish to mail in a hard copy, you can send it to:

Cherokee Nation IRB
1296 Skill Center Circle
Tahlequah, Oklahoma 74464

Please note that sending in a hard copy application will delay the CN IRB's reviewing process.

Application Checklist

The following section is a checklist of all the material that should be completed and submitted with your application. Please follow the instructions for each item and include those items that apply to your proposal.
(If you are requesting an continuation/renewal review please skip to the next section)

☐	Proposal:	All pages of a proposal 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. **Proposals should contain at least**: 1- Overview, 2- Introduction, 3- Methods, 4- Study Population, 5- Risk/Benefits, 6- Data Security/Monitoring, 7- Analysis, and 8- Dissemination. For more information please see the "Proposal Guidance" on our website.
☐	Bibliography:	The same formatting as your proposal should be applied to your bibliography. Page numbers are not required.
☐	Consent Forms:	Cherokee Nation requires that informed consents be written at an **8th grade** reading level. **Assents should be written at an age appropriate level**. This goal is in keeping with Federal Plain Language guidelines and the Federal Plain Writing Act of 2010. Please check your reading level before submitting your document. **Consents should include the follow**: 1. Study Title 2. Performance Sites 3. Contacts 4. Purpose of the Study 5. Subjects Criteria & Number 6. Study Procedures 7. Benefits 8. Risks/Discomforts 9. Right to Refuse 10. Privacy 11. Incentive Information 12. *Video or Audio Recording. For more information please see the "Informed Consent Guidance" on our website. If you are requesting a **waiver of consent**, the CN IRB requires a statement of wavier reasoning or verbal script for oral consents be provided.
☐	HIPPA/Confidentiality Certificate:	(if applicable) If you are obtaining health information with any identifiers please include a HIPPA authorization form **OR** a waiver of HIPPA. Also, if you have a Confidentiality Certificate for your project, please include it.
☐	IRB Letter of Approval:	(if applicable) If you are not a Cherokee Nation employee/volunteer, you must submit an IRB approval letter from the Principal Investigator's Institution, **OR** an IRB approval letter from the Indian Health Service (IHS), **OR** a short statement of pending IRB approval from either listed locations.
☐	Letter of Support:	The CN IRB requires that all research projects have a letter of support from a tribal sponsor. For more information please see the document "Tribal Sponsor Guidance" on our website.
☐	Personal CVs:	Please submit the Principal Investigator and Key Personnel CV/Resumes.
☐	CITI Certifications:	Please the Principal Investigator and Key Personnel CITI Certifications.
☐	Recruitment Materials:	(if applicable) Please submit any recruitment or publicity materials - such as flyers, brochures, posters, media announcements.
☐	Measure Materials:	(if applicable) Please submit any forms or papers used to collect data **OR** from which data are abstracted. Examples of these are questionnaires, interview questions or outlines, and medical record data collection sheets.
	If this is a DRUG/BIOLOGIC study, please include these additional documents:	
☐	Investigators Drug Brochure:	CN IRB **requires** a copy of the most current Investigator's Brochure from the sponsor. In accordance with FDA regulations [21 CFR 312.23 (a) (5)] an Investigator's Brochure **must contain the following information**: 1- A brief description of the drug substance and the formulation, including the structural formula, if known. 2- A summary of the pharmacological and toxicological effects of the drug in animals and, to the extent known, in humans. 3- A summary of the pharmacokinetics and biological disposition of the drug in animals and, if known, in humans. 4- A summary of information relating to safety and effectiveness in humans obtained from prior clinical studies. 5- A description of possible risks and side effects to be anticipated on the basis of prior experience with the drug under investigation or with related drugs, and or precautions or special monitoring to be done as part of the investigational use of the drug.

Please submit as one Word of PDF document.

One Word of PDF document.

One Word of PDF document. ↓

☐	Food Supplement Background:	(if applicable) If you are submitting a project that will use dietary supplements, foods, food-derived products, or other products regulated as dietary ingredients (e.g., spices) (see [FD&A Act, section 201(ff)], for exact inclusion criteria), then **you must provide** (1) regarding a benefit related to a classical nutrient deficiency, provided the claim discloses the prevalence of the such disease in the United States, (2) describing the role of a nutrient or dietary ingredient intended to affect the structure of function in humans, (3) characterizing the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function, or (4) describing general well-being from consumption of a nutrient or dietary ingredient. [FD&C Act section 403(r) (6)]. It may also be necessary for you to submit an IND. You can check if you need an IND at FDA.gov
☐	FDA 1572 Form	(if applicable) This form will provide the IRB with a statement of assurance that the researchers will comply with FDA regulations related to the conduct of a clinical investigation. You can get a FDA 1572 form at fda.gov.
If this is a DEVICE study, please include these additional documents:		
☐	Device Manual:	Please included a copy of the original manual for the device that will be used in the study. If you have more than one manual please combine and submit only one document.
☐	Support Document:	CN IRB requires one of the following documents: 1- FDA Letter **OR** 2- Letter from Sponsor **OR** 3- Letter explaining why the investigation is exempt from the IDE requirements under 21CFR812.2(c) or otherwise exempt or appropriately completed.