RENEWAL/CONTINUATION PROCESS GUIDANCE

WHAT IS RENEWAL AND WHY DO I NEED TO DO IT?

- *Federal regulations require an IRB to conduct substantive, meaningful continuing review of human subject research that is within the IRB's jurisdiction.*

For the Cherokee Nation IRB (CN IRB), continuing review of human subject research projects is required annual (at minimum) - regardless of the research risk level or review type (Exempt, Expedited, or Full Board). Continual review is necessary even if there are no changes to the research procedures, recruitment materials, or subject population since the IRB approval period. Moreover, project's which have completed data collection and are only doing data analysis and dissemination preparation, must still undergo continuing review.

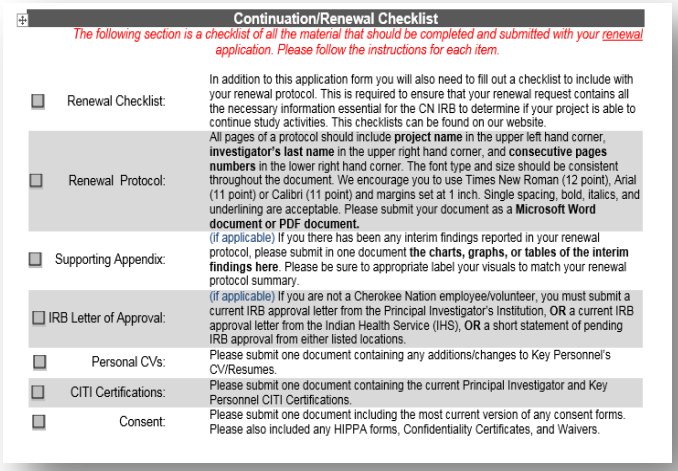
Changes to the protocol, personnel or study documents may be submitted at the same time as the continuing review, but any proposed changes to the protocol or study documents must be submitted as an amendment rather than as part of the continuing review application. Amendments should be submitted before changes are scheduled to occur, irrespective of the length of time till, before, or after a research's protocol is approved or renewed.

The Principal Investigator is responsible for submitting a renewal application prior to the expiration of the current CN IRB approval so that no lapse in study approval occurs. Renewal applications must be turned in 60 days prior to the current approval expiration. If CN IRB approval expires, all research activities involving human subjects MUST STOP, including subject contact, data collection, and data analysis. No new subjects may be enrolled after CN IRB approval lapses. Even if the continuing review application has been submitted to the CN IRB, all research activities must stop until the CN IRB renews approval for the project. The only exception is if CN IRB concludes it is in the best interests and safety of individual subjects to continue participation in the research interventions or interactions.

If human subject research activities continue after the expiration date, the investigator is out of compliance with the federal regulations. If you engage in human subject research activities while CN IRB approval for your project has lapsed, you will be required to complete an Unanticipated Problem report.

WHAT DO I NEED TO DO TO RENEW OR CONTINUE MY RESEARCH?

Renewals can be submitted via the Cherokee Nation IRB (CN IRB) online application process. Renewal applications should be submitted as early as possible, **but no later than 60 days in advance of the approval expiration date**, to ensure the continuation review does not occur after the expiration date. If the project is not reviewed and approved by the expiration date, all research activities MUST STOP, until the CN IRB renews approval for the project. The only exception is participant safety, such that discontinuing follow-up or active therapy may place them at an increased risk.



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 Checklist:	In addition to this application form you will also need to fill out a checklist to include with your renewal protocol. This is required to ensure that your renewal request contains all the necessary information essential for the CN IRB to determine if your project is able to continue study activities. This checklists can be found on our website.
☐ 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. Please submit your document as a **Microsoft Word document or PDF document.**
☐ Supporting Appendix:	(if applicable) If you there has been any interim findings reported in your renewal protocol, please submit in one document **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 one document containing any additions/changes to Key Personnel's CV/Resumes.
☐ CITI Certifications:	Please submit one document containing the current Principal Investigator and Key Personnel CITI Certifications.
☐ Consent:	Please submit one document including the most current version of any consent forms. Please also included any HIPPA forms, Confidentiality Certificates, and Waivers.

The following information must be submitted for continuing review:

- **Renewal Checklist:** A simple checklist to ensure that your application is complete can be found on our website.

- **Renewal Protocol:** A summary of the original study aims and goals, with a list of key personal. Updates on all competed research activity, including any interim findings or a summary of any risks or benefits discovered. An update on the remaining activities which are being, or will be, completed in this year's approval. Provide a list of any changes (approved or not approved by CN IRB) to the

research study protocol or study materials. If ANY subjects were withdrawn from the study voluntarily, or non-voluntarily, please explain in as much detail as possible the reason(s). Describe the number and nature of any complaints that have been made about the research project.

• **Supporting Appendix:** Contains all of the tables, graphs, and charts from significant findings/discoveries from the research. As well as any additional or new material or graphics that are important to the study.

• **IRB Letters of Approval**: Prior letter(s) of approval from CN IRB along with letter(s) of approval from PI entity's IRB or a statement of pending approval from PI entity's IRB (if applicable).

• **Personnel CV:** Copies of CV and resume for any NEW key personnel.

• **CITI Certifications:** A copy of the most current CITI certification documents for all key personnel.

• **Informed Consent:** A copy of the most current informed consent is required.