



Eastern Band of Cherokee Indians Medical IRB

Instructions for Protocol Submission

(Note: this page is for information only; inclusion in the submission is optional)

Submission requires information to be submitted electronically as a single PDF file, CD, or email with attachments in Adobe Acrobat PDF or Microsoft Word format (NOTE: All materials should be in the order noted and contained in ONE file.) Paper copies may be requested of the submitter on a case-by-case basis.

The PDF, CD, or emailed file must include:

- The Protocol Application Form
- The Protocol Application Signature Pages
- Minors as Participants Protocol Application Form, when applicable
- Waiver or Alteration of Consent Request Form, when applicable
- A Detailed Protocol that includes:
 - DATE OF SUBMISSION (top of page 1)
 - Study Title, Principal Investigator and all Co-investigators
 - Purpose/Background of the Project and Research Question/Hypothesis
 - Methods and Measures including study design; description of procedures, tests, survey instruments, questionnaires, or other interventions or interactions; all data elements to be collected; outcome measures and analytical plan.
 - Description and Source of Study Population, Data, Specimens, or Information
 - Inclusion and Exclusion Criteria
 - Participant Risks and Benefits
 - Procedures to be used to ensure confidentiality
 - A plan to report any adverse events, problems, deviations or protocol changes to the IRB.
 - References
- The Investigator's Brochure if applicable
- The full grant application to the funding agency when applicable
- The Informed Consent documents
- The Assent documents when applicable
- Other information when applicable (e.g., full Curriculum Vitae, Tribal affiliation or membership, supporting documents, submission-related tools products)

Questions regarding protocol submission should be directed to the interim MIRB Administrator, Martha Salyers, at martsaly@nc-chokeee.com, 828 359 6180. Submissions that do not contain all the required information will be returned without review.