Eastern Band of Cherokee Indians Medical IRB
Protocol Submission Checklist

Submission requires information to be submitted <u>electronically through the Mentor system.</u> All materials should be included in the form submission and all other documents are to be uploaded as attachments. Instructions for the Mentor account creation process and a detailed description of submission creation can be found on EBCI PHHS website at [Medical Institutional Review Board | Eastern Band of Cherokee Indians (ebci-nsn.gov)](). Paper copies may be requested of the submitter on a case-by-case basis.

The protocol submission sent through a Mentor account must include:

☐ All required components on the new submission form:
- o All co-investigators, research staff, and protocol title
- o Proposed estimated start date and estimated end date
- o Sites, review type, and total number of subjects

☐ All required components under "Application Sections" following initial save of new submission:
- o Risk/Benefit Assessment subsection
- o Research Activities Involving Human Subjects subsection
- o Informed Consent subsection OR Waiver/Alteration of Informed Consent explanation
  - ▪ Required questions and uploaded form
- o Subject Population and Methods subsection
- o Ensure Personnel subsection is accurate

☐ Protocol Application Form (required to attach document in Mentor):
- o General information on page 1
- o Abstract and prior scientific peer review question
- o Biographical sketch for principal investigator and each co-investigator

☐ Informed Consent documents (required to attach document in Mentor)

☐ Minors as Participants Protocol Application Form, when applicable

☐ Waiver or Alteration of Consent Request Form, when applicable

☐ Investigator's Brochure, when applicable

☐ Full grant application to the funding agency, when applicable

☐ Assent documents, when applicable

☐ Other information, when applicable (e.g., full Curriculum Vitae, Tribal affiliation or membership, supporting documents, submission-related tools products)

Once the fields are completed and all documentation is uploaded, an electronic signature is required from the PI and all Co-PIs prior to final submission in Mentor.

Questions regarding protocol submission should be directed to the MIRB administrator, Megan Yates ([meganyates@ebci-nsn.gov]()). Submissions that do not include all the required information will be returned without review.