

GUIDANCE ON STUDY CLOSURE

DEFINING STUDY CLOSURE

- *Cherokee Nation IRB (CNIRB) defines closure of research as when no further research, follow-up, or data analyses will be performed on a study.*

It is important to note that a study is not considered completed/closed simply because no additional subjects are being enrolled. Any ongoing research activities, whether involving active participation with subjects or not, means the study cannot be considered completed/closed. If a research protocol is nearing completion the CNIRB must be notified as this is a significant change in activity. However if a research protocol has been completed/closed, dissemination activities may continue so long as all presentation material is submitted to CNIRB (see Dissemination Guidance).

WHAT DOES CNIRB REQUIRE FOR STUDY CLOSURE?

To allow for substantive review of research activities at study closure, the investigator is required to submit the Final Report. This report **MUST** include:

1. Any new information learned from the approved research protocol including, but not limited to: any new risks, safety issues or problems, serious adverse events or unanticipated problems, and all significant findings or discoveries.
2. A data disposal plan in accordance with your original proposal. If you plan to keep data for future research please provide a copy of the current informed consent in study closure final report.
3. Explanation if any subjects were withdrawn for any reason including adverse reactions or noncompliance. Provide a description of any known reasons for why each subject withdrew.
4. Any complaints about the research project **MUST** be attached along with a summary describing the number and nature of the complaints.

The Principal Investigator is responsible for making arrangements to assure data and records are stored properly and remain confidential. Should your plan include retaining data for future analysis we strongly recommend that the data be irreversibly stripped of all identifiers.