



Chickasaw Nation Department of Health Institutional Review Board Expedited Review Policy

Effective Date: April 2006	Policy Number: 07 RRI 1412
Applicability / Class: CNDH / O	Department: Administration
Date of Review: June 2020	Approval:

- I. Purpose:

The Chickasaw Nation Department of Health (CNDH) has implemented tribal guidelines to assure the safety, well-being, confidentiality, dignity, and integrity of American Indians served by the CNDH when participating in research. Furthermore, the CNDH has delegated to the Institutional Review Board (IRB) the responsibility for developing those processes by which proposed living human subjects research, participant recruitment, data collection, or dissemination of findings may be reviewed for approval.
- II. Policy:
 - A. To provide a mechanism to expedite the approval process in circumstances where full CNDH IRB review is either not feasible or not warranted.
 - B. To define those circumstances in which expedited approval is permitted.
 - C. To define the structure of the expedited approval process.
- III. Procedure:
 - A. The CNDH IRB procedures are determined by CNDH policy as well as the federal guidelines on human subject research as outlined in [45 CFR 46](#).
 - B. Federal policy provides for “expedited review” for certain types of research involving no more than minimal risk and for minor changes in previously approved research projects.
 - C. The CNDH IRB expedited approval process will require review by the IRB Chair (or designee) and at least one IRB member (including the Secretary

of Health) who is familiar with the project in question but has no conflict of interest.

- D. Requests for expedited review must involve only those activities with no more than minimal risk to the participants **and** meet the criteria as defined by the Office of Human Research Protection (OHRP). <http://www.hhs.gov/ohrp/humansubjects/guidance/expedited98.htm>
 - E. Public dissemination of research study data may qualify for expedited review. If so determined, the Chair will designate at least two persons with relevant expertise and no conflict of interest as reviewers. Reviewers will submit their review and recommendations to the Chair. Expedited review of publications and/or presentations shall comply with the standards as described in policy [07 RRI 1411](#) "Release and Dissemination of Research Results and Findings".
 - F. The investigator will submit the request to the CNDH IRB Administrator or Chair. The request should include the pertinent criteria justifying expedited review.
 - G. The IRB Chair and/or Administrator (or designee) will review the request. If it is determined that the proposal does not qualify for expedited review, the investigator will be notified and the proposal scheduled for full IRB review at the next meeting.
 - H. If the IRB Chair and/or Administrator (or designee) determines that the proposal meets the criteria for expedited review, an IRB member with knowledge of the project but with no conflict of interest may be contacted for joint review.
 - I. The IRB Chair, and/or Administrator, or designee will notify the investigator.
 - J. The IRB Chair, and/or Administrator, or designee will make a report to the full CNDH IRB at the next scheduled meeting.
- IV. Reference(s):
- CNDH policies 09 ADM 1400, 1401, 1410, 1411.

- CNDH policy 09 ADM 7106
- OPRR 1993 Protecting Human Research Subject Institutional Review Board Guidebook, <http://www.hhs.gov/ohrp/policy/>
- Code of Federal Regulations TITLE 45 PUBLIC WELFARE DEPARTMENT OF HEALTH AND HUMAN SERVICES PART 46 PROTECTION OF HUMAN SUBJECTS Revised January 19, 2017. Effective January, 2018
- Cherokee Nation Institutional Review Board Publication Policy.