



Chickasaw Nation Department of Health Institutional Review Board

Effective Date: October 1994	Policy Number: 07 RRI 1410
Applicability/Class: CNDH / O	Department: Administration
Date of Review: July 2016	Approval:

I. Purpose:

The Chickasaw Nation has the inherent sovereign authority to govern itself, and to provide for the health and general well-being of the Chickasaw people. In this respect, the Chickasaw Nation shall administer its system of health service delivery according to the highest standards of ethics and professional conduct to ensure the best possible service to the people receiving health services under such authority.

Furthermore, the Chickasaw Nation recognizes the value of medical, social, and physical science research to the Chickasaw Nation, to the Chickasaw people, and to society in general. Therefore, the Chickasaw Nation may from time to time participate in research projects that are of value to the interests of the Chickasaw Nation, the Chickasaw people, and the Native Americans and Alaskan Natives it serves.

The Chickasaw Nation has instituted a research review committee to carry out the primary responsibility of reviewing and approving or denying any proposed research, data collection, or participant recruitment. This committee is registered with the United States (US) Department of Health and Human Services (DHHS) as a federally recognized Institutional Review Board (IRB) under the name "Chickasaw Nation Department of Health (CNDH) IRB #1". The required federal wide assurance (FWA) is filed under this same name. The IRB will operate under the coordination of the Chickasaw Nation Department of Health.

All proposed research projects must be reviewed and approved by the Chickasaw Nation Department of Health Institutional Review Board, regardless of review by any other external research review entity.

II. Policy:

The CNDH shall be responsible for implementing guidance for, and coordinating the operations of, the Chickasaw Nation Department of Health IRB (CNDH IRB).

III. Procedure:

- A. Purpose (of committee): The CNDH IRB shall review all proposals to conduct living human subjects research, collect individuals' data, or recruit participants where the proposed intent is to publish, or otherwise make public, the results or findings of such research or data collection. The CNDH IRB shall have the authority to approve or deny all such research, data collection, or participant recruitment proposed to occur within the boundaries of the CNDH service area.
- B. Structure: The CNDH IRB shall be organizationally located within the CNDH management structure and shall report directly to the CNDH leadership council.
- C. Membership:
1. The voting members of the CNDH IRB shall consist of:
 - a. The CNDH Secretary or designee;
 - b. At least one Chickasaw community member;
 - c. The CNDH chief of staff or designee;
 - d. At least two other CNDH physicians from different services;
 - e. At least one CNDH staff representative; and
 - f. At least one Chickasaw Nation staff representative from a division other than the CNDH.
 2. The CNDH shall designate such other personnel to participate as non-voting support staff for the IRB.
 3. Five voting members shall constitute a quorum for the purpose of conducting CNDH IRB business. At least one non-scientific member must be present at all meetings of the IRB in order to conduct business. At least one physician representative must be present to vote on any biomedical research issues.
- D. Functions:
1. The CNDH IRB shall develop processes by which all proposed research, data collection, or participant recruitment may be reviewed for approval.
 2. The IRB shall utilize federal guideline criteria by which to evaluate the merit of the all research.
 3. The CNDH IRB shall issue authorization for all research, data collection, or participant recruitment duly approved.
 4. The CNDH IRB shall review all results or findings of approved research, data collection, or participant recruitment prior to any

publication or public presentation of the same.

E. Reporting:

1. The CNDH IRB shall maintain minutes of all meetings, including all business conducted, actions taken, and recommendations made.
2. The CNDH IRB shall maintain an inventory of all proposed, pending, on-going, and completed research, data collection, or participant recruitment projects, including copies of all progress and final reports of the results and findings. All such information shall be maintained in a secure and fireproof central location.
3. The IRB shall report the issuance of research authorizations to the CNDH medical executive council and report its general activities annually to the CNDH leadership council.
4. The CNDH IRB shall review all relevant accreditation standards and minimum requirements for performance criteria on an annual basis.

IV. Reference(s):

- Chickasaw Nation Executive Policy Statement No. 01-02-01.
- JC – Patient Rights & Organizational Ethics, Patient & Family Education and Responsibilities, Leadership and Management of Information sections.