Chickasaw Nation Department of Health Institutional Review Board Exempt Policy

Effective Date: February 2010	Policy Number: 07 RRI 1413
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 human subjects research, participant recruitment, data collection, or dissemination of findings may be reviewed for approval.

II. Policy:

A. To provide a mechanism to determine if research is exempt from CNDH IRB review and approval.

B. To define those circumstances in which exemption from CNDH IRB review and approval is permitted.

C. To define the structure of the exemption 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 exemption from IRB review for certain types of research as described in section Subpart A, Section 46.101, paragraphs b-i.

C. Exemption from CNDH IRB review does not apply to dissemination of findings. Any and all publications of research results must receive prior review and approval by the CNDH IRB as described in policy 09 ADM 1412 “Release and Dissemination of Research Results and Findings”. “Publications” is defined as all written reports, papers, manuscripts,

abstracts, and journal or book articles based on research conducted within the Chickasaw Nation. Oral, poster, or PowerPoint presentations are also included in this definition and covered by this policy, as are academic theses and dissertations.

D. The CNDH IRB exemption process will require review by the IRB Chair and Administrator, or designee. A research study may be classified as exempt even if it has undergone full or expedited review.

E. Requests for exemption to CNDH IRB review must meet the criteria as defined in 45 CFR 46 Subpart A, Sec. 101 "To what does this policy apply?" paragraphs b-i.

F. The investigator will submit the request to the CNDH IRB Chair or Administrator. The request should include the pertinent criteria justifying exemption from review.

G. The IRB Chair and Administrator or designee will review the request. If it is determined that the proposal does not qualify for exemption, the investigator will be notified.

H. Only the IRB Chair and/or Administrator or designee may determine if the proposal meets the criteria for exemption; in no case shall a research investigator associated with the project or a person with an obvious conflict of interest make the decision to exempt a study from IRB review.

I. The IRB Chair and/or Administrator or designee will notify the investigator.

J. The IRB Chair or designee will make a report to the full IRB at the next scheduled meeting.

IV. Reference(s):

- CNDH policies 07 RRI 1400, 1401, 1410, 1411, 1412
- CNDH policy SOP 07 MS 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