Participant Rights Pertaining to Research

Effective Date: October 1994	Policy Number: 07 RRI 1401
Applicability/Class: CNDH / O	Department: Administration
Date of Review: June 2020	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, cultural, 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 American Indians it serves. However, the Chickasaw Nation must also accept the responsibility to assure the safety, well-being, confidentiality, dignity, and integrity of the American Indian people it serves when participating in such research. The Chickasaw Nation has delegated the authority for fulfilling this tribal responsibility to the Chickasaw Nation Department of Health (CNDH).

II. Policy:

The CNDH shall assure the safety, well-being, confidentiality, dignity, and integrity of the Chickasaw people and all American Indians served by the CNDH when participating in research. In this respect, the CNDH shall outline the rights of patients agreeing to participate in any research project.

III. Procedure:

A. All persons and their legal guardians where appropriate, voluntarily electing to participate in approved research have the right to be fully informed of the project's purpose, anticipated interventions, risks, complications, and benefits.
    1. A person's decision to participate in clinical trials or research needs to

be based on his or her comprehension and sound information. In instances of research conducted involving patients of the CNDH the following items are documented in the patient's record:

a. a copy of any informational materials provided to the patient,
b. a copy of the signed consent form,
c. the name of the person who provided the information, and
d. the date the consent form was signed.

B. All persons have the right to refuse to participate in any research projects and such refusal shall in no way affect the patient's eligibility for or receipt of health care services from the CNDH.

C. All persons asked to participate in any research project shall be given a full description of the project's purpose, potential benefits, and potential risks or discomforts. Such persons shall also be given a full description of any alternatives or additional services that may be advantageous to them, if applicable.

D. All persons asked to participate in any research project shall be given a full description of the project's procedures to be followed, particularly any procedures that are experimental in nature. Expected duration of participation in the research shall also be provided.

E. A written and signed informed consent statement shall be obtained from each person agreeing to participate in any research project. The consent form shall include a description of the patient's right to privacy, confidentiality, and safety. One copy of the signed consent will be provided to the research participant and one will be placed in the medical record, if applicable.

F. Every person initially agreeing to participate in a research project may withdraw from and discontinue such participation at any time without compromising their access to any other health care services from the CNDH .
    1. In all instances of a participant's withdrawing from any on-going research project, the researchers and the CNDH shall be responsible for:
        a. informing the participant of any required interventions necessary to assure the maintenance of their health and safety as a result of such withdrawal;
        b. providing health services and interventions necessary to assure the maintenance of their health and safety as a result

of such withdrawal; and

c. monitoring such subject on an on-going basis to assure that no adverse impact to the participant's s health and safety results from such withdrawal from the research project.

2. Withdrawal from an on-going research project shall not preclude a person's right to participate in any other future research project that may be of benefit to them.

G. When research procedures are completed, the principle investigator alleviates, to the extent possible, any confusion, misinformation, stress, physical discomfort, or other harmful consequences the participant may have experienced as a result of research procedures.

H. Persons participating in a research project shall be informed of the outcomes, results, and findings of such research at the conclusion of the project.

IV. Reference(s):

- Chickasaw Nation Executive Policy Statement No. 01-02-01.
- Joint Commission – Patient Rights & Organizational Ethics, Care of Patients, Patient & Family Education and Responsibilities, Leadership and Management of Information sections.
- Chickasaw Nation Executive Policy Statement .
- Amdur & Bankert (2007). Institutional Review Board Member Handbook.