Committee: Rules Committee Author: Chuck Hoskin, Jr.

Date: 09-11-24 Committee Date: 09-26-24 Sponsor: Candessa Tehee & Julia Coates

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### An Act

#### Legislative Act 36-24

## THE CHEROKEE NATION INSTITUTIONAL REVIEW BOARD REFORM ACT OF 2024

#### BE IT ENACTED BY THE CHEROKEE NATION:

#### Section 1. Title and Codification

This legislative act shall be titled and codified in Title \_\_\_\_, Chapter \_\_\_\_ of the Cherokee Nation Code Annotated as the "Cherokee Nation Institutional Review Board Reform Act of 2024."

#### Section 2. Findings

The Council of the Cherokee Nation finds that participation in research projects across a variety of academic and medical disciplines is potentially beneficial to Cherokee Nation and its citizens with appropriate statutory, regulator and policy safeguards and oversight. The Council further finds that the Cherokee Nation Institutional Review Board (IRB) has served these interests since its inception pursuant to Resolution 67-97 (August 11, 1997) and as modified by Resolution 37-01 (July 20, 2001). The IRB has carefully balanced the risks and benefits inherent in research projects, ensured that research meets high ethical standards and protected research subjects through requirements such as informed consent. The Council finds that the present IRB operates pursuant to Council resolutions that provide an ill-defined organizational structure and, given the breadth of potential research projects spanning a wide range of academic and medical disciplines, is best arranged outside of the Cherokee Nation Health Department. Based on these findings the Council concludes that resolutions 67-97 and 37-01 should be repealed and replaced with this Act.

#### Section 3. Legislative History

R-67-97

R-37-01

#### Section 4. Purpose

The purpose of this Act is to sunset the current, and create a successor, Cherokee Nation Institutional Review Board by the repeal of Resolution 67-97 (August 11, 1997) and Resolution 37-01 (July 20, 2001) and by operation of this Act.

#### **Section 5.** Substantive Provisions

#### § 1. Definitions

- **A. Institutional Review Board:** A body with authority to review research studies to ensure compliance with applicable regulations, commonly accepted ethical standards and institutional policies in an ethical manner that adequately protects research participants.
- **B. Predecessor IRB:** The Institutional Review Board established and operating under Resolution 67-97 (August 11, 1997) and Resolution 37-01 (July 20, 2001)
- **C. Successor IRB or IRB:** The Institutional Review Board established by this Act, succeeding the Predecessor IRB.
- § 2. Repeal and Replacement of Resolutions 67-97 (August 11, 1997) and Resolution 37-01 (July 20, 2001); predecessor IRB members to continue as successor IRB members for 90 days.
  - **A.** Resolutions 37-01 and 67-97, establishing and governing the operations of the Predecessor IRB, are hereby repealed by operation of this Act, subject to Section 4, § 3 of this Act.
  - **B.** Actions of the Predecessor IRB as of the date of enactment of this Act are hereby ratified as compliant with Cherokee Nation law in effect at the time of such action.

#### § 3. Successor IRB ("IRB")

- **A.** Creation: A Successor IRB, hereafter IRB, is hereby established with full authority and oversight as it relates to any subject matter or research project that fell under the authority and oversight of the Predecessor IRB, subject to the provisions of sub-section C of this Section of the Act.
- **B.** Organization within the Executive Branch: The IRB shall be organized under the Department of Evaluation and Compliance, provided:
  - a. The Principal Chief may reorganize the IRB under any executive branch department that he or she determines can meet the purposes and policies of this Act, provided the Principal Chief provides the Council with 90 days' notice of such reorganization, unless such time period waved by Council resolution or rendered moot by Council appropriation of funds for the IRB.

#### C. Authority; Qualifications; Transitional Structure; Permanent Structure

- a. **Authority:** IRB shall have full authority to approve or disapprove proposed research projects and to monitor approved research projects.
- b. **Transitional Structure:** All members of the Predecessor IRB as of the date of enactment of this Act, shall by operation of this statute be members of the IRB

and operate under the extant by-laws, policies and procedures of the successor IRB on a transitional basis not to exceed 90 days, after which the membership shall be appointed and meet the qualifications set forth in subparagraphs c-d of this subsection.

#### c. Minimum Member Qualifications

- i. At least a supermajority of IRB members shall have at least
  - 1. A master's degree.
  - 2. Five years' experience in the field of academic or health research.
- ii. A majority of IRB members shall be citizens of the Cherokee Nation
- iii. A majority of IRB members shall be employed by the Cherokee Nation or its entities.
- iv. At least two IRB members shall not be employed by the Cherokee Nation or its entities.
- d. **Permanent Structure Within 90 days of Enactment:** Within 90 days of enactment of this Act, membership The IRB shall consist of seven members, four of whom shall be appointed by the Principal Chief and confirmed by the Council of the Cherokee Nation and three of whom shall be appointed by the four appointed and confirmed members with notice to the Principal Chief and the Council, all of whom shall serve initial staggered terms set forth below as measured from the date of enactment of this Act, followed by regular term of four years:
  - i. Seat 1 (one year initial term), appointed by the Principal Chief, subject to confirmation by the Council of the Cherokee Nation
  - ii. Seat 2 (one year initial term term), appointed by the Principal Chief, subject to confirmation by the Council of the Cherokee Nation
  - iii. Seat 3 (two year initial term), appointed by the Principal Chief, subject to confirmation by the Council of the Cherokee Nation
  - iv. Seat 4 (two year initial term), appointed by the Principal Chief, subject to confirmation by the Council of the Cherokee Nation
  - v. Seat 5 (three year initial term) appointed by members in seats 1-4 no later than December 31, 2024.
  - vi. Seat 6 (three year initial term) appointed by members in seats 1-4 no later than December 31, 2024.
  - vii. Seat 7 (four year initial term) appointed by members in seats 1-4 no later than December 31, 2024.

- e. **Officers**: The IRB shall select among its members the following officers, all of whom shall be citizens of the Cherokee Nation:
  - i. Chairperson
  - ii. Co-Chairperson
  - iii. Recording Secretary
- f. **Staff:** The Principal Chief shall assign such staff to support the IRB as he or she deems necessary to meet the purposes and policies of this Act within the designated executive branch department.
- g. **Cherokee Cultural Advisor:** The Executive Director of Language shall, for the purposes of ensuring that the IRB operates in a manner mindful of Cherokee cultural values, either:
  - i. Designate a staff member from the Language Department as a Cherokee Cultural Advisor to the IRB, in which case the staff member serves as an non-voting ex officio member of the IRB who otherwise exercises all rights and obligations afforded IRB members, or
  - ii. Designate a member of the IRB as serving as Cherokee Cultural Advisor to the IRB.
- h. **By-Laws, Policies, Procedures:** The IRB shall adopt by-laws, policies and/or procedures no later than December 31, 2024, which shall include any subject or process authorized by this act, incoming but not limited to:
  - i. Standards for approval and disapproval of proposed research project.
  - ii. Process for reconsideration of rejected research proposals.
  - iii. Process for making records available to Cherokee Nation elected officials available for in-camera inspection as authorized by this Act.
  - iv. Record retention.
  - v. Disclosing and resolving potential IRB member conflicts of interest.
  - vi. Process for hearing and resolving claims by research proposal applicants that an IRB approval or disapproval decision was influenced by political considerations within the meaning of this Act, the process for which shall limited to a review and disposition of such claims by the IRB, which shall be a final administrative disposition of such claims.
  - vii. Frequency of regular meetings, special meetings, attendance and compensation.

#### i. Independence; Conflict of Interest:

- i. **Independence:** Decisions of the IRB shall be free of political influence, including by any elected official of the Cherokee Nation, provided that nothing herein:
  - 1. Prohibits communication between the IRB or any of its members or support staff and any elected official of the Cherokee Nation for purposes of factual inquiry on any matter before the IRB or the attendance of elected officials at meetings of the IRB.
  - 2. Prohibits the IRB from, upon request, making research proposals and records reflecting the decision of the IRB to approve or disapprove a project available to elected officials for in camera inspection after the approval or approval decisions has been made, as well records relating to any decision on reconsideration of a disapproval of a research project.
  - 3. Prohibits the attendance of elected officials of attending meetings of the IRB, except during executive session.
  - 4. Prohibits the public or private expression by any elected official of an opinion of a research project that is, has previously been, or in the future be under review by the IRB.
- ii. Conflict of Interest: No IRB member shall participate in any IRB meeting or otherwise be involved in any IRB discussion or decision making on any proposed research project in which the IRB member is or may reasonably foreseeably be involved in the subject as a researcher, participant or as a competitor for any grant or other funding relevant to the subject and in violation of the foregoing is a basis for immediate removal from the IRB by action of the IRB.
- iii. **Disclosure:** IRB members shall be required to disclose any facts relating to a conflict of interests as defined in Section
- j. **Compensation:** Beginning no later than fiscal year 2026, IRB members shall be compensated for their service on IRB not to exceed \$1000 per month, provided:
  - i. In the case of current employees of the Cherokee Nation, either through an addendum to their employment contract or, where the employee is an employee not subject to an employment contract, such extra duty assignment or other increase in compensation for the period of service on the IRB.
  - ii. In the case of non-employees, through a service contract.
- k. **Notice to Principal Chief and Council:** No later than December 31, 2024, and within 45 days upon any periodic change in membership, by-laws, policies and procedures, shall provide a written report on such matters to the Principal Chief and the Council of the Cherokee Nation.

#### D. Not a Public Body within the Meaning of FOIA

- a. Neither the Predecessor nor the Successor IRB described in this Act is a "Public Body" within the meaning of the Cherokee Nation Freedom of Information Act, provided:
  - i. The IRB shall communicate the date, time and location of IRB meetings to be made available to the Principal Chief and members of the Council of the Cherokee Nation.
  - ii. Any elected official of the Cherokee Nation may attend any IRB meeting, except during executive session.
  - iii. Minutes of all IRB meetings are maintained for a period of at least 10 years and said minutes are available for in camera inspection by any elected official of the Cherokee Nation.

#### E. Annual Report

- a. "Draft Annual Cherokee Nation IRB Report" to Principal Chief, Council: Beginning November 1, 2025, and each November 1 thereafter, the IRB shall provide to the Principal Chief and the Council of the Cherokee Nation for a period of review and comment of 45 days, a "Draft Annual Cherokee Nation IRB Report," provided such report shall include
  - i. Summary of all proposed research projects considered by the IRB for the preceding fiscal year
  - ii. All final approval or disapproval action taken by the IRB responsive to such proposals
  - iii. Whether any such proposals remain pending final approval or disapproval action, tabled or other such posture and the number of times and period of time such proposals have been tabled.
  - iv. Any requests for reconsideration of any such proposals, and any grievances presented by applicants of any such proposals.
- b. **Annual IRB Report:** Beginning no later than December 31, 2025, and no later than each December 31 thereafter the Draft Annual Cherokee Nation IRB Report to the Principal Chief and Council shall be restyled "Annual Cherokee Nation IRB Report" made available for public review on Cherokee Nation's website.

Enacted by the Council of the Cherokee Nation on the 15th day of October, 2024.

Mike Shambaugh, Speaker
Council of the Cherokee Nation

ATTEST:

Dora Smith Patzkowski, Secretary Council of the Cherokee Nation

Approved and signed by the Principal Chief this 28th day of 000000, 2024.

Chuck Hoskin, Jr., Principal Chief

Cherokee Nation

**ATTEST:** 

Shella Bowlin, Secretary of State

Cherokee Nation

#### YEAS AND NAYS AS RECORDED:

Sasha Blackfox-Qualls	Yea	Melvina Shotpouch	Yea
Candessa Teehee	Yea	Kendra McGeady	Yea
Lisa Hall	Yea	Dora Smith Patzkowski	Yea
Mike Dobbins	Yea	Joe Deere	Yea
E.O. "Jr." Smith	Yea	Kevin Easley, Jr.	Yea
Daryl Legg	Yea	Danny Callison	Yea
Joshua Sam	Yea	Julia Coates	Yea
Codey Poindexter	Yea	Johnny Kidwell	Yea
Mike Shambaugh	Yea		

## <u>ADMINISTRATIVE</u> **CLEARANCE** Dept/Program: Signature/Initial Date **Executive Director:** Signature/Initial Date. Treasurer (Required: Grants/Contracts/Budgets): Signature/Initial Date **Government Relations:** Date Signature/Initial **Administration Approval:** 9/10/24 LEGISLATIVE CLEARANCE: Legal & Legislative Coordinator: Signature/Initial Standing Committee & Date: Chairperson: Signature/Initial

# Cherokee Nation Act/Resolution Proposal Form

X Act	Resolution

TITLE:

## THE CHEROKEE NATION INSTITUTIONAL REVIEW BOARD REFORM ACT OF 2024

DEPARTMENT CONTACT:	Chuck Hoskin Jr.
RESOLUTION PRESENTER:	Canaan Duncan

COUNCIL SPONSOR: Candessa Tehee, Julia Coates

#### **NARRATIVE:**

The purpose of this Act is to sunset the current, and create a successor, Cherokee Nation Institutional Review Board by the repeal of Resolution 67-97 (August 11, 1997) and Resolution 37-01 (July 20, 2001) and by operation of this Act.