

Cherokee Council House  
Cherokee, North Carolina

\_\_\_\_\_  
DATE

RESOLUTION NO. \_\_\_\_\_(2018)

- WHEREAS, The Tribe's Medical Institutional Review Board (MIRB) has been assigned the task of reviewing health-related research requests made to the Eastern Band, AND
- WHEREAS, The MIRB has reviewed and approved a research request made by Don Bailey, PhD, Distinguished Fellow and Chair, RTI International Fellows Program, Research Triangle Institute (RTI), Durham, North Carolina, Principal Investigator, entitled "Early Check Formative Research," in collaboration with Dr. Richard Bunio, Clinical Director, Cherokee Indian Hospital Authority, AND
- WHEREAS, This proposal has been approved by the Research Triangle Institute International Institutional Review Board, AND
- WHEREAS, The state of North Carolina by law performs newborn blood screening panels on all newborns in the state (NCGS 130A-125), which test for a variety of congenital and inherited conditions, AND
- WHEREAS, Early Check is a research project that will offer expanded, voluntary screening for newborns to identify children with rare health conditions before symptoms appear, and establish an evidence base if there is a benefit of doing so, AND
- WHEREAS, In the main Early Check study, parents will be given the choice of screening for a carefully selected panel of additional conditions, not on current Newborn Screening (NBS) panels in NC, using the same blood sample taken for regular newborn screening, AND
- WHEREAS, Other organizations involved in this effort include the University of North Carolina at Chapel Hill, Duke University, Wake Forest University, and the NC State Newborn Screening Lab, which is part of the Division of Public Health, NC Department of Health and Human Services, AND
- WHEREAS, This application is related to the formative research effort that will help the project team develop appropriate outreach and messaging to mothers across North Carolina for the Early Check study, and the research will consist of semi-structured small group discussions (3-4 participants) with postnatal women (up to one year post-birth) to help determine the best way to reach, interact with, and inform pregnant women in North Carolina, AND

WHEREAS, The success of the program's outreach activities depends on an in-depth understanding of pregnant women as the priority audience, including which communication channels they prefer and what messaging resonates with them; and in the group discussions, the researchers' team will specifically investigate parents' communication preferences, openness to Early Check, and prenatal and postnatal behaviors to gain insights that will inform outreach plans, AND

WHEREAS, The researchers are including members of the Eastern Band of Cherokee Indians who voluntarily participate to assure their input into adding tests for Spinal Muscular Atrophy (SMA) and Fragile X Syndrome to the Newborn Screening panels in NC, AND

WHEREAS, The Secretary of the Public Health and Human Services Division (PHHS) has reviewed the request and the MIRB's recommendations and has also given approval, AND

WHEREAS, The researcher acknowledges that all information obtained from this research is the property of the Eastern Band of Cherokee Indians and will be forwarded to the EBCI Secretary of PHHS for review and neither the Principal Investigator nor the Co-Investigators will use this information in any manner not authorized,

NOW THEREFORE BE IT RESOLVED, by the Tribal Council of the Eastern Band of Cherokee Indians, in Council assembled, at which a quorum is present, that Don Bailey, PhD, and co-investigators are hereby granted permission to carry out the above-named research project as described in their MIRB proposal, carrying out all follow-up and reporting as required by the Tribal Medical Institutional Review Board.

Submitted by: Vickie L. Bradley, Secretary  
Public Health and Human Services Division,  
Eastern Band of Cherokee Indians