



To: Martin McCaffrey
Neonatal-Perinatal Medicine

From: Office of Human Research Ethics

Date: 11/25/2024

RE: Determination that Research or Research-Like Activity does not require IRB Approval

Study #: 24-2664

Study Title: PQCNC (Perinatal Quality Care Collaborative of North Carolina) Cardiac Care in Obstetrics

This submission, Reference ID 451089, was reviewed by the Office of Human Research Ethics, which has determined that this submission does not constitute human subjects research as defined under federal regulations [45 CFR 46.102 (e or l) and 21 CFR 56.102(c)(e)(l)] and does not require IRB approval.

Study Description: Purpose: A leading cause of maternal mortality in North Carolina is unrecognized cardiac conditions leading to a cardiac related mortality. This project will spread established best practices for screening, identification and escalation of care to proper specialists. Participants: Inpatient maternal delivery services in the state of North Carolina.

Procedures (methods): PQCNC using the AIM (Alliance for Innovation in Maternal Health) Cardiac Care Bundle will deploy a statewide action plan to reduce the impact of cardiac conditions on maternal mortality in North Carolina.

Please be aware that approval may still be required from other relevant authorities or "gatekeepers" (e.g., school principals, facility directors, custodians of records), even though IRB approval is not required.

If your study protocol changes in such a way that this determination will no longer apply, you should contact the above IRB before making the changes.