To: Martin McCaffrey
Neonatal-Perinatal Medicine

From: Office of Human Research Ethics

Date: 12/08/2020
RE: Determination that Research or Research-Like Activity does not require IRB Approval
Study #: 20-3398

Study Title: Comprehensively Lessening Opioid Use Impact (clOUDi) on Moms and Babies
This submission, Reference ID 317127, 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: This statewide QI project will seek to insure that best evideced care is provided to mothers in the prenatal period and mothers and their infants at risk for neonatal abstinence syndrome (NAS) in the peripartum and postpartum period.

Participants: Hospitals delivering maternity care across the state of North Carolina

Procedures (methods):The goal of the maternal intervention will be making certain the American College of Ob Gyn (ACOG) recommendation of screening all mothers delivering babies for substance use disorder using a validated verbal screening tool is being carried out for 100% of mothers delivering in the state of North Carolina. For mothers screening positive for opioid use disorder a brief intervention and referral for treatment as recommended by ACOG will be initiated.

The goal of the infant intervention will be standardizing care of infants at risk for NAS in delivering hospitals with regard to assessment tool and medications used to treat infants requiring pharmacologic treatment. It is the recommendation for this project, given the variability of methods used to treat such infants, that newborn care sites adopt the Eat Sleep and Console (ESC) methodology.

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.