To: Martin McCaffrey
Neonatal-Perinatal Medicine

From: Office of Human Research Ethics

Date: 8/20/2016
RE: Determination that Research or Research-Like Activity does not require IRB Approval
Study #: 16-2224

Study Title: Antibiotic Stewardship and Newborn Sepsis (ASNS)

This submission 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 (d or f) and 21 CFR 56.102(c)(e)(l)] and does not require IRB approval.

Study Description:

Purpose:

Antibiotic Stewardship Perinatal Quality Improvement Teams (PQITs) will share strategies and lessons learned to develop potentially better practices and employ QI methodologies to establish a standard of care in North Carolina hospitals including: (1) providing the education and support necessary to develop standards of care for identification and management of infants at risk for early onset sepsis; (2) engaging families to further provide education on the necessity and appropriate use of antibiotics.

Participants: Perinatal Quality Improvement Teams (PQITs) from hospitals delivering babies across the state will be invited to participate in this initiative sponsored by the Perinatal Quality Collaborative of North Carolina. The number of teams participating may range from 20-50.

Procedures (methods): PQCNC will facilitate and coordinate hospital teams across the state through the convening of an expert team that develops an evidence based action plan, charter and secure web-based data support system. Teams will employ quality improvement techniques that include creating a local action plan for executing recommended evidenced based activities, communicating progress in antibiotic stewardship and sepsis management with all staff, and implementing Plan Do Study Act cycles (PDSA). The statewide collaborative will serve as a learning laboratory for all teams through weekly email newsletters, monthly webinars and quarterly face to face learning sessions.

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.