## Neonatal Abstinence Syndrome Initiative
## IRB Review

**To**: Martin McCaffrey

**From**: Office of Human Research Ethics

**Date**: 3/17/2015
**RE**: Determination that Research or Research-Like Activity does not require IRB Approval
**Study #:** 13-4068

**Study Title**: Care of Infants With Neonatal Abstinence Syndrome

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:Create a multidisciplinary hospital based community focused on providing a standardized approach to the identification, evaluation, treatment and discharge of the NAS infant and family within hospitals

Participants: 32 North Carolina Hospitals providing care for newborns

Procedures (methods): Working with perinatal quality improvement teams in participating hospitals the initiative will focus on identification and care of infants with NAS from the time between the admission of the infant and the discharge of the infant. NICU and Nursery teams will participate in the collaborative organized by PQCNC. Teams will execute an action plan based on best evidence and developed by an Expert Team. The collaborative will employ face to face learning sessions, web conferencing and coaching to support perinatal quality improvement teams (PQIT's) to use quality improvement methods to improve the delivery of care to infants with NAS.

**Regulatory and other findings:**

The IRB has determined that this submission allows for a full waiver of HIPAA authorization for the conduct of quality improvement--the primary purpose of which is not to develop or contribute to generalizable knowledge. This project is considered to be a health care operation, and the covered entity may use or disclose PHI for the study as part of its health care operations under the Privacy Rule.

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.