



## Newborn Hypoglycemia Care and Prevention

To: Martin Mccaffrey  
Neonatal-Perinatal Medicine

From: Office of Human Research Ethics

Date: 1/22/2019

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

Study #: 18-3343

Study Title: Newborn Hypoglycemia Care and Prevention

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:** Reduce by 25% the need for newborn infants to have intravenous catheters placed to treat hypoglycemia and reduce by 25% the need for newborns to be elevated to a higher level of care to treat their hypoglycemia.

**Participants:** Delivery Hospitals Across North Carolina

**Procedures (methods):** Incorporate and standardize within hospitals best evidenced practices of early skin to skin care, early feeding and use of glucose gel to prevent and treat hypoglycemia.

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.