



The Care of the Late Preterm Infant

To: Martin Mccaffrey
Neonatal-Perinatal Medicine

From: Office of Human Research Ethics

Date: 1/17/2024

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

Study #: 23-3162

Study Title: Care of the Late Preterm Infant

This submission, Reference ID 419199, 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: To standardize newborn care for infants 35-36 6/7 weeks gestation that assures the safest possible readiness for discharge using evidence based guidelines.

Participants: Hospitals Enrolled in the Perinatal Quality Collaborative of North Carolina (PQCNC) Care of the Late Preterm Infant initiative

Procedures (methods): This project will focus on standardizing care of the late preterm infant and preparing families for discharge with a focus on nutrition and feeding, screening for hyperbilirubinemia, effective safe sleep counseling and post-discharge follow up within 48 hours.