THE UNIVERSITY
of NORTH CAROLINA
at CHAPEL HILL

OFFICE OF HUMAN RESEARCH ETHICS
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(919) 966-3113
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Federalwide Assurance (FWA) #4801

To: Karen Metzguer
Pediatrics
CB:7596

From: Biomedical IRB

Date: 10/21/2010

RE: Determination that Research or Research-Like Activity does not require IRB Approval
Study #: 10-1918

Study Title: Increasing Exclusive Breastfeeding in the Term Well Newborn During the Maternity Stay

This submission was reviewed by the above-referenced IRB. The IRB 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: This is a quality improvement initiative to support hospital teams in NC to improve processes known to be associated with higher initiation of breastfeeding and success of mother's to exclusively breastfeed. Participants: All NC maternity services within hospitals have been invited to participate in the collaborative. Procedures: Hospital teams receive training in both evidence based practices and quality improvement science and collect information about their current practices related to supporting mother's to breastfeed exclusively. Across 9 months (January through September 2011) these teams use quality improvement strategies to map current practices, identify opportunities, test new ways of supporting mothers and create new standard processes to achieve their aim of increasing exclusive breastfeeding for mothers and babies at discharge.

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.

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To: Karen Metzguer
Pediatrics
CB:7596

From: Biomedical IRB

Date: 10/21/2010

RE: Determination that Research or Research-Like Activity does not require IRB Approval
Study #: 10-1917

Study Title: Increasing the Number of Babies Born with Birth Weights less than 1500 Grams who have Mother's Milk Available for the First 28 Days

This submission was reviewed by the above-referenced IRB. The IRB 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: To improve processes known to be associated with higher initiation of pumping as well as sustaining the ability to pump breast milk for babies who cannot nurse. Participants: All NC newborn critical care centers have been invited to participate in the collaborative. The list of currently registered teams is attached. Procedures: Hospital teams receive training in both evidence-based practices and quality improvement science and collect information about their current practices related to supporting mother's to pump. Across 9 months (Jan through Sept 2011) these teams use quality improvement strategies to map current practices, identify opportunities, test new ways of supporting mothers and create new standard processes to achieve their aim of increasing exclusive breastfeeding for mothers and babies at discharge. During this same period they participate in monthly educational programs.

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.