Conservative Management of Preeclampsia Initiative
IRB Review

To: Martin McCaffrey

From: Office of Human Research Ethics

Date: 2/03/2014
RE: Determination that Research or Research-Like Activity does not require IRB Approval
Study #: 14-0136

Study Title: Conservative Management of Preeclampsia (CMOP)

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 team on providing a standardized approach to diagnosis and management of patients with preeclampsia

Participants: Multidisciplinary teams from 20 hospitals across the state of North Carolina

Procedures (methods): Teams from Labor & Delivery Units across the state of North Carolina will be invited to participate in the collaborative organized by the Perinatal Quality Collaborative of North Carolina. Currently 20 hospital teams have self identified. These teams will include at least an obstetrician, nurse, senior administrator and patient representative. These teams will jointly execute an action plan based on current guidelines from the American College of Obstetrics and Gynecology. The structure of the collaborative will include three face to face learning sessions, monthly web conferencing, weekly emails and coaching to support CMOP perinatal quality improvement teams (PQIT's) to use quality improvement strategies to implement elements of the action plan.

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..