THE UNIVERSITY
of NORTH CAROLINA
at CHAPEL HILL

OFFICE OF HUMAN RESEARCH ETHICS
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To: Martha Carlough
Family Medicine

From: Biomedical IRB

Approval Date: 2/22/2021
UNC Administrative Review Due Date : 2/21/2022
RE: Notice of IRB Approval by Expedited Review (under 45 CFR 46.110)
Submission Type: Initial
Expedited Category: 5.Existing or non-research data
Study #: 21-0386

Study Title: Chatham Maternity Care Center (MCC) Evaluation - Prospective Study

This submission, Reference ID 322680, has been approved by the IRB. It has been determined that the risk involved in this research is no more than minimal. **This research requires annual UNC administrative review.** Under the revised 'Common Rule' of 2018, this study does not require continuing review and IRB approval will not expire.

Study Description:

Purpose: The purpose of this study is to perform a secondary data analysis on maternity care patients at UNC Chatham Hospital in the first three years (opened September 2020).

Participants: Participants include women of reproductive age who establish prenatal care at one of the catchment area clinical sites (UNC Chatham Primary Care, UNC Pittsboro Family Medicine, PHS Siler City and Moncure clinics and Chatham County Health Dept) and all women who deliver at UNC Chatham MCC through December 2023.

Procedures (methods): Variables during the prenatal, intrapartum, and postpartum period will be collected for mothers and neonatal variables for linked infants. These will be used in a secondary data analysis to provide descriptive statistics as part of the evaluation of Chatham MCC

Study Regulatory and other findings:

This research, which involves children, meets criteria at 45 CFR 46.404 and/or 21 CFR 50.51 (research involving no greater than minimal risk). The IRB has determined that the study-specific rationale provided by the investigator in application section A.2.A is sufficient to justify this finding.

This research, which involves pregnant women, meets criteria set forth in section 45 CFR 46.204. The IRB has determined that the study-specific rationale provided by the investigator in application section A.2.B is sufficient to justify this finding. In accordance with 46.204(d), the research holds no prospect of benefit for the woman nor the fetus but the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means.

The IRB has determined that the study-specific rationale provided by the investigator is sufficient to justify the waiver of informed consent for research [45 CFR 46.116(d)] and waiver of HIPAA authorization [45 CFR 164.512(i)(2)(ii)].

Submission Regulatory and other findings:

As a reminder, although the UNC-Chapel Hill OHRE/IRB may have approved or made a determination that this study can commence, at this time UNC-Chapel Hill in response to direction from the UNC System Office has reduced campus activity significantly due to the COVID-19 outbreak. All human subject research activities are expected to follow all institutional and UNC Health policies, including those that may limit direct contact of participants. If you need to modify or alter your study design due to COVID-19 in order to conduct your research activities, please submit a modification and advise in the "Cover page" that this is "COVID-19 Related".

Investigator's Responsibilities:

As an institution accredited by the Association for the Accreditation of Human Research Protection Programs (AAHRPP), all research approved under expedited procedures must receive an administrative review at least annually. It is the Principal Investigator's responsibility to submit a UNC administrative review report as requested by the IRB. Failure to respond to this request is considered non-compliance with IRB requirements and University policies.

Your approved consent forms and other documents are available online at http://apps.research.unc.edu/irb/index.cfm?event=home.dashboard.irbStudyManagement&irb_id=21-0386.

You are required to obtain IRB approval for any changes to any aspect of this study before they can be implemented.

New Safety Information should be reported to the IRB, in IRBIS, as per OHRE SOP 1401.

Please be aware that additional approvals may still be required from other relevant authorities or "gatekeepers" (e.g., school principals, facility directors, custodians of records).

The current data security level determination is Level III. Any changes in the data security level need to be discussed with the relevant IT official. If data security level II and III, consult with your IT official to develop a data security plan. Data security is ultimately the responsibility of the Principal Investigator.

This study was reviewed in accordance with federal regulations governing human subjects research, including those found at 45 CFR 46 (Common Rule), 45 CFR 164 (HIPAA), 21 CFR 50 & 56 (FDA), and 40 CFR 26 (EPA), where applicable.

CC:
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Emily Hawes, Family Medicine
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