

Institutional Review Board (IRB)

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Principal Investigator Grace Chan, MD, MPH, PhD
Protocol Number IRB-P00023058
Protocol Title Burden of Antibiotic Resistance in Neonates from Developing Societies (BARNARDS) - Ethiopia
Date: August 17, 2016

NOTICE OF EXPEDITED APPROVAL**IRB Approval Date: 8/11/2016****IRB Activation/Release Date: 8/17/2016****IRB Expiration Date: 8/10/2017**

The Institutional Review Board has approved the above referenced protocol through expedited review procedures. We are now able to release this approval to you since you have adequately responded to the IRB's questions and concerns.

Risks were determined to be minimal with potential for direct benefit.

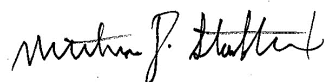
The IRB has determined that only one parent/guardian is required to provide permission for their child to participate in this study.

The IRB has determined that you have met the regulatory requirements necessary in order to obtain informed consent through a method other than a written consent document (verbal or REDCap form). It is the IRB's understanding that the proposed methods to obtain electronic consent have received local approval from St. Paul's Hospital Millennium Medical College IRB.

Assent is not required as subjects are too young to understand the research and its ramifications.

The occurrence of unanticipated problems should promptly be reported to this office. Any revisions, amendments, or changes to the protocol require prior IRB approval. The IRB has asked this office to notify investigators that clinical investigation protocol files are subject to audits at some future time.

Sincerely,



Matthew Stafford, Assistant IRB Director
For the Institutional Review Board

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