Appendix A

EMORY UNIVERSITY

Institutional Review Board

TO: Konny Huh
Principal Investigator
Global Health

DATE: October 24, 2011

RE: **Expedited Approval**
IRB00054047
Prenatal exposure to β2-adrenergic agonists in relation to autism, autism spectrum disorder and developmental delay: a case-control study

Thank you for submitting a new application for this protocol. This research is eligible for expedited review under 45 CFR 46.110 and/or 21 CFR 56.110 because it poses minimal risk and fits the regulatory category F5 as set forth in the Federal Register. The Emory IRB reviewed it by expedited process on 10/24/2011 and granted approval effective from **10/24/2011** through **10/23/2012**. Thereafter, continuation of human subjects research activities requires the submission of a renewal application, which must be reviewed and approved by the IRB prior to the expiration date noted above. Please note carefully the following items with respect to this approval:

- A complete HIPAA/Consent waiver was granted

Any reportable events (e.g., unanticipated problems involving risk to subjects or others, noncompliance, breaches of confidentiality, HIPAA violations, protocol deviations) must be reported to the IRB according to our Policies & Procedures at www.irb.emory.edu, immediately, promptly, or periodically. Be sure to check the reporting guidance and contact us if you have questions. Terms and conditions of sponsors, if any, also apply to reporting.

Before implementing any change to this protocol (including but not limited to sample size, informed consent, study design, you must submit an amendment request and secure IRB approval.

In future correspondence about this matter, please refer to the IRB file ID, name of the Principal Investigator, and study title. Thank you

Andrea Goosen, MPH, CIP
Research Protocol Analyst
This letter has been digitally signed