



HUMAN INVESTIGATION COMMITTEE
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NOTICE OF FULL BOARD APPROVAL

To: William Lyman
Pediatrics
Children's Research Center

From: Virginia Delaney-Black, M.D., M.P.H. _____
Chairperson, Medical/Pediatric Institutional Review Board (MP4)

Date: December 01, 2010

RE: HIC #: 104610MP4F
Protocol Title: RT-01-M GC/MS Methods to Determine Environmental Factors on Fetus and Newborn
Sponsor: ° NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEV.
° MICHIGAN STATE UNIVERSITY
Protocol #: 1010008916

Expiration Date: October 27, 2011

Risk Level / Category: Pediatric: 45 CFR 46.404 - Research not involving greater than minimal risk
Adult: Research not involving greater than minimal risk

The above-referenced protocol and items listed below (if applicable) were **APPROVED** following *Full Board Review* by the Wayne State University Institutional Review Board (MP4) for the period of 12/01/2010 through 10/27/2011. This approval does not replace any departmental or other approvals that may be required.

- Revised Protocol (received in the IRB office 12/01/2010) and revised Protocol Summary Form (revisions received in the IRB office 12/01/2010)
- Revised HIPAA Summary Form and revised HIPAA Authorization Form with consent (revisions received in the IRB office on 12/01/2010)
- Parental Permission/Research Informed Consent (submission/revision dated 11/30/2010)

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- ° Federal regulations require that all research be reviewed at least annually. You *may* receive a "Continuation Renewal Reminder" approximately two months prior to the expiration date; however, it is the Principal Investigator's responsibility to obtain review and continued approval **before** the expiration date. Data collected during a period of lapsed approval is unapproved research and can never be reported or published as research data.
 - ° All changes or amendments to the above-referenced protocol require review and approval by the HIC **BEFORE** implementation.
 - ° Adverse Reactions/Unexpected Events (AR/UE) must be submitted on the appropriate form within the timeframe specified in the HIC Policy (<http://www.hic.wayne.edu/hicpol.html>).

NOTE:

1. Upon notification of an impending regulatory site visit, hold notification, and/or external audit the HIC office must be contacted immediately.
2. Forms should be downloaded from the HIC website at **each** use.