



IRB Administration Office
87 East Canfield, Second Floor
Detroit, Michigan 48201
Phone: (313) 577-1628
FAX: (313) 993-7122
<http://irb.wayne.edu>

NOTICE OF EXPEDITED CONTINUATION APPROVAL

To: William Lyman
Pediatrics
Children's Research Center

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

Date: October 26, 2011

RE: IRB #: 104610MP4F
Protocol Title: RT-01-M GC/MS Methods to Determine Environmental Factors on Fetus and Newborn
Funding Source: Award: 015265-001
Protocol #: 1010008916

Expiration Date: October 25, 2012

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

Continuation for the above-referenced protocol and items listed below (if applicable) were APPROVED following Expedited Review by the Chairperson/designee of the Wayne State University Institutional Review Board (MP4) for the period of **10/26/2011 through 10/25/2012**. This approval does not replace any departmental or other approvals that may be required.

- Waiver of consent to collect urine routinely collected for clinical purposes continued and approved (as described in the amendment approved 1-10-11).
- Parental Permission/Research Informed Consent with HIPAA Authorization (dated 3-16-11).

-
- 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 IRB **BEFORE** implementation.
 - Adverse Reactions/Unexpected Events (AR/UE) must be submitted on the appropriate form within the timeframe specified in the IRB Administration Office Policy (<http://www.irb.wayne.edu/policies-human-research.php>).

NOTE:

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

*Based on the Expedited Review List, revised November 1998