WAYNE STATE UNIVERSITY

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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 riskResearch not involving greater than minimal risk

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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