A.8 IRB Approval Letter
OMB# 0925-0647 EXPIRATION DATE: 1/31/2015

Office of Research
Integrity and Compliance

2300 Children's Plaza, Box 205
Chicago, Illinois 60614-3394
773.755.6306
Fax 773.755.6304

Affiliated with
Northwestern University's
Feinberg School of Medicine

CHILDREN'S MEMORIAL HOSPITAL
IRB APPROVAL NOTICE
EXPEDITED NEW STUDY

TO:	**Jane Holl, MD, MPH**
PROTOCOL TITLE:	**Analysis of Environmental Chemicals in Dried Blood Spots**
IRB #:	**2011-14674**
APPROVED:	**June 8, 2011 – Expedited Review**
EXPIRATION OF IRB APPROVAL:	**June 7, 2012**

This protocol was approved under the following risk/benefit determination as described in CFR 45 Part 46, Subpart D:

45 CFR §46.404 Research not involving greater than minimal risk.

The Children's Memorial Hospital Institutional Review Board (CMH IRB) reviewed and approved, via expedited review as authorized by 45 CFR 46.110 and 21 CFR 56.110 the above-named protocol.

This research was reviewed and approved under expedited review category #2: Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows: a) from healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection many not occur more frequently than 2 times per week; or b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

Federal regulations require that an IRB conduct continuing review of research not less than once per year, regardless of whether initial approval was via full board or expedited procedures. Please note the expiration date for your current IRB approval and be aware that you must submit a progress report for IRB review prior to the expiration in order to obtain IRB approval for the next approval period. If the current approval expires and you do not obtain approval for another approval period, research on this study, including subject enrollment, must cease until you regain approval. If you have questions about your obligations as principal investigator, please contact the ORIC staff as listed on the ORIC website: http://www.childrensmrc.org/researchadministration/oric/irb2.

YOUR OBLIGATIONS AS PRINCIPAL INVESTIGATOR:

As the Principal Investigator, you are ultimately responsible for the conduct of the study, the protection of the rights and welfare of human subjects and adherence to the CMH IRB policies and procedures, including the following:

1. Perform the project by qualified personnel according to the approved protocol and ensure that all individuals who will interact with subjects and/or have access to identifiable research data have completed the CMH education requirement.

2. Submit the continuing review progress report for review and an approval on an annual basis as per CMH IRB policies and procedure.

3. Do not implement changes in the approved protocol or consent form(s) without prior CMH IRB approval (except to eliminate apparent immediate hazards to safeguard the well being of human subjects).

4. If written consent is required, obtain the legally effective written informed consent from human subjects or their legally responsible representative using only the currently approved CMH IRB stamped consent form(s).

5. Follow the CMH IRB Adverse Events, Other Unanticipated Problems, and Violations reporting criteria.

6. If this study is a sponsored study, you may NOT begin work on this study including subject enrollment until your contract/award is fully executed. Please contact the Office of Sponsored Programs for information about the status of the clinical trial agreement or grant award.

7. Follow the CMH policy pertaining to the access of medical records from Health Information Management.

Best wishes for a successful study.

Sincerely,

Vita Land, MD, MBA, IRB Chair
Institutional Review Board
Children's Memorial Hospital