University of Connecticut Health Center
Human Subjects Protection Office

Institutional Review Board

To: Sharon Lavigne
Principal Investigator
Pediatrics
MC-7120

From: IRB Office
MC-3926

Date: December 30, 2008

Re: **Final Approval for Continuation of Project**
Review Category: Expedited ***Expedited Category:*** b2,7
IRB Number: 07-086-3 ***IRB Panel:*** Panel 03
Project Title: Pilot Project for a National Monitoring System for Major Adverse Effects of Medication Use During Pregnancy and Lactation
Approved Investigators: Lavigne, Sharon A~
Protocol Version: Version 3, December 2008

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The study referenced above was approved for continuation on 12/29/2008 and remains valid through 12/28/2009. Should you wish to continue this study beyond that date you must apply to the Institutional Review Board Office for continuation of the study. The modification submitted with this request was also reviewed and was approved 12/29/2008. If applicable to your study, copies of the stamped and dated consent form must be used when obtaining consent and the form must be signed and dated by the participant and the individual obtaining consent.

All approved studies are subject to audit by the Research Compliance Monitor. Our Department of Health And Human Services Federal Wide Assurance Number is 00006064.

It is the responsibility of the PI to ensure that all investigators and staff associated with this study 1)follow the approved protocol; 2) use the approved forms; 3) comply with all IRB policies including the reporting of non-compliance with the approved protocol, unanticipated problems involving risk to subjects or others, adverse events, and any suspensions or terminations of IRB approval; and 4) comply with applicable regulations and the requirements or determinations of the IRB. Policies are available from the web site, http://resadm.uchc.edu/hspo/. If applicable to your study, copies of the stamped and dated consent form must be used when obtaining consent and the form must be signed and dated by both the participant and individual obtaining consent. PI's are also responsible for ensuring that IRB approval has been obtained and maintained at any collaborating sites involved in the research.

Approval from the IRB for any modification or addition to the protocol, forms or recruitment materials, must be obtained prior to implementation, except when necessary to eliminate immediate hazards to the subjects in which case the change must be reported within 5 days of occurrence. Administrative changes that pose no increased risk (e.g. correction of typographical errors, approval of an advertisement) may be approved through expedited review however the Chair reserves the right to send any request for modification to the full board.

c: Ginger Nichols MC-6210

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