From: Human Subjects Review-OD (CDC)
Sent: Wednesday, January 30, 2008 2:19 PM
To: Yowe-Conley, Tineka (CDC/CCHP/NCBDDD) (CTR); Reefhuis, Jennita (CDC/CCHP/NCBDDD)
Cc: NCBDDD Human Subjects Review (CDC)
Subject: FW: 2087:Approval of continuation with site restriction

DATE: 1/30/2008

FROM: IRB Administrator
Human Research Protection Office

Office of the Chief Science Officer, OD/CDC

SUBJECT: IRB Approval of Continuation of Protocol #2087, "The National Birth Defects Prevention Study" (Site Restriction)

TO: Jennita Reefhuis [NZR5]
NCBDDD/DBDDD

CDC's IRB "B" has reviewed and approved your request to continue protocol #2087 for the maximum allowable period of one year and it will expire on 1/29/2009. The protocol was reviewed in accordance with the expedited review process outlined in 45 CFR 46.110(b)(1), Categories(3,5,7).

If other institutions involved in this protocol are being awarded CDC funds through the CDC Procurement and Grants Office (PGO), you are required to send a copy of this IRB approval to the CDC PGO award specialist handling the award. You are also required to verify with the award specialist that the awardee has provided PGO with the required documentation and has approval to begin or continue research involving human subjects as described in this protocol.

As a reminder, the IRB must review and approve all human subjects research protocols at intervals appropriate to the degree of risk, but not less than once per year. There is no grace period beyond one year from the last IRB approval date. It is ultimately your responsibility to submit your research protocol for continuation review and approval by the IRB. Please keep this approval in your protocol file as proof of IRB approval and as a reminder of the expiration date. To avoid lapses in approval of your research and the possible suspension of subject enrollment and/or termination of the protocol, please submit your continuation request at least six weeks before the protocol's expiration date of 1/29/2009.

Any problems of a serious nature should be brought to the immediate attention of the IRB, and any proposed changes to the protocol should be submitted as an amendment to the protocol for IRB approval before they are implemented.

If you have any questions, please contact the Human Research Protection Office at (404) 4947 or e-mail: huma@cdc.gov.

Adriane Niare, MPH, CHES
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IRB Administrator
OCSO/OSRS/HRPO
404-639-4947