DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Centers for Disease Control
and Prevention (CDC)

Memorandum

Date December 29, 2014

From LaShonda Roberson, DHSc, MPH
LCDR, USPHS
IRB-B Administrator, Human Research Protection Office

Subject IRB Approval of Continuation of CDC Protocol #2087, "The National Birth Defects Prevention Study" (Expedited)

To Jennita Reefhuis, PhD
NCCBDDD/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 1/29/2016. The protocol was reviewed in accordance with the expedited review process outlined in 45 CFR 46.110(b) (1), categories 3 and 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 along with available IRB approvals from all collaborators. 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 along with all completed supporting documentation at least six weeks before the protocol's expiration date of 1/29/2016.**

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

If you have any questions, please contact your National Center Human Subjects Contact or the CDC Human Research Protection Office (404) 639-7570 or e-mail: huma@cdc.gov.

cc:

Scott Campbell

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Centers for Disease Control
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Memorandum

Date August 8, 2013

From Jason Abel
IRB Administrator Human Research Protection Office

Subject IRB Approval of Amendment to CDC Protocol 2087, " The National Birth Defects Prevention Study" (Expedited)

To Jennita Reefhuis
NCCBDDD/NBBB

CDC's IRB-B has reviewed and approved your request to amend protocol 2087, "The National Birth Defects Prevention Study". These changes included the following: Modification 1: Change in defects studied; Although NBDPS ascertained 30 birth defects, BD-STEPS will focus on a subset of these. Infants are eligible for inclusion in BD-STEPS if they have one or more defects from the list of 17 birth defects included in Attachment 5. In addition to selecting birth defects with unknown or uncertain etiology, these defects were selected for the following reasons; the defect is considered to be a major defect (affecting survival, requiring substantial medical care, or resulting in marked physiological or psychological impairment); the defect is usually identifiable in the first six weeks of life; and the defect is consistently ascertainable and classifiable. See protocol pages 16-17 for description of BD-STEPS case defintion. Modification 2. Change in Questionnaire Questions. A large portion of the BD-STEPS interview will be maintained from the NBDPS to make pooling of the CBDRP's NBDPS and BD-STEPS data possible; pooled data will facilitate the analysis of rare exposures and the examination of trends over time. While the BD-STEPS interview instrument contains many of the same sections,innovative questions have been added in response to some of the findings from NBDPS and in the literature. Changes include shortening the interview, adding questions about maternal diseases, and expanding sections to provide increased detail (e.g. indication and dose for specific medications). See protocol pages 27-28 for full description of the interview questions. The new questionnaire is included as Attachment 18. Modification 3. Centralized Interview. BD-STEPS interviewing for all the sites will be done by one central CDC-funded contract interviewing facility, which will increase consistency and efficiency. Contact information for the subjects will be encrypted and sent from the individual CBDRP to the interviewing facility via the CDC provided secure SAMS (Secure Access Management Services) system. Interviews will be conducted via the telephone using a system that allows eligible participants to see a local phone number displayed on their caller ID display for each of the sites (Voice over Internet Protocol, VoIP). See protocol page 26. Modification 4: Genetic data collection. Genetic data collection will be collected from saliva in BD-STEPS instead of cheek cells for NBDPS. All amended genetic collection materials are included as attachment 25-32. Modification 5: Collaborating Centers Collaborating Centers for BD-STEPS will most likely be a subset of the NBDPS Centers participating in NBDPS data collection. While existing NBDPS Centers will continue to participate in data analyses, it is expected that not all NBDPS Centers will collect new data as

part of BD-STEPS. When Centers are named, an amendment will be submitted with named Centers; new partners will be added using Form 1370 if needed at this time. Modification 6. Medical Records. At the end of the interview, requests will be made of participants with certain procedures/conditions for mailing an additional consent for medical/dental records. Medical records contain specific information that might be hard for women to recall, and medical record review allows validation of exposures reported by the mother in the questionnaire. Initial topics for which medical records will be requested include fertility treatments and dental treatments. Complete study materials for collection of medical records are described on page 28 of the protocol and included as attachments 19-22. Modification 7. Consent Addition The written consent for saliva samples contains a new section, "Sharing your genetic and health information for future research," that was not in the previous NBDPS written (genetics) consent. This section was added because of a new NIH GWAS policy that requires data from NIH-supported GWAS to be deposited into the NIH GWAS data repository, currently designated as the database of Genotypes and Phenotypes (dbGaP). See p. 3 of the consent (Attachment 26) for additional language that describes how these data will be potentially shared.

The action was reviewed in accordance with the expedited review process outlined in [45 CFR 46.110(b)(1), Category 0,3,5, and 7 or 46.111(b)(2), minor changes to previously approved research during the period (of one year or less) for which approval is authorized].

Reminder: IRB approval of protocol #2087 will still expire on 1/29/2014.

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

If you have any questions, please contact your National Center Human Subjects Contact or the CDC Human Research Protection Office (404) 639-7570 or e-mail: huma@cdc.gov.

cc:
Scott Campbell