DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Memorandum

Date November 20, 2018

From Jerrell Little
IRB-Committee 2 Administrator
Human Research Protection Office

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

To Jennita Reefhuis, PhD
NCCBDDD/NBBB

CDC's IRB-Committee 2 has reviewed and approved your request to amend protocol 2087, "The National Birth Defects Prevention Study". These changes included the following:

Consent forms have been updated to include a change in incentives offered and the process. In addition to the $20 gift card received with the Introductory Packet, women who complete the core maternal telephone interview will also receive a $30 gift card, which will be sent with the Thank You Letter (Att 23 and 27).

For the bloodspot component, previously a $10 giftcard was sent to women with the Bloodspot Introductory materials, however, the $10 gift card will only be sent to women who sign and send back the completed consent form.

For the infectious disease component (new), the process will follow that of the bloodspot consent. A $10 gift card will be sent to women who sign and send back the completed consent form.

There are no changes in the documentation regarding reading level since previous approved language was used to update these documents.

For births from October 1997 through December 2011, the Centers for Birth Defects Research and Prevention (CBDRP) collaborated on the National Birth Defects Prevention Study (NBDPS), a case control study of risk factors for birth defects. NBDPS interviewing ended March 31, 2013; NBDPS analyses are ongoing.

Beginning with births in January 2014, the CBDRP began collaboration on a case-control study called the Birth Defects Study To Evaluate Pregnancy exposureS (BD-STEPS). While many aspects of BD-STEPS were consistent with NBDPS, and the data will be combined from both studies for analysis when possible, substantial portions of BD-STEPS are different from NBDPS and have been previously described in submitted and approved IRB amendments. The official CDC IRB title for Protocol 2087 was changed in 2013 to "Centers for Birth Defects Research and Prevention" in order to cover NBDPS analyses and BD-STEPS data collection.

With a second round of BD-STEPS funding, the CBDRP collaborative will expand on the knowledge learned from NBDPS and the activities of BD-STEPS to date. The intent of the next round of funding (referred to as BD-STEPS II) is to carry out the same basic BD-STEPS study design with the following changes: (1) addition of questions to the maternal interview on infections, travel potentially related to infection, and marijuana use; (2) procedures for consenting participating mothers to link to State-based notifiable disease reporting; (3) addition of eligible birth defect case groups for defects that are more likely to be related to maternal infection during pregnancy; and (4) changing the incentive structure to promote participation.

Due to these protocol modifications, several previously approved materials have been updated and some new materials have been developed, all of which are being submitted to IRB for approval. Submitted documents will

include track and clean versions of changed documents and new documents (clean drafts only) before implementation. Specifically, these changes are noted below.

Modification 1: NEW INFECTIOUS DISEASE COMPONENT

The following are new documents for the Infectious Disease (ID) Component – Att47 – ID Consent, Att48 – ID Incomplete Letter, Att49 – ID FAQ, Att50 – ID Reminder Letter, Att51 – ID Reminder Script, Att52 – ID Thank You Letter. Att23 IntvThankYou_IDIntro (singleton) and Att 27 IntvThankYou_IDIntro (multiple) have been updated to introduce participants to this new component. The full description of the ID component is available in the BD-STEPS_Protocol. Spanish versions are being transcribed by CDC MLS but will be submitted once finalized.

Modification 2: LETTER OF AUTHORIZATION

Replace previous Att4_LetterofAuthorizationDHR2013-18 with Att4_GA_NCBDDD_MOU_Feb2012. The updated letter of authorization is the current understanding between NCBDDD and the GA DPH.

Modification 3: CASE DEFINITIONS

BD-STEPS Case Definitions: Att5 – Case Definitions is updated to include expanded definitions, inclusion of ICD-10 CM Codes, as well as the addition of new defects added to BD-STEPS II (pages 26-35). Clinicians associated with the study reviewed and provided the most recent medical review standards.

Modification 4: INCENTIVE CHANGES

Participants are send a $20 gift card with the Introductory Packet. They will receive an additional incentive, which is sent to women after completing the core maternal telephone interview as a $30 gift card. The additional language to include an additional gift card is included in the following attachments: Att6 – Intro Letter, Att23 – IntvThankYou (singleton), Att 27 IntvThankYou_IDIntro (multiple), Att25 – Bloodspot Consent (singleton), Att28 - Bloodspot Consent (multiple).

Modification 5: QR CODES

The use of QR codes has been added to Att6 – Intro Letter. The QR code allows participants to add the phone number and save it in their cell phone. The BD-STEPS Communication Committee approved the addition of a QR code to aid in participants answering when called since the majority of participants are contacted through their cell phone and many cell phone users are apprehensive about answering phone calls from unknown callers, this will help participants know when they are being called about the study.

Modification 6: BLOODSPOT CONSENT

The bloodspot consent form (Att25 - Bloodspot Consent (singleton) and Att28 - Bloodspot Consent (multiple)) includes changes to when participants receive the incentive, after they sign and send the consent form back, they will be mailed a $10 gift card. A site specific addition (NY Only) was completed for the NY Department of Health which requires a second signature in order to indefinitely store bloodspot samples (per the previously approved protocol).

Modification 7: DATA SHARING GUIDELINES

There were several changes made to the Data Sharing Guideline since moving to an electronic database and the process of submitting projects (Att33 – DSGuidelines). Other changes include an updated Confidentiality & Data Use Oath for everyone who uses or has access to data and describes how genetic projects are processed. This version was reviewed and approved by the CBDRP Data Sharing Committee.

Modification 8: CATI QUESTIONNAIRE

There were several major changes completed in the questionnaire (Att18 - CATI) including: addition of sections on Infections and Travel (now sections T and U), addition of section on Marijuana (now section BB), reordering of sections on Fevers (was section S, now section R) and Genitourinary Infections (was section R, now section S), moved STD questions (previously R29-R42) from Genitourinary Infections section and added them to the new Infection section (now section T). The additional questions are estimated to extend the interview up 10 minutes from the previous version. The questionnaire is estimated to take 55 minutes to complete depending on the extent of participants' response. Spanish versions are being transcribed by CDC MLS but will be submitted once finalized.

Modification 9: INTRO PHONE SCRIPTS

Several small changes were completed for the telephone introductory script (Att17 - Intro Scripts) as well as the addition of the Massachusetts only script. Previously, Massachusetts scripted followed the general script but with the addition of site specific requirements, it was necessary to change to a site specific script. The Spanish version will be submitted after translation updates are complete.

Modification 10: INTRO PACKET PRINT MATERIALS

The final print materials are attached; English and Spanish versions are attached (Att7 - Human Subjects, Att8 - Calendar 2017-2020, Att9 - Q&A, Att10 - Medication Summary, and Att16A - BD-STEPS Facesheet.).

Modification 11: NEW BD-STEPS NEWSLETTER

The annual BD-STEPS Newsletter to be distributed to participants is attached in English and Spanish (Att24 - BD-STEPS Newsletter).

Modification 12: STILLBIRTH CATI QUESTIONNAIRE

The changes tracked (and clean) in the Spanish version of Stillbirth CATI Questionnaire (Att36) were previously approved in the English version by CDC IRB.

Modification 13: BD-STEPS PROTOCOL

The several changes made throughout the BD-STEPS Protocol reflect the changes submitted in this amendment. An additional section for the infectious disease component and ascertainment of information from State Health Departments is described in full. Changes to incentives and compensation have been updated for the additional $30 gift card for competition of the telephone interview, the change for bloodspot incentive to be sent after a signed consent form is received, and the new $10 gift card for the return of a signed consent form for the infectious disease component.

Modification 14: GENETICS EQA CHANGES

There were small modifications to the procedures for genetic late external quality assessment (EQA). These changes were completed in the following documents: Att34B – EQA Methylation and Att34C – EQA Sequencing. For Genome-Wide Arrays, there was a change from 3 to 2 arrays required for EQA. There was a change for the EQA of sequencing that explains facility requirements and capabilities.

The action was reviewed in accordance with the expedited review process outlined in [45 CFR 46.110(b)(1), categories 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 1/29/2019.

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