

**Memorandum**

Date December 12, 2018 UPDATE: Added Modification 7

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:

For the BD-STEPS Stillbirth Component, in addition to the \$10 gift card sent with the Stillbirth Supplement Intro Packet, an additional \$10 gift card will be sent to women who complete the Still Supplement telephone interview with the Thank You Letter. This change has been documented in SB Intro Letter, SB Thank You Letter, SB Phone Script, and SBnoBD Intro Letter. The language added was previously approved by the CDC IRB for a different component of the study.

Modification 1: LETTER OF AUTHORIZATION

Replace previous Att4_GA_NCBDDD_MOU_Feb2012 with Att4_LetterofAuthorizationDHR2018-23. The updated letter of authorization is the current understanding between NCBDDD and the GA DPH.

Modification 2: CASE DEFINITIONS

BD-STEPS Case Definitions: Att4A – Stillbirth Case Definitions is updated to include ICD-10 CM & Procedure Codes. Clinicians associated with the study reviewed and approved the most recent medical review standards.

Modification 3: INCENTIVE CHANGES

For the Stillbirth supplemental telephone interview, participants are sent a \$10 gift card with the Introductory Packet. Participants will receive an additional incentive, a \$10 gift card, will be sent to women after completing the Stillbirth supplemental telephone interview. The language to include an additional gift card is included in the following attachments: Att37 – SB Intro Letter, Att44 – SB IntvThankYou, and Att46 - SBnoBD_Intro Letter.

Modification 4: CATI QUESTIONNAIRE

There were several minor changes to the SB supplemental questionnaire (Att36 - SB Supple Questionnaire). Spanish versions are available in track and clean versions.

Modification 5: INTRO PHONE SCRIPTS

Several small changes were completed for the SB telephone introductory script (Att45 - SB Intro Scripts). The Spanish version will be submitted after translation updates are complete.

Modification 6: MINOR REVISION

The following documents contain minor revisions: change 'compensate' to 'thank' Att6 - IntroLetter.

Modification 7: NBDPS CONSENT RECONCILIATION

During the span of the NBDPS, there were three separate consent forms, this document proposes the alignment and clarification that was incorrectly stated during the time participants consented into the study. Document 'ReconilingConsents_Nov_2018_Final.docx' describes the reconciliation.

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