



Memorandum

Date December 23, 2015

From Jason Abel
IRB-A Administrator, Human Research Protection Office

Subject IRB Approval of Amendment #1 to CDC Protocol #6768.0, "Congenital Heart Surveillance To Recognize Outcomes, Needs, and well-beinG (CH STRONG)" (Expedited)

To Sherry Farr, MSPH, PhD
NCBDDD/DBDDD

CDC's IRB A has reviewed and approved your request to amend protocol #6768.0, "Congenital Heart Surveillance To Recognize Outcomes, Needs, and well-beinG (CH STRONG)".

This approval is for amendment #1 of protocol 6768.

Amendment #1 includes:

- Modification 1. The study coordinator and MACDP site lead are given authority to access personal identifying information (p 16-17 in the clean and marked protocol). This addition is necessary so that surveillance activities can proceed in the event that the project officer is absent or otherwise unavailable at any given time throughout the study period.
- Modification 2. A phone script and reminder postcard have been prepared and added as attachments. The previous version of the protocol mentioned that participants would receive phone calls and postcards reminding them to complete the survey if they have not already done so (p 13-14 in the clean and marked protocol), but the phone script and postcard were not provided as attachments prior to this amendment.

The action was reviewed in accordance with the expedited review process outlined in 45 CFR 46.110(b)(2), minor changes to previously approved research during the period of one year for which approval is authorized.

Reminder: IRB approval of protocol #6768.0 will still expire on 08/13/2016.

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:
Campbell, Scott (CDC/ONDIEH/NCBDDD)