Attachment 7

CDC IRB Approval (Continuation)

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Memorandum

Date November 9, 2012

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

Subject IRB Approval of Continuation of CDC Protocol #2513, "School Associated Violent Deaths, United States" (Expedited)

To JEFFREY HALL, PhD., M.S.P.H
NCIPC/DVP

CDC's IRB-B has reviewed and approved your request to continue protocol 2513 for the maximum allowable period of one year and it will expire on 11/9/2013. The protocol was reviewed in accordance with the expedited review process outlined in 45 CFR 46.110(b) (1), category 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 11/9/2013.**

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:
Jahlani Akil

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Memorandum

Date November 9, 2012

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

Subject IRB Approval of Amendment to CDC Protocol 2513, "School Associated Violent Deaths, United States" (Expedited)

To JEFFREY HALL, PhD., M.S.P.H
NCIPC/DVP

CDC's IRB-B has reviewed and approved your request to amend protocol 2513, "School Associated Violent Deaths, United States". These changes included the following: Modification 1. The attachments contain 1) clean proposed new instruments and 2) cross walks developed to provide information about revisions implemented. The first two tabs contain the original and the revised interview tools (sans the cover page). These tabs provide a means of moving back and forth between the versions of the instrument. The remaining tabs include eliminated items, revised items, and completely new items. 1. The eliminated items tab is for all items that we cut from the interview and a reason for removal. Collectively these removals will help streamline and focus the interview tools and decrease respondent burden. Decisions were based upon analyses of information regarding missing values and considerations of a given items utility with the study's overall prevention objectives. 2. The revised items tab contains items that were in the original instrument but changed the content of the items and a reason for revision. 3. The next tab contains wholly new items. This includes only newly added items. It does not contain items that were changed as a result of our decision to revise an existing item. All items were added to enhance either the scope or relevance of the information previously collected. They were also added based on more recent research addressing violence within school settings. 4. The remaining tabs are provided to further ease the process of identifying and evaluating changes between the previous and proposed instrument versions.

The action was reviewed in accordance with the expedited review process outlined in [45 CFR 46.110(b)(1), Category 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 #2513 will still expire on 11/9/2013.

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:
Jahlani Akil