

Date: December 19, 2012

From: Stephen Blumberg, Ph.D.  
Chair, NCHS Research ERB

Anjani Chandra, Ph.D.  
Vice Chair, NCHS Research ERB

To: Kristen Miller, Ph.D.

Subject: Protocol #2010-19 "NCHS Laboratory-based Questionnaire Design", Amendment #27 "Evaluation of Violence Against Children Survey (VACS) – Malawi"

The NCHS Research Ethics Review Board reviewed Protocol #2010-19 "NCHS Laboratory-based Questionnaire Design", Amendment #27 "Evaluation of Violence Against Children Survey (VACS) – Malawi" using the review process, based on 45 CFR 46.

Description of proposed modification:

Amendment #27 "Evaluation of Violence Against Children Survey (VACS) – Malawi"

Protocol #2010-19 Amendment #27 is approved.

The Board also approved the following waivers:

- 1) In accordance with 45 CFR 46.116(d), the Board has granted a waiver of the requirement to inform parents of youth 13-17 years of age of the purpose of the research 1) that the research presents no more than minimal risk of harm to the subjects, 2) the waiver will not adversely affect the rights and welfare of the subjects, and 3) the research could not practicably be carried out without the waiver.
- 2) In accordance with 45 CFR 46.117(c), the Board has granted a waiver of documented consent, having determined 1) that the research presents no more than minimal risk of harm to subjects and 2) that the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality.

**Of Note: Please be aware that this approval is limited to the 20 interviews that will be carried out by the NCHS Laboratory-Based Questionnaire Design Staff.**

IRB approval of protocol #2010-19 will expire on **09/24/13**.

If it is necessary to continue the study beyond the expiration date, a request for continuation approval should be submitted about 6 weeks prior to 09/24/13.

**There is no grace period of one year from the last approval date. In order to avoid lapses in approval of your research and the possible suspension of subject enrollment, please submit your continuation request at least six (6) weeks before the protocol's expiration date of 09/24/13. It is your responsibility to submit your research protocol for continuing review.**

Any problems of a serious nature resulting from implementation of these changes should be brought to the attention of the Research ERB, and any additional proposed changes should be submitted for IRB approval before they are implemented.

Please submit "clean" copies of the revised protocol, consent forms, and any other revised materials to this office for the official protocol file.

Please call me or Verita Buie, Dr.P.H., if you have any questions.

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