Attachment I NCHS Ethics Review Board Approval documentation for research involving human subjects

From: Mackay, Andrea (CDC/OPHSS/NCHS)
Sent: Thursday, September 25, 2014 11:09 AM

To: Whitaker, Karen R. (CDC/OPHSS/NCHS); Miller, Kristen S. (CDC/OPHSS/NCHS); Schenker, Nathaniel (CDC/OPHSS/NCHS)

Cc: Minino, Arialdi M. (CDC/OPHSS/NCHS); Blumberg, Stephen J. (CDC/OPHSS/NCHS); Madans, Jennifer H.

(CDC/OPHSS/NCHS); Powell-Griner, Eve (CDC/OPHSS/NCHS)

Subject: Continuation of Protocol #2010-19 NCHS Laboratory-Based Questionnaire Design

Date: September 24, 2014

From: Stephen Blumberg, Ph.D.

Chair, NCHS Research ERB

Arialdi Miniño, M.P.H.

Vice Chair, NCHS Research ERB

To: Nathaniel Schenker, Ph.D.

Karen R. Whitaker, B.S. Kristen S. Miller, Ph.D.

Subject: Continuation of Protocol #2010-19 "NCHS Laboratory-Based Questionnaire Design"

The NCHS Research ERB reviewed the request for continuation approval of Protocol #2010-19 "NCHS Laboratory-Based Questionnaire Design" at the convened ERB meeting on August 20, 2014 using the review process based on 45 CFR 46. Continuation of Protocol #2010-19 is approved for the maximum allowable period of one year.

ERB approval of protocol #2010-19 will expire on 09/24/15.

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 09/24/15.

There is no grace period beyond 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 09/24/15. It is your responsibility to submit your research protocol for continuing review.

Any problems of a serious nature should be brought to the immediate attention of the Research ERB, and any proposed changes should be submitted for Research ERB approval <u>before</u> they are implemented.

Please call or e-mail Andrea MacKay, M.S.P.H., if you have any questions.

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

Arialdi Miniño, M.P.H. Vice Chair, NCHS Research ERB