

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

From: Buie, Verita (CDC/OSELS/NCHS)
Sent: Thursday, October 13, 2011 6:38 PM
To: Whitaker, Karen R. (CDC/OSELS/NCHS)
Cc: Blumberg, Stephen J. (CDC/OSELS/NCHS); Chandra, Anjani (CDC/OSELS/NCHS); Madans, Jennifer H. (CDC/OSELS/NCHS); Powell-Griner, Eve (CDC/OSELS/NCHS)
Subject: Continuation of Protocol #2010-19 NCHS Laboratory-Based Questionnaire Design

Date: October 13, 2011

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

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

To: Karen Whitaker, B.S.

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

The NCHS Research Ethics Review Board reviewed the request for new Protocol #2010-19 NCHS Laboratory-Based Questionnaire Design, using the review process based on 45 CFR 46.

Protocol #2010-19 is approved for the maximum allowable period of one year.

IRB approval of protocol #2010-19 will expire on 09/24/2012.

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 09/24/2012.

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 09/24/2012. 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, DrPH, if you have any questions.

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

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