

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

From: LaRochelle, Dewey H. (CDC/CCHIS/NCHS)
Sent: Thursday, September 17, 2009 9:18 AM
To: Miller, Kristen S. (CDC/CCHIS/NCHS); Whitaker, Karen R. (CDC/CCHIS/NCHS); Willson, Stephanie (CDC/CCHIS/NCHS)
Cc: Blumberg, Stephen J. (CDC/CCHIS/NCHS); Chandra, Anjani (CDC/CCHIS/NCHS); Madans, Jennifer H. (CDC/CCHIS/NCHS); Moien, Mary (CDC/CCHIS/NCHS)
Subject: Continuation of Protocol #2002-03 Laboratory Based Questionnaire Design (QDRL)

September 16, 2009

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

Continuation of Protocol #2002-03 Laboratory Based Questionnaire Design (QDRL)

To: Karen Whitaker,

The NCHS Research ERB reviewed the request for approval of Continuation of Protocol #2002-03 Laboratory Based Questionnaire Design (QDRL) on September 16, 2009 at the full Board meeting. Continuation of Protocol #2002-03 is approved for the maximum allowable period of one year.

IRB approval of protocol #2002-03 will expire on **10/17/2010**.

OF NOTE:

The Board is approving ONLY the continuation of the original wording of the documents. The suggestions for changes to the documents must be submitted as an amendment. A continuation request cannot have any changes. Please submit an amendment request for these changes.

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 10/17/2010.**

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 10/17/2010. 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 before they are implemented.

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

Please call or e-mail me or Dewey LaRochelle if you have any questions.

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

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