

# ***Attachment 6***

***ERB Approval***

**From:** LaRochelle, Dewey H. (CDC/CCHIS/NCHS)  
**Sent:** Wednesday, September 30, 2009 4:00 PM  
**To:** Burt, Vicki L. (CDC/OSELS/NCHS); Johnson, Clifford L. (CDC/OSELS/NCHS); Porter, Kathryn S. (CDC/OSELS/NCHS); Zipf, George (CDC/OSELS/NCHS)  
**Cc:** Blumberg, Stephen J. (CDC/OSELS/NCHS); Chandra, Anjani (CDC/OSELS/NCHS); Madans, Jennifer H. (CDC/OSELS/NCHS); Moien, Mary (CDC/OSELS/NCHS)  
**Subject:** Continuation of Protocol #2005-06 National Health and Nutrition Examination Survey (NHANES)

September 30, 2009

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

Continuation of Protocol #2005-06 National Health and Nutrition Examination Survey (NHANES)

To: Kathryn S. Porter, MD

The NCHS Research ERB reviewed the request for approval of Continuation of Protocol #2005-06 National Health and Nutrition Examination Survey (NHANES) on 09/16/2009 at the full Board meeting. Continuation of Protocol #2005-06 is approved for the maximum allowable period of one year.

IRB approval of protocol #2005-06 will expire on **09/30/2010**.

Of Note:

1. In the future, the Board would like to request a list of the consent forms to go with all the attachments so they can be sure they have them all.
2. There was also a lack of uniformity in the unanticipated event write-ups (eg., sometimes blood pressure was noted, sometimes not; sometimes prior history of the condition was noted, sometimes not). Also, in the future the Board would like to know whether the person mentioned in the unanticipated events continued with the survey. Not all the write-ups mention what happened to the participant after the incidents reported.
3. The Board is curious what useful information is being gained by the continuation of the Hepatitis C screening since the time line for results seems very long.

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 09/30/2010.**

**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 09/30/2010. 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