

# ***Attachment 6***

***ERB Approval***

**From:** Buie, Verita (CDC/OSELS/NCHS)  
**Sent:** Wednesday, September 15, 2010 5:02 PM  
**To:** Porter, Kathryn S. (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 #2005-06 National Health and Nutrition Examination Survey

September 15, 2010

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

To: Kathryn S. Porter, M.D., M.S.

The NCHS Research ERB reviewed the request for approval of Continuation of Protocol #2005-06 National Health and Nutrition Examination Survey on 09/15/10. Continuation of Protocol #2005-06 is approved for the maximum allowable period of one year.

Of Note: The ERB appreciates the response dated 9/10/10 to the questions raised about the continuation and approves the proposed actions and changes.

Specifically:

- 1) As noted on page 2, the ERB looks forward to receiving either a report or a protocol amendment addressing how the specified criteria have been used to determine whether current exam and laboratory test results are reported to respondents. Given the volume of tests and exams conducted, the ERB requests that this amendment be submitted no later than June 30, 2011 to give the ERB sufficient time to review this information before the next continuation request is considered.
- 2) Because it has not been used, the ERB requests removal of the check box on the "Consent/assent and parental permission for examination at the MEC" that gives parents the option to refuse receipt of written results. After the current supply of these forms is gone, please remove this check box and add a sentence informing participants that they will receive a report of findings.
- 3) Similarly, after the current supply of specimen storage consent forms are used, please proceed with amending the language for the check boxes as specified on page 5 of the 9-10-2010 response.
- 4) Please proceed immediately with placing a sticker with the phone number to receive results in the NHANES Health Measurements sheet and consent brochure as specified as well as providing the correct phone number for inquiries on the back of the consent brochure.

IRB approval of protocol #2005-06 will expire on **09/30/11**.

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 09/30/11.

**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 09/30/11. It is your responsibility to submit your research protocol for continuing review. Active research and studies that have not yet begun may be continued for a maximum of five years. If five years have elapsed since the original "new protocol" approval, and further contact with subjects or collection of protected health information is ongoing or planned, approval of a "new " protocol must be requested using the appropriate form and documentation. Please be aware that this protocol will need to be submitted for approval as a "new" protocol for the 09/30/11 submission.**

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 Verita Buie, Dr.P.H., if you have any questions.

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

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