Attachment 6

ERB Approval

From:	Mackay, Andrea (CDC/OPHSS/NCHS)
Sent:	Thursday, October 16, 2014 4:31 PM
To:	Porter, Kathryn S. (CDC/OPHSS/NCHS); Woodring, Joseph V. (CDC/OPHSS/NCHS); Burt, Vicki L. (CDC/OPHSS/NCHS); Zipf, George (CDC/OPHSS/NCHS)
Cc:	Blumberg, Stephen J. (CDC/OPHSS/NCHS); Minino, Arialdi M. (CDC/OPHSS/NCHS); Madans, Jennifer H. (CDC/OPHSS/NCHS); Powell-Griner, Eve (CDC/OPHSS/NCHS)
Subject:	Continuation of Protocol #2011-17 "National Health and Nutrition Examination Survey (NHANES)"

Date: October 16, 2014

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

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

To: Joseph V. Woodring, D.O., M.P.H, M.T.M.&H.
Kathryn Porter, M.D., M.S.
Vicki Burt, R.N.,Sc.M.
George Zipf, M.S.

Re: Continuation of Protocol #2011-17 "National Health and Nutrition Examination Survey (NHANES)"

The NCHS Research Ethics Review Board reviewed the request for continuation of Protocol #2011-17 "National Health and Nutrition Examination Survey (NHANES)", using the review process based on 45 CFR 46 on 10/15/14.

Protocol #2011-17 is approved for the maximum allowable period of one year.

Of Note:

1. **The Board requires that DHANES provide the Board with the determination of the DHANES physician advisory group after their review of the reporting of testosterone results to participants.**

2. **The Board requests clarification of the data collection protocol followed in incidents (such as those reported on p. 66, incident #8) in which the sample**

person "missed having his blood pressure and resting heart rate recorded..." due to an episode that occurs during an examination. What data are collected for the SP in such circumstances?

3. **The Board recommends the following changes to the Examination consent brochure for the next time it is printed:**

   a. Page 4: Final paragraph/3rd sentence: Rather than beginning the sentence with "But," the sentence can begin with "Because the body composition scan…"

   b. Page 5/Final section ("Will I get my results?"): Suggest a paragraph break between 5th and 6th sentences (After "In general, we give results….guardians of children" and before "Some results, like those for….")

   c. Page 5/Final paragraph: May consider simplifying these sentences: "Some tests are not reported because they are used only for research and not for medical care. We may understand more about some test results in the future, and some tests may be repeated or read again. We will not report the results of future tests to you.

ERB approval of protocol #2011-17 will expire on 11/10/2015.

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 11/10/2015.

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 11/10/2015. 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 Andrea MacKay, M.S.P.H.. if you have any questions.

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

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