



Date: August 19, 2014

From: Stephen Blumberg, Ph.D.
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To: Carol DeFrances, Ph.D.
Paul Beatty, Ph.D.
Clarice Brown, M.S.

Subject: Continuation of Protocol #2009-21 National Hospital Care Survey (NHCS)

The NCHS Research ERB reviewed the request for continuation approval of Protocol #2009-21 National Hospital Care Survey (NHCS), using the expedited review procedure, based on 46.110 of 45 CFR 46(b)(1), category 5 research that uses materials collected solely for nonresearch purposes and category 8b continuing review of research previously approved by the convened board where no subjects have been enrolled and no additional risks have been identified. Continuation of Protocol #2009-21 is approved for the maximum allowable period of one year.

IRB approval of protocol #2009-21 will expire on 09/16/15.

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 09/16/15.

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 09/16/15. 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 call or e-mail Andrea MacKay, M.S.P.H., if you have any questions.

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