

## Attachment A

Date: January 7, 2016

From: Arialdi Miniño, M.P.H.  
Chair, NCHS Research ERB

James Craver, M.A.A.  
Vice Chair, NCHS Research ERB

To: Lauren Harris-Kojetin, Ph.D.  
Christine Caffrey, Ph.D.

Subject: New Protocol #2016-02 National Study of Long Term Care Providers Feasibility Project

The NCHS Research Ethics Review Board reviewed the request for new Protocol #2016-02 National Study of Long Term Care Providers Feasibility Project, using the full board review process based on 45 CFR 46. Protocol #2016-02 is approved for the maximum allowable period of one year.

In addition, the Convened Board agreed to grant the following waivers to Protocol #2016-02 National Study of Long Term Care Providers Feasibility Project under normal review procedures:

- 1) In accordance with 45 CFR 46.116(d), the Board voted to approve a waiver of the requirements to obtain informed consent of residential care residents and adult day service participants. The Board determined that the study would pose no greater than minimal risk to residents and participants and that omission of the consent process would not adversely affect their rights or welfare.
- 2) In accordance with 45 CFR 46.116(d), the Board voted to approve a waiver of documentation of informed consent of facility directors.

ERB approval of protocol #2016-02 will expire on 01/07/2017.

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 01/07/2017.

**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 01/07/2017. 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 ERB approval before they are implemented.

Please call me or Andrea MacKay, M.S.P.H., if you have any questions.

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