DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Disease Control and Prevention
National Center for Health Statistics
3311 Toledo Road
Hyattsville, Maryland 20782

Date: October 4, 2017

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

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

Subject: New Protocol #2017-08 National Study of Long-Term Care Providers: Residential Care Community Survey and Adult Day Services Center Survey

The NCHS Research Ethics Review Board reviewed the request for new Protocol #2017-08 National Study of Long-Term Care Providers: Residential Care Community Survey and Adult Day Services Center Survey, using the full board review process based on 45 CFR 46 at the September 20, 2017 Board Meeting. Protocol #2017-08 is approved for the maximum allowable period of one year.

In addition, the Convened Board agreed to grant the following waivers to Protocol #2017-08 National Study of Long-Term Care Providers: Residential Care Community Survey and Adult Day Services Center Survey under normal review procedures:

1. In accordance with 45 CFR 46.116(d), the Board voted to approve a waiver of the requirement to obtain informed consent of sampled residential care residents and adult day care participants. The Board determined that the study would pose no greater than minimal risk to participants and that omission of the consent process would not adversely affect the rights or welfare of the subjects. The Board noted that the data are already collected and contained in the medical records and no directly identifying data are collected. The Board also agreed that it would not be practicable for the investigators to contact residents/participants, the next of kin, or their legal guardians before obtaining the data.
2. In accordance with 45 CFR 46.116(c), the Board voted to approve a waiver of documentation of informed consent of the directors (respondents) because the research could not practicably be carried out without the waiver
3. In accordance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Regulation (45 CFR 164.512), the Board voted to approve a waiver of patient authorization for release of patient medical record data by health care providers. The Board determined that the disclosure of protected health information involves no more than minimal risk to privacy of individuals. The Board determined that:
   a. There was an adequate plan to protect the identifiers from improper use and disclosure
   b. There was an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, and that an adequate research justification was provided for retaining the following identifiers: date of birth, date of healthcare visit, and zip code.
   c. There were adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted by this subpart. The Board also agreed that the research could not practicably be conducted without the waiver. The Board agreed that the research could not practicably be conducted without access to and use of the protected health information.

ERB approval of protocol #2017-08 will expire on 10/04/2018.

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 10/04/2018.

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 10/04/2018. 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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