Att F – ERB Approval Letter

Date: February 4, 2019

From: Arialdi Miniño, MPH.

Chair, NCHS ERB

James M. Craver, MAA Vice Chair, NCHS ERB

To: Kelly Myrick PhD

Brian Ward, PhD

Subject: Continuation of Protocol #2016-07 National Electronic Health Records Survey (NEHRS)

The NCHS Ethics Review Board reviewed the request for the continuation of Protocol #2016-07 National Electronic Health Records Survey (NEHRS) using the review process based on 45 CFR 46 at the January 16, 2019 convened Research ERB meeting. Protocol #2016-07 National Electronic Health Records Survey (NEHRS) is approved for the maximum allowable period of one year.

ERB approval of protocol #2016-07 will expire on 02/09/2020.

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 02/09/2020.

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 02/09/2020. It is your responsibility to submit your research protocol for continuing review.

Alternatively, at least six weeks before the protocol's expiration date, you may submit a closure request and a new request for protocol approval. If the project is then determined to be excluded or exempt from the revised Common Rule, or if the research is eligible for expedited review under the revised Common Rule, then annual continuation requests will no longer be required.

Any problems of a serious nature should be brought to the attention of the ERB, and any additional proposed changes should be submitted for ERB approval <u>before</u> they are implemented.

Please contact me or Kyle Wise, if you have any questions.

Arialdi Miniño, MPH Chair, NCHS ERB

James M. Craver, MAA Vice Chair, NCHS ERB