

Attachment 15

ERB Approval

From: Wise, Kyle (CDC/DDPHSS/NCHS/OD) <iog7@cdc.gov>
Sent: Tuesday, October 27, 2020 10:31 AM
To: Lukacs, Susan (CDC/DDPHSS/NCHS/DHNE) <srl2@cdc.gov>; Paulose, Ryne
(CDC/DDPHSS/NCHS/DHNE) <rnp0@cdc.gov>
Cc: Craver, James (CDC/DDPHSS/NCHS/OD) <ewf6@cdc.gov>; O'Connor, Kathy
(CDC/DDPHSS/NCHS/DHCS) <kdo7@cdc.gov>; Buie, Verita
(CDC/DDPHSS/NCHS/OD) <gnx5@cdc.gov>
Subject: Extension of Protocol #2018-01 National Health and Nutrition Examination Survey (NHANES)

To Whom it may Concern:
Protocol #2018-01 National Health and Nutrition Examination Survey (NHANES) was set to expire on 10/26/2020 and has been granted a 5 month extension to allow appropriate time for submitting a new Protocol under the 2018 Common Rule, the new expiration date is 3/26/2021.

Thank You
-Kyle Wise

Date: October 24, 2019

From: Aialdi Miniño, M.P.H
Chair, NCHS ERB

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

To: Duong T. Nguyen, D.O.
Susan Lukacs, D.O., MSPH

Subject: Continuation of Protocol #2018-01 The National Health and Nutrition Examination Survey (NHANES)

The NCHS Ethics Review Board reviewed the request for Continuation of Protocol #2018-01 The National Health and Nutrition Examination Survey (NHANES), using the Full Board review process based on 45 CFR 46, at the October 16, 2019 convened Board meeting. Protocol #2018-01 is approved for the maximum allowable period of one year. The Board believes that this protocol continues to operate at a level of risk to participants that is no more than minimal, as defined by 45 CFR 46 and existing guidelines.

ERB approval of protocol #2018-01 will expire on 10/26/2020.

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 10/26/2020.

There is no grace period beyond one year from the last approval date. In order to avoid lapses in approval of your protocol and the possible suspension of subject enrollment, please submit your continuation request at least six (6) weeks before the protocol's expiration date of 10/26/2020. It is your responsibility to submit your 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 protocol 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 before they are implemented.

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

Arialdi Miniño, M.P.H.
Chair, NCHS ERB

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