

From: [Wise, Kyle \(CDC/DDPHSS/NCHS/OD\)](#)
To: [Whitaker, Karen R. \(CDC/DDPHSS/NCHS/DRM\)](#)
Cc: [Minino, Arialdi M. \(CDC/DDPHSS/NCHS/DVS\)](#); [Craver, James \(CDC/DDPHSS/NCHS/DAE\)](#); [Madans, Jennifer H. \(CDC/DDPHSS/NCHS/OD\)](#); [Miller, Donna M. \(CDC/DDPHSS/NCHS/OD\)](#)
Subject: Continuation of Protocol #2016-16 NCHS Laboratory-Based Questionnaire Design
Date: Friday, October 25, 2019 10:22:08 AM

Date: October 25 2019

From: Arialdi Miniño, M.P.H.

Chair, NCHS ERB

James M. Craver, M.A.A.

Vice Chair, NCHS ERB

To: Karen Whitaker, B.S.

Subject: Continuation of Protocol #2016-16 NCHS Laboratory-Based Questionnaire Design

The NCHS Ethics Review Board reviewed the request for Continuation of Protocol #2016-16 NCHS Laboratory-Based Questionnaire Design, using the Full Board review process based on 45 CFR 46 at the October 16th, 2019 convened Board meeting.

Protocol #2016-16 NCHS Laboratory-Based Questionnaire Design is approved for the maximum allowable period of one year.

ERB approval of protocol #2016-16 will expire 12/01/2020

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 12/01/2020.

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 12/01/2020. 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