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

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

To: Carol DeFrances, Ph.D.
Kelly Myrick, Ph.D.

Subject: New Protocol #2016-08 National Ambulatory Medical Care Survey Supplement on Culturally and Linguistically appropriate Services (CLAS)

The NCHS Research Ethics Review Board reviewed the request for new Protocol #2016-08 National Ambulatory Medical Care Survey Supplement on Culturally and Linguistically appropriate Services (CLAS), using the full board review process based on 45 CFR 46. Protocol #2016-08 is approved for the maximum allowable period of one year.

In addition, the Convened Board agreed to grant a waiver of documentation of informed consent for Protocol #2016-08 National Ambulatory Medical Care Survey Supplement on Culturally and Linguistically appropriate Services (CLAS) under normal review procedures.

ERB approval of protocol #2016-08 will expire on 02/19/2017.

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 02/19/2017.

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 02/19/2017. 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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