



Memorandum

Date March 19th, 2015 April 7, 2016

From Denise M. Marshall, BS
IRB Administrator, Human Research Protection Office

Subject IRB Approval of Amendment #1 to CDC Protocol #57686854.0, "Proposal for the National ALS Registry Persistence of Zika virus in semen and urine of adult men with confirmed Zika virus infection

To Paul Mead, MD, MPH
NCEZID/DVBD

CDC's IRB C has reviewed and approved your request to amend protocol #6854.0, "Persistence of Zika virus in semen and urine of adult men with confirmed Zika virus infection." The amendment includes adding a health department contact letter and health department contact phone script.

The action was reviewed in accordance with the expedited review process outlined in 45 CFR 46.110(b)(2), minor changes to previously approved research during the period of one year for which approval is authorized.

Reminder: IRB approval of protocol #6854.0 will still expire on 10/18/2015 03/24/2017.

Any problems of a serious nature must be brought to the immediate attention of the CDC IRB, and any proposed changes to the protocol should be submitted as an amendment to the protocol for CDC IRB approval before they are implemented.

If you have any questions, please contact your National Center Human Subjects Contact or the CDC Human Research Protection Office (404) 639-7570 or e-mail: huma@cdc.gov.

cc:

NCEZID Human Subjects Review Amy Sandul, CIP, MPH, DHSc