DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Centers for Disease Control
and Prevention (CDC)

Memorandum

Date March 25, 2016September 20th, 2012

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

Subject IRB Approval of New CDC Protocol #63516854.0, "Monoclonal Gammopathy of Undetermined Significance and MicroRNAs in Ranch Hand VeteransPersistence of Zika virus in semen and urine of adult men with confirmed Zika virus infection" (Expedited)

To Paul Mead, MD, MPH
NCEZID/DVBD

CDC's IRB C has reviewed the request for approval of new protocol #6854.0, "Persistence of Zika virus in semen and urine of adult men with confirmed Zika virus infection" and has approved the protocol for the maximum allowable period of 12 months. This review was expedited in accordance with 45CFR46.110(b)(1), categories 3 and 7, and it was determined that the study involves no greater than minimal risk to subjects. CDC IRB approval will expire on 03/24/2017.

The request for a waiver of documentation of informed consent was reviewed in accordance with 45 CFR 46.117 (c)(2) and has been approved.

If other institutions involved in this protocol are being awarded CDC funds through the CDC Procurement and Grants Office (PGO), you are required to send a copy of this IRB approval to the CDC PGO award specialist handling the award. You are also required to verify with the award specialist that the awardee has provided PGO with the required documentation and has approval to begin or continue research involving human subjects as described in this protocol.

As a reminder, the IRB must review and approve all human subjects research protocols at intervals appropriate to the degree of risk, but not less than once per year. There is no grace period beyond one year from the last IRB approval date. It is ultimately your responsibility to submit your research protocol for continuation review and approval by the IRB along with available IRB approvals from all collaborators. Please keep this approval in your protocol file as proof of IRB approval and as a reminder of the expiration date. **To avoid lapses in approval of your research and the possible suspension of subject enrollment and/or termination of the protocol, please submit your continuation request along with all completed supporting documentation at least six weeks before the protocol's expiration date of 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:
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