

**Memorandum**

Date April 26, 2017

From Jerrell Little
IRB-B Administrator
Human Research Protection Office

Subject CDC Approval of New Protocol 7005.0, "Determining the Prevalence and Duration of Persistent Zika Virus RNA in Pregnant Women and Congenitally exposed Infants in Puerto Rico in 2017-2018" (Expedited)

To Margaret Honein, PhD, MPH
NCCBBBD/DCDD

CDC's IRB-B has reviewed the request for approval of new protocol 7005.0, "Determining the Prevalence and Duration of Persistent Zika Virus RNA in Pregnant Women and Congenitally exposed Infants in Puerto Rico in 2017-2018," and has approved the protocol for the maximum allowable period of one year. CDC IRB approval will expire on 4/18/2018. The protocol was reviewed in accordance with the expedited review process outlined in 45 CFR 46.110(b)(1) under categories 2b, 3, 4, 5, and 7.

The IRB determined that the study poses minimal risk to subjects and pregnant women and children are allowed.

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 have 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. 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 at least six weeks before the protocol's expiration date of 4/18/2018.

Any problems of a serious nature should be brought to the immediate attention of the IRB, and any proposed changes to the protocol should be submitted as an amendment to the protocol for 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 at (404) 639-7570 or email at huma@cdc.gov).

CC:
CGH Human Studies