

Memorandum

Date December 11, 2017

From Clarietha T. Washington

IRB Administrator, Human Research Protection Office

Subject CDC IRB Approval of Continuation of Protocol #6949.0, "Monitoring and Evaluation Protocol

for the Zika Contraception Access Network (Z-CAN)" (Expedited)

To Maura Whiteman, PhD, BS CCHP/NCCDPHP/DRH

CDC's IRB "C" has reviewed and approved the request to continue protocol "6949.0, "Monitoring and Evaluation Protocol for the Zika Contraception Access Network (Z-CAN)", for the maximum allowable period of one year. CDC IRB approval will expire on 12/22/2018. The continuation action was reviewed in accordance with the expedited review process outlined in 45 CFR 46.110(b)(1), categories 7.

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 Error! Reference source not found.8.

Any problems of a serious nature must be brought to the immediate attention of the CDC IRB, and any proposed changes to the protocol are required to be submitted as an amendment to the protocol for CDC IRB approval <u>before</u> 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 e-mail: huma@cdc.gov.

cc: Joan Redmond Leonard Nicole (Nicky) Cohen