DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Memorandum

Date March 6, 2017

From Jason Abel
IRB-A Administrator, Human Research Protection Office

Subject IRB Approval of Amendment #3 to CDC Protocol #6921.0, "Zika en Embarazadas y Ninos en Colombia (ZEN Colombia)" (Expedited)

To Margaret Honein, PhD, MPH
NCCBDDD/DBDDD

CDC's IRB A has reviewed and approved your request to amend protocol #6921.0, "Zika en Embarazadas y Ninos en Colombia (ZEN Colombia)".

This approval is for amendment #3 of protocol 6921.
Amendment #3 includes:

1- Modifications in response to issues and inconsistencies identified during the launch of the study by our colleagues at the INS and the CDC scientific study team :
   - Removed reference to "home" for interval study visits.
   - Deleted the volume of blood taken at enrollment, clinic, delivery, and sick visits.
   - Clarify which samples and tests are being conducted as standard of care versus conducted as part of ZEN
   - Added additional personnel from INS.
   - Made minor modifications in the protocol to clarify inconsistencies.
   - Made minor modifications to study consent and permission forms to clarify inconsistencies.
   - Made minor modifications to other study documents to clarify inconsistencies.

2- Modified the questionnaires based on concerns raised by our INS colleagues during the launch.

3- Modified questionnaires to align with the NIH-sponsored cohort study with similar objectives of studying ZIKV during pregnancy.

4- Additional minor wording and formatting changes by the CDC scientific study team.

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 #6921.0 will still expire on 09/22/2017.

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:
NCEZIDHumanStudies (CDC)