



Date February 24, 2017

From Jerrell Little
IRB-B Administrator
Human Research Protection Office

Subject IRB Approval of Amendment to CDC Protocol 6848, "Zika virus persistence in body fluids of patients with Zika virus infection in Puerto Rico" (Expedited)

To Tyler Sharp, PhD
NCEZID/DBVD

CDC's IRB-B has reviewed and approved your request to amend protocol 6848, "Zika virus persistence in body fluids of patients with Zika virus infection in Puerto Rico". These changes included the following:

Summary of changes to ZIPER Protocol Modification 1: We edited the document for clarity and to correct typos. Modification 2: We remove procedures that are no longer relevant to the study. The deletions include: notifying ZIKV positive results in real time to the PI (page 26); ZIKV results are not faxed to the site coordinator (page 31); Modification 3: description on sample size calculations for the interim analyses were included on page 25. Modification 4: we corrected response options in the questionnaire that were in Spanish and translated them to English. Modification 5: added collection of breastmilk to phone script on page 41. Modification 6. Edited specimen collection procedures to reflect current practice (page 55). Modification 7. So far only one participant has been willing to take part in the semen sub-study, this study complicates logistics for participants since we need the semen sample within one hour of collection, which means they need to produce it at the site as opposed to producing it at home and bringing the specimen to the clinic. We would like to add an additional \$50 dollars reimbursement for time spent in the study for those participating in the semen sub-study. Modification 8. We have removed the name of the hospital in Guayama from the information flyer on page 69, to use it at other participating hospitals. Modification 9. There are no longer enough Zika RNA positive adult men in San Juan to complete the sample size for the semen sub-study. We will also enroll participants from Ponce and Guayama into the semen sub-study. We have removed the study site in the appx and refer to ZIPER study sites in general on page 65. On page 68 of appendix 11, we have also added a description of how abnormal results will be communicated to participants of the semen sub-study. We have described the additional incentive for the semen sub-study on page 65. Results from the conventional semen analyses will be recorded in a laboratory form included on page 69. Modification 10. We have added a lab results form for participants who would like to receive printed results. This is described on page 31 and 72. Modification 11. We have initiated a collaboration with Colorado State University to investigate the viral diversity of Zika virus in various body fluids over time to determine if diversity correlates with persistence of Zika virus in blood or semen. The text relevant to this collaboration was added on appendix 14, pages 73.

The action was reviewed in accordance with the expedited review process outlined in [45 CFR 46.110(b)(1), Category 0 or 46.111(b)(2), minor changes to previously approved research during the period (of one year or less) for which approval is authorized].

Reminder: IRB approval of protocol #6848 will still expire on 03/15/2018

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