DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Memorandum

Date October 23, 2017

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

Subject IRB Approval of Amendment #7 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 #7 of protocol 6921.
Amendment #7 includes:

- 1. We took out the Hammersmith Infant Neurological Evaluation due to the inability to find proper
- resources to train on this tool. In addition, we received expert advice that this evaluation does not provide useful information in typically developing infants.
- 2. We developed a summary flyer to present to the parents before the study clinic visits that describe which assessments will be conducted for that visit (Appendix J2).
- 3. We developed a Study Reports Form that will be given to the parents after all results are reviewed by clinician (Appendix J3) and a letter for the participant's personal clinician if the results require follow-up (Appendix I5).
- 4. Separated the physician information flyer between 0-6 months and 6 months to 4 years to make it more relevant for the physicians receiving information around what is expected from them (Appendix I2 and I3).
- 5. Added information about the eye exam, including standard of care and differentiating what the study staff will do as opposed to when the participants will be referred (protocol, page 14).
- 6. The infant permission form was updated to include information on sharing results from study developmental and evaluation visits with the clinician if further follow-up is necessary (Appendix C2).
- 7. Contact information was added to the infant permission form in the instance that the person providing permission is not the mother who is already in the study but a father or guardian of the baby.
- 8. Updated contact information sheet (Appendix E1) to include multiple infants to account for twins or multiple infants.
- 9. Updated the schedule of study activities to properly reflect activities based on changes made to protocol (Appendix H1).
- 10. We are adding already developed communication materials to distribute to parents on developmental milestones (Appendix J5)

- 11. Updated the protocol throughout adding information to the literature review, objectives, hypotheses, sample size calculations relevant to the extension of the follow-up period.
- 12. Added a section in the protocol entailing the details of the follow-up (protocol pages 17-19).
- 13. Communication materials updated or developed to include this follow-up.
- Included contact information for infant follow-up from 6 months to 4 years of age (Appendix E1).
- 14. Developed an eligibility screener (Appendix B3) and follow-up consent and permission form (Appendix C6).
- 15. Developed a parent-child questionnaire to address questions related to demographics, feeding difficulties, environmental exposures, parental relationships, and stress to be asked at every visit. The enrollment questionnaire is longer as it has some demographic and relationship questions that will be asked only once (Appendix F8). The follow-up questionnaire is asked at every subsequent visit. (Appendix F9).
- 16. Developed a summary of all the developmental assessments that will be conducted and a time table for each assessments (Appendix H5).
- 17. Updated Schedule of Study Activities (Appendix H1), Abstraction Info (Appendix H2), Sample Size Calculations (Appendix H3), and Analytic Plan (Appendix H4) to reflect study activities for follow-up of infants.
- 18. Standardized and validated developmental tools (Appendices F10-12, F15, and F18) for the 6 months to 4 years of age. We have purchased these from the respective companies and were having issues getting them in time for the amendment. We will provide those to IRB as soon as those are received but did not want to delay the amendment review process.
- 19. We deleted the sexual activity questions from the maternal follow-up questionnaire (Appendix F3) as these questions were sensitive and participants were feeling offended by the fact that these questions were being asked of them repeatedly. We are keeping these questions in the enrollment questionnaire and only asking at that one time point.
- 20. Minor updates to communication materials were made based on feedback from the field.
- 21. We will be conducting additional cytomegalovirus (CMV) infection testing using infant urine samples to examine co-infections within this cohort. This information was added to the protocol (page 14) and to the infant permission form (Appendix C2)
- 22. We added 3 questions in the maternal follow-up questionnaire (Appendix F3) in lieu of the sexual activity questions to be asked one time at the initial postpartum visit. These questions are to provide information on risk factors for CMV infection results which we will be obtaining from the STORCH tests conducted.
- 23. Updated Pregnant Woman Eligibility Form (Appendix B1) to include better instructions and skip patterns to help facilitate filling out the form properly.
- 24. Given the difficulty in finding appropriate clinicians to report out ZIKV results, if have added a statement that study staff will report results to participants if clinician is not available (protocol page 21).
- 25. Updated eye exam to state that we will help facilitate standard of care, especially among participants that do not receive an exam from the study (protocol, page 14).

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 09/22/2018.

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:
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