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UNIVERSIDAD DE PUERTO RICO, RECINTO DE CIENCIAS MÉDICAS
UNIVERSITY OF PUERTO RICO, MEDICAL SCIENCES CAMPUS

OFICINA DEL RECTOR
OFFICE OF THE CHANCELLOR

COMITE DE DERECHOS HUMANOS (IRB)
INSTITUTIONAL REVIEW BOARD

Date: June 21, 2017

Protocol Number: 1350117

Principal Investigator: Carmen Zorrilla

Department / Division: School of Medicine - Department of OBGYN

Sponsor: CDC

Title: Determining the Prevalence and Duration of Persistent Zika Virus RNA in Pregnant Women and Congenitally exposed Infants in Puerto Rico in 2017-2018

This is to certify that this research proposal/protocol was evaluated on **June 21, 2017** and meets **expedite** IRB review category **#2 (b), 3, 4, 5 & 7**. The research proposal was **approved.** The approval period for this study is **June 21, 2017** to **June 21, 2018**.

The following documents were reviewed under this submission:

- ☒ Protocol
- ☒ Survey Instruments in English and Spanish Version
- ☒ Human Subject Certified
- ☒ Curriculum Vitae
- ☒ HIPAA Certified
- ☒ Authorization Letter
- ☒ Informed Consent Document in Spanish and English Version (Maternal and Infant)
- ☒ HIPAA Identifiers
- ☒ Others: CDC Confidentiality Statement, ZIRP Study 7005 Submission Approval CDC/IRB, Biosafety Letter, CDC Assurance Confidentiality, ZIRP Study Manual Operations, CDC-AoC Amendment 2017-04

Remember:

- According to UPR Policies, if a proposed Project involves a component of research that falls under the jurisdiction of the Biosafety, Institutional Animal Care and Use and /or Radiation Safety Committees approval must be obtained from the appropriate Compliance Office.

For additional information please contact Human Research Subjects Protection Office at 787-758-2525 exts. 2510 to 2515; e-mail opphi.rcm@upr.edu.

Cordially,

Luz A. Muñiz, EdD
Chairperson IRB 3

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1. Research must be conducted according to the proposal that was approved by the IRB.
2. Changes to the protocol or its related consent document must be approved by the IRB prior to implementation.
3. All serious or unexpected adverse events/drug reactions should be reported.
4. Each subject should receive a copy of the consent document, if appropriate.
5. Records must be retained for at least three years.
6. Any future correspondence should include the IRB identification number provided and the study title.