Form Approved
OMB Number: 0920-XXXX
Expiration Date: XX/XX/XXXX

Attachment 3a
Hospital-Based Informed Consent Document (English)

PR DEPARTMENT OF HEALTH
MATERNAL, CHILD AND ADOLESCENT HEALTH DIVISION
CONSENT FORM TO PARTICIPATE IN A RESEARCH STUDY

TITLE: Puerto Ricko Zika Pospartum Emergency Response Survey (PR-ZPER)

PROTOCOL NUMBER: B1020116

SPONSOR: Maternal, Child and Adolescent Health Division, Assistant Secretariat of Family and Integrated Services, Puerto Rico Department of Health.

INVESTIGATORS: Manuel I. Vargas Bernal, Principal Investigator and personnel of PR Department of Health.

PLACE: The study will take place in 36 birthing hospitals in Puerto Rico with 100 or more births in 2016.

TELEPHONE NUMBERS ASSOCIATED WITH THE STUDY: Maternal, Child and Adolescent Health Division: (787) 765-2929 extension 4582.

This consent form could have words that you do not understand. Please ask to the person responsible for this study to explain any words or information about the study that you don't clearly understand. You will receive a copy of this document.

I. INTRODUCTION

You have been selected to participate in a research study. Before you decide to participate, please read this consent form carefully, and ask any questions that you may have about this study to be sure that you understand study procedures, including the risks and benefits.

II. STUDY PURPOSE

The purpose of the PR-ZPER is to gather detailed information about experiences and behaviors during pregnancy related to the Zika virus, including interactions with health care providers, reciept of information about Zika during preganncy, exposure to Zika virus, as well as other information. Any woman who had a live birth in one of 36 hospitals that had 100 births or more in 2016 could be selected to participate. Among selected women, their husband or male partner is also selected to participate in a father's survey

III. PARTICIPANTS OF THE STUDY

The participant understands that her participation in this study is voluntary, and he is free to not answer any of the questions or to stop the survey at any time without any consequences. If this consent is not signed or if it is canceled in the future, this will not affect health care services that he or is wife or partner is currently receiving or will receive in the future at any hospital or health care provider. Approximately 2,900 women who had a live birth in the 36 hospitals that registered 100 or more births in 2016 and their husbands or male partners could be selected to participate.

IV. PROCEDURES

Your participation in the study will take approximately 20 minutes and only consists of answering a questionnaire. This survey has questions aimed at obtaining information about behaviors and attitudes during your pregnancy related to Zika virus. Some questions may be sensitive, such as questions about sexual relations during pregnancy. In addition, the questionnaire can be combined with information that the health department has from other sources.

V. RISK OR INCONVINIENCE

Given that the nature of this study is completing a questionnaire, it does not represent any physical risk. The type of questions asked do not pose a psychological or social risk for the woman, and none of the reports generated will include information that could identify a participant. However, if you do not feel comfortable answering a question you have the right to not answer it or to stop answering the questionnaire.

VI. BENEFITS

Although you will not directly benifit if you particpate in this study, the findings will help to identify health problems, plan services, and to identify strategies or succesful programs for women.

VII.COSTS

There is no cost for your participation in this study.

VIII. PARTICIPANTS INCENTIVE

You will not be paid to particpate in this study. However, once you complete the questionnarie, you will receive a calendar "*El primer año de vida de mi bebé (My baby's first year),*" and a crib

net. Other incentives available include insect repellant. An additional gift card will be provided if the husband or male partner is available and agrees to participate.

IX. PRIVACY AND CONFIDENTIALITY

The information that you provide will be held private to the extent permitted by law. All the information provided on the questionnaire will be used only for study purposes. The name, address, telephone number, or other information that could identify a woman will not appear on the questionnaire, findings, or reports. This information about you and your health that could identify you could be released to others as part of his study. These agencies include:

- The US Department of Health and Human Services
- The Centers for Disease Control and Prevention
- The Institutional Review Board (IRB) of the University of Puerto Rico, Center for Medical Sciences

The results of this study may be published in reports, scientific journals, or presented at conferences.

Women who participate in this survey may be contacted again to participate it a telephone follow-up questionnaire about to postpartum maternal and infant health and experiences related to Zika virus.

This authorization will remain valid until the study is completed unless you canceled it before. You may cancel this authorization at any moment by sending a written message to the principal investigator, Manuel I. Vargas Bernal, MD, MPH to the following address:

División Madres, Niños y Adolescentes,
Departamento de Salud
PO Box 70184,
San Juan PR 00936-8184
Telephone: (787) 765-2929 extension: 4582 or 4550.

X. COMPENSATION IN CASE OF DAMAGE

Even though this study does not present any risks, in case of physical or mental injury as a result of this study, you will receive free medical treatment. The Department of Health will not offer any remuneration directly to you. However, by signing this consent you will not give up any legal rights.

XI. PARTICIPATION AND VOLUNTARY RETIREMENT

The participation in this study is completely voluntary. You are free to not answer certain questions. You may decide not to participate or to leave the study at any moment. Your decision will not result in any penalty or loss of benefits to which you have a right.

XII. QUESTIONS

If you have any questions about this study, about your participation, or if you think that you have suffered some injury associated to the study, you can contact the principal investigator: Dr. Manuel I. Vargas Bernal, telephone: (787) 765-2929, ext. 4582. If you have any questions about your rights as a participant you can contact:

Institutional Review Board
Telephone: (787) 758-2525 extensions: 2510 thru 2515
E-mail: opphi.rcm@upr.edu

Please do not sign this consent unless you have had the opportunity to ask questions and receive satisfactory answers. If you agree to participate in this study, you will receive a signed copy of this consent with the seal of the IRB and the date that the form was signed.

XIII. CONSENT

I have read the information on this consent form (or someone read it for me). All my questions about the study and my participation have been answered. By signing this consent form, I am not giving up any of my legal rights.

Participant's Name (Print letter)

_____ _____

Participant's Signature Date

_____ _____

Investigator Signature Date