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

TITLE: Puerto Rico Pregnancy Risk Assessment Monitoring System Zika Pospartum Emergency Response (PRAMS-ZPER)

PROTOCOL NUMBER: B1020117

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 33 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 4672, 4805, 4804 and 4806.

This consent form could have words that you may not understand. Please feel free to ask the person responsible of this study about any concerns that you may have. It's very important that you understand all the information in this consent. 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 carefully this consent form and clarify all the questions that you may have in order for you to understand this study, including the risks and benefits.

II. STUDY PURPOSE

The purpose of this study is to learn more about the Zika virus and related attitudes and behaviors among people who recently had a baby or a pregnant partner. Every male or female partner, or father of a the baby of a woman that had a live birth in the 33 selected birthing hospitals could partipate in this study.

III. PARTICIPANTS OF THE STUDY

It is important that you understand that your participation in this study is voluntary and you are free to not answer some of the questions or stop the survey at any time without consequences. If this consent is not signed or is canceled in the future, it will not affect the health care services you or someone else is currently receiving in the hospital or by healthcare providers, or any other healthcare services anyone may receive in the future.

The sample size is aproximately 2,000 people who recently had a baby or a pregnant partner in some of the 33 selected birthing hospitals.

VI. PROCEDURES

Your participation in the study will take aproximately 20 minutes and only consist of answering a questionnaire. You may complete the survey on paper or electronic form. This survey has questions aimed at obtaining information about: Zika virus and related attitudes and behaviors, including interaction with the health care provider and participation in the pregnancy. Some questions may be sensitive, such as questions about sexual behavior during pregnancy. Also, your quiestionnaire can be linked with other sources of information of the PR Department of Health.

After you complete the survey, the interviewer will provide a short educational intervention that will take aproximately 15 minutes. The educational intervention will provide information about things you can do or expect after the birth of a new baby.

Your participation in the this survey is voluntary.

VII. RISK OR INCONVINIENCE

The nature of this study (complete a questionnaire) does not represent any physical risk either the type of questions represents psychological or social risk for the person completing it and none of the generated reports will have identifiers. However if you do not feel comfortable completing the questionnaire or some of the questions, you have the option to skip the questions you do not wish to answer or stop answering this survey.

VIII. BENEFITS

Although you will not be directly benifited if you particpate in this study, the findings will help us identify health problems, plan services and identify strategies or succesful programs for families in Puerto Rico.

IX. COSTS

There is no cost for your participation in this study.

X. PARTICIPANTS REWARD

You will not be paid to particpate in this study. However, once you complete the questionnarie, you will receive a small gift in appreciation for your time.

XI. PRIVACY AND CONFIDENTIALITY

All the information that you provide in the questionnaire will be completely confidential and will be used only for study purposes. The name, address, telephone number or other information that may identify the particpant will not appear on the questionnaire or in the findings report.

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

This authorization will be valid until the study is finalized unless you cancel 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
Teléfonos: (787) 765-2929 extensión: 4582 ó 4550.

XII. COMPENSATION IN CASE OF DAMAGE

Even though this study does not represent risks, in case of physical or mental injury as a result of this study, you will receive cost free medical attention. The Puerto Rico Department of Health will not offer any remuneration directly to you. However, by signing this consent you will not resign to any legal rights.

XIII. PARTICIPATION AND VOLUNTARY RETIREMENT

Your participation in this study is completely voluntary and you are free to not answer this survey. You can decide to not participate or leave the study at any moment. There is no penalty or loss of benefits or rights for not participating or answering all questions.

XIV. 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 some 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 clarify questions and concerns about the study. If you sign this consent to participate in the study, you will receive a signed copy of this consent sealed with the IRB approval.

XV. CONSENT

I have read the information on this consent form (or someone read it for me). I clarified all questions and concerns about the study. By signing this consent, I do not resign at any of my legal rights.

Participant's Name & Middle Name (Print letter)

Participant's (Paternal) Last Name (Print letter)

Participant's (Maternal) Last Name (Print letter)

x_____ _____ /_____ /_____
Participant's Signature Date *(month/day/year)*

x_____ _____ /_____ /_____
Principal Investigator Date *(month/day/year)*

_____ _____
Interviewer/Surveyor Printed Name Surveyor ID #

x_____ _____ /_____ /_____
Interviewer/Surveyor Signature Date *(month/day/year)*