Institutional Review Board (IRB) Protocol Review and Informed Consent

Protection of human subjects is an essential component of the Zika Postpartum Emergency Response (ZPER) surveillance. CDC Emergency Operations Center will obtain approval for the overall project from the CDC Institutional Review Board (IRB). The Puerto Rico Department of Health (PRDH) will determine if additional review is needed locally through a 1federally assured IRB for approval of their surveillance methodology. IRB review and approval must be completed prior to data collection. All materials, including the questionnaire, protocol, cover letter, etc., must be presented to the local IRB. No physical risks will occur to mothers through ZPER. However, the ZPER questionnaire will obtain sensitive and individually identifiable data on mothers.

All adverse events must be documented and reported to the CDC and the local IRB. An adverse event is defined by the CDC IRB as an incident in which the protection of the respondent may have been violated. CDC is required to report all adverse events to the CDC IRB as they occur.

Informed Consent

Each questionnaire will include an informed consent document that includes all required elements of informed consent. A signed, written consent form is required for participation.

The informed consent documents are included at the end of this appendix. A written ascent is required for participants aged 14 years and younger. It is also included at the end of this appendix.

The ZPER informed consent document includes the following ***required*** elements of informed consent:

1. A statement that CDC provides support for the project.

2. An explanation of the purposes of the project.

3. The expected duration of the subject's participation.

4. A description of the procedures to be followed.

    a. For ZPER, this includes a notification that data may be linked to other sources.

5. A description of any reasonably foreseeable risks or discomforts to the subject, including a statement that some questions may be sensitive.

6. A description of any benefits to the subject or to others which may reasonably be expected from the project.

    a. For ZPER, indirect benefits to society may include health improvements for women and infants.

7. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.

    a. For ZPER, confidentiality is protected "to the extent permitted by law."

8. An explanation of whom to contact for answers to pertinent questions about the project.

9. An explanation of whom to contact for answers to pertinent questions about the participant's rights in the project.

10. A statement that participation is voluntary.

11. A statement that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled.

12. A statement that the subject may discontinue participation at any time or choose not to answer certain questions without penalty or loss of benefits to which the subject is otherwise entitled.

13. An explanation of how the mother was chosen, the approximate number of people chosen for the study, and the reason for the identification number on the questionnaire.

14. For a tablet survey, the introductory scripts must include an explicit prompt for permission to continue with the survey.

The list above includes only those elements of informed consent that apply to ZPER. A comprehensive list of elements of informed consent can be found online at http://www.hhs.gov/ohrp/policy/consentckls.html. The regulatory code 45 CFR 46 governs human subjects protections and is available online at http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html

Protecting the Privacy of ZPER Data

To minimize unauthorized disclosure of individually identifiable data, the following policies must be adopted:

- All information collected shall be held in confidence to the extent allowed by law. All state staff and contractors involved in data collection shall be trained concerning procedures and practices to ensure privacy of data and shall sign a confidentiality pledge.

    - All new hires will be trained concerning these procedures and practices when they begin work.

- Most health departments and contract agencies require all staff to sign a confidentiality pledge. If Puerto Rico health department or contract staff have signed a confidentiality agreement for the agency, then that will be sufficient for data collection. If the Puerto Rico health department or contracting agency does not have its own confidentiality pledge, contact CDC about developing one for ZPER staff.

- All ZPER staff will complete the CDC ZPER Human Subjects Training to ensure the protection of human subjects participating in ZPER, adherence to the ZPER protocol, and understanding of the implications of breaches in protocol. The training includes 4 modules covering 1) human subjects protections, 2) adverse events, 3) human subjects considerations for in-person surveys, and 4) maintaining confidentiality.

- No individually identifiable information will be provided to persons other than PRDH ZPER staff, contractors working on the ZPER project, or CDC system administrators as they maintain the data collection system. In special circumstances where it is required to debug software, it may be necessary to share this information with technical support staff to correct the problem. PRDH staff should verify that these staff have signed a confidentiality pledge before releasing any identifiable information.

- Individually identifiable information may be released ***only if authorization is explicitly granted by the affected individual or legal guardian.***

- No individually identifiable information will be presented in any reports arising from analysis of data collected as part of ZPER.

- Completed questionnaires and any files with personal identifiers must be kept in a locked file cabinet or a locked room; access to these files must be limited to authorized personnel.

- All electronic files will have restricted access; the operations tracking software will be password-protected. Backup files of ZPER data must also be secured.

- Only a few individuals from CDC and the CDC contractor may have access to identified data. In all other cases, data sent to CDC will be de-identified.

- PRDH must decide on a policy regarding the archival and destruction of ZPER questionnaires.

- PRDH must ensure that any contractors who may be responsible for any portion of the ZPER operations also follow all policies described above.

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

TITLE: Zika Pospartum Emergency Response (PR-ZPER)

PROTOCOL NUMBER:

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 2015.

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 may not understand. Please feel free to ask to the responsible person of this study about those concerns that you could 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 make all questions that you may have to understand this study, including the risks and benefits.

II. STUDY PURPOSE

The purpose of the PR-ZPER is to learn more about the Zika virus and related attitudes and behaviors among women who recently had a live birth, including interaction with the health care provider. Every women that had a live bith in some of the 36 selected birthing hospital could partipate in this study.

III. PARTICIPANTS OF THE STUDY

The participant understands that her participation in this study is voluntary and she is free to not answer some of the questions or stop the survey at any time wothout consequences. If this consent is not sign or is canceled in the future, this is not going to

affect the health care services she will receive in the hospital or by healthcare providers, now or in the future.

The sample size is aproximate 2,739 women that had a live bith in some of the 36 selected birthing hospital.

IV. PROCEDURES

Your participation in the study will take aproximately 20 minutes and only consist of answering a questionnaire. This survey has questions aimed at obtaining information about: Zika virus and related attitudes and behaviors among women who recently had a live birth, including interaction with the health care provider. Some questions may be sensitive, such as questions about sexual behavior during pregnancy.

V. 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 woman 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 stop answering this survey.

VI. BENEFITS

Although you will not be directly benifited if you particpate in this study, these findings will help to identify health problems, planning services and to identify strategies or succesful programs for women in PR.

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*".

IX. 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 will be finalized unless you canceled it before. You may cancel this authorization at any moment 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.

X. 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 PR Department of Health will not offer any remuneration directly to you. However, signing this consent you will not resign to any legal right.

XI. PARTICIPATION AND VOLUNTARY RETIREMENT

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

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 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.

XIII. CONSENT

I have read the information on this consent form (or someone read 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 (Print letter)

_____ _____

Participant's Sign Date

_____ _____

Principal Investigator Sign

PR DEPARTMENT OF HEALTH
MATERNAL, CHILD AND ADOLESCENT HEALTH DIVISION
ASSENT FORM
ZIKA POSPARTUM EMERGENCY RESPONSE SURVEY (PR-ZPER)

ASSENT FORM FOR CHILDREN 7 TO 14 YEARS

TITTLE OF THE STUDY: ZIKA POSTPARTUM EMERGENCY RESPONSE SURVEY (Z-PER)
PRINCIPAL INVESTIGATOR: Manuel I. Vargas Bernal
TELEPHONE NUMBERS: 787-765-2929 xt-4582

Introduction

This assent form can be difficult to understand and may have information that you do not understand. Please, feel free to ask to the interviewer to make clarifications that you may have about this study. Also you may ask the interviewer to talk with you privately.

Study Purpose
We are conducting a study called "Zika Postpartum Emergency Response Survey" (Z-PER). This study investigates what information the pregnant women in Puerto Rico have about Zika infection. Also, this study collects information such as: Zika virus and related attitudes and behaviors among women who recently have a live birth including interactions with health care providers.

What is going to happen with me on this study?
Young people like you may participate on this study. Your participation is completely voluntary; no one can force you to participate. The purpose of the study is to collect information through a questionnaire about your pregnancy and about Zika.

Why me?
We selected you because you were pregnant and had a baby.

What do I have to do?
Only you have to answer a survey that has questions about your pregnancy and other questions related to Zika virus infection. It will take only 20 minutes for you to answer.

How many persons will be in this study?
Around 2,739 women and youths like you that had a baby were selected to participate in the study.

Something wrong, can happen to me?

Nothing wrong will happen to you. You only have to answer some questions that the interviewer will provide you in a paper. But if you feel uncomfortable answering some questions you do not need to answer them.

Which good things could happen if I am part of this study?
This information will help to improve the services related with the prevention of Zika virus infection. We may apply for funding opportunities to bring education about how to prevent Zika virus infection in the community including pregnant women.

Do I have other options?
You can decide which questions you want to answer, including leaving blank the entire questionnaire or to not participate in the study.

What happens if I don't want to participate in the study?
If you decide to participate in the study, then, you can sign this consent and answer the questionnaire that the interviewer brings to you. If you do not want to participate just let the interviewer know about your decision.

If you want to participate in this study, we need you to sign this consent in the line below. Signing this consent means that you want to participate in this study. Even though you have signed this consent, you can leave the study at any moment if you do not wish to continue.

SIGNS FOR THE STUDY

Participant's Name (Print Letter)

_____ _____

Participant's Sign Date

"I was present when_____ read this consent and say that she or he wanted
(Participant's Name)
to participate in this study"

_____ _____
_____

Witness Name Sign
Date

_____

Interviewer's Name

_____ _____

Interviewer's Sign Date