APPENDIX J-1. CONSENT FORM FOR SEMI-STRUCTURED INTERVIEWS WITH Z-CAN PHYSICIANS

Introduction: The University of Puerto Rico and the Centers for Disease Control and Prevention (CDC) invite you to be in a research study. The study involves semi-structured interviews with 25 health care providers participating in the Zika Contraception Access Network (Z-CAN) program.

The purpose of this interview is to evaluate the Z-CAN program, learn how to improve the program, and explore the long-term sustainability of patient-centered reversible contraceptive services in Puerto Rico.

Joining the study is voluntary. You may decide not to join, or you may withdraw your consent to be in the study at any time, for any reason, without penalty. You do not need to be in this study to remain a Z-CAN provider. If you decide not to join the study or withdraw your consent, you keep the same benefits of Z-CAN participation as outlined in your initial contract.

You will be given a copy of this consent form. You may ask the research staff any questions you have at any time. Contact information is provided at the bottom if you have questions about your rights as a study participant or concerns about the study.

Who can participate?
Participants must be physicians who are currently providing Z-CAN services.

How long will you need me?
Your interview will last about 45-60 minutes today.

What do you want me to do if I decide to be in this study?
If you agree to be in the study, you will be asked to sign this consent form. Once you have signed the consent form, a research staff member will begin the interview. We will ask about conducting patient-centered contraceptive counseling, facilitators and barriers that you've encountered in the program, and recommendations to improve the program. During the interview, the research staff member will take notes and record the interview. You may choose not to answer any question at any time, for any reason, or you may choose to withdraw from the study at any time. Choosing not to answer a question does not affect your relationship with the Z-CAN program.

Are there any risks to me if I decide to be in this study?
There are no known physical risks to being part of this study. If you feel uncomfortable with some of the questions, you do not have to answer or you may decide to withdraw from the study at any time. Steps will be taken to protect the privacy and confidentiality of the answers you share today. In particular, your individual comments will not be shared with other clinic employees, physicians, or others affiliated with the Z-CAN program. Any data will be reported in aggregate.

Are there any benefits from being in this study?

You will not benefit personally from being in this study. You will be helping to improve the Z-CAN program. You will also be helping to build a long-term program to provide patient-centered reversible contraceptive services to women in Puerto Rico.

Will I receive anything for being in this study?
No

Where will the information collected during this study be stored?

- We will store the consent forms and any information collected during this interview in a locked file cabinet that only study staff can access.
- We will store all electronic files in a password-protected database that only study staff can access.
- All of the paper-based, audio, and digital information will be stored in locked facilities at CIES, Floor M, Plaza Universitaria, 3 Avenida Universidad, University of Puerto Rico.

Will the information I give you be kept private?

- The information you give us as part of this study will be protected under the Privacy Act (System of Records Notice 09-20-0136). We will do all that we can to keep your information private, except when required to share specific information by law.
- We will store the notes from the interviews and the audio-recordings only for transcription, translation, and analysis. Once the interviews are transcribed and translated, the recordings will be destroyed.
- When we present or publish the results of this research, we will not include any information that could identify you or the clinic in which you work.

Who should I call if I have questions about this study, have been harmed by the study, or have questions about my rights as a research volunteer?
If you have questions about the study, wish to cancel your participation in the study, or believe you may have been harmed by participation in the study, please contact xxx at (xxx)-xxx-xxxx (toll free number) or xxx (email).

If you have questions about your rights as a participant in this study, please contact the Human Subjects Protections Office (IRB) at (787) 758-2525 or xxx (email).***Do I have to participate in this study?***
Participating in this study is voluntary. You may decide not to participate or you may withdraw your consent at any time, for any reason, without penalty. Participation in this study does not affect your role in the Z-CAN program.

Signature
I have been told about the study. I have been allowed to ask questions. I had all of my questions answered. I would like to be in the study. By signing this form, I agree to participate.

Do not sign this consent form until you have had the chance to ask questions and get satisfactory answers. If you sign, agreeing to participate in this study, you will receive a signed and dated copy of this document with the IRB's approval seal on each page.

Participant Name Date

Participant Signature Date

I have discussed the purpose of the study with the participant, including the risks, benefits and alternatives to participating (including the alternative of not participating). The participant has had the opportunity to ask questions and in my opinion the participant is able to freely consent to participate in the study.

Name of staff person obtaining consent Date

Signature of staff person obtaining consent Date