



University of California, San Diego
and
Tulane University

Consent to Act as a Research Participant Interview

Addressing the Rise of Congenital Syphilis:
Working toward Setting-specific Solutions among High-Risk Pregnant Women

Sponsor: March of Dimes (**INSERT GRANT NUMBER**) and Center for Disease Control & Prevention

University of California, San Diego Principal Investigator: Dr. Jennifer Wagman

Tulane University Principal Investigator: Dr. Emily Harville

INTRODUCTION: Hello, my name is _____. I work with the University of California. The University of California, San Diego and Tulane University are working together on a project to understand the health behaviors of pregnant women in Kern County, CA. I'd like to invite you to take part in this study. This consent form contains information about the research project. To be sure that you understand your part in this research, we are reading this form to you. Please ask us to explain anything you may not understand.

REASON FOR THE RESEARCH: You are being asked to take part in a project to understand pregnant women's goals about their health and how they think health services can be improved. We would like to learn about women's health behaviors, where they go for health information, and how they access services in Kern County, CA. You were selected for this study either because you are a health care provider in this area.

STUDY PROCEDURES: All interviews will be conducted by research assistants from the University of California, San Diego. We will conduct about 20 interviews (10 in Kern County, CA and 4 in Baton Rouge Parish, LA). As part of this study we will also be conducting about 8 focus groups (4 in Kern County, CA and 4 in Baton Rouge Parish, LA) with pregnant women, and expect up to 100 people to participate in this research. Interviews will be conducted in a meeting room in your clinic or hospital, or an area conveniently located to you. The information will be gathered in the following ways:

Interviews: Interviews are done in private with one person. Each interview will last about an hour to an hour and a half. Interviews may be tape recorded if the participant agrees. The interviewer will also take notes. We will conduct interviews with prenatal care providers who work in Kern County, CA. We will ask prenatal care providers to give their thoughts on how to support the health and safety of pregnant women in Kern County, CA.

CONFIDENTIALITY: Any information collected during interviews will stay private and will be kept in secure locked files. Tapes of the interviews will be written down on paper, and the tapes will be erased after this is completed. Names of participants are not written down on the paper transcripts, but are kept in separate secure files. We will ask to record the interview so we can transcribe them at a later date, but if you do not want to be recorded we will not record your interview and you can still participate in the study. We ask you to not discuss anything we talk about with anyone outside the interview. Your responses will not be reported to supervisors or used for evaluations.

RISKS FROM BEING IN THE STUDY: The risks due to being in the study are small. They include:

- Social consequences if what you say becomes known to others. These risks are minimal. We will keep all information safe and private. We will not release any information connected to your name without your consent.
- Some of the questions are personal and sensitive. Some questions may be hard to answer, and others could make you embarrassed or upset. You will not be required to answer any question that you do not want to answer. You can stop at any time during any of the interviews. Or, you can refuse to be in the study altogether.

There may be some unforeseeable risks from being in the study that we are not yet aware of. If we do find new risks associated with this study, we will communicate these to you.

COSTS: There is no cost to you for being in this study.

BENEFITS: There are no direct benefits to you for being in the study. Talking about your experiences may help you. After the interview has been completed, you may want to talk with someone about the things that were discussed during the interview. If so, please ask us and we can provide you with extra information and/or refer you to someone else to talk to. Also, the information collected in these interviews may help us understand how to help pregnant women access health services.

IF YOU DECIDE NOT TO BE IN THE RESEARCH: You can decide not to be in this study. Your decision will not affect any care you receive from any health care providers in the area.

COMPENSATION: You will be given a \$25 gift card at the end of the interview. This is for your time.

STAYING IN THE RESEARCH: We would like you to complete the interview, but this is your choice and you can leave the study at any time.

LEAVING THE RESEARCH STUDY: Your decision to take part is voluntary. You may decide not to take part at all, or to leave even after the interview has started. If you want to leave from the study, you can inform study staff or call the Principal Investigators. This will not affect your access to any health services. The alternative to participation in this study is to not participate. The Principal Investigator may terminate your involvement in the study without your consent if it is deemed by the Principal Investigator to be in your best interests.

WHO CAN YOU CALL IF YOU HAVE QUESTIONS: Dr. Jennifer Wagman and/or _____ has explained this study to you and answered your questions. If you have other questions or research-related problems, you may reach Dr. Jennifer Wagman at 858-534-9619.

YOUR RIGHTS AS A PARTICIPANT: If you have any questions about your rights as a participant you may contact the Human Research Protection Program Office at the University of California, San Diego (Tel: 858-657-5100) or Tulane University (Tel: 504-988-2665). If you are injured as a direct result of participation in this research, the University of California will provide any medical care you need to treat those injuries. The University of California will not provide any other form of compensation to you if you are injured. You may call the Human Research Protections Program Office at 858-246-HRPP (858-246-4777) for more information about this, to inquire about your rights as a research subject or to report research-related problems. If there is any part of this consent that you do not understand, ask the investigator before signing.

Human Research Protections Program UC San Diego	
Approved	
Current Approval:	10/19/2017
Do not use after	10/18/2018

STATEMENT OF CONSENT for ADULT

This statement of consent is to acknowledge that you have been asked to take part in an interview about pregnant women’s goals regarding their health and how they think services can be improved so they can better protect their health.

In signing this document you agree that the study representative has explained the significance of the research, the duration of the project, the interview in which you will take part, all of the methods to be used, and the risks that you may take.

You have been given an opportunity to ask questions about this research project. All questions were answered in a way that you understand. If you have other questions about this research, you can ask the study representative or the principal investigator. If you have any questions concerning your rights as a participant in this study, you can contact the Human Research Protection Program at the University of California, San Diego or Tulane University.

In signing below you acknowledge that you understand that your participation is voluntary, that you can decline to be in the study or leave the study at any time, and that if you decline to join the study or if you leave the study, you will not lose any access to health benefits or services. You are signing your name to indicate your consent to be in this study. You will be given a copy of the consent form.

SIGNATURE OF PARTICIPANT

DATE

PRINTED NAME OF PARTICIPANT

PERSON OBTAINING CONSENT

DATE

