Form Approved
OMB No. 0920-0840
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Pathways: Qualitative Interviews with Post-Partum Women Associated with Congenital Syphilis Cases (Case Mothers)

Generic Information Collection Request under OMB #0920-0840

Attachment #4
Consent Form

INFORMATION AND INFORMED CONSENT

Thank you for your interest in this research study. My name is [**INTERVIEWER NAME**] and I am with the Pathways Project.

Before you decide whether to agree to be in this study, please listen as I read a form aloud and ask as many questions as you need to be sure you know what you will be asked to do.

Introduction: Researchers are doing this study from the Division of STD Prevention, Centers for Disease Control and Prevention (CDC). They are trying to learn more about how to help women protect themselves and their babies from being affected by syphilis and are interested in hearing your perspective.

What is the purpose of this study? The purpose of this study is to learn more about how to help women protect themselves and their babies.

Why am I being asked to be in this study? You have been asked to take part in this study because you and possibly your baby were affected by syphilis. By being in this study, you may be able to help us improve education and care for other women at risk for syphilis during pregnancy.

How long will you need me? I expect the interview to take about one hour and thirty minutes.

What is going to happen during the study? I will be asking the questions, listening and taking notes. I will draw a line on a piece of paper to help us create a timeline of events that you share and we talk about. In addition, I will record what you say on a digital recorder. This is so I have an accurate record of what you say.

What do you want me to do if I decide to be in this study? During the interview, I will be asking you some questions about your pregnancy and about what you remember from that time in your life. I will also ask questions about when you learned you had syphilis, about what you were told about that, and about how you felt about it. I will also ask about health care you received while you were pregnant, and what you think other women need to know based on your own experience.

I hope that you will share your honest opinions and views on this topic as we value your experience and perspectives on this issue. There are no right or wrong answers. Some things may be difficult to talk about, but what you share from your own life may help other women and their babies.

Are there any risks to me if I decide to be in this study? There is low risk to you if you decide to be in this study. Since I may ask you several personal questions during the interview, you may feel uneasy or uncomfortable. You do not have to answer any questions you do not want to during the interview. You may pause or stop the interview at any time.

Are there any benefits from being in this study? By being in this study, you may be able to help us improve education and care for other women at risk for syphilis during pregnancy. Knowing more about your experiences may help us create better ways to reach and educate people, or to deliver services to women who need them.

Will the things I tell you be kept private? I will not tell anyone outside of the research team what you said and that you were part of this study. The things you tell me during the interview will be kept secure by the research team. The information you provided in your interview will be kept separate from your name to further protect your privacy. I will protect your identity and information that you give to me. What you tell me will be kept private to the extent allowed by law. For example, any information you provide that suggests you or someone else is in danger will need to be reported according to the law.

What is going to happen with the digital recording of my interview? After the interview, a person working on the study will listen to the digital recording and write down what was said. Only the people working on the study will be able to listen to the digital recording. At the end of the study, I will erase the digital recording and shred all notes from your interview, including the timeline.

What will you do with my interview? The digital recording and transcripts from your interview will be used to write a report on what we, the research team, have found. The people working on the study will review all the interview responses to help us understand what we have found. We may also publish a paper in a journal, so that we can share what we found with other people. We will not use your name in the report or in any papers we write, and nothing that you say will be directly connected to you. We will do our best to ensure that no one will be able to know what you said or that you were in this study from anything that we write. We will destroy all records with your contact information after the study is complete.

Is there any cost if I take part in this study? The costs to you for being in this study is your time for taking part in the interview. You may also incur transportation costs, e.g., gas, public transportation, to get to the interview location.

Is there any reimbursement if I take part in this study? No, there is no payment for taking part in this study, although you will receive a token of appreciation of a $60 Visa gift card for your participation. This token of appreciation is in honor of the transportation, childcare, or other costs you may have as a result of participating in this study.

Who should I call if I have questions about this study or think I may have been harmed by this study?
If you have any questions about this study, you may call Geetika Nadkarni at (571) 527-3164.
If you have questions about your rights as a participant in this study, call CDC's Human Research Protection Office at 1-800-584-8814, Leave a message with your name and phone number and refer to CDC protocol #7118.

DO YOU HAVE ANY FURTHER QUESTIONS ABOUT THIS STUDY?

DO YOU WISH TO CONTINUE?

TO ENSURE EVERYTHING IS CAPTURED ACCURATELY I WOULD LIKE TO RECORD TODAY'S INTERVIEW. DO I HAVE YOUR PERMISSION TO RECORD?

IF YES: [TURN RECORDER ON.]

IF NO:[INTERVIEWER RECORDS TIME/DATE OF ORAL CONSENT AND DOES NOT TURN ON RECORDING]

IF YES: SINCE WE ARE NOW ON THE RECORD I'D LIKE TO GO OVER ONCE AGAIN WHY WE ARE MEETING TODAY.

IF YES; [RESTATE PURPOSE OF THE INTERVIEW, CONFIRM THAT THE PARTICIPANT WAS READ THE CONSENT FORM AND WAS OFFERED A CHANCE TO ASK QUESTIONS.]