Form Approved
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APPENDIX B. CONSENT FORM FOR POTENTIAL AND ENROLLED PARTICIPANTS UNEXPOSED TO COVID-19 (BD-STEPS INTERVIEWED)

Authorization to release pathology materials
Study of the impact of COVID-19 on pregnancy in selected jurisdictions

Sponsor: This investigation is being conducted by the U.S. Centers for Disease Control and Prevention (CDC) in collaboration with state health departments.

Why am I being asked to take part in this research?
You previously participated in the Birth Defects Study to Evaluate Pregnancy exposureS (BD-STEPS) by completing a telephone interview. We thank you for helping us with this study, and we extend again our deepest sympathy to you and your family on the loss of your baby.

Because of the current COVID-19 pandemic, we are now studying if women who have COVID-19 while they are pregnant are more likely to have a stillborn baby. We know you already answered our questions during the telephone interview, but we are asking you to participate in a new part of the study because your pregnancy was before the current pandemic, and you didn't have COVID-19 during your pregnancy. Participating in this new part of the study will allow us to better understand how COVID-19 may affect pregnancies.

What is the purpose of this study?
The purpose of this research study is to better understand how having COVID-19 during pregnancy might make it more likely for a baby to be stillborn. The results will help researchers and public health professionals make recommendations for pregnant women with COVID-19.

What will happen if I say yes to participating in the study?
If you decide to join the study, any tissue samples that were already taken from your baby or the placenta during an exam (autopsy or placental exam) when the baby was delivered that are still kept at the hospital will be sent to CDC for testing. Depending on the number of samples, it is possible that all tissue samples will be sent to CDC, with none remaining at the hospital for potential further testing. We will not ask you for any new samples or to answer any more questions in an interview or on a survey.

The tissue samples that will be shipped to CDC are from the placenta (placental tissue) and from the baby (fetal tissue) when the baby was delivered. You can decide to participate in this study by allowing us to have access to the tissue samples.

What are the potential risks to me if I decide to participate?

The risks to you if you decide to participate in this study are very low; however, it may be very difficult to be reminded of your experience when you lost your baby. Once the specimen(s) are released to our care, the hospital assumes no further legal responsibility for their storage. If all tissue specimens are released, there will be no more tissue available for future clinical testing.

What are the potential benefits to me if I decide to participate?

This study will not help you directly and there will be no compensation for participating in this study. If you participate, the information we learn will help us understand if having COVID-19 during pregnancy is more likely to result in stillbirth. You will not get any results of the tests that are done on the tissue samples because the tests are only for research purposes. Your participation in this study can help other pregnant women and their babies.

What information is being collected from me and how will it be protected?

All information that we gather in this study will be kept confidential. This is assured by a Certificate of Confidentiality that protects your legal rights under the Public Health Service Act *(under section 301[d] of the Public Service Act 42 U.S.C. 241[d])*. The Certificate of Confidentiality prevents study staff from being forced under a court order or other legal action to identify your child or anyone else in this study. This protection lasts forever (even after death) for all participants in the research study during any time the Certificate was in effect. But you should know that the researchers are not prevented from reporting information from you to authorities to prevent serious harm to yourself or others. De-identified information obtained from you may be shared with researchers when and if it has been approved by human research subject review committees. This information will not include any identifiable information about you or your baby such as names or addresses. Researchers will never use any names in reports or publications. We will share what we learn with other health professionals through medical publications. None of these publications will include information that could identify you or your baby in any way.

Do I have to participate in this study?

Taking part in this study is completely voluntary. You may choose not to take part in this study at all. If you decide not to be part of this study, there will not be any changes to your regular healthcare. If you decide to be in this study, you may change your mind anytime and stop being in the study without penalty. Whether you choose to participate or not in this study, you will not lose any services, benefits, or rights.

Who do I call if I have questions?

< PI name and local contact information >

Acknowledgment and Signatures

This study information sheet is not a contract. This study information sheet tells you what will happen during the study if you choose to participate. Your signature shows that this study has been explained to you, your questions have been answered to your satisfaction, and you agree to participate in the study. You are not giving up any legal rights by signing this form and your participation is completely voluntary. You may choose not to participate in the study at any time.

Enclosed in this mailing is a second copy of this study information sheet to keep for your records.

If you choose to participate, please check **the box below and please return the signed form to us**:

☐ I agree to participate in this study. I grant permission to release tissue samples already collected including tissue from the baby (fetal tissue) and tissue from the placenta (placental tissue). These samples will be shipped to the <<state>>] Department of Public Health State Lab, who will then ship them to the CDC Infectious Disease Pathology Branch for scientific research.

Participant Name (Please Print) _____

Participant Signature _____ Date signed: __/__/____

Participant Date of Birth __/__/____