

<<date>>

«motherfirstname» «motherlastname»

«Address1»

«Address2»

«City», «State» «Zip»

Dear Ms. «motherlastname»:

In 20XX, you may recall that you participated in a research study on the causes of stillbirths, called the Birth Defects Study to Evaluate Pregnancy exposureS (BD-STEPS), by completing a telephone interview. Your participation in this study is helping us learn more about why stillbirths happen, and we want to thank you for your commitment to helping keep pregnant women and their babies healthy.

We want to express again our deepest sympathy for the loss of your baby through stillbirth and hope that, with time, you have been able to find some peace. We know that the loss of a baby is a very difficult situation and incredibly painful for families to go through. Sadly, this remains a reality for many families and takes a serious toll on their well-being, which is why we are doing another study to better understand the impact of COVID-19 on babies lost through stillbirths. This study does not require any interviews and it might help us learn more about why stillbirths happen.

We would like to invite you to this study, which is funded by the Centers for Disease Control and Prevention (CDC). We know that you and your doctor may have had many discussions about the death of your baby, including information from the autopsy report or other tests. For this part of the study, we are asking for your permission to obtain any tissue samples that may have been taken from your baby at the time of delivery. Most hospitals are required to keep these samples for several years. Depending on the number of the samples, it is possible that all samples will be sent to CDC and none will remain in the hospital. Please take your time to decide whether you would be willing to learn more about this study and possibly participate. We have included more details on the study in the next paragraph should you want to learn more.

Information on the study:

We're working with other researchers to better understand how COVID-19 and other infections affect pregnancy and may increase the chances of having a stillborn baby. As part of the study, we will compare tests on tissue samples from stillborn babies before the pandemic began to tissue samples from stillborn babies whose mothers had COVID-19 during their pregnancy to see what changes may have happened because of COVID-19. The results will help researchers and public health professionals make recommendations on COVID-19 and help keep pregnant women and their babies healthy.

Attached with this letter is a consent form containing more information about the study and asking if you would like to participate. If you choose to participate, you only need to sign and return the form to us. If you decide that you would rather not participate, there is nothing that you need to do.

We have enclosed a \$10 gift card to thank you for taking the time to read this letter and learn about our study. It is yours to keep no matter what you decide.

We hope that you will consider partnering with us on this important study. Please do not hesitate to contact me directly at <PI's phone number> if you have any questions.

Sincerely,

< PI name and local contact information >