

January 15, 2021

Ms. «motherfirstname» «motherlastname»
«address1»
«address2»
«city», «state» «zip»

Dear Ms. «motherlastname»:

On behalf of the Birth Defects Study To Evaluate Pregnancy exposureS (BD-STEPS), we want to thank you for allowing us to interview you for our study. We will learn more about the causes of birth defects and other pregnancy problems by gathering information from a large number of women. Your willingness to participate has been most valuable to us and will be of value to other women and children in the future. We have included a \$30 gift card to thank you for your time.

To keep participants informed, we publish an electronic newsletter every year that updates participants on the progress of the study. You can access this newsletter at www.bdsteps.org.

<<To better understand genetic and other biologic factors that may contribute to birth defects and other pregnancy problems, we are also asking for your permission to request some of the leftover heel stick blood that was already collected shortly after your baby’s birth by the < **Screening Program**>. For every baby born in <State>, a few drops of blood from the baby’s heel (bloodspots) are dried on a card to test for rare conditions. After the tests are done, there are usually some bloodspots left over. The bloodspot samples will allow us to study genetic and other biologic factors that may contribute to the causes of birth defects. Your participation is voluntary, meaning you can choose to take part or not. And, you may withdraw your child’s bloodspot samples from this study at any time.

Please read the enclosed information called “Informed Consent for Release of Leftover Newborn Bloodspots.” If you choose to participate in the study, please sign the consent form and return it to us in the postage-paid envelope. A second copy of the consent form is enclosed for your records. After we receive the signed consent form, we will mail you a \$10 gift card as a token of appreciation for your time and interest.>>

To help us understand more about how infectious diseases before and during pregnancy may contribute to birth defects and other pregnancy problems, we are asking for your permission to request your infectious disease information that was already reported by your physician to the <**INSERT State Health Department/Agency**>. We are asking for this from all participants, even if they did not report an infectious disease during the telephone interview. The <**State Health Department/Agency**> collects information on nationally reportable infectious diseases to monitor, control, and prevent infectious diseases. If we have your permission, the <**State Health Department/Agency**> has agreed to provide your infectious disease information for infections reported the two years before and during your pregnancy. The information provided will be used to study how infectious diseases may play a role in why some pregnancies are affected by birth defects or other pregnancy problems.

Please read the enclosed information called “Informed Consent for Release of Infectious Disease Results.” If you choose to participate, please sign the consent form and return it to us in the postage-paid

envelope. A second copy of the consent form is enclosed for your records. After we receive the signed consent form, we will mail you a \$10 gift card as a token of appreciation for your time and interest.

<<AR & MA only: Also, we may invite you soon or in the future to participate in other parts of BD- STEPS. Some parts may include a gift card for your time.>>

If you have any questions, please contact one of our study staff at 1-888-743-7324 or you can contact me at <Local **PI/Study Coordinator contact name and local contact number**>.

Thank you for helping us to better understand and prevent birth defects.

Sincerely,

<Insert local **PI name and local contact**>

Enclosures