ATTACHMENT C3: INFORMATION SHEET IN QUESTION AND ANSWER FORMAT TO BE MAILED TO WOMEN WHO HAVE AGREED TO PARTICIPATE AND THOSE WHO ARE UNSURE WHETHER THEY WANT TO PARTICIPATE

EVALUATING THE QUALITY OF INTERVIEW DATA COLLECTED BY TERATOLOGY INFORMATION SERVICES ABOUT PREGNANCY OUTCOMES, MATERNAL AND INFANT HEALTH, FOLLOWING MEDICATION USE DURING PREGNANCY AND LACTATION

Information Sheet

Who is conducting this study?
This study is being conducted by the Texas Teratogen Information Service, the Connecticut Pregnancy Exposure Information Service, the Utah Pregnancy RiskLine, and the Centers for Disease Control and Prevention (CDC).

What is the purpose of this study?
The purpose of this study is to find out if information collected from women who call teratology information services can be used to learn about the safety of medicines taken during pregnancy or breastfeeding. The purpose of this project is not to study medicines. This is an evaluation project to look at how much information and the kind of information we can get from this type of phone interview.

How long will you need me for this study?
If you participate in the study, you will complete 3 or 4 confidential phone interviews. The interviews will be conducted over a period of no more than one year after you enroll in the study.

If you enroll while you are pregnant, the first interview will be done very soon after you enroll. The second interview will be when you are about 7 months pregnant. The third interview will be about one month after your baby is born. The last interview will be when your baby is about 3 months old.

If you enroll while you are breastfeeding, the first interview will be done very soon after you enroll. The second interview will be about 1 month later. If you are still taking a medicine and breastfeeding, a third interview will be done about 2 months after that.

What do you want me to do if I decide to be in this study?
You will participate in 3 or 4 confidential telephone interviews. During these interviews, we will ask about:

- medicines, vitamins, or herbal products you took while you were pregnant or breastfeeding, how much you took, and why you needed to take them
- medical conditions, injuries, or surgery you had while you were pregnant or breastfeeding

- prenatal tests you had while you were pregnant
- some other exposures you may have had while pregnant or breastfeeding
- your previous pregnancies

Are there any risks to me if I decide to be in this study?
Some of the questions you will be asked are about sensitive topics, such as your use of alcohol or recreational drugs. You do not have to answer any questions you do not want to answer.

Some women find it hard to talk about their pregnancies. You can choose not to answer any questions that are hard for you to discuss. There are no other likely risks to you from taking part in the study.

Are there any benefits from being in this study?
The information you provide will be used to look at the quality of data obtained from the interviews and the effects of medicines used during pregnancy or breastfeeding. The information will not be used for any other purpose.

Your taking part in this study may help others in the future learn about the risks and safety of medicines used during pregnancy and breastfeeding. However, there are no direct benefits to you or your family from being part of the study. You will not be paid for your time to take part in the study.

What alternatives do I have if I don't want to be in your study?
You do not have to take part in the study. It is your choice. You can withdraw from the study at any time. There will be no penalty if you choose not to participate or if you withdraw. Whether you participate in or complete the study will not affect the medical care you receive or your use of the <Name of teratology information service>. You can call the service at any time to obtain information and counseling about medicines or other exposures while you are pregnant or breastfeeding whether or not you participate in the study.

Will the information I give you be kept private?
All of the answers you provide during the study will be kept private to the extent allowed under federal laws. This is assured by the Privacy Act of 1974 *(5 U.S.C. § 552a)* and by a Certificate of Confidentiality that protects your legal rights under the Public Health Service Act *(section 301[d] of the Public Health Service Act 42 U.S.C. 241 [d])*. These documents prevent study staff from giving out information without your permission, and prevent the staff from being required to identify you or anyone else in the study by a court order or other legal action. This protection lasts forever for anyone who takes part in the study. However, you should understand that these documents do not prevent the study staff from reporting information obtained from you to authorities in order to prevent serious harm to yourself or others. They also do not prevent the study staff from reporting information needed for evaluating or auditing the project.

Only the local staff who work on the study will have access to answers you provide during the study that could identify you. This includes things like your name, phone numbers, email address, expected date of delivery, date of your last menstrual period, birth or delivery dates. This information will be kept by the local study staff until the end of the project. Then it will be destroyed. However, the information you provided while talking with the <Name of teratology information service> counselor before you agreed to take part in the study will be kept by that service as per their usual practices, just as it would be if you had not taken part in the study.

Any information that could identify you will not be shared with anyone besides the local staff who work on the study. Your answers to the interview questions will be shared, without identifying you, with study staff from the Centers for Disease Control and Prevention. When you agree to take part in the study, you are telling us it is OK to share your answers with the CDC. But we will not share any information that could identify you with the CDC. When the study if over, the results from all three services that take part in the study will be combined and shared with others at scientific meetings and in medical journals.

Who should I call if I have questions or concerns about this study?
If you have questions or concerns at any time during the study, if you would like to know more about the study, or if you would like to know whether anyone besides the local study staff has had access to your records, you can contact <Local project coordinator's name> at <Phone number for local project coordinator>.

Who should I call if I have a question about my rights as a research volunteer?
If you have questions about your rights as a subject in this research study, you can call <Name of chair of local Institutional Review Board> who is the chair of the local Institutional Review Board at <Phone number for local Institutional Review Board>.

Do I have to be in this study?
No. You do not have to take part in this study. It is your choice. And you can withdraw from the study at any time.