APPROVED
OMB# 0920- XXXX_____
OMB EXP. DATE____/____/_____

ATTACHMENT C2a: TELEPHONE SCRIPT TO EXPLAIN THE PROJECT AND OBTAIN VERBAL INFORMED CONSENT FROM WOMEN WHO ARE PREGNANT

This telephone script is to be used when the project coordinator contacts a caller to the <Name of teratology information service> to explain the project and obtain informed consent to participate.

Note: Read only the wording that appears in regular font when conducting the interview. Wording in italics contains instructions to the interviewer and should not be read.

Purpose.
Hello. May I speak with <Name of the woman>? This is <Project coordinator's name> from the <Name of teratology information service>. You recently spoke with one of our counselors about medicine you had taken. At the end of that call, you said you were interested in learning more about a project we have. This project is to learn about the safety of medicines during pregnancy and breastfeeding. Is now a good time for me to explain more about the project? *(Circle one)*

Yes
No

If no, go to tracking form.

Our service is part of a research study with the Centers for Disease Control and Prevention and two other information services for women who are taking medicines while they are pregnant or breastfeeding. The purpose of this research is to find out if information collected from women who call our services can be used to learn about the safety of medicines. The purpose of the research 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.

The women who participate in thus project must be at least 18 years of age, live in the United States, and cannot be in jail. You are being asked to take part in this study because you meet all of these criteria and you took a medicine while you were pregnant.

Procedures.
The project involves three or four confidential phone interviews while you are pregnant and after your baby is born. The first interview will take about 40 minutes. Each follow-up interview will take about 20 minutes. During these interviews, we will ask about medicines, vitamins, or herbal products you took while you were pregnant or breastfeeding. We will ask how much medicine you took and why you needed to take it. We will ask about medical conditions, injuries, or surgery you had while you were pregnant. We will also ask about prenatal tests and some other exposures you may have had while pregnant. And we will ask about your previous pregnancies

Each of the three information services plans to interview about 250 women, for a total of 750 persons taking part in the study.

Voluntary.
You do not have to take part in the study. It is your choice. And you can withdraw from the study at any time. There will be no penalty if you choose not to take part in the study or if you withdraw. Whether you take part 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 take part in the study.

Risks.
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.

Benefits.
The answers 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.

Confidentiality.
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.

In order to contact you for each of the interviews, we need to collect items like your name, phone numbers, and email address. In order to know how far along your pregnancy was or how old your baby was when you took specific medicines or had other exposures, we need to collect certain data. These data include your due date, the date of your last menstrual period, and your baby's birth date. These data will be kept by the local study staff until the end of the project. Then they will be destroyed.

Only the local staff who work on the study will have access to answers you provide during the study that could identify you. While the study is going on, all of the data we collect on paper will be kept at the local study site in locked cabinets with limited access. All the data we collect in computer files will be password protected with limited access. The data that can identify you will be kept separate from your answers to the questions in the interviews. When you agree to be part of the study, you will be assigned a study ID number. This number will be the only link between your name and your answers to the interviews. When the study is finished, all data that can identify you will be destroyed and the study ID number will be removed from your answers. 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.

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. A final file that contains only your answers to the study questions and those of all of the other women who were part of the study will be sent to the CDC. These data will be sent over CDC's Secure Data Network. When the study is 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.

Contacts.
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>. 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 you have any questions now about what I've explained? *(Circle one)*

Yes
No

If yes, go to the relevant section above.

Do you want to take part in this study? *(Circle one)*

Yes
No
Not sure

If no, go to End of Consent below.
If not sure, go to Participant Unsure below.
If yes, fill in the information below and continue with the next question.

*Participant's name*_____
Date and time verbal consent given _____

I'd like to send you by mail a written summary of the things that I have explained. The mailing address you provide will only be used to mail this to you. Your mailing address will not be kept by the study staff.

What is the best address to use to mail this to you?

_____
_____

The first interview will probably take about 40 minutes. Do you have time for me to conduct that interview now? *(Circle one)*

Yes
No

If yes, enter the participant's name on the Subject Identification Number form and proceed with the enrollment questionnaire.
If no, go to tracking form. Once the tracking form has been completed, enter the participant's name on the Subject Identification Number form.

If participant unsure:
That's fine. I can send you by mail a written summary of all the things that I have explained. The mailing address you provide will only be used to mail this to you. Your mailing address will not be kept by the study staff.

What is the best address to use to mail this to you?

_____

_____

I will plan to call you back in about 2 weeks to see if you have decided whether to take part in the study.
Go to tracking form.

End of Consent:
That's fine. Thank you for your time. If you have any other questions about medicines, chemicals, illnesses, or other exposures, please feel free to contact the <Name of teratology information service> again. Goodbye.