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

APPROV	/ED	
OMB#	0920 -XXXX_	
OMB EX	KP. DATE/	/

ATTACHMENT C1b: TELEPHONE SCRIPT FOR PERMISSION TO BE CONTACTED ABOUT THE PROJECT WHEN THE COUNSELOR IS THE SAME AS THE STUDY COORDINATOR

This telephone script should be used to ask callers to the <Name of teratology information service> if they are interested in being contacted by the project coordinator to learn about potential participation.

This script should be used with all callers to the service during the study period (up to a maximum of 250 enrollees) who meet all of the following criteria:

- The caller is currently pregnant or breastfeeding.
- During the call, she reported taking a prescription or over-the-counter medication, a dietary supplement, or an herbal preparation, at any time during pregnancy or while breastfeeding.
- The caller is 18 years or older.
- The caller resides within the United States
- The caller is not currently incarcerated.
- *The caller speaks English.*

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.

At the end of the call after all information and counseling about the caller's exposure(s) have been provided, read the following:

Before we hang up, I have one more question. Our service is part of a project with the Centers for Disease Control and Prevention and two other teratology information services. The purpose is to find out if information collected from women who call us can be used to learn about the safety of medicines taken during pregnancy and breastfeeding. This involves three or four confidential telephone interviews in which you would be asked about medicines and other exposures you had <during pregnancy/while breastfeeding>, your health, and the health of your baby. Whether you participate in 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 regardless of whether you participate in the study.

Would you be interested in learning more about this project and the possibility of participating? If so, I can explain it now or we can schedule another call at a convenient time. Today, you are not agreeing to be part of the study, only to learn more about it. (*Circle one*):

Yes

No

If no, go to End of Call below.

Public reporting burden of this collection of information is estimated to average 3 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Information Clearance Officer; 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30333; ATTN: PRA (0920-XXXX).

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To participate in the project, you must be at least 18 years of age, live in the United States, and cannot be in jail.

Are you under 18 years of age? (Circle one): Yes No

If yes, go to Nonparticipant below.

Do you live in the United States? (Circle one): Yes No

If no, go to Nonparticipant below.

Are you now in jail? (Circle one): Yes No

If yes, go to Nonparticipant below.

OK, that means you are eligible to be part of the study. It will probably take about 20 minutes to explain the project and answer any questions. Is now a convenient time to do this? (*Circle one*)

Yes

No

If yes, go to verbal informed consent.

If no, go to tracking form.

End of Call:

OK. Thank you for your time. If you have any additional questions about medicines, chemicals, illnesses, or other exposures, please feel free to contact the <Name of teratology information service> again. Goodbye.

Nonparticipant:

OK. Unfortunately, that means you are not eligible to be part of the study. Thank you for your time. If you have any additional questions about medicines, chemicals, illnesses, or other exposures, please feel free to contact the <Name of teratology information service> again. Goodbye.