

The Children's Total Exposure to Persistent Pesticides and Other Persistent Organic Pollutants (CTEPP) Study

Telephone Sample Subjects Recruitment

Battelle
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Standard Operating Procedure

CTEPP-SOP-1.12

Title: Telephone Sample Subjects Recruitment

Source: Battelle

U.S. Environmental Protection Agency
Office of Research and Development
Human Exposure & Atmospheric Sciences Division
Exposure Measurements & Analysis Branch

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STANDARD OPERATING PROCEDURE (SOP)
FOR TELEPHONE SAMPLE SUBJECTS RECRUITMENT

Prepared by: _____	Date: _____
Reviewed by: _____	Date: _____
Approved by: _____	Date: _____
Approved by: _____	Date: _____
Approved by: _____	Date: _____

1.0 Scope and Applicability

This standard operating procedure (SOP) describes the procedure for recruiting the study subjects from the telephone sample in North Carolina (NC) and Ohio (OH).

2.0 Summary of Method

The procedures for recruiting households by telephone sampling are illustrated in Figure A. A telephone sample list including addresses is ordered from a commercial survey sampling firm. Using this address list, introductory letters are sent to targeted homes prior to making initial telephone contacts. Follow-up calls using standardized telephone scripts begin five days after the mailing of the letters. A Computer Assisted Telephone Interview (CATI) system is developed to facilitate the recruitment process.

Initial telephone contact includes screening and a brief interview. To ensure participation of each eligible family, a follow-up visit and multiple follow-up calls are conducted. More than 64 eligible telephone sample households are expected to be enrolled in each state. The final participants are randomly selected from all households who are willing to participate.

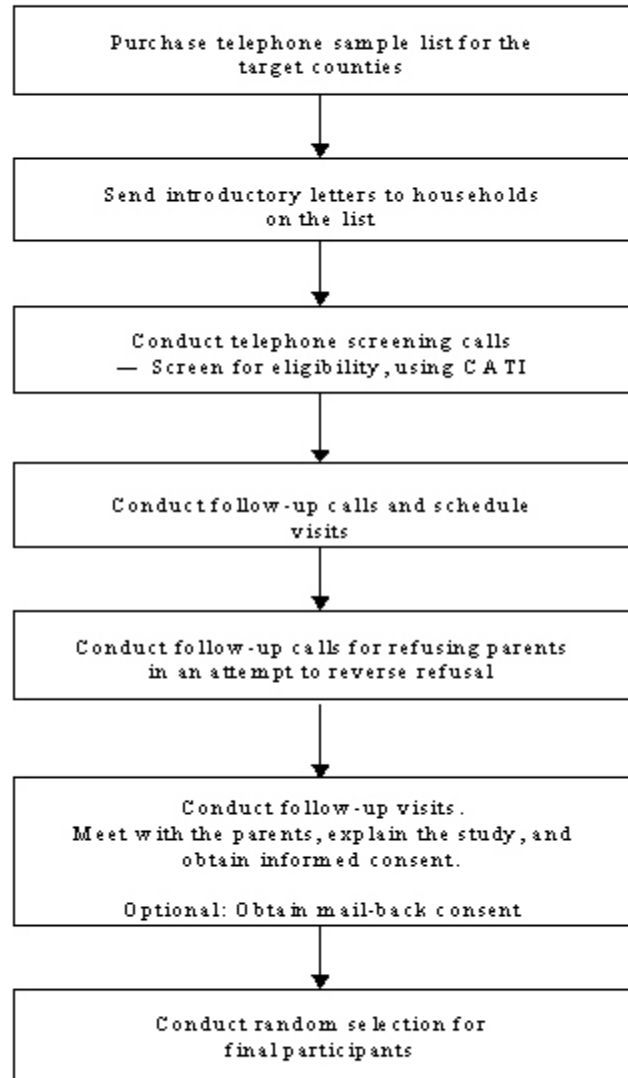
3.0 Definition

Non-residential, non-working, and fax machine numbers are excluded. An eligible household is defined as a household with at least one child aged 1½ to 5, who lives in the household on a regular basis (not temporary visit), and the child does not go to a child day care during the day. If the child goes to a baby sitter's home more than two days per week regularly (regardless if it's full-day or part-day), it counts as "go to a child day care." [That is, if the child goes to a baby sitter's home for two days or less per week, the child can be included in the study.] The WIC income criteria are used to determine the household's income status (i.e., low or mid-to-high).

CTEPP Recruitment Protocol

Figure A

Sample Component: Telephone Sample



4.0 Cautions

Many parents may have concerns about project staff's inquiries about their children. To alleviate their fear and concerns, the EPA Task Order Project Officer's (TOPO) phone number will be provided for them to confirm the legitimacy of the study. Confidentiality is guaranteed (with the certificate of confidentiality). Endorsements of child care licensing agencies and other child care service associations and positive feedback from pilot study participants (included in the CTEPP study brochure) are used to facilitate participation. The consents of the pilot study participants have been obtained for using their names in the CTEPP study brochure. Recruitment activities will begin upon the receipt of the Office of Management and Budget (OMB) approval.

5.0 Responsibilities

- 5.1 The Battelle Field Team Leader (FTL) coordinates the tasks for recruiting telephone sample subjects.

6.0 Apparatus and Materials

6.1 Materials

- 6.1.1 Certificate of Confidentiality
- 6.1.2 Letters of Support
- 6.1.3 Telephone Sample Lists
- 6.1.4 Introductory Letters to Parents
- 6.1.5 Informed Consent Forms
- 6.1.6 Study Brochures
- 6.1.7 EPA Press Release
- 6.1.8 Computer Assisted Telephone Interview (CATI) System
- 6.1.9 Training Manual for Recruitment Staff

7.0 Procedure

7.1 Pre-recruitment Preparation

Before the initial contact with any study subjects, the following tasks should be completed.

- 7.1.1 Obtain a Certificate of Confidentiality
Obtain a Certificate of Confidentiality from the Department of Health and Human Services (DHHS). Due to the nature of this study, some participants may have concerns about confidentiality. To ease their concerns and encourage participation, the project has obtained a Certificate of Confidentiality from the DHHS. With the

certificate, project staff can give an honest and binding assurance to study participants that information they provide may not be disclosed without their consent (Public Health Service Act, 42 U.S.C. ' 241 (d)). [Note: The Certificate of Confidentiality was issued by the National Institute of Mental Health/NIH/DHHS.]

7.1.2 Obtain Letters of Support

Contact the following agencies/organizations to obtain letters of support: state child day care centers licensing agencies, state and local child care organizations.

7.1.3 Obtain Telephone Sample Lists

Purchase the CTEPP telephone sample list from a commercial survey sampling firm. Instructions are prepared by the sampling statistician for the survey sampling firm to select the telephone sample in the targeted counties. The sample file includes addresses, which can be used for mailing introductory letters prior to making the initial telephone contacts.

7.1.4 Program the Computer Assisted Telephone Interview (CATI) System

CATI screening surveys are developed by using the standardized telephone scripts and Form #1 (Recruitment Survey). The CATI system should be tested before its implementation.

7.1.5 Prepare Introductory Letters for Parents

Prepare introductory letters for parents and submit the letters to the TOPO for approval. After approval, her signature is scanned into a computer file to be used in the letter.

7.1.6 Prepare Informed Consent Forms

Prepare informed consent forms for parents. The consent forms are reviewed and approved by the TOPO.

7.1.7 Prepare Study Brochures

Prepare study brochures for parents. The study brochures are reviewed and approved by the TOPO.

7.1.8 Conduct a Focus Group Meeting

To further enhance the understanding of study participation issues, a small group of potential participants may be invited to attend a focus group discussion meeting. The TOPO will determine the needs of such meeting.

7.1.9 Finalize all Project Materials

Complete all final changes for the project materials before the study is submitted for Battelle Institutional Review Board (IRB) review.

7.1.10 Obtain Battelle IRB Approval for the CTEPP Study

IRB approval must be obtained before contacting study subjects.

7.1.11 Obtain EPA Human Subjects Approval for the CTEPP study

EPA human subjects approval must be obtained before contacting study subjects.

7.1.12 Conduct Training for Recruitment Staff

Training for the recruitment staff is conducted before the recruitment starts. A training manual is provided to the recruitment staff. The manual includes the SOPs for conducting recruitment activities. The following topics are discussed during training: study background, standard operating procedures for the CATI, and the recruitment scripts.

7.1.13 Prepare Press Release Materials

To raise public awareness of the project, a press release describing the CTEPP study in layman's terms is prepared by the EPA. It is distributed to local newspapers and TV/radio stations in the targeted areas before the recruitment starts.

7.1.14 Procure a Project 1-800 Hot Line

To encourage study participation, a toll-free number has been obtained for the CTEPP study (1-877-810-9530, ext. 506).

7.2 Telephone Screening

Goal of telephone screening: to enroll at least 64 children from the targeted counties in each state (24 low-income and 40 middle/high-income). The target response rate is 75%. The following are step-by-step procedures.

7.2.1 Obtain the Telephone Sample Lists in the Target Counties

A telephone sample list including addresses is ordered from a commercial survey sampling firm.

7.2.2 Mail Introductory Letters and Study Materials

An introductory letter and study brochure are mailed to the selected households prior to making initial telephone contacts. The letters are mailed in batches (or waves).

7.2.3 Conduct Telephone Screening Calls

Telephone screening calls are conducted five days after the mailing of the letters. Standardized telephone scripts and a CATI system are used to facilitate the recruitment process. The initial telephone contact includes eligibility screening and a brief interview.

7.2.4 Conduct Follow-up Visits

To ensure participation of each eligible family (especially in the case of refusal), follow-up visits to the households are made, as needed, by project staff.

7.2.5 Conduct Random Selection for Final Participants

More than 64 eligible telephone sample households are expected to be enrolled in each state. The final participants are randomly selected from all eligible households who are willing to participate.

7.2.6 Obtain Informed Consent

A signed informed consent form is obtained from each participant by the project staff.

8.0 Records

All recruitment records and paper documents are kept in the project recruitment files. Electronic files are stored in the recruitment folders and archived on a CD ROM disk after the project is completed. Consent forms and other subject identification files are stored in a secured file cabinet. All electronic files are protected by passwords. Only authorized project personnel are allowed to access the files. All records will be archived for three years after the completion of the study.

9.0 Quality Control and Quality Assurance

The results of subject recruitment and supporting data and documents should be reviewed and verified by the Battelle Field QC Officer, the FTL, and the Task Order Leader (TOL).

10.0 Reference

Not applicable.