

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

Day Care Center Sample Subjects Recruitment

Battelle
Columbus, OH 43201
Contract No. 68-D-99-011

Standard Operating Procedure

CTEPP-SOP-1.11

Title: Day Care Center Sample Subjects Recruitment

Source: Battelle

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

Notice: The U.S. Environmental Protection Agency (EPA), through its Office of Research and Development (ORD), partially funded and collaborated in the research described here. This protocol is part of the Quality Systems Implementation Plan (QSIP) that was reviewed by the EPA and approved for use in this demonstration/scoping study. Mention of trade names or commercial products does not constitute endorsement or recommendation by EPA for use.

STANDARD OPERATING PROCEDURE (SOP)
FOR DAY CARE CENTER SAMPLE SUBJECTS RECRUITMENT

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1.0 Scope and Applicability

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

2.0 Summary of Method

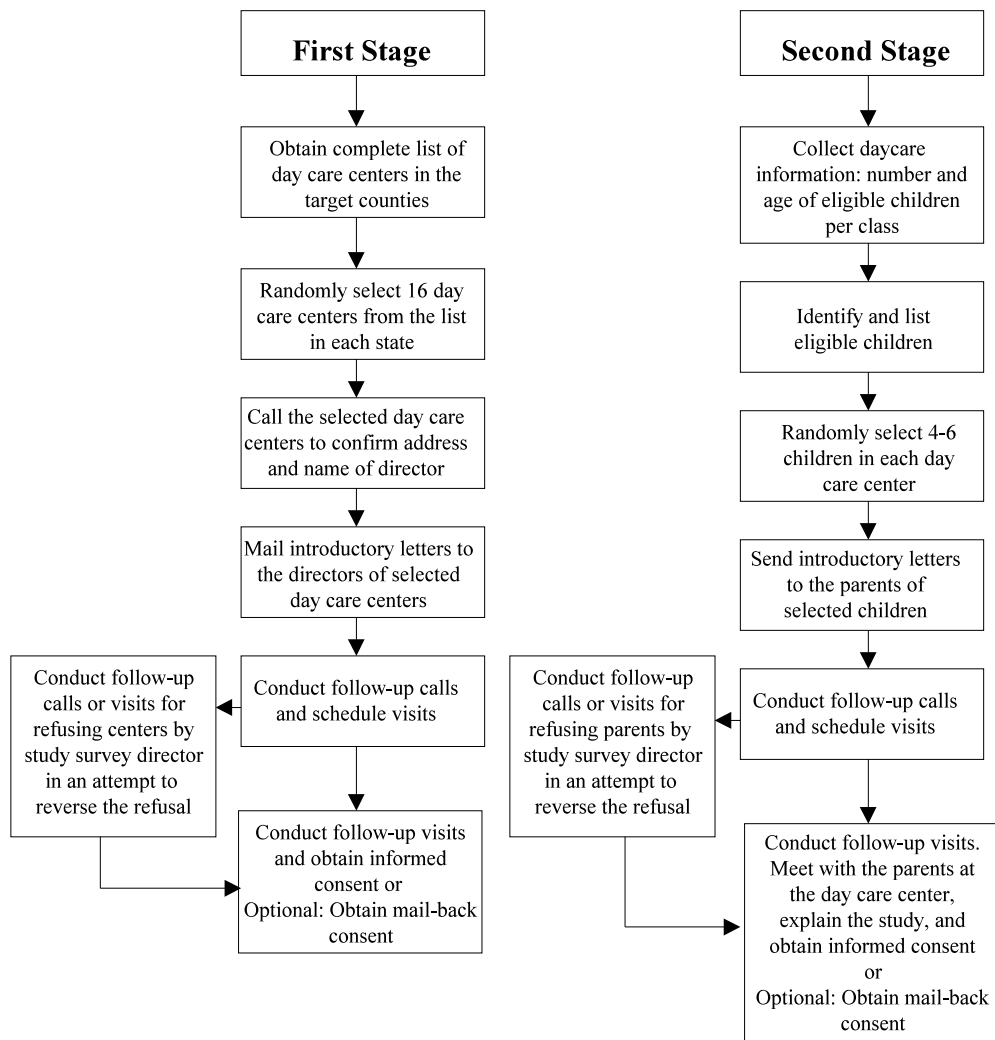
The procedures for recruiting day care centers are illustrated in Figure A. There are two stages in this phase of recruitment. The objective of the first stage is to enroll day care centers for the study. Six target counties in each state are selected using regional, urbanicity, and income guidelines. A complete list of day care centers in each county is prepared and sorted by urbanicity and income. From these lists, the number of targeted day care centers in each state is randomly selected (See CTEPP-SOP-1.10).

Screening calls are conducted by the recruitment team to confirm the addresses and names of the targeted day care directors. After confirmation, the recruitment team sends a FedEx package (containing an introductory letter, a study brochure, and a gift certificate) to each day care center director. About 2-3 days after the mailing of the letters, the recruitment team makes follow-up calls to each day care center director. To ensure participation of each center, the project team makes follow-up visits to the center director and the Battelle project director or the EPA principal investigator contacts the center as needed. To complete the first stage recruitment activities, informed consent forms are obtained from each day care center.

The second stage recruitment activities begins with the collection of the number of age-eligible children in each classroom. A list of the first names or initials of all age-eligible children is obtained from each center. Then, the sampling staff randomly selects four to six children in each day care center.

Following the selection of the children, the recruitment team asks the day care director to distribute the introductory letters and letters of support to the parents of the selected children. In consultation with the day care center director, the recruitment team sets up an appropriate time to meet with the parents at the day care center two to three days after the letters are sent.

During the meeting with the parents, the recruitment team establishes rapport with the parents and the child by giving a small gift to the child (e.g., a book, small toy, etc.). The recruitment team emphasizes the positive experiences of pilot study participants. An informed consent form is obtained from the parents and the parents are asked to complete the Recruitment Survey (Form #1). Finally the recruitment team schedules an initial sampling date with each family.



3.0 Definition

A child day care center is defined as a commercial or not-for-profit service provider who provides child care services to seven or more pre-school age children at a location other than the service provider's personal residence. Home child care will be excluded from the study. All child day care centers must be licensed to operate in NC or OH.

4.0 Cautions

Most child day care centers are sensitive to government regulatory agencies. They may also have concerns about the objectives of the CTEPP study for fear that the results of the study might have negative effect on their centers (i.e., study results indicating high level of contaminants). To alleviate their fear and concerns, the recruitment team guarantees confidentiality (using a Certificate of Confidentiality) and uses the endorsement of the child care licensing agencies and other child care service associations. The team also uses the positive feedback of pilot study participants (included in the CTEPP study brochure). Recruitment activities begin upon receipt of approval from the Office of Management and Budget (OMB).

5.0 Responsibilities

5.1 The Battelle Field Team Leader (FTL) coordinates the tasks for day care centers recruitment. The FTL is the contact person for the recruitment tasks.

6.0 Apparatus and Materials

6.1 Materials

- 6.1.1 Certificate of Confidentiality
- 6.1.2 Letters of Support (licensing agencies, state and local organizations)
- 6.1.3 Complete Lists of Child Day Care Centers
- 6.1.4 Supplemental Lists of Child Day Care Centers (CD ROM database, Internet search)
- 6.1.5 Introductory Letters to Day Care Center Directors and Parents
- 6.1.6 Informed Consent Forms
- 6.1.7 Study Brochures
- 6.1.8 EPA Press Release
- 6.1.9 Training Manual for Recruitment Staff

7.0 Procedure

7.1 Pre-recruitment Preparation

The following tasks will be completed before the initial contact with any study subjects.

- 7.1.1 Obtain a Certificate of Confidentiality
Contact the Department of Health and Human Services (DHHS) to obtain a Certificate of Confidentiality. 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 DHHS. With the certificate, the team 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)). Battelle will assist the EPA project staff in the application of a Certificate of Confidentiality with the DHHS/OPRR (Office for Protection from Research Risk).
- 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 Complete Lists of Child Day Care Centers
Contact NC and OH child care licensing agencies to obtain the lists of centers in the selected counties.
- 7.1.4 Obtain Supplemental Lists of Child Day Care Centers
Obtain supplemental lists of child day care centers through searches of CD ROM telephone database (Pro CD) and Internet.
- 7.1.5 Prepare Introductory Letters for Day Care Center Directors and Parents
Prepare introductory letters for day care center directors and parents and submit the letters to the Project officer for approval. With the approval of the EPA Task Order Project Officer, 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 day care center directors and parents. The consent forms are reviewed and approved by the EPA Task Order Project Officer.

7.1.7 Prepare Study Brochures

Prepare study brochures for day care center directors and parents. The brochures are reviewed and approved by the EPA Task Order Project Officer (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 the 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

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 Computer Assisted Telephone Interview (CATI) system, 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 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 First Stage Recruitment

Goal of first stage of recruitment: to enroll at least 14 day care centers in each state (4 low-income and 10 regular day care centers). The following are step-by-step procedures.

- 7.2.1 Obtain Complete List of Day Care Centers in the Target Counties
- 7.2.2 Randomly Select 16 Day care Centers in Each State
- 7.2.3 Verify the Contact Information of the Selected Day Care Centers
Call each selected day care center to verify the name of the center director and the address and phone number.
- 7.2.4 Mail Introductory Letters and Study Materials
Once the address and name are confirmed, send a FedEx package (with an introductory letter, study brochure, and a gift certificate) to each day care center director.
- 7.2.5 Conduct Follow-up Calls
About two to three days after the mailing of the letters, follow-up calls are made to each day care center director.
- 7.2.6 Conduct Follow-up Visits (Refusal Conversation)
To ensure participation of each center (especially in the case of refusal), follow-up visits to the centers are made, as needed, by project staff.
- 7.2.7 Obtain Informed Consent
Signed informed consent form is obtained from each day care center by the project staff.

7.3 Second Stage Recruitment

Goal of second stage of recruitment: to enroll at least 64 children from the day care centers (24 low-income and 40 middle/high-income). The following are step-by-step procedures.

7.3.1 Collect Day Care Center Information

Second stage recruitment activities begin with the collection of the day care center information on the number of age-eligible children in each classroom. A CTEPP Data Sheet should be completed for each center.

7.3.2 Identify and List Eligible Children

The first names or initials of all age-eligible children are obtained (using the CTEPP Data Sheet) and a random number is assigned to each child.

7.3.3 Randomly Select Four to Six Children in Each Day Care Center

Four to six children in each day care center are randomly selected according to the sampling procedures.

7.3.4 Distribute Introductory Letters and study materials

Following the selection of the children, ask the day care director to help with the distribution of the parent recruitment package (with an introductory letter, study brochure, and a gift certificate). The introductory letter informs the parents about an upcoming visit from the project staff at the day care center. Parents may call the project toll-free number (1-877-810-9530, ext. 506) for more information.

7.3.5 Conduct Follow-up Calls

Conduct follow-up calls to answer the questions of parents who call the project toll-free number.

7.3.6 Conduct Follow-up Visits

In consultation with the day care center director, an appropriate time to meet with the parents at the day care center is set up two to three days after the parent recruitment packages are sent. During the meeting with the parents, project staff will establish rapport with the parents and the children by giving a small gift to each selected child (e.g., a book, small toy, etc.). Emphasis is placed on the positive experiences of pilot study participants.

7.3.7 Obtain Informed Consent

An informed consent should be obtained from the parents and the parents are asked to complete the Recruitment Survey (Form #1). An initial sampling date is scheduled with each family.

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 Field Team Leader, and the Task Order Leader.

10.0 Reference

Not applicable.