

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

Obtaining Informed Consent

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

Standard Operating Procedure

CTEPP-SOP-1.13

Title: Obtaining Informed Consent

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 OBTAINING INFORMED CONSENT

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|--------------------|-------------|
| 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 method for obtaining informed consent from study subjects.

2.0 Summary of Method

After an eligible subject provides verbal consent, project staff schedule a visit to meet with the subject in person to explain study activities and answer questions about the study. During the visit, project staff demonstrate how to collect samples of food, urine, and hand wipes, and how to fill out the Child Activity Diary. Staff determine whether the subject needs money for the preparation of additional food for the sample. If it is determined that advance payment is needed, project staff will pay the subject \$25 and ask for a receipt. Once all questions are answered, the subject is asked to sign the consent form. A copy of the consent form is provided to the subject.

3.0 Definition

Not applicable

4.0 Cautions

Staff should be sensitive to the study subjects' concerns. Confidentiality and safety of project activities should be stressed. Staff should dress appropriately and treat the subjects with respect and courtesy. It is very important to establish rapport and trust with the study subjects.

5.0 Responsibilities

5.1 The recruitment team members are responsible for obtaining the signed informed consent forms.

5.2 The Battelle Field Team Leader (FTL) oversees the recruitment activities.

6.0 Apparatus and Materials

6.1 Materials

6.1.1 Informed consent forms

6.1.2 Money order (\$25) and receipt for the advance payment

6.1.3 Field sampling materials (for demonstration)

6.1.4 Project calendar

7.0 Procedures

- 7.1 Schedule a visit with the subject.
To maximize efficiency (i.e., to maximize the number of subjects that can be visited per day), schedule the visits based on the proximity to one another (e.g., conduct the visits in the same county).
- 7.2 Visit the subject at the appointment time.
- 7.3 Explain the study activities and the consent form.
Demonstrate how to collect samples of food, urine, and hand wipes, and how to fill out the Child Activity Diary and Food Diary.
- 7.4 Answer subject's questions and refer specific questions to the FTL or Battelle Task Order Leader (TOL) if needed. Use the CTEPP toll-free number (1-877-810-9530, ext.506) to contact the FTL.
- 7.5 Ask the subject to sign the consent form.
- 7.6 Give the subject a copy of the blank consent form.
- 7.7 Pay the subject \$25 if money is needed in advance for the food sample. Ask the subject to sign a receipt for the \$25 payment.
- 7.8 Discuss the sampling schedule with the subject. Provide the subject with a project calendar.
- 7.9 Ask the subject if s/he is interested in participating in the video taping study. If yes, explain the video taping study consent form, answer the subject's questions, and ask the subject to sign the consent form. Give the subject a copy of the consent form.

8.0 Records

The consent forms and the subject identification files are stored in a secured file cabinet until the conclusion of the study. All electronic files are protected by passwords. Only authorized project personnel have access to the files. Electronic files are archived on a CD ROM after the study is completed. All records will be archived for three years after the completion of the study.

9.0 Quality Control and Quality Assurance

The consent forms and related document should be reviewed and verified by the Battelle Field QC Officer and the FTL.

10.0 Reference

Not applicable.