

National Human Exposure Assessment Survey (NHEXAS)

Maryland Study

Quality Systems and Implementation Plan for Human Exposure Assessment

Emory University
Atlanta, GA 30322

Cooperative Agreement CR 822038

Standard Operating Procedure

NHX/SOP-G10

Title: Training of Phlebotomists

Source: Harvard University/Johns Hopkins University

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

1. Title of Standard Operating Procedure

Harvard University/Johns Hopkins University Standard Operating Procedure:
G10 Training of Phlebotomists, Rev. 0.1

2. Overview and Purpose

The field team for the NHEXAS Phase I Field Study consists of one Field Interviewer, a Phlebotomist, and two Field Technicians, designated FT1 and FT2.

- The interviewer will visit the respondent's home on Day 1 and Day 8 to explain the consent form and incentive information; administer questionnaires; teach the target individual how to use the personal air sampler; and collect water, food, dermal wipe, and urine samples.
- The Phlebotomist will visit the home on Day 2 to take blood samples and to pick up a urine sample and the personal air monitor.
- FT1 will visit the home on Day 1 and Day 8 to set up and take down equipment for sampling indoor and outdoor air for metals, pesticides, and PAHs.
- FT2 will visit the home only on Day 1, to sample dust and soil and to draw plans of the house and yard.

All personnel are responsible for the labeling and handling of the samples they take until they deliver the samples to the Field Coordination Center (FCC) and formally transfer custody to the Field Coordinator (FC) or his designate.

Phlebotomists will be trained in the tasks they will do; they will not attend the full training program for interviewers and technicians.

This SOP outlines the responsibilities of the Phlebotomist before, during, and after sampling at residences; and the training system that will teach Phlebotomists what they need to know to handle these responsibilities. The overall responsibilities of the Phlebotomist are:

- To collect samples that are representative of the respondent, by carefully following the defined procedures.
- To label and record all samples and observations accurately, and deliver them to the appropriate recipients.
- To behave professionally with respondents, colleagues, and the public.

3. Discussion

This and the related SOPs, G07 "Training of Field Technicians," G08 "Training of Interviewers," and G09 "Training of Laboratory Technicians," and the appropriate field and laboratory SOPs will be the basis for field and laboratory manuals to be used by staff. For details such as how to test an air sampler, refer to the appropriate SOPs.

Phlebotomists will be licensed in the state of Maryland. Experience in field surveys or sampling is preferred. A second language (appropriate to the population being surveyed) is advantageous.

Phlebotomists will be trained professionals from Westat, who will receive further training in procedures specific to this investigation.

4. Personnel Responsibilities

4.1 Planning Training Curriculum

Harvard and Westat personnel will plan the curriculum for the 1-week training session.

4.2 Hiring Phlebotomists

Candidates for positions will be interviewed and selected by Westat.

4.3 Training Phlebotomists

Training for Phlebotomists will take place at the Westat offices in Rockville, MD. Training will be by Harvard and Westat engineers familiar with all aspects of the field instrumentation. The training will be supplemented by actual field sampling in residences occupied by Westat staff members.

4.4 Audits

During the 15-month survey period, audits will be performed by HSPH, JHU, and/or Westat personnel, and by an independent entity. See Section 8.2.

5. Required Equipment and Materials

Field Manual (including SOPs)
Sampling equipment (listed in SOP for each medium)
Labels, logsheets, forms

6. Responsibilities of Phlebotomists

Table 1 shows the Phlebotomist's responsibilities organized by medium (blood, urine, etc.) and day. Day 1 is the day on which a particular household is first visited, and will differ for different households.

Indoor and outdoor air, dust, and soil sampling are handled entirely by the field technicians. Dermal wipe, duplicate diet, and water are handled entirely by the interviewer. Phlebotomists have no responsibilities for these media.

[Will FCC staff prepare blood sampling kits? Coolers w/ dry ice & cold packs? Field packets?]

Table 1 Responsibilities -- Phlebotomist

Medium	Visit 1 (Day 1)			Visit 2 (Day 2)			Visit 3 (Day 8)		
	Before	During	After	Before	During	After	Before	During	After
Blood	--	--	--	Prepare sample kit.	Take blood samples.	Deliver samples to JHU or transfer site.	--	--	--
Urine	--	--	--	--	Collect Day 2 sample.	Deliver sample to JHU or transfer site.	--	--	--
Air - Personal	--	--	--	--	Collect Personal Exposure Monitor (PEM). Take and record flow reading.	Deliver sample to JHU or transfer site.	--	--	--

7. Curriculum

7.1 Contact with respondents

7.1.1 Behavior

- Maintain the privacy and confidentiality of respondents.
- Be courteous and professional.
- If it is necessary to move any of the respondents' possessions to set up equipment or take a sample, ask permission, move the items carefully, and leave them in plain sight.

7.1.2 Conversation

- Be prepared to answer questions about the survey, including confidentiality (see SOP G02 "Confidentiality Assurance").
- Avoid conversation on unrelated topics, especially controversial topics.
- Do not give advice on environmental or health concerns, even if asked by the respondent.

7.1.3 Appearance

- Clothing should be neat and clean. Do not wear clothing or pins that express personal opinions or advertise products.
- Wear photo ID badge.

7.2 Sample Handling

7.2.1 Labeling, logsheets, and forms

- Trainees will learn the labeling and tracking system, and practice the procedures. For general information, see HSPH SOPs G03 "Identification Numbers for Samples and Forms" and G04 "Chain of Custody and Sample Tracking." For labeling of samples for each medium, see the SOP for that medium.
- How to assemble and prepare the labels and forms that will be needed for each field visit.
- How to use field log codes for problems such as a rotameter reading outside the approved tolerances, and for any circumstances that might affect the representativeness of a sample.
- How to log in samples and records after a visit.

- How to use a bar code reader.

7.2.2 Storage and shipping

- How to handle each type of sample until it is delivered to the field coordination center. See SOPs "Chain of Custody and Sample Tracking" and "Storage of Samples." The SOP for each medium describes any special requirements (e.g., chilling) and tells where samples go for analysis.

7.3 Equipment Preparation

7.3.1 General

- How to pack sample kit for each visit, and check list.
- What to do on site if equipment breaks or is missing.

7.3.2 Containers and seals

- What containers and seals are needed for each visit.
- How to prepare, label, and pack them.
- What to do with unused ones after a visit.

7.4 Blood Samples

- Samples needed for project.
- How to handle sample after collection.

7.5 Urine Samples

- How to handle sample after collection.

7.6 Personal Air Sampler (Personal Exposure Monitor, PEM)

- How to measure flow reading.
- How to handle sample after collection.

8. Quality Assurance Procedures

8.1 Testing

8.1.1 During training

- Trainees will be tested on skills such as using a rotameter to measure the flow reading of a PEM.
- At end of training, trainees will be evaluated while performing actual field sampling

at the residence of a Harvard or Westat staff member.

8.1.2 During survey

- During the early weeks of the survey, instructors will accompany field staff, evaluate their performance, and provide any help needed.

8.2 Audits

During the 15-month survey period, the following audits will be performed:

- internal audits every six months by HSPH, JHU, and/or Westat personnel
- one performance audit by an independent entity

9. References

Harvard University/Johns Hopkins University Standard Operating Procedures:

- G02 Confidentiality Assurance
- G03 Identification Numbers for Samples and Forms
- G04 Chain-of-Custody and Sample Tracking
- G05 Storage and Shipping of Samples
- G06 Problem Management
- G07 Training of Field Technicians
- G08 Training of Interviewers
- G09 Training of Laboratory Technicians
- G11 Training of Field Coordination Center Staff
- F03 Collection, Storage, and Shipment of Personal Air Samples for Metal Analysis
- F10 Collection, Storage, and Shipment of Urine Samples for Metal and Pesticide Analysis
- F11 Collection, Storage, and Shipment of Blood Samples for Metal, Pesticide, and PAH Analysis
- F12 Duplicate Sampling
- D01 Data Flow Procedures