

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-G02

Title: Ensuring Confidentiality of Respondents' Records

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 Procedures:
G02 Ensuring Confidentiality of Respondents' Records, Rev 1.0.

2 Overview and Purpose

The purpose of this SOP is to provide procedures designed to ensure respondent confidentiality while maintaining access to records cross-referenced to the individual.

3 Discussion

The free participation of respondents is an integral and necessary part of the NHEXAS investigation. Because of the large burden placed upon potential respondents, there is a high probability of the respondent leaving the investigation. Furthermore, during the course of the investigation, information and environmental and biological samples will be collected that could potentially be used in a matter not advantageous to the respondent.

In order to allay any reluctance of the respondent toward participation because of these confidentiality considerations, procedures must be in place to ensure anonymity of respondents.

Confidential information is information that would enable someone looking at the records to identify the respondent, or information that the respondent would prefer to have kept private:

- Name
- Location of home: address, telephone number, GPS reading, census tract
- Income
- Medical conditions, including prescription drugs taken

4 Personnel Responsibilities

4.1 Sampler Preparation: Not applicable.

4.2 Field Collection

Data collected in the field will come from repeated visits to an individual's private residence. It will be the responsibility of the Field Team Coordinator to ensure that such visits impose the minimum infringement on the respondent's privacy. Individual Field Teams will be responsible for maintaining the privacy of the respondents they visit. All Westat employees sign confidentiality agreements, agreeing to maintain the confidentiality of all study data. Violation of the agreement is grounds for immediate dismissal.

4.3 Storage: Not applicable.

4.4 Shipment: Not applicable.

4.5 Analysis: Not applicable.

5 Required Equipment and Reagents

Encryption algorithm on database management system

Locking filing cabinets (2):

in the Field Coordination Center and in the office of the Principal Investigator

Informed Consent Forms

6 Procedure

Below are outlined several specific points designed to ensure confidentiality for the respondents.

Our procedures have been developed to:

- ensure respondents that their privacy will be maintained, and
- obtain consistent, high-quality data.

6.1 Identification Numbers

Before the initial visit, a unique identification number will be associated with each respondent. This ID number will be part of the ID number assigned to each sample taken at the respondent's home. All files and samples will be coded with ID numbers only. See HSPH SOP G03 "Identification Numbers for Samples and Forms."

6.2 The Linking List

A list relating respondents' ID numbers to names and addresses will be kept on file by the Field Coordinator with backup kept by the Principal Investigator. These files will be encrypted using a key known only to them. Hard copies of the linking list will be kept in locked filing cabinets in both the Field Coordination Center and the office of the Principal Investigator.

With the exception of the linking list, all data files will be identified only by the ID number of the samples. Questionnaire, environmental, and biological sample data will all be encoded in this fashion. No unencrypted data file will be maintained that affords linking of data to individuals. Only the linking list will afford access to the original respondents.

The names and addresses of respondents will be revealed only to staff with a need to know, such as the FCC staff who arrange the visits and the field staff who visit the home.

After data collection has been completed, at a time deemed appropriate by the Principal Investigator with consultation with the EPA Principal Collaborator, this linking list will be destroyed. At that point, there will no longer be any method to link directly any one individual with any of the data taken in the field.

6.3 Field Collection

The Field Team (Field Interviewer and Field Technicians) will arrange appointment schedules convenient to both the respondent and themselves. It is the responsibility of the Field Team to conduct themselves in a courteous and professional manner designed to ensure maximum cooperation with the respondents in the study. Confidentiality is of paramount importance in this investigation. The attitude and bearing of the Field Team will have significant impact upon the perception of the study by the respondents.

The Field Team members must, of course, know the home addresses and names of all the respondents. The FCC staff will give the Field Team a Visit Form (SOP F01 "Field Sampling: General Information") that includes this information along with the date and time of the visit and notes such as special equipment requirements. Individual Field Teams will be responsible for maintaining the privacy of the respondents they visit.

The field packet for each household and Cycle will be kept in a file folder labeled, for example, "Household 123, Cycle 1." The folder for the current Cycle will contain the names and address of the household, directions if any, and appointment information. Before each visit, FCC personnel will prepare a Visit Form for the Field Team. After the last visit of the Cycle, all material with identifying information will be moved to the folder for the next Cycle. Thus this material will be in only one folder: the folder for the next or current Cycle.

6.4 Notes and Reports

Appointment lists and other notes identifying individual respondents, which must be maintained for the duration of data collection, will be kept in the locking file cabinet at the Field Coordination Center. Such records will be destroyed after data collection has been completed, at a time deemed appropriate by the Principal Investigator with consultation from the EPA Principal Collaborator.

Data reported in EPA reports, manuscripts, publications, or other communications will be presented in such a fashion to ensure that no direct link can be made to any individual. This will be ensured primarily through the use of summary and aggregate statistical representations of data. In the case of specific reference to cases, care will be taken to ensure anonymity of the respondent. For example, no specific reference will be made to any datum, including those listed in Section 3.

6.5 Uses of Data

The data collected will not be used for any purpose other than those outlined on the informed consent form. Specifically, the purpose of the project is to identify routes of and factors influencing environmental exposures to certain classes of pollutants. No other use for the data is implied. The informed consent form is under development. It will be completed after finalization of the questionnaires, any modifications to the study design, and approval by the Institutional Review Boards of the appropriate consortium members.

6.6 Access to Data

Data sets turned over to the Environmental Protection Agency will comply with all of these confidentiality requirements. In particular, EPA will not be supplied with the linking list that affords identifying the data collected with any individual. Access to the linking list will be on a need basis. Inquiry and access will be noted and records kept for the lifetime of the linking list. The last entry on that list will be the destruction-of-the-list notification.

7 Quality Assurance Procedures

Not applicable.

8 References

Harvard University/Johns Hopkins University Standard Operating Procedures:

G03 Identification Numbers for Samples and Forms

F01 Field Sampling: General Information