

National Human Exposure Assessment Survey (NHEXAS)

Arizona Study

Quality Systems and Implementation Plan for Human Exposure Assessment

The University of Arizona
Tucson, Arizona 85721

Cooperative Agreement CR 821560

Standard Operating Procedure

SOP-UA-F-23.1

Title: Reimbursement for Field Collection of Diet Samples

Source: The University of Arizona

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.

Reimbursement for Field Collection of Diet Samples

1.0 PURPOSE AND APPLICABILITY

This SOP provides a uniform procedure for the financial reimbursement of primary respondents for their collection of diet samples for the NHEXAS AZ project, the AZ Border Project (BORDER AZ) and other Health and Environment projects. Respondents will be reimbursed for replicate food and beverage samples collected over a 24 hour sampling period.

2.0 DEFINITIONS

- 2.1 AZ BORDER = The US border region is defined as 100 km north of the border. In this study, we define the border as 40 km north of the border. The Arizona Border Study or "Border AZ" is an alias for "Total Human Exposure in Arizona: A Comparison of the Border Communities and the State" conducted in Arizona by the University of Arizona / Battelle / Illinois Institute of Technology Consortium.
- 2.2 BACK-UP FIELD KIT = Each field vehicle carries a box containing back-up forms in case of field implementation problems.
- 2.3 BUCKET = A plastic container with a buckle top or tight-fitting lid. One bucket is assigned to each household to be sampled. Household identification and stage numbers are listed on the outside of the container. The bucket contains all paperwork and questionnaires to be completed by field staff or household respondents. It serves as the primary vehicle for securing and transporting forms, data and samples to and from the field through the course of the study.
- 2.4 CHAIN OF CUSTODY RECORD = A vital data tracking and quality assurance form which is attached to every field sampling data sheet.
- 2.5 COOLER = One of three alternative methods for keeping collected foods at 4°C during and after collection until shipment. "Cooler" may be a 40 quart cooler with reusable ice packs, an electric cooler, or storage in the primary respondent's refrigerator. The choice of cooling agent (cooler) will be determined by the Team Leader as appropriate.
- 2.6 DUPLICATE SAMPLE = A duplicate portion of food consumed by the primary respondent. Duplicate portions will be estimated visually by the respondent and will be approximately identical to the portion consumed in terms of preparation method, ingredients and quantity.
- 2.7 HOUSEHOLD(HH) = The residence occupied by study respondent(s).

- 2.8 HOUSEHOLD IDENTIFICATION NUMBER (HHID) = A unique number and character combination which is assigned to each respondent household for identification purposes. This number must be recorded on all data (forms, samples, questionnaires and correspondence) associated with a study household.
- 2.9 LIQUID FOOD CONTAINER = A high density polyethylene plastic screw-top container. It is used for the collection of the liquid portion of the day composite food sample such as beverages.
- 2.10 MEAL = Any foods consumed by the respondent at a single "sitting". "Meal" includes breakfast, lunch, dinner and snacks, regardless of the quantity consumed.
- 2.11 N/A = Not Applicable.
- 2.12 NHEXAS Arizona = Acronym for National Exposure Assessment Survey, a research project conducted in Arizona by the University of Arizona / Battelle / Illinois Institute of Technology Consortium.
- 2.13 PACKET = A sturdy, envelope-like container that can be fully closed and is large enough to hold the physical data forms generated from sampling and surveying a study household.
- 2.14 SOLID FOOD CONTAINER = A polyethylene re-sealable container. It is used for the collection of the solid portion of the one-day composite sample. Meals are collected in individual freezer Ziploc bags, sealed, and stored in the solid food containers.
- 2.15 TEAM LEADER = The member of the field team who is primarily responsible for respondent contact, data collection, field form and questionnaire completion, and site QC checks of all data.
- 2.16 TWENTY FOUR (24) HOUR FOOD DIARY = A daily data tracking sheet completed by the respondent and used to record specific information regarding food samples collected and stored for the one day dietary composite sample.
- 2.17 VISIT = A scheduled appointment with participating respondents at their place of residence (HH) for the collection of samples, questionnaires and other data.

3.0 REFERENCES

- 3.1 Lebowitz, M.D. 1993. Study Design (Revision of 31 Dec. 1993). EPA NHEXAS Cooperative Agreement.
- 3.2 RTI/5417/02-03 IG. 1993. *Procedure for collection, storage and shipment of home contact duplicate diet food and beverage samples for metal contaminants* in Guidelines

for Measuring Personal Dietary Exposure to Environmental Contaminants.

4.0 DISCUSSION

- 4.1 This SOP outlines the correct procedure used to reimburse respondents for their participation in the duplicate food diary collection portion of the NHEXAS AZ project, the AZ Border Project (BORDER AZ) and other Health and Environment projects. The Team Leader arranges for reimbursement once the HH has agreed to collect food. Respondents are currently paid \$15 in advance for duplicate diet collection.
- 4.2 The Team Leader will notify the Field Coordinator of any homes where the primary respondent has agreed to collect the 24 hour duplicate diet. The Field Coordinator will then arrange for the funds (currently \$15) to be drawn from the diet reimbursement account and give the funds to the Team Leader. The Field Coordinator will record specific information regarding the disbursement on the Subject Payment Log (Figure 1). The Team Leader will sign a hand receipt (Figure 2) for the amount received and accept custody/responsibility for the cash.
- 4.3 Once in the Field, the Team Leader will give the cash to the respondent and the respondent will be asked to sign a hand receipt for the amount (Figure 2). The receipt will be returned to the Field Coordinator and filed in the confidential HH packets located in the locked file cabinets in the Field Coordinators office.
- 4.4 Beverage duplicate portions are not collected in for the AZ Border project.

5.0 RESPONSIBILITIES

- 5.1 The Team Leader is responsible for:
- (a) arranging sampling dates and times with the HH;
 - (b) notifying the Field Coordinator of any impending HH visits requiring food reimbursement funds;
 - (c) forwarding the amount of reimbursement to the respondent;
 - (d) obtaining a signed receipt from the respondent once the cash is disbursed;
 - (f) forwarding the signed receipt to the Field Coordinator upon return to the Field Office.
- 5.2 All Team Members are responsible for:
- (a) witnessing the transfer of funds to the respondent;
 - (b) signing the hand receipt as a witness when the transfer is complete;

5.3 The Field Coordinator is responsible for:

- (a) arranging for funds availability once notified by the Team Leader;
- (b) documenting the payment on the Advance Subject Payment Log (Fig 1);
- (c) generating the Hand Receipt (Fig. 2) and forwarding it with the cash to the Team Leader;
- (d) archiving completed hand receipts once returned from the field in the confidential HH Files.
- (e) completing in field QA audits of the diet collection and reimbursement procedure in 10% of all HH visits.
- (f) arranging for additional operational advances to replenish the Diet Reimbursement Account as funds are disbursed.
- (g) maintaining all bank account summaries and statements;

5.4 The CO-Principal Investigator is responsible for;

- (a) performing a quarterly review or audit of the diet reimbursement records maintained by the Field Coordinator.

6.0 MATERIALS AND REAGENTS

6.1 Materials

ADVANCE SUBJECT PAYMENT LOG. (Fig 1.)
REIMBURSEMENT FOR FIELD COLLECTION OF DIET SAMPLES HAND
RECEIPT.(Fig 2.)

6.2 Reagents - N/A

7.0 PROCEDURE

7.1 Preparation

7.1.1 Field Site Selection Criteria - N/A

7.1.2 Reagents - N/A

7.1.3 Standards & Blanks - N/A

7.1.4 Disbursement Preparation

- (a) The Team Leader coordinates with the HH for duplicate diet collection at least seven days in advance of the first HH visit.
- (b) The Team Leader notifies the Field Coordinator of the need for diet reimbursement funds.
- (c) The Field Coordinator withdraws the necessary funds from the diet reimbursement account and completes the documentation used to track funds disbursement (Figure 1) and (Figure 2).
- (d) The funds are forwarded to the Team Leader in US Currency. The Team Leader signs a Hand Receipt for the reimbursement amount.

7.1.5 Diet Reimbursement Account Replenishment

- (a) The Field Coordinator submits the original copies of the Subject Payment Log (Figure 2) to the departmental administrative assistant with a memo requesting that additional funds be disbursed to replenish the account.
- (b) A photocopy of the memo and the pages of the log are maintained by the Field Coordinator.
- (c) Funds are typically deposited in the account within 30 days of a request for replenishment.

7.2 In Field Reimbursement

- (a) The Team Leader instructs the Respondent on how to collect the duplicate diet samples in accordance with SOP UA-F-15.X.
- (b) The Team Leader gives the cash (usually \$15) to the respondent on the day that the instructions are given. The amount disbursed is recorded on the receipt.
- (c) Pre-payment for food samples is intended to prevent financial burden on respondents who agree to participate in the duplicate diet portion of the project.
- (d) The Team Leader stresses that it is essential that respondents eat their 'usual meals' when collecting the duplicate portion of their diet.
- (e) It is critical the sample collected is reflective of the 'normal' diet of the respondent. The Team Leader explains that pre-payment is intended to offset financial burden rather than pay for a 'free meal' at a restaurant that participants would not usually eat in.
- (f) Request that the respondent sign the attached receipt for the amount owed. Team Leaders will be held responsible for any funds disbursed without first obtaining a signed hand receipt.
- (g) A second field team member witnesses the transfer of funds and signs the hand receipt.
- (h) The Team Leader must submit the signed Hand Receipt with the rest of the household packet to the Field Coordinator for QA review.

POST FIELD ACTIVITIES

- (i) The Field Coordinator files the Hand Receipt in the Confidential File Folders maintained in locked file cabinets in the Field Coordinators Office.
- (j) The Field Coordinator verifies disbursement in 10% of all HH where duplicate diet collection is completed through a follow-up telephone call to the participating respondent.

7.3 Calculations

7.3.1 If participants are collecting the 24 hour duplicate diet portion, they are reimbursed \$15.

7.4 Quality Control

- (a) Field Teams consist of 2 - 3 Team Members assigned to different tasks while in the HH. At least one Team Members needs to witness the transfer of funds from the Team Leader to the Respondent and sign the Hand Receipt.
- (b) The Field Coordinator verifies transfer from Team Leader to respondent through a follow-up telephone call to the participating respondent or guardian.
- (c) The CO-Principal Investigator and Administrative Assistant audit the diet reimbursement records maintained by the Field Coordinator.

7.4.1 Tolerance Limits - N/A

7.4.2 Detection Limits - N/A

7.4.3 Corrective Actions

Apparent mis-labeling problems detected in the field may be corrected by the Team Members when appropriate and in accordance with SOP #UA-C-2.X.

8.0 RECORDS

8.1 Advance Subject Payment Log (Figure 1).

This log records critical tracking and disbursement data for the field collection of duplicate diet samples. The log is maintained by the Field Coordinator and is subject to periodic audits by the project CO-Principal Investigator.

8.2 Reimbursement for field collection of diet samples hand receipt (Figure 2).

This receipt is generated by the Field Coordinator once the funds have been drawn from the diet reimbursement account. The Team Leader signs the receipt when accepting custody of the cash. A second team member signs the receipt as a witness to the transfer of funds between the Team Leader and the respondent.

Figure 2. Reimbursement for Field Collection of Diet Samples - Hand Receipt.

NHEXAS AZ DIET REIMBURSEMENT RECEIPT			
Respondents First Name: _____		IRN# _____	HHID: _____
<input checked="" type="checkbox"/> 24 Hour Duplicate Diet Collection		RECEIPT# _____	
Reimbursement Funds Custody			
Field Coord. _____	Sig. _____	Date: ____/____/____	
Team Leader: _____	Sig. _____	Date: ____/____/____	
<p>Respondent, Please read and sign below:</p> <p>I certify that I have received payment of _____ dollars as reimbursement for a 24 Hour Duplicate Diet sample of foods and beverages. I realize that the food and beverage samples will not be returned to me after analysis for metals and pesticides in accordance with the NHEXAS research project at the University of Arizona.</p> <p>Respondent (Or Guardian) Full Name: _____ Date: ____/____/____</p> <p>Respondent (Or Guardian) Signature : _____</p>			
FEES FROM STATE AGENCIES			
<p>The purpose of this statement is to determine whether the University is required to report your reimbursement to state and federal agencies for income tax reporting purposes:</p> <p><input type="checkbox"/> I have not received payment for fees from any Arizona State agencies this calendar year, nor do I expect to receive payment for fees from any Arizona State agencies this calendar year. I also certify that I do not expect to receive payment as a result of my participation in other UofA research studies this calendar year.</p>			

Figure 3. Relative Timing of Sample Collection (page 1 of 3).

Sample Collection: Relative Timing

Stage 1 (n=300)

Questionnaires:

Descriptive

Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
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Stage 2 (n=125)

Questionnaires:

Descriptive Update
Baseline
Diet Diary *
Time / Activity *
Technician
Supplement

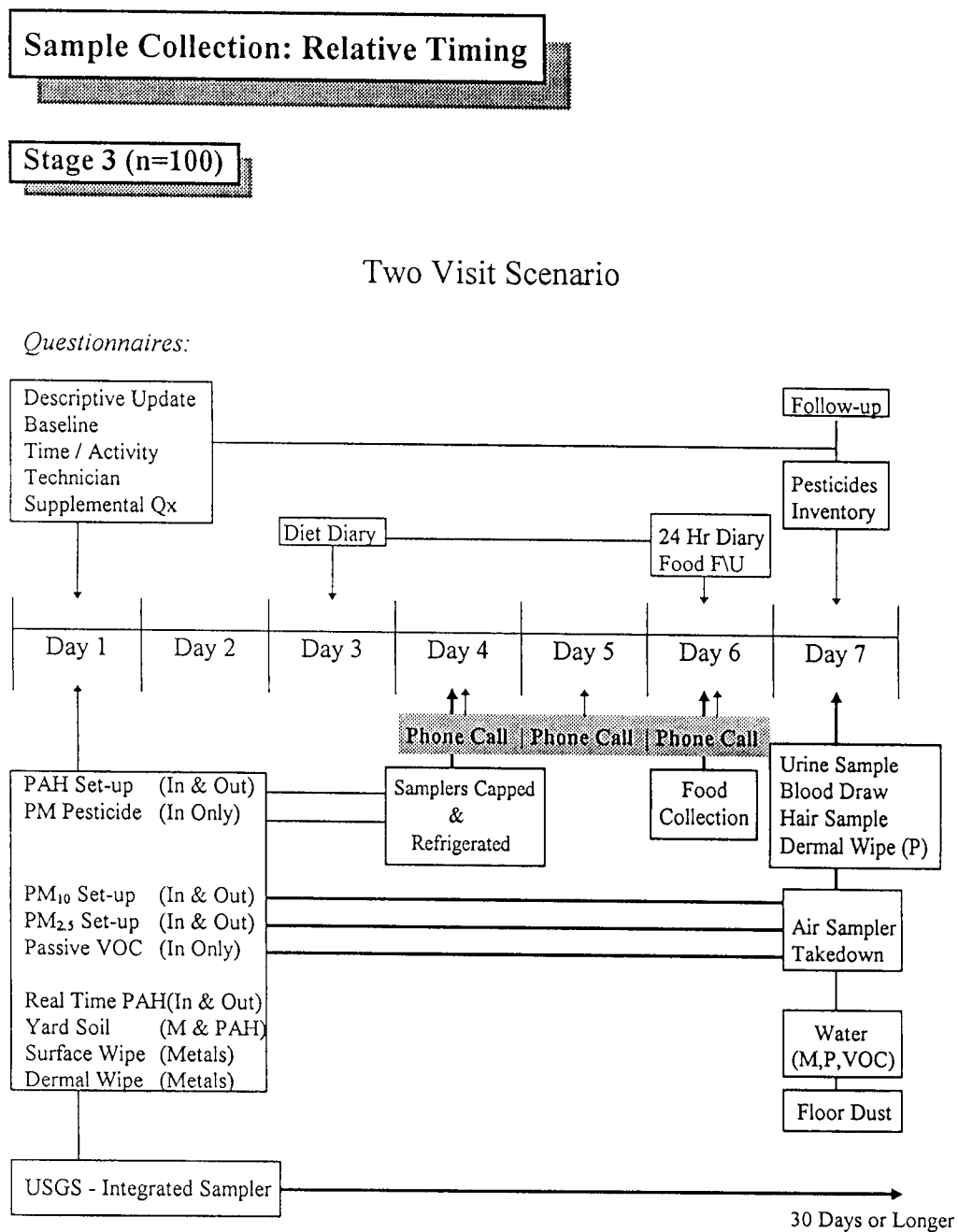
* One day recall

Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
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Sample Collection:

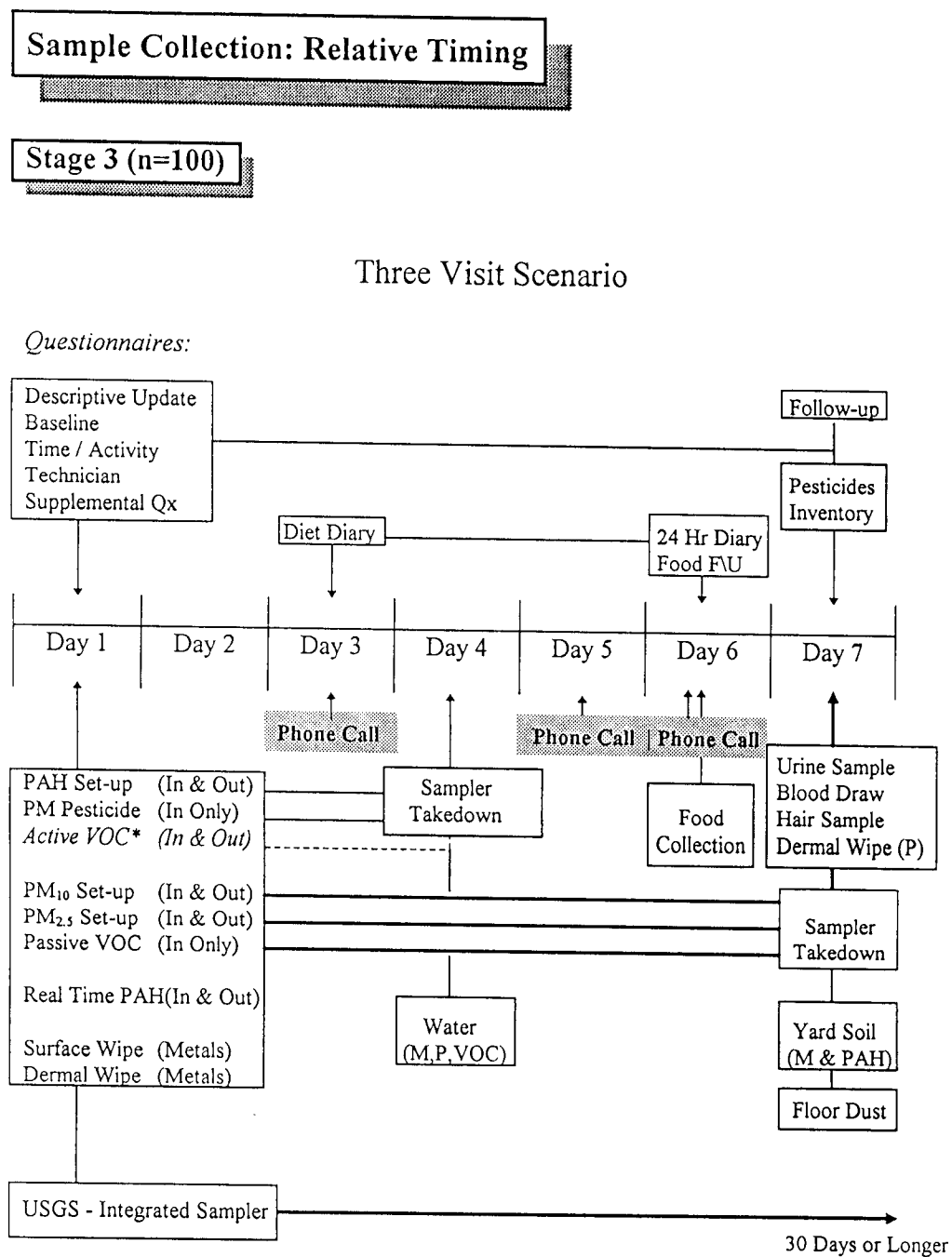
Yard Soil
Floor Dust

Figure 3. Relative Timing of Sample Collection (page 2 of 3).



* Active VOC is collected in a subset of 25 homes only

Figure 3. Relative Timing of Sample Collection (page 3 of 3).



* Active VOC is collected in a subset of 25 homes only

Figure 4. Field Notes and Troubleshooting Guide

No field notes or Troubleshooting guides are currently on record for UA-F-23.1. Additions will be appended and the SOP reviewed and updated in accordance with UA-G-1.X as appropriate.