



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-C-5.0

Title: Flow and Custody of Field Data Forms

Source: The University of Arizona

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

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Flow and Custody of Field Data Forms

1.0 Purpose and Applicability

This SOP describes the flow of field data forms through the data processing system and defines who is responsible for the data at any time. It applies to field data forms collected and processed by NHEXAS Arizona. Border and other Health + Environment Projects.

2.0 Definitions

- 2.1 BACKUP: (v.) The process of creating a duplicate of a file, directory, or drive to protect against data loss during a hardware or software failure. (n.) The duplicate copy created during this process.
- 2.2 BUCKET: A plastic container with a buckle top. One bucket is assigned to each household to be visited. HHID and visit number are listed on the outside of the container. The container holds all paperwork to be completed by field staff or household residents through a series of household visits.
- 2.3 DATA CLEANING: The process of locating and correcting data processing errors. They can be individual level errors in the electronic and physical data, or they can be system level errors in the data collection, packaging, coding, entry, and cleaning procedures themselves. This process is also referred to as "data validation."
- 2.4 DATA, ELECTRONIC: Data stored on some type of magnetic or optical medium (for example: floppy disk, hard disk, bernoulli, tape).
- 2.5 DATA PROCESSING BATCH (DP BATCH): A collection of household packets or physical data forms reviewed for quality assurance and ready for data entry. Each DP batch is assigned a unique numeric or alphanumeric code that is written on all forms in the DP batch and is entered into the database corresponding to that form.
- 2.6 DATA, VERIFIED: Electronic data that was re-entered into the same table and database into which it was originally entered, and compared against the original entered values.
- 2.7 FORM, PHYSICAL: The paper or "hard copy" version of a data form. This is also referred to as a "physical data form."
- 2.8 HOUSEHOLD: The residence occupied by study respondents.
- 2.9 HOUSEHOLD IDENTIFICATION NUMBER (HHID): A unique identification number assigned to a study household containing subjects.
- 2.10 HRP SITE: The Health Related Professions building, located at 1435 North Fremont Avenue; Tucson, AZ 85719. This is an annex of the Respiratory Sciences Center and the primary site of operations for NHEXAS Arizona.

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- 2.11 INDIVIDUAL RESPONDENT NUMBER (IRN): A number assigned to subjects in a household based on age. Subjects are ranked by age in order of oldest to youngest. The oldest participant is assigned an IRN of 1, the second oldest is assigned an IRN of 2, and so on. Individual subjects are identified by an HHID IRN combination number.
- 2.12 KEYPUNCH: A primary area in which data entry and data verification of NHEXAS Arizona field data takes place. It is located in the Respiratory Sciences Center, Room 2329; Arizona Health Sciences Center (AHSC); 1501 N. Campbell Avenue; University of Arizona; Tucson, AZ 85724. Data are also entered and verified at the HRP site (see above).
- 2.13 LOGBOOK: The notebook where all documentation of the arrival and departure of individual physical forms within a household packet is kept.
- 2.14 NHEXAS Arizona: Acronym for National Human Exposure Assessment Survey, a research project conducted in Arizona by the University of Arizona/Battelle/Illinois Institute of Technology consortium.
- 2.15 PACKET: A sturdy, envelope-like container that can be fully closed and is large enough to hold the physical data form(s) generated by a study household, laboratory, research site, or data processing batch. One type of packet is used for one type of physical data forms (eg., manila envelopes would be used for all lab forms processed at the HRP site). Packets are either color coded, labeled according to their contents, or both. What are referred to as "household packets" are relevant to this SOP (see PACKET, HOUSEHOLD below).
- 2.16 PACKET, HOUSEHOLD: A packet containing the physical data forms generated from sampling and surveying a study household.
- 2.17 PACKET PREP: def (1) personnel in this part of the project prepare material for use in the field. This includes (a) pre printing labels (b) assembling all data forms and questionnaires to be completed (c) assigning equipment for field use; def (2) location in the building where packet assembly is performed.
- 2.18 QA = QUALITY ASSURANCE: All those planned and systematic actions necessary for ensuring the validity, integrity, preservation and retrievability of the data.
- 2.19 QC = QUALITY CONTROL: Those quality assurance actions providing a means to control and measure the characteristics of an item, process, or the establishment of requirements.
- 2.20 RESPONDENT: A person in the study population of NHEXAS Arizona. Each family is assigned an HHID. Within a family respondents are assigned Individual Respondent Numbers (IRN). Each respondent is identified by an HHID IRN combination number. Respondents are also referred to as subjects.

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- 2.21 STUDENT DATA PROCESSING: The area of the HRP site in which one or more Student Data Assistants enter, verify, clean, validate, and/or QA check post-field data.
- 2.22 TEAM LEADER: Leader of a field team responsible for subject contact, scheduling field visits, collection of data, and completion of all field forms and questionnaires.
- 2.23 TEAM MEMBER: Member of a field team responsible for assisting the team leader in the collection of data and quality control checks in the field.
- 2.24 TRACKING = the method of determining where a data batch is in the data system and what procedures were performed on the data.
- 2.25 TRACKING DATABASE: A database system containing information about the custody, transfer, and storage of hard copy data, electronic data, field samples, and field sample alloquats.

3.0 References

None

4.0 Discussion

In order to minimize the potential for misplacement or loss of field data, it is critical to have a chain of custody plan. With clear documentation of who or what has custody at any given time, one can easily pinpoint the current location of both physical and electronic field data.

5.0 Responsibilities

- 5.1 Materials Technician
 - 5.1.1 Assembles forms (blank) to be used in the field
 - 5.1.2 Transfers assembled forms (blank) to Team Leaders

5.2 Team Leader

- 5.2.2 Maintains custody of all field forms and questionnaires while in the field.
- 5.2.3 Transfers all completed field forms and questionnaires to Project Field Coordinator for intermediate and final QA checks.
- 5.2.4 Resolves problem(s) on any field forms and questionnaires that failed intermediate QA checks.
- 5.3 Project Field Coordinator (or Delegate)

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- 5.3.1 Receives completed field forms and questionnaires from Team Leader.
- 5.3.1 Performs intermediate and final QA checks on completed field forms and questionnaires (see SOP# UA-C-2.0).
- 5.3.2 Assembles completed household packets.
- 5.3.3 Completes "HHID Report" form (Figure 4) for each household packet, and inserts it into the packet.
- 5.3.5 Completes the field section of the "Household Packet Transfer Log" (Figure 3) for each household packet ready for transfer to the Project Data Coordinator.
- 5.3.4 Transfers household packets listed on the "Household Packet Transfer Log" to the Project Data Coordinator.
- 5.4 Project Data Coordinator (or Delegate)
 - 5.4.1 Receives completed household packet(s) from the Project Field Coordinator.
 - 5.4.2 Completes the appropriate areas of the "Household Packet Transfer Log" (Figure 3) for all instances of household packet custody transfer between the field section and the data section.
 - 5.4.3 Maintains custody of household packets (or physical form(s) contained therein) after their transfer from the Project Field Coordinator and prior to their transfer to storage, with the exception of any duration at either Keypunch or Student Data Processing.
 - 5.4.4 Compares the "HHID Report" in each household packet with the packet's actual contents and reports any discrepancies to the Project Field Coordinator. If no discrepancies, then she or he writes initials and current date in "received by" area of "HHID Report."
 - 5.4.5 Reviews contents of each household packet for completion of QA check; for any packet lacking complete QA checks on all forms, he or she transfers custody of packet(s) to Project Field Coordinator. If the latter occurs, then he or she completes the appropriate section of the "Household Packet Transfer Log" indicating a return of packet(s).
 - 5.4.6 Completes appropriate sections of the batch custody form, including assignment of the DP batch code.
 - 5.4.7 Makes a photocopy of the batch custody form for records prior to batch transport to Keypunch.
 - 5.4.8 Transports the batch to Keypunch and transfers custody in person.

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- 5.4.9 Receives a photocopy of the signed batch custody form from Keypunch at the time of batch delivery.
- 5.4.10 Retrieves both the physical and electronic DP batches from Keypunch.
- 5.4.11 Installs empty databases on computer(s) accessible by Keypunch personnel in anticipation of the next DP batch deliveries.
- 5.4.12 Assigns data cleaning, validation, and filing tasks to Student Data Assistant(s).
- 5.4.13 Verifies the filing of the physical forms and questionnaires in the appropriate storage unit(s).
- 5.4.14 Replaces the photocopy of the batch custody form with the completed original batch custody form in the "Data Processing Batch Sheets" notebook.
- 5.4.15 Forwards the validated electronic data batch to the Project Data Manager for update of the master database.

5.5 Student Data Assistant(s)

- 5.5.1 Maintains custody of both physical and electronic DP batches for the duration of data cleaning, validation, electronic QA checks, and filing of the physical data forms.
- 5.5.2 Writes initials and current date on batch custody forms at the appropriate custody transfer junctures.
- 5.5.3 Completes "append form" when a DP batch is cleaned, validated, and ready for appendage to the master database (see SOP# UA-D-16.0).

5.6 Keypunch

- 5.6.1 Receives DP batches by signing batch custody forms and completing "Household Packet Contents Log" in the Logbook (see SOP# UA-C-6.0).
- 5.6.2 Codes, enters, and verifies data and completes batch tracking form at each stage.
- 5.6.3 Notifies the Project Data Coordinator when the batch is completed.
- 5.6.4 Notifies the Project Manager if the batch is not picked up within one week.

5.7 Project Data Manager

5.7.1 Creates master database(s) and defines them with the appropriate dictionary programs.

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- 5.7.2 Updates, appends and corrects master databases and completes documentation associated with such appendages and/or corrections.
- 5.7.3 Analyzes data files as per instruction of the On-Site Principal Investigator.
- 5.8 On-Site Principal Investigator: Oversees all aspects of the project at HRP.

6.0 Materials and Reagents

6.1 Materials

- 6.1.1 Computers linked to the HRP Local Area Network as described in UA-D-1.0.
- 6.1.2 Batch Custody Form for physical data forms (Figure 1).
- 6.1.3 Raw Database Retrieval Form (Figure 2).
- 6.1.4 "Household Packet Transfer Log" form(s) (Figure 3): This form serves as a record of household packet custody transfer between the Project Field Coordinator and the Project Data Coordinator.
- 6.1.5 "HHID Report" form(s) (Figure 4): This form summarizes the contents of a household packet and serves as the custody transfer record for the individual forms and questionnaires contained in the packet; it is inserted into the household packet prior to transferring custody to the Project Data Coordinator. It may be generated via the tracking database.
- 6.2 Reagents (Not Applicable)

7.0 Procedure

- 7.1 Preparations (Not Applicable)
- 7.2 Standards and Blanks (Not Applicable)
- 7.3 Procedure Description

The following section describes who is responsible for the data at a given stage. The data flow is listed sequentially and the responsible party(ies) is (are) identified in boldface capital letters. A diagrammatic representation is presented in Figure 5.

7.3.1 The MATERIALS TECHNICIAN (or delegate) assembles all blank forms needed for a series of field visits to a study household. The forms are placed in the bucket assigned to the household and and given to the TEAM LEADER.

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- 7.3.2 The TEAM LEADER disperses blank questionnaires, collects completed questionnaires, completes field sampling forms, and passes them to the PROJECT FIELD COORDINATOR.
- 7.3.3 The **PROJECT FIELD COORDINATOR** assembles forms and questionnaires into a packet(s) representative of data gathered in the home, performs intermediate and final QA checks, and transfers form(s) failing QA checks to **TEAM LEADER**.
- 7.3.4 TEAM LEADER resolves problem(s) on form(s) failing QA checks and transfers them back to the PROJECT FIELD COORDINATOR.
- 7.3.5 The **PROJECT FIELD COORDINATOR** provides final QA checks on the physical data forms. Each form is dated and initialed in the "FOR OFFICE USE ONLY" box on the form. She or he then transfers the packets to the **PROJECT DATA COORDINATOR**.
- 7.3.6 The PROJECT DATA COORDINATOR reviews contents of each household packet for completion of QA checks; for any packet lacking complete QA checks on all forms, he or she transfers custody of packet(s) back to PROJECT FIELD COORDINATOR. Once QA checks are completed, the packet(s) is transferred back to the PROJECT DATA COORDINATOR.
- 7.3.7 The PROJECT DATA COORDINATOR compares the "HHID Report" in each household packet with the packet's actual contents. If any discrepancies are found, then the packets are transferred back to the PROJECT FIELD COORDINATOR. Once all forms in packet(s) are accounted for on the "HHID Report" form(s), the packet(s) is transferred back to the PROJECT DATA COORDINATOR.
- 7.3.8 The PROJECT DATA COORDINATOR prepares the DP batch(es) and the batch custody form (Figure 1). APPENDEX A 1/21/15
- 7.3.9 The PROJECT DATA COORDINATOR delivers DP batch(es) to KEYPUNCH and signs the batch custody form after "to Keypunch."
- 7.3.10 KEYPUNCH personnel log the DP batch(es) into the Logbook maintained by Keypunch staff.
- 7.3.11 **KEYPUNCH** personnel code the data according to coding protocols provided by the **PROJECT DATA COORDINATOR**. The "Coding, Data Entry, and Data Verification Log" form is dated and initialed after "Coded by" (see UA-C-6.0).
- 7.3.12 **KEYPUNCH** personnel enter the data on data screens provided by the **PROJECT DATA COORDINATOR**. The "Coding, Data Entry, and Data Verification Log" form is dated and initialed after "Entered by" (see UA-C-6.0).
- 7.3.13 **KEYPUNCH** personnel re-enter or verify the data. The "Coding, Data Entry, and Data Verification Log" form is dated and initialed after "Verified by" (see UA-C-6.0).

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- 7.3.14 **KEYPUNCH** personnel notify the **PROJECT DATA COORDINATOR** that the physical and electronic DP batches are ready to be picked up and the batch custody form is dated and initialed (after "Called for pick-up)."
- 7.3.15 **KEYPUNCH** personnel photocopy the completed batch custody form and mail it to the **PROJECT DATA COORDINATOR**.
- 7.3.16 The **PROJECT DATA COORDINATOR** retrieves the physical forms (batches) and corresponding electronic data (batches) and completes the batch custody form (Figure 1) and the "Raw Database Retrieval Form" (Figure 2).
- 7.3.17 The PROJECT DATA COORDINATOR assigns data cleaning and QA tasks to one or more STUDENT DATA ASSISTANTS.
- 7.3.18 The PROJECT DATA COORDINATOR receives validated electronic data from the STUDENT DATA ASSISTANTS. This data is backed up both on and off system on the file back-up bernoulli in the PROJECT DATA COORDINATOR's office.
- 7.3.19 The PROJECT DATA COORDINATOR receives the batch custody forms and assigns the STUDENT DATA ASSISTANTS the task of filing the packets or physical data forms making up the batch. The batch custody form is dated and initialed after "Filed by".
- 7.3.20 The **PROJECT DATA COORDINATOR** curates the batch custody forms in a notebook.
- 7.3.21 The PROJECT DATA COORDINATOR curates a back up of the validated, electronic DP batches off of the LAN system.
- 7.3.22 The PROJECT DATA COORDINATOR provides the PROJECT DATA MANAGER with a copy of the validated electronic data.
- 7.3.23 The **PROJECT DATA MANAGER** creates and maintains master databases with with the validated electronic data.
- 7.3.24 The **PROJECT DATA MANAGER** analyzes files or provides analysis files to the **ON-SITE PRINCIPAL INVESTIGATOR**.
- 7.4 Calculations (Not Applicable)
- 7.5 Special QA Checks

7.5.1 Tolerance Limits

(a) All data forms and questionnaires within a household packet should be fully QA checked by the Project Field Coordinator. The Project Data Coordinator reviews the contents of all transferred packets for the occurrence of full QA checks. Any packet failing the review will be returned to the Project Field Coordinator for QA completion.

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- (b) All data forms and questionnaires within a household packet should be accounted for on the "HHID Report" form. The Project Data Coordinator compares the contents of each transferred packet with the information provided on the "HHID Report" form. Any packet lacking forms or containing forms not accounted for on the report form will be returned to the Project Field Coordinator for packet completion and/or revision of "HHID Report" form.
- (c) DP batches are supposed to be transported to Keypunch on a certain day of each week. A maximum of five business days beyond the original scheduled day of transport is allowable under special circumstances. The latter includes insufficient trained personnel, lack of transportation, and questionable data forms.
- (d) Physical and electronic DP batches are supposed to be retrieved from Keypunch within one week of notification that they are ready. A maximum of five business days beyond the original scheduled day of retrieval is allowable under special circumstances. The latter includes insufficient trained personnel, lack of transportation or electronic storage media, and malfunctioning of LAN or pertinent computer hardware/software.

7.5.2 Detection Limits

- (a) For the processes outlined in this SOP that must occur within a certain time frame, all deviations are detectable via the batch custody forms.
- (b) For the custody transfers of physical data, all errors are detectable because the person representing a link in the chain of custody verifies the claim(s) of the person representing the previous link. This is an independent verification of both the key variable(s) and the presence or absence of physical data.
- (c) Any error(s) in key variable(s) originating with the Team Leader(s) that went undetected by the Project Field Coordinator will unfortunately be passed through the entire chain of custody, unless discovered by field staff.

7.5.3 Corrective Actions

(a) If the transport of a DP batch to Keypunch exceeds five business days beyond the original scheduled day of transport, then the reason(s) for lack of transport will be addressed immediately. If the usual trained personnel are absent, then the On-Site PI will select someone to perform the job. If usual transportation is unavailable, then the UA shuttle bus or other state vehicle will be used. If the

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data forms to be sent are questionable, then the DP batch will be voided and the data forms sent at a later date, with a different DP batch code.

If the retrieval of a DP batch from Keypunch exceeds five (b) business days beyond the original scheduled day of retrieval, then the reason(s) for lack of retrieval will be addressed immediately. If the usual trained personnel are absent, then the On-Site PI will select someone to perform the job. If usual transportation is unavailable, then the University of Arizona shuttle bus or other state vehicle If the LAN or pertinent computer will be used. hardware/software are malfunctioning, then data will be retrieved manually via floppy disks if possible. If this is impossible, then data will be retrieved from tape backup(s). If this is impossible, then we will have to wait until pertinent equipment is fixed or otherwise resumes its normal functioning.

8.0 Records

- 8.1 The "Batch Custody Form" (Figure 1) is filed in the "Data Processing Batch Sheets" notebook in the Project Data Coordinator's office, University of Arizona, Tucson AZ.
- 8.2 The "Raw Database Retrieval Form" (Figure 2) is filed in a tracking notebook in the Project Data Coordinator's office, University of Arizona, Tucson AZ.
- 8.3 The "Household Packet Transfer Log" forms are filed in a place commonly accessible to both the field and data sections.
- 8.4 Completed "HHID Report" forms are filed in the Project Data Coordinator's office.

Figure 1: Example of "Batch Custody Form"

	E	затен ец	STODY E	FORM; DE	batch	#				
Ple	ase date,	initial	and ch	eck box	œs:					
D 7	ATA EN	TRY								
		pickur inch: DP: DP: iled:		ched to	By: By: By: By: By: By: By: batch:		Received By: Received By: Received By: Deceived By:			
HOUSEHOLD PACKETS OR FORMS										
	Key Variables	To KP	At KP	To HRP	To SDP	To Files	Comments:			
1		[]	[]	[]	[]	[]				
2		[]	[]	[]	[]	[]				
3		[]	[]	<u>[/]</u>	[]	[]				
4		[]	[]	[]	[]	[]				
5		[]	[]	[]	[]	[]				
6		[]	[/]	[]	[]	[]				
7		[]	[]	[]	[]	[]				
8	 	[]	[]	[]	[]	[]				
9		[/	[]	[]	[]	[]				
10		[]	[]	[]	[]	[]				
11	<i> </i> -	[]	[]	[]	[]	[]				
12		[]	[]	[]	[]	[]				
13		[]	[]	[]	[]	[]				
14		[]	[]	[]	[]	[]				
15	/	[]	[]	[]	[]	[]				
/	7	للعن	لانبو	KPP.	Way.	* L	Form ID: UA-C-4.0-1.0			
	\			•	•	12	11/N2 1			

Figure 2: Example of "Raw Database Retrieval Form"

RAW DATABASE RETRIEVAL FORM: PURPLE PACKETS

DP Batch	#:
Keypunch	Notification Date: / / *
* Complete	e steps one through three below within five working days of this notification date.

DATABASE	(1) MOVE TO WORKSTOR DIRECTORY ON IPOMEA	(2) MAKE A TEMPORARY BACK UP COPY	(3) INSTALL EMPTY DATABASE ON SCORAZ
HOUSE4	by:	by:	by:
HOUSE4	by:	by:	by:
HOUSE4	by:	by://	by:
DUSTMIT	by:	by:	by:
DUSTMIT	by:	by:	by://
DUSTMIT	by: on://	by:	by:/
TECH4	by:	by:	by:
FIELD4	by:	by:	by:
FIELD4	by:	by:	by:/
CHECK4	by:	by:	by:/
	by:	by:	by:/
	by:	by:	by:
	HOUSE4 HOUSE4 HOUSE4 DUSTMIT DUSTMIT TECH4 FIELD4 FIELD4	DATABASE WORKSTOR DIRECTORY ON IPOMEA	DATABASE WORKSTOR DIRECTORY ON IPOMEA DY:

Figure 3: Example of "Household Packet Transfer Log"

Household Packet Transfer Log

field / data QA or Inc Return Date Data Init Field Init Resubmit Date From Data to Field (as applicable) Returned z Z Z Z z z Z Z z z z Z z Z z z Z z > > \succ > \succ \succ > \succ Data Init Field Init From Field to Data Date Stage HHID

FORM ID = UA-C3.0-2.0

Figure 4: Example of "HHID Report" form

Figure 5: Field Data Flow Chart

```
PRINCIPLE AND
                        ON-SITE PRINCIPLE
                        INVESTIGATORS
data process
complete
                        PROJECT DATA
                        MANAGER
                            х
                            х
                            x
                        PROJECT DATA 0 0 0 0 0 0 0 0 0 0 0 STUDENT DATA
                        COORDINATOR x x x x x x x x x x x x
                                                               ASSISTANTS
                                                                   * o
                            ох
                                                                    * 0
                                                                     * 0
                            ОХ
                         KEYPUNCH
                                                                  PHYSICAL
                                                                     FORMS
                            0
                                                                     FILED
                            0
                        PROJECT DATA
                         COORDINATOR
                        PROJECT FIELD
                         COORDINATOR +
                    MATERIALS
                                             + TEAM LEADER
                   TECHNICIAN + +
forms
                                                       TEAM MEMBER(S)
                                     SUBJECT(S)
originate
```

```
Figure 4. Chart exhibiting flow of data.

+ + + + = Flow of forms

* * * * = Flow of packets

0 0 0 0 = Flow of batches

x x x x = Flow of electronic data batches

- - - - = Flow of analysis files derived from data
```

Appendix A: Batch Description and Custody Records

BATCH DESCRIPTION AND CUSTODY RECORD

2. DP Batch: Date 3. Forwarded to: 4. Forwarded by: Tech. ID Init. O Student DP (HRP) 5. Received on: O Keypunch (Main Dept.)... Other..... 6. Filed on: Init. HHID F.S. Date IRN To Processing From Processing File (If app.) Receive Forward 1. 2. 3. 4. 5. 6. 7. 8. 9. 10. 11. 12. 13. 14. 15.

1. Form: