The Arizona Border Study

An Extension of the
Arizona National Human Exposure Assessment Survey (NHEXAS)Study
Sponsored by the Environmental Health Workgroup of the Border XXI Program

Quality Systems and Implementation Plan for Human Exposure Assessment

The University of Arizona
Tucson, Arizona 85721

Cooperative Agreement CR 824719

Standard Operating Procedure **SOP-UA-C-8.0**

Title: Flow and Custody of University of Arizona Laboratory Data

Source: The University of Arizona

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

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~~NHEXAS Arizona Project~~

Title: **FLOW AND CUSTODY OF UNIVERSITY OF ARIZONA LABORATORY DATA**	
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	1	2	3	4	5	6

Form TP-1

FLOW AND CUSTODY OF UNIVERSITY OF ARIZONA LABORATORY DATA

1.0 Purpose and Applicability

This SOP describes the flow and custody of laboratory data generated by NHEXAS ~~Arizona~~ Border and Other Health + Environment through data processing and delivery to the Project Data Manager for creation of the master database (SOP# UA-D-27).

ESG 7.14.97

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.

2.3 DATA, ELECTRONIC = Data stored on some type of magnetic or optical medium (for example: floppy disk, hard disk, bernoulli, tape)

2.4 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.

2.5 DATA CLEANING = This is the 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."

2.6 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.

2.7 DATA + C = Lab Data plus the custody form of that lab data set. The giver and receiver of lab data must make certain the chain of data custody is unbroken.

2.8 FORM, PHYSICAL = This is the paper or "hard copy" version of a data form. This is also referred to as a "physical data form."

2.9 INDIVIDUAL RESPONDENT NUMBER (IRN) = A number assigned to a subject in a household based on recruitment status and age. Individual subjects are identified by a HHID IRN combination number.

2.10 NHEXAS Arizona = Acronym for **N**ational **H**uman **EX**posure **A**ssessment **S**urvey conducted in Arizona by the University of Arizona/Battelle/Illinois Institute of Technology consortium.

2.11 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 "lab packets" are relevant to this SOP (see PACKET, LAB below).

2.12 PACKET, LAB = A packet containing a DP batch of one type of physical data form generated during laboratory analysis or from non-household research sites.

2.13 TEAM LEADER = Field team member responsible for subject contact, scheduling field visits, collection of data, completion of all field forms and questionnaires, QA & QC checks on forms and samples.

2.14 RESPONDENT = A person in the study population of NHEXAS Arizona.

2.15 SAMPLE + C = Physical sample plus the sample custody form. Each time a sample is transferred, the giver and receiver must sign and date the form. The chain of custody must never be broken.

2.16 TEAM MEMBER = Field assistant under the direction and supervision of the team leader.

2.17 TRACKING = the method of determining where a data batch is in the data system and what procedures were performed on the data.

2.18 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 (Not Applicable)

4.0 Discussion (Not Applicable)

5.0 Responsibilities

5.1 Project Laboratory Supervisor

5.1.1 Receives samples and custody forms from the Project Field Coordinator.

5.1.2 Assigns laboratory tasks to Laboratory Technicians.

5.1.3 Receives data forms from Laboratory Technicians.

5.1.4 Performs QC and QA checks on laboratory data forms.

5.1.5 Is responsible for maintaining a copy of every lab form given to the Data Coordinator in the Project Lab Notebook for each sample type analyzed.

5.1.6 Prepares "Lab From Transfer Log" form(s) and delivers original physical data forms to the Project Data Coordinator.

5.1.7 Transfers or stores unexpended samples with custody forms.

5.1.8 Files custody forms of expended samples in a Laboratory Custody Form notebook with the comment "sample expended" in the "relinquished by" column.

5.1.9 Ships or curates analyzed sample as per protocol instructions.

5.2 Laboratory Technician

5.2.1 Completes tasks assigned by the Project Lab Supervisor.

5.2.2 Delivers data from completed laboratory analysis to the Project Lab Supervisor.

5.3 Project Field Coordinator

5.3.1 Delivers samples with custody forms to the Project Lab Supervisor or to his or her delegate.

5.4 Project Data Coordinator

5.4.1 Develops and defines data entry screens, coding, and cleaning protocols for laboratory data, in consultation with the Project Laboratory Supervisor and On-Site Principal Investigator.

5.4.2 Trains and supervises Student Data Assistants in working with lab data.

5.4.3 Assigns data batching, data entry, data verification, data cleaning, QA checks of electronic lab data, and filing tasks to Student Data Assistants.

5.4.4 Curates a copy of all cleaned, validated DP batches of electronic lab data.

5.4.5 Provides the Project Data Manager with a copy of cleaned, validated DP batch(es) for creation or update of the master database(s).

5.5 Student Data Assistants

5.5.1 Complete all assignments made by the Project Data Coordinator.

5.5.2 Follow appropriate protocols when completing assigned tasks.

5.5.3 Make backups of cleaned, validated DP batches of electronic lab data.

5.6 Project Data Manager

5.6.1 Creates master databases and defines them with the appropriate dictionary programs.

5.6.2 Updates, appends and corrects master databases and completes documentation associated with such corrections.

5.6.3 Analyzes data files as per instruction of the Principal Investigator.

5.7 Principal Investigator: Oversees all aspects of the project.

6.0 Equipment

6.1 Materials

6.1.1 Computers linked to the HRP network as described in UA-D-1.0

6.1.2 Chain of Custody Record form used for samples (Figure 1)

6.1.3 "Data Processing Batch Description" form (Figure 2)

6.1.4 "Lab Form Transfer Log" form (Figure 3)

6.1.5 "Post Filing Custody Record" form (Figure 4)

6.1.6 "Misplaced Data Forms and Packets" form (Figure 5)

6.2 Reagents (Not Applicable)

7.0 Standard Operating Procedure

7.1 Preparations (Not Applicable)

7.2 Standards and Blanks

See the NHEXAS Arizona laboratory and field protocols for descriptions of standards and blanks pertaining to specific types of samples.

7.3 Procedure Description

The following section describes who is responsible for the lab data and residual at a given stage. The lab data flow is listed sequentially and the responsible party(ies) is (are) identified in boldface capital letters. A diagrammatic representation is presented in Figure 6.

7.3.1 **FIELD STAFF** collect samples and complete the sample custody form that always stays with the sample.

7.3.2 Sample + C are delivered to the **PROJECT FIELD COORDINATOR.**

7.3.3 **PROJECT FIELD COORDINATOR** delivers the Sample + C to the **APPROPRIATE LABORATORY** according to the specified protocol.

7.3.4 The **LABORATORY SUPERVISOR** receives the Sample + C and treats it according to a specified laboratory protocol.

7.3.5 The **LABORATORY SUPERVISOR** may assign the sample treatment to a **LABORATORY ASSISTANT.**

7.3.6 The **LABORATORY TECHNICIAN** completes chain of custody form, analyzes the data and returns the Sample + C to the **LAB SUPERVISOR.**

7.3.7 The **LAB SUPERVISOR** examines the lab data form for completeness and provides a QA check.

7.3.8 The **LABORATORY SUPERVISOR** places a copy of the checked lab data form in the appropriate lab data notebook.

7.3.9 The **LABORATORY SUPERVISOR** (or designate) transfers the Sample + C to the next lab for further analysis or curates the unexpended Sample + C according to the specified protocol.

7.3.10 The **LABORATORY SUPERVISOR** files and accumulates laboratory data forms for designated intervals and completes an initial "Lab Form Transfer Log."

7.3.11 Data forms and custody (Data + C) are transferred from the **LABORATORY SUPERVISOR** to the **PROJECT DATA COORDINATOR.**

7.3.12 The **PROJECT DATA COORDINATOR** reviews the lab forms for occurrence of QA checks. Any form lacking a sufficient QA check will be returned to **LABORATORY SUPERVISOR** for QA completion. In this case, custody is transferred back to the Laboratory Supervisor.

7.3.13 The **PROJECT DATA COORDINATOR** compares the received lab forms with those recorded on the "Lab Form Transfer Log" as having been recently transferred. She or he reports any discrepancies to the **LABORATORY SUPERVISOR** and notes them on the transfer log.

7.3.14 The **PROJECT DATA COORDINATOR** (or delegate) assembles the lab data forms into a DP batch, assigns a batch code, and describes the DP batch on the lab batch tracking form.

7.3.15 The **PROJECT DATA COORDINATOR** assigns the DP batch to a first **STUDENT DATA ASSISTANT** for coding and data entry. This student maintains custody of the DP batch during coding and data entry.

7.3.16 A second **STUDENT DATA ASSISTANT** re-enters or verifies the data. This second student maintains custody of the DP batch during data verification.

7.3.17 The second **STUDENT DATA ASSISTANT** notifies the **PROJECT DATA COORDINATOR** that verification of the DP batch is complete.

7.3.18 The **PROJECT DATA COORDINATOR** assigns data cleaning and QA tasks to a **STUDENT DATA ASSISTANT.**

7.3.19 The **PROJECT DATA COORDINATOR** receives cleaned, validated, backed up, and QA checked electronic data from the **STUDENT DATA ASSISTANTS.**

7.3.20 The **PROJECT DATA COORDINATOR** assigns a **STUDENT DATA ASSISTANT** the task of filing the forms comprising the DP batch. Once they are filed, he or she records his or her initials and the current date on the the batch custody form.

7.3.21 The **PROJECT DATA COORDINATOR** becomes the general custodian of the filed physical data forms. **NHEXAS PERSONNEL** who need to access these forms may sign them out by completing a "Post Filing Custody Record" form (Figure 4). By doing this, one accepts custody of the form(s) while they are signed out.

7.3.22 The **PROJECT DATA COORDINATOR** curates a copy of the cleaned, validated, backed up, electronic lab data.

7.3.23 The **PROJECT DATA COORDINATOR** provides the **PROJECT DATA MANAGER** with a copy of the cleaned, validated, backed up, electronic lab data.

7.3.24 The **PROJECT DATA MANAGER** creates and maintains master lab databases with the cleaned, validated, backed up, electronic lab data and the "to append" form is dated and initialed (see UA-D-16.0).

7.3.25 The **DATA SYSTEM MANAGER** analyzes files or provides analysis files to the **PRINCIPAL INVESTIGATOR.**

7.3.26 Data from **OTHER LABS** will go to the **PI or Co-PI.** Such data will be transferred to the **PROJECT DATA MANAGER** and **PROJECT DATA COORDINATOR** for formation of master databases.

7.4 Calculations (Not Applicable)

7.5 Special QA Checks

7.5.1 Tolerance Limits

(a) See specific field and laboratory SOPs for tolerance limits pertaining to samples + C.

(b) All lab data forms should be fully QA checked by the Project Lab Supervisor. The Project Data Coordinator reviews all transferred forms for the occurrence of full QA checks. Any forms failing the review will be returned to the Project Lab Supervisor for QA completion.

(c) All lab data forms transferred from the Lab Supervisor to the Project Data Coordinator should be accounted for on the "Lab Form Transfer Log" form. Any discrepancies between forms listed as transferred and forms actually received will be noted on the transfer log and brought to the attention of the Project Lab Supervisor.

(d) Accumulated, completed lab forms should be transferred from the Lab Supervisor to the Data Coordinator on a certain day of each month. A maximum of ten business days beyond the original scheduled day of transfer is allowable.

7.5.2 Detection Limits

(a) See specific field and laboratory SOPs for detection limits pertaining to samples + C.

(b) For the processes outlined in this SOP that must occur within a certain time frame, all deviations are detectable via the batch custody forms.

(c) 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.

(d) 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) See specific field and laboratory SOPs for corrective actions pertaining to samples + C.

(b) The Lab Supervisor will complete QA checks on any forms returned by the Data Coordinator.

(c) For any misplaced lab data form, a search for it will begin within one business day of it being recorded on the "misplaced forms" sheet. The searching parties will be the person who currently maintains custody and the person who most recently relinquished custody. In the above situation, the former will notify the latter of the misplacement. If the form(s) have not been located within five business days, then all personnel in the data section

will be notified of the misplacement via memo, e-mail, or meeting announcement. If appropriate, all personnel in the field section will be notified as well. At this point, the intensity of the search effort will depend upon the relative importance of the misplaced form(s).

8.0 Records

8.1 The original sample custody sheet remains with the sample at all times or, if the sample is expended, is filed in the Lab Custody Form notebook.

8.2 Copies of the physical laboratory data forms are filed in notebooks or other appropriate storage containers and remain in the custody of the Project Lab Supervisor.

8.3 Completed batch custody forms are retained by the Project Data Coordinator and filed in a notebook or other appropriate storage container at the HRP site.

8.4 Completed lab batch tracking forms remain in the "Data Entry and Validation Records" notebook under the custody of the Project Data Coordinator.

8.5 The entered physical laboratory data forms (originals) are filed in a notebook or other appropriate storage container, for future reference, under the custody of the Project Data Coordinator.

8.6 The "Missing Data Forms and Packets" form is retained by the person who maintained custody at the time of misplacement. Further, a copy of this form (or duplicate information) is maintained by the Project Data Coordinator for all misplaced physical data.

Figure 1. Chain of Custody Record form used for samples

Chain of Custody Record
NHEXAS Arizona Project (CR-821560)
Respiratory Sciences
1435 N. Fremont Ave
Tucson, AZ 85719
(520) 626 - 4226

Sample Type ______________________. page ____ of ____.

Generated by ______________________/______________________
print name *signature*

Date Generated	Time	Sample ID	# of Containers	Remarks
___/___/___	___:___			

History of Sample Handling and Custody

Relinquished or Received	Signature	Date mo / day / yr	Time	Action
[Rel] or [Rec]		___/___/___	___:___	
[Rel] or [Rec]		___/___/___	___:___	
[Rel] or [Rec]		___/___/___	___:___	
[Rel] or [Rec]		___/___/___	___:___	
[Rel] or [Rec]		___/___/___	___:___	
[Rel] or [Rec]		___/___/___	___:___	
[Rel] or [Rec]		___/___/___	___:___	
[Rel] or [Rec]		___/___/___	___:___	
[Rel] or [Rec]		___/___/___	___:___	
[Rel] or [Rec]		___/___/___	___:___	
[Rel] or [Rec]		___/___/___	___:___	
[Rel] or [Rec]		___/___/___	___:___	
[Rel] or [Rec]		___/___/___	___:___	
[Rel] or [Rec]		___/___/___	___:___	
[Rel] or [Rec]		___/___/___	___:___	
[Rel] or [Rec]		___/___/___	___:___	

FORM = UA-G4.0 - 1.2 Attach Additional Pages as Necessary

Figure 2. "Data Processing Batch Description" form

DP Batch#:

DATA PROCESSING BATCH DESCRIPTION

Page ___of___

This form describes:
House Dust Mite Project Lab Evaluation Sheet

TOTAL # OF PHYSICAL DATA FORMS IN DP BATCH: _____

	COLLECTION DATE	HHID	LOC	COMMENTS
1.	/ /			
2.	/ /			
3.	/ /			
4.	/ /			
5.	/ /			
6.	/ /			
7.	/ /			
8.	/ /			
9.	/ /			
10.	/ /			
11.	/ /			
12.	/ /			
13.	/ /			
14.	/ /			
15.	/ /			
16.	/ /			
17.	/ /			
18.	/ /			
19.	/ /			
20.	/ /			
21.	/ /			
22.	/ /			
23.	/ /			
24.	/ /			
25.	/ /			

	COLLECTION DATE	HHID	LOC	COMMENTS
26.	/ /			
27.	/ /			
28.	/ /			
29.	/ /			
30.	/ /			
31.	/ /			
32.	/ /			
33.	/ /			
34.	/ /			
35.	/ /			
36.	/ /			
37.	/ /			
38.	/ /			
39.	/ /			
40.	/ /			
41.	/ /			
42.	/ /			
43.	/ /			
44.	/ /			
45.	/ /			
46.	/ /			
47.	/ /			
48.	/ /			
49.	/ /			
50.	/ /			

Replace with alternative form 11/22/95

See Appendix A.

Form ID: UA-C-7.0-3.0

Figure 3. "Lab Form Transfer Log" form (example)

LAB FORM TRANSFER LOG

From Lab to Data					From Data to Lab (as applicable)						Initials:
Key Var(s)	Stage	Date	Lab Init	Data Init	Returned	QA or Inc	Return Date	Data Init	Lab Init	Resubmit Date	Lab/Data
		__/__/__			Y N	[ ] [ ]	__/__/__			__/__/__	__/__
		__/__/__			Y N	[ ] [ ]	__/__/__			__/__/__	__/__
		__/__/__			Y N	[ ] [ ]	__/__/__			__/__/__	__/__
		__/__/__			Y N	[ ] [ ]	__/__/__			__/__/__	__/__
		__/__/__			Y N	[ ] [ ]	__/__/__			__/__/__	__/__
		__/__/__			Y N	[ ] [ ]	__/__/__			__/__/__	__/__
		__/__/__			Y N	[ ] [ ]	__/__/__			__/__/__	__/__
		__/__/__			Y N	[ ] [ ]	__/__/__			__/__/__	__/__
		__/__/__			Y N	[ ] [ ]	__/__/__			__/__/__	__/__
		__/__/__			Y N	[ ] [ ]	__/__/__			__/__/__	__/__
		__/__/__			Y N	[ ] [ ]	__/__/__			__/__/__	__/__
		__/__/__			Y N	[ ] [ ]	__/__/__			__/__/__	__/__
		__/__/__			Y N	[ ] [ ]	__/__/__			__/__/__	__/__
		__/__/__			Y N	[ ] [ ]	__/__/__			__/__/__	__/__
		__/__/__			Y N	[ ] [ ]	__/__/__			__/__/__	__/__
		__/__/__			Y N	[ ] [ ]	__/__/__			__/__/__	__/__
		__/__/__			Y N	[ ] [ ]	__/__/__			__/__/__	__/__
		__/__/__			Y N	[ ] [ ]	__/__/__			__/__/__	__/__
		__/__/__			Y N	[ ] [ ]	__/__/__			__/__/__	__/__

Form ID: UA-C-7.0-1.0

Electronic output from the tracking system may be attached to this form for transfer

1/17/94
[illegible]

Figure 4. "Post Filing Custody Record" form (example)

POST FILING CUSTODY RECORD

FORM OR QUESTIONNAIRE NAME:______________________

Describe Form			Signed OUT			Signed IN	
HHID	Key: ______	Key: ______	Date	By	Loc. of Form(s)	Date	By
			__/__/__			__/__/__	
			__/__/__			__/__/__	
			__/__/__			__/__/__	
			__/__/__			__/__/__	
			__/__/__			__/__/__	
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			__/__/__			__/__/__	
			__/__/__			__/__/__	
			__/__/__			__/__/__	
			__/__/__			__/__/__	

Figure 5. "Misplaced Data Forms and Packets" form (example)

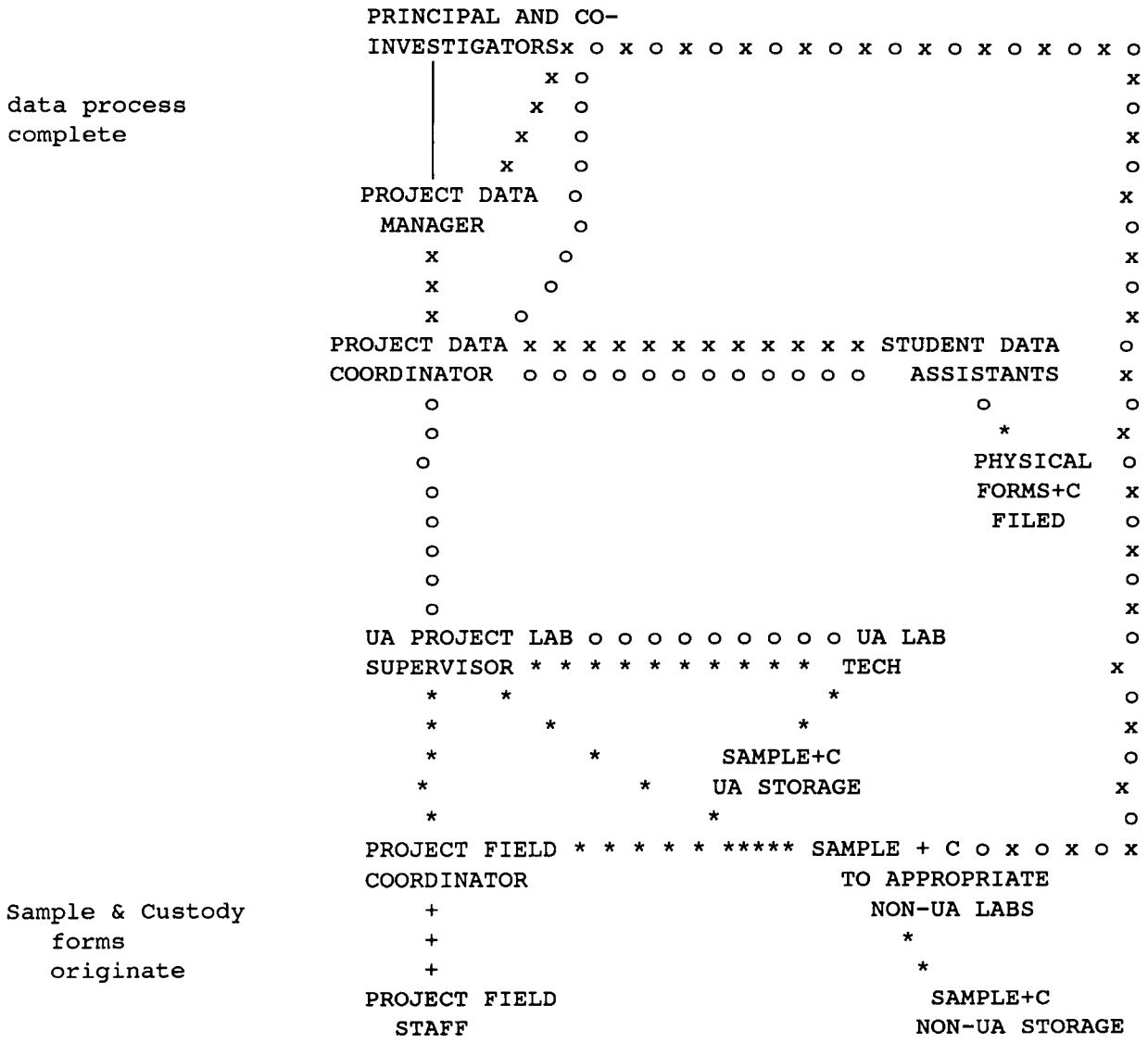
MISPLACED DATA FORMS AND PACKETS

FORM TITLE: _____
STAGE: _____

LOST			FOUND				
Key Variable(s) _____ _____	Date Missing	By	Date Found	By	Where Found	Date Filed	Comments

cereus:\laura\ws2\wkproced\custody\missform.fm
Form ID: UA-C-6.0-3.0

Figure 6. Chart exhibiting flow of Samples + C and Data + C



Legend:

+ + + + = Flow of sample+C from field
* * * * = Flow of sample+C to labs
o o o o = Flow of lab data physical batches
x x x x = Flow of electronic lab data batches
- - - - = Flow of analysis files derived from lab data

Appendix A: Batch Description and Custody Records

BATCH DESCRIPTION AND CUSTODY RECORD

1. Form : _____

2. DP Batch: ☐☐☐

3. Forwarded to: Date

○ Student DP (HRP) ..... ☐☐ / ☐☐ / ☐☐

○ Keypunch (Main Dept.)... ☐☐ / ☐☐ / ☐☐

○ Other..... ☐☐ / ☐☐ / ☐☐

4. Forwarded by: Init. ☐☐ Tech. ID

5. Received on: ☐☐ / ☐☐ / ☐☐ by ____ Init. ☐☐ Tech. ID

6. Filed on: ☐☐ / ☐☐ / ☐☐ by ____ Init. ☐☐

	HHID	F.S.	Date	IRN (If app.)	To Processing		From Processing		File
					Forward	Receive	Forward	Receive	
1.	☐☐☐☐☐☐	☐	☐☐ / ☐☐ / ☐☐	☐☐	☐	☐	☐	☐	☐
2.	☐☐☐☐☐☐	☐	☐☐ / ☐☐ / ☐☐	☐☐	☐	☐	☐	☐	☐
3.	☐☐☐☐☐☐	☐	☐☐ / ☐☐ / ☐☐	☐☐	☐	☐	☐	☐	☐
4.	☐☐☐☐☐☐	☐	☐☐ / ☐☐ / ☐☐	☐☐	☐	☐	☐	☐	☐
5.	☐☐☐☐☐☐	☐	☐☐ / ☐☐ / ☐☐	☐☐	☐	☐	☐	☐	☐
6.	☐☐☐☐☐☐	☐	☐☐ / ☐☐ / ☐☐	☐☐	☐	☐	☐	☐	☐
7.	☐☐☐☐☐☐	☐	☐☐ / ☐☐ / ☐☐	☐☐	☐	☐	☐	☐	☐
8.	☐☐☐☐☐☐	☐	☐☐ / ☐☐ / ☐☐	☐☐	☐	☐	☐	☐	☐
9.	☐☐☐☐☐☐	☐	☐☐ / ☐☐ / ☐☐	☐☐	☐	☐	☐	☐	☐
10.	☐☐☐☐☐☐	☐	☐☐ / ☐☐ / ☐☐	☐☐	☐	☐	☐	☐	☐
11.	☐☐☐☐☐☐	☐	☐☐ / ☐☐ / ☐☐	☐☐	☐	☐	☐	☐	☐
12.	☐☐☐☐☐☐	☐	☐☐ / ☐☐ / ☐☐	☐☐	☐	☐	☐	☐	☐
13.	☐☐☐☐☐☐	☐	☐☐ / ☐☐ / ☐☐	☐☐	☐	☐	☐	☐	☐
14.	☐☐☐☐☐☐	☐	☐☐ / ☐☐ / ☐☐	☐☐	☐	☐	☐	☐	☐
15.	☐☐☐☐☐☐	☐	☐☐ / ☐☐ / ☐☐	☐☐	☐	☐	☐	☐	☐

Draft