

XVI. DATA FLOW

A. Data sent to DCAC

1. Faxed XVI-1
 - a. Screening Form
 - b. Enrollment Log
 - c. Incident Report

2. Mailed XVI-1
 - a. Forms
 - b. Data Question Logs
 - c. Delinquency Reports
 - d. PSG data
 - e. Cry Recordings
 - f. Event data

B. Data sent to CTOC

1. Faxed XVI-2
 - a. Monitor Use forms

2. Federal Express XVI-2
 - b. Urine

APPENDIX

XVI. DATA FLOW

A. Data to DCAC

1. Faxed

a. **Screening Form (Form A)**

- FAX completed form to DCAC: FAX# 617-638-5066
- File original in subject's study chart
- DCAC will FAX Site Study ID# for infants Monday - Friday, 9:AM-5:PM, within 24 hours of receipt of Form A
- Write Study ID# on original form

b. **Enrollment Log**

- DCAC will FAX Enrollment Log to Sites each Monday
- Site will complete form and FAX back to DCAC (FAX# 617-638-5066) within 1 week of receipt

c. **Incident Reports (Form J1)**

- Sites will FAX completed Incident Reports to DCAC within 48 hours of the site being notified of the Incident. (For further details see **Section V-35**) (FAX# 617-638-5066)

2. Mailed

Once a week the DCAC should receive data from each site including:

a. **Forms (B, C, D, E, F3, H1, H2s, H4, H5, H6, I, K1, K2, K3, NCAST)**

- Check for completeness and accuracy
- For NCR forms: remove the yellow copy labeled "local Copy" and store locally in subject's chart
- For Xerox forms: make a local copy and store locally in subject's chart
- Complete a **Transmittal log**
On the Transmittal log, write in the STUDY ID of the infant, the type(s) of form(s) you are sending and the completion date of the form(s).
- Make a copy of the Transmittal log for your records. Send the original forms and the Transmittal log to the DCAC.

b. **Completed Data Question logs**

- Check the Data Question Log for completeness and accuracy
- Make a xerox copy of the log for local use.

c. Completed Delinquency Reports

- Check the Delinquency Report for completeness and accuracy
- Make a xerox copy of the Report for local use.
- Complete a separate **Transmittal log** for the Delinquency Reports
On the Transmittal log, write in the STUDY ID of the infant, the type(s) of form(s) you are sending and the completion date of the form(s).

d. PSG data

During the week, the site will archive PSGs completed during the week onto optical disc. The optical disc, the Optical Disc Transmittal form and completed F3 forms, including the review of the PSG (page 5 of F3 form), will be included in the site's weekly data packet to the DCAC.

e. CRY recordings

Once a month, regardless of how full the tape is, a CRY cassette tape and the Tape Content Log should be included in a weekly data packet to the DCAC.

f. Event data

A DAT tape will be included in the weekly packet to the DCAC. This DAT tape will contain **all downloads** that occurred during the previous week. Record the Event Record Label for each download on the CHIME Event Recording Transmittal Log and include a copy of the Log with the DAT tape.

Once a week these data should be mailed to:

Rose Dobosz
B.U. School of Public Health
85 E. Newton St., Rm 802
Boston, MA 02118 Phone:(617) 638-5010

B. Data to CTOC

1. Faxed

a. Monitor Use Forms

Monitor Use Forms track actual usage, problems, repairs, returns and transfers of each CHIME monitor. These forms should be faxed to the CTOC a minimum of once per week. **FAX # 216-459-3252**

2. Federal Express

a. Shipment of Urine

If urines are stored locally at (-20 C) they must be shipped to the CTOC within 1 month of collection. If urine is stored at (-70 C) locally, there shipment can be delayed up to three months time.

- Complete the Urine Recording and Transmittal Form.

- Record site address on the top of the fiberboard box with permanent marker.
 - Shipments must use dry ice. Ice chips or ice pellets will work best.
 - Weigh the dry ice to be used.
 - Place a layer of dry ice along the bottom of the Styrofoam insert of the Multipurpose Mailer.
 - Place the fiberboard box on its side in the Styrofoam insert of the Multipurpose Mailer.
 - Fill the remainder of the Styrofoam insert with dry ice and close. Make sure the top of the fiberboard box is covered with dry ice.
 - Make sure the top on the Styrofoam insert is securely closed.
 - Place the Urine Recording and Transmittal Form and Packing Identification Sheets on top of the Styrofoam insert and close the corrugated top on the Multipurpose Mailer.
 - Fill out the dry ice shipping label and attach to the Multipurpose Mailer. Make sure the weight of the ice (in kg) is recorded accurately.
 - Complete the Special Handling Section (section 5) of the Federal Express Air bill pertaining to dry ice. Be sure to record the weight of the dry ice. Remember, this is the weight of the dry ice only and not the weight of entire package. The weight on the Air bill should match the weight recorded on the package dry ice label.
 - Arrange for overnight shipment with Federal Express.
- Ship to: Beccie Mendenhall
 GCRC Lab Rm S224
 Metro Health Medical Center
 2500 MetroHealth Drive
 Cleveland, Ohio 44109
 Phone: 216-459-4269
- Notify the CTOC that a dry ice shipment is coming by calling Beccie Mendenhall at 216-459-4875.

APPENDIX XVI

Form drafts currently in use: alphabetically by form	1
Form drafts currently in use: by date of form	2
Manual Sections currently in use	3

FORM DRAFTS CURRENTLY IN USE

FORM	DRAFT DATE
A	4/07/94
B	5/01/94
C	5/01/94
D	5/01/94
E	5/01/94
H1	5/01/94
H2-MISSED	10/26/94
H2-PHONE	5/27/94
H2-VISIT	5/27/94
H2-WEEKLY	11/18/94
H4	5/01/94
H6	5/01/94
I	3/14/95
JI	8/26/94
K1	5/01/94
K2	5/01/94
K3	12/21/94

FORM DRAFTS CURRENTLY IN USE

DRAFT DATE	FORM
4/07/94	A
5/01/94	B
	C
	D
	E
	H1
	H4
	H6
	K1
	K2
5/27/94	H2-PHONE
	H2-VISIT
8/26/94	JI
10/26/94	H2-MISSED
11/18/94	H2-WEEKLY
12/21/94	K3
3/14/95	I

MANUAL SECTIONS CURRENTLY IN USE

MANUAL SECTION	DRAFT DATE
I	03/20/95
II	06/01/95
III	06/01/95
IV	06/01/95
V	10/02/95
VI	06/01/95
VII	10/02/95
VIII	05/01/94
IX	10/02/95
X	05/25/93
XI	05/25/93
XII	05/18/94
XIII	06/01/95
XIV	10/02/95
XV	---
XVI	10/02/95