

### III. INTAKE PROCEDURES

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### APPENDIX

Intake Checklist

Urine Recording and Transmittal Form

Shipment of Urine Packing Identification Sheet

## A. Intake Checklist

- Complete Screening Form A** for all potentially eligible subjects according to site specific procedures.
- Obtain Informed Consent** for all eligible subjects that agree to participate.
  - FAX Completed Screening Form A to DCAC FAX #:** 617-638-5066.
  - Receive Study ID# within 24 hours.** DCAC will FAX sites a list of Study IDs for all infants enrolled within a 24 hour time period.
  - Record Study ID#** onto page 2 of the Screening Form A.
  - Create chart for study infant.**
  - Contact Monitor Company** for Home Monitoring Setup.
  - Enter information from Form A into CHIME Management Tool.**
  - Complete Family Interview** - Form B (refer to **CHIME Coding Manual**).
  - Complete Infant History** - Form C (refer to **CHIME Coding Manual**).
  - Check Forms B & C** for completeness and accuracy.
  - Collect 5cc of urine.** Label sample with infant's name, Study ID# and date sample obtained. Store sample in conventional freezer (-20°).
- Tear out yellow copies** of forms B & C for local use.
- File copies** in infant's study chart for local use.
- Enter information from Forms B & C into CHIME Management Tool.**
- Generate *Infant Schedule*** using CHIME Management Tool.
- Give parents/caregivers copy of *Infant Schedule*** and review study requirements.
- Log in the completed forms B & C in Transmittal log.**

## B. Family Interview - Form B

### 1. WHEN to complete Family Interview - Form B

After completing Screening Form A, obtaining consent and receiving Study ID# from DCAC.

### 2. WHERE to obtain information

#### Tracking Form

-By in-person interview

#### Demographics

-By in-person interview (questions 1-15)

#### Maternal Obstetrical & Medical History

-Obstetrical information (questions 16-28) can be obtained from family interview, chart review, or both.

-Medical Problems Prior to pregnancy (questions 29-46) can be obtained from family interview, chart review, or both.

-Medical Problems During pregnancy (Questions 47-131) can be obtained from family interview, chart review, or both.

- a. Environmental Exposures (Questions 116-119)
- b. Other Substances (Questions 120-126)
- c. Prenatal Care (Questions 127-131)

-Labor & Delivery (Questions 132-176) information can be obtained from family interview, chart review, or both.

### 3. HOW to complete Form B

Refer to coding Instructions for Form B in the **CHIME Coding Manual**.

### 4. WHAT to do with Form B when completed

- a. Check for completeness and accuracy.
- b. Enter tracking information (page 1) into local CHIME database.
- c. Tear out yellow copy.
- d. File yellow copy in infant's study chart for the local use.
- e. Store all Form B originals collected during the week.
- f. Write in form B's to be sent to the DCAC on the **Transmittal log**.
- g. Once a week, make copy of transmittal log for your records, and send original Form B's to DCAC:

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

## C. Infant Medical History - Form C

### 1. WHEN to complete Infant Medical History - Form C

After completing Screening Form A, obtaining consent and receiving Study ID# from DCAC.

### 2. WHERE to obtain information

After interviewing primary caretaker(s), information for Infant Medical History can be obtained through family interview and/or chart review.

### Neonatal Information

- Information can be obtained from chart review (Questions 1 - 116).

### History Following Newborn Discharge

- Information can be obtained from family interview (Questions 117 - 225).

### 3. HOW to complete Form C

Refer to coding Instructions for Form C in the **CHIME Coding Manual**.

### 4. WHAT to do with Form C when completed

- a. Check for completeness and accuracy
- b. Tear out yellow copy
- c. File yellow copy in infant's study chart for the local use
- d. Enter gestational age information from Form C into local CHIME database
- e. Every week the DCAC will FAX sites a list of all newly enrolled subjects and their gestational age at birth. **SITES MUST VERIFY GESTATIONAL AGES AND FAX THE CORRECTED AGES TO THE DCAC WITHIN ONE WEEK.**
- f. Store all Form C originals collected during the week.
- g. Write in all Form C's on the **Transmittal log**.
- h. Once a week, make copy of transmittal log for your records and send original Form C's to DCAC:  
Rose Dobosz  
B.U. School of Public Health  
85 East Newton Street Suite 802  
Boston, MA 02118  
Phone: (617) 638-5010

## D. Urine Protocol

### 1. Urine Collection

The CTOC will provide all sites with the necessary supplies for storage and shipment except **urine collection bags**. Five cc of urine should be collected on every study infant at intake. If unable to collect urine at intake, try and collect urine at soonest time available. Age of collection is not an issue for future analyses.

Medications will not effect urine results with the exception of MCT (Medium chain Triglycerides) which is an additive found in some infant formulas. Infants should stop using formulas with MCT three days prior to urine collection. While most baby formulas do not contain MCT, many of the premature baby formulas and special formulas do. The following baby formulas contain MCT: Enfamil Premature, Similac Special Care, Pregestimil, Alimentum and Portagen. Any formula that you have never heard of should be checked for MCT.

Urine should sit out no more than two hours before needing refrigeration. Sites should have a portable cooler to transport urines if collection is done at the infant's home. Urines should not sit in a refrigerator for more than 12 hours before being transferred to a -20 degree freezer. Urine should be stored in 5cc tubes and placed in sample boxes. These sample boxes should be maintained in a freezer at -20 F. The sample boxes will be shipped to the CTOC in multipurpose mailers. These mailers consist of a styrofoam container inside a corrugated box. Dry ice must be used to keep the samples frozen. At the CTOC the urine will be stored at -70F (See section **3. Shipment of Urine**, for further details)

### 2. Labeling of Urine Sample

#### a. Supplies Required:

5cc Urine Tube

Freezer tape

Sharpie extra fine point permanent marker

Fiberboard Sample Box

Packing Identification Sheet (example at end of this section)

Urine Recording and Transmittal Form (example at end of this section)

#### b. Procedure:

1)Cut 1 ½ inch piece of freezer tape

2)Using the Sharpie permanent marker, record the Infant's Name, Study ID and Date urine was collected on the 1 ½ inch piece of freezer tape.

3)Place the tape completely around the tube while overlapping the tape and place in box for storage. Record the exact location of the urine tube in the box on the **Packing Identification Sheet** which corresponds to the Fiberboard Sample Box you are using for storage. Fill out the **CHIME Urine Recording and Transmittal Form**. Make sure that all information is legible.

### **3. 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.

#### **a. Supplies Required**

Urine Recording and Transmittal Form (example at end of this section)

Fiberboard Sample Box

Permanent Marker

Multipurpose Mailer

Dry Ice

Dry Ice Shippers Label

Federal Express Airbill

#### **b. Procedure:**

- 1) Complete the Urine Recording and Transmittal Form.
- 2) Record site address on the top of the fiberboard box with permanent marker.
- 3) Shipments must use dry ice. Ice chips or ice pellets will work best.
- 4) Weigh the dry ice to be used.
- 5) Place a layer of dry ice along the bottom of the styrofoam insert of the Multipurpose Mailer.
- 6) Place the fiberboard box on its side in the styrofoam insert of the Multipurpose Mailer.
- 7) 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.
- 8) Make sure the top on the styrofoam insert is securely closed.
- 9) 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.
- 10) 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.
- 11) Complete the Special Handling Section (section 5) of the Federal Express Airbill 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 airbill should match the weight recorded on the package dry ice label.

12) Arrange for overnight shipment with Federal Express.

Ship to: Michael Nowak  
GCRC Lab Rm S224  
Metro Health Medical Center  
2500 MetroHealth Drive  
Cleveland, Ohio 44109  
Phone: 216-459-4269

13) Notify the CTOC that a dry ice shipment is coming by calling Michael Nowak at 216-459-4875.

### **E. Scheduling at Intake**

Once Forms A, B, and C are completed, study personnel should use the management tool to schedule the following visits with the parent(s)/primary caretaker(s):

#### **1. Family Monitor Training Session**

Monitor training of primary caretaker(s) may occur prior to discharge but **MUST** be completed within 1 week of the infant's monitor start date. See **Section V: Home Monitor Protocol** for further procedure details.

#### **2. Polysomnograph Testing** (See **Section VII: PSG Recordings** for further details.)

##### **a. Healthy Term Infants**

When a Healthy Term infant is enrolled, the DCAC will inform the site at what age to perform a PSG.

##### **b. Apnea of Infancy Infants**

Apnea of Infancy subjects should be scheduled within 2 weeks of monitor start date.

##### **c. Premature Infants**

An overnight polysomnograph must be scheduled for preterm infants within 2 weeks of monitor start date.

##### **d. Siblings of SIDS Infants**

Siblings of SIDS should be scheduled for a PSG at 1 month adjusted age. Surviving twins of SIDS victims should be scheduled for a PSG as soon as possible after the death of their twin.

### 3. Cry Recording

**Preterm** and **AOI infants** will have a total of 2 cry recording sessions. The first will take place at the conclusion of the PSG at intake, the second recording session will be at one month post-intake.

**Healthy Term** and **Siblings** will have either 2 or 3 cry recording sessions depending on when the PSG is scheduled to occur.

- If the PSG is scheduled within 2 weeks of intake, the first cry recording session will be at the conclusion of the PSG and the second and final cry recording session will be at one month post-intake.
- If the PSG is scheduled within 2 weeks of one month post-intake, the first cry recording session will be at intake and the second and final cry recording session will be at the conclusion of the PSG.
- If the PSG is scheduled for more than 2 weeks after one month post-intake, then 3 cry recording sessions should be completed. The first at intake, the second at one month post-intake and the third at the conclusion of the PSG. See **Section VIII: Cry Protocol** for further details.

### 4. Developmental Assessments

At 44, 56 and 92 weeks PCA, development will be assessed using the **Bayley Scales of Infant Development (BSID)**, revised 1992 version. Parent-infant interaction will also be evaluated using the **Feelings About Parenting** questionnaire, **Depression and Health Subscales of the Parenting Stress Index** and the **Nursing Child Assessment Instruments**. Developmental assessments should be scheduled in conjunction with the infant's Medical Follow-up visits. For scheduling information refer to **Section IV: Additional Scheduling Procedures**. For specific details regarding the developmental assessments see **Section IX: Bayley Scales of Infant Development Testing**, **Section X: Feeding Scale**, **Section XII: PSI Depression Subscales/Feelings About Parenting**

### 5. Initial Medical Follow-up Visit

Medical Follow-up visits will occur throughout the period the infant is **home monitored**. Follow-up can be conducted at the Clinical Site or at the caretaker's home. **All infants** will have their **initial Medical Follow-up visit 4 weeks after their monitor start date**. For infants born after 38 weeks gestation, this initial visit may correspond to one of the required developmental testing visits at:

44 weeks (1 month)  
56 weeks (4 months)

For preterm births, an additional visit prior to their 44 week PCA visit is always required. While on the CHIME monitor, infants should not go beyond **8 weeks** without a Medical Follow-up Visit. Visits will be scheduled according to infants Post-Conceptual Age (PCA). The CHIME management tool can assist study personnel in scheduling these visits. See **Section IV: Additional Scheduling Procedures** for further details.

# Intake Checklist

- Complete Screening Form A** for all potentially eligible subjects according to site specific procedures.
- Obtain Informed Consent** for all eligible subjects that agree to participate.
- FAX Completed Screening Form A to DCAC FAX #:** 617-638-5066.
- Receive Study ID# within 24 hours.** DCAC will FAX sites a list of Study IDs for all infants enrolled within a 24 hour time period.
- Record Study ID#** onto page 2 of the Screening Form A.
- Create chart for study infant.**
- Contact Monitor Company** for Home Monitoring Setup.
- Enter information from Form A into CHIME Management Tool.**
- Complete Family Interview** - Form B (refer to **CHIME Coding Manual**).
- Complete Infant History** - Form C (refer to **CHIME Coding Manual**).
- Check Forms B & C** for completeness and accuracy.
- Collect 5cc of urine.** Label sample with infant's name, Study ID# and date sample obtained. Store sample in conventional freezer.
- Tear out yellow copies** for local use.
- File copies** in infant's study chart for local use.
- Enter information from Forms B & C into CHIME Management Tool.**
- Generate *Infant Schedule*** using CHIME Management Tool.
- Give parents/caregivers copy of *Infant Schedule*** and review study requirements.
- Log in the completed forms in Transmittal Log.