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## **A. Exclusion Criteria for All CHIME Study Groups**

**Any ONE of the following factors listed below EXCLUDES an infant from participating in ANY study group:**

### **Respiratory Diagnosis:**

- Current diagnosis of Pneumonia as confirmed by x-ray
- Any diagnosis requiring **HOME** treatment with: supplemental oxygen, bronchodilators, diuretics or steroids

### **Cardiac Diagnosis:**

- Any history of congenital heart disease (**EXCEPT**: currently asymptomatic PDA or ASD or small muscular VSD not requiring treatment)

### **Neurologic Disorders:**

- Ventriculoperitoneal shunt
- Home anti-convulsant therapy
- Congenital brain anomalies documented by head ultrasound, CT or MRI (e.g. absence of corpus callosum or other anomalies that might result in a non-SIDS diagnosis in the result of a sudden death.)

### **Gastro-esophageal reflux currently requiring drug treatment**

### **Chromosomal Abnormalities**

### **Congenital Anomalies**

(anomalies that might result in a non-SIDS diagnosis in the result of a sudden death e.g. Mid-facial hypoplasia or cleft palate)

### **Any inborn error in metabolism**

(including MCAD deficiency or carnitine deficiency)

### **Caretaker CURRENTLY using illicit drugs**

**Inability to communicate with caretaker**  
**(language barrier)**

**No phone**

## **B. Definition of Study Groups**

If **NONE** of the criteria listed in Part A are present; eligibility will be evaluated for participation in one of the following groups:

1. Healthy Term Infants (Controls)
2. Apnea of Infancy Infants
3. Premature Infants
4. Siblings of SIDS Infants

## 1. Healthy Term Infants (Controls)

An infant must meet the following criteria to be included in the HEALTHY TERM INFANTS group:

- Gestational age of 38 - 42 weeks
- Appropriate for Gestational Age (AGA)  
(Birth weight greater than 10<sup>th</sup> percentile and less than 90<sup>th</sup> percentile of the Colorado Growth Chart. See **CHIME CODING MANUAL**)
- Age of 30 days or less postnatally for planned monitor start date
- 1 minute APGAR  $\geq 4$  and 5 minute APGAR  $\geq 7$
- Has not been admitted to special care nursery
- No neonatal stay beyond mother's discharge or neonatal stay after 48 hours of birth
- Infant **HAS NOT** received any medications or treatments (other than vitamins, eye prophylaxis or vaccines) in nursery
- No apnea/ALTE
- Not a full or half sibling of SIDS victim (includes parental report of SIDS even if no autopsy performed)
- No family history of SIDS in cousins, aunts, or uncles  
(SIDS death must have occurred within the past 10 years and family must state that the cause of death was confirmed by autopsy.)

## 2. Apnea of Infancy Infants

An infant must meet the following criteria to be included in the APNEA OF INFANCY group:

- Infants age  $\geq$  12 hours and < six months postnatal when ALTE occurred
- If index event occurs during newborn hospital stay, AT BIRTH the infant must be > 34 weeks gestation and weigh > 1750 grams.
- Index event ALTE occurred less than two weeks before CHIME evaluation, occur during period when home monitoring was **NOT** prescribed and infant must be placed on a CHIME monitor within 2 weeks of discharge.
- No specific etiology for ALTE has been defined
- Clinically diagnosed ALTE meeting **EACH** of the following severity criteria:
  - color change (blue, pale)
  - muscle tone change (limp, stiff)
  - apnea which requires significant intervention  
*meaning, one or more of the following:*
    - minimal stimulation
    - vigorous stimulation
    - mouth-to-mouth
    - chest compressions (cardiopulmonary resuscitation)

**Please note:** *If vigorous stimulation, mouth-to-mouth or chest compressions is used to stimulate infant, it is acceptable if information is unavailable for either color change **OR** muscle tone but neither should be no.*

### **3. Premature Infants**

**An infant must meet the following criteria to be included in the PREMATURE INFANTS group:**

- Birth weight of 1750 grams or less
- Gestational age of 34 weeks or less
- Infant age at discharge less than 120 days
- Home monitoring can be started within 2 weeks of discharge

#### 4. Siblings of SIDS Victims

An infant must meet the following criteria to be included in the SIDS group:

- Infant is a full or half sibling of one or more previous SIDS victims
- Siblings SIDS death must be confirmed by autopsy.
- Infant age at planned monitor start date less than 30 days post-natal **UNLESS** infant is a surviving twin of SIDS victim
- If **INFANT IS A SURVIVING TWIN** of SIDS victim:  
less than 4 weeks after death of twin and less than 6 months chronological age
- Does **NOT** meet criteria for inclusion in Apnea of Infancy group
- Does **NOT** meet criteria for inclusion in Premature group

## C. Determining Gestational Age at Birth

### 1. Consider all Gestational Ages available

To determine an infant's gestational age assignment, consider all methods available, including: Newborn exam (e.g. Dubowitz), Prenatal Ultrasound and LMP. If gestational age assignment is noted as a range (i.e. 32-34 weeks) use midpoint of range (i.e.33 weeks).

**a.If LMP is less than or equal to 2 weeks of other methods, use LMP.**

#### Example # 1

A premature infant is 29 weeks by LMP and 31 weeks by exam. The infant's gestational age at birth is **29 weeks**.

#### Example # 2

A sibling of SIDS infant is 40 weeks by LMP, 38 weeks by exam and 39 weeks by ultrasound. The infant's gestational age at birth is **40 weeks**.

**b.If methods differ by more than 2 weeks use:**

- 1)Newborn exam (if available) OR
- 2)Ultrasound (if newborn exam unavailable)

#### Example # 3

A premature infant is 31 weeks by LMP, 28 weeks by exam and 29 weeks by ultrasound. The infant's gestational age at birth is **28 weeks** (exam).

#### Example # 4

A premature infant is 28 weeks by LMP and 31 weeks by ultrasound. The infant's gestational age at birth is **31 weeks** (ultrasound).

## 2.Rounding Gestational Ages to whole numbers

If gestational age is given with decimal point (i.e. 30.7 weeks), round to nearest whole number (i.e.31 weeks) EXCEPT in the following circumstances:

### a.Healthy term infants must be 38-42 weeks gestation to be eligible for CHIME.

- 1)For those Healthy term infants whose gestational age is recorded as **37.5-37.9 weeks, round down to 37 weeks.**
- 2)For gestations recorded as 42.1-42.5 weeks, round up to 43 weeks.

### b.Premature infants must be 34 weeks gestation or less to be eligible for CHIME.

- 1)For those premature infants whose gestational age is recorded as **34.1-34.5 weeks, round up to 35 weeks.**

#### Example # 1

A Healthy term infant is 40.5 weeks by LMP and 41 weeks by exam. The infant's gestational age at birth is **41 weeks (LMP rounded up).**

#### Example # 2

An AOI infant is 37-39 weeks by LMP and 41 weeks by exam. The infant's gestational age at birth is **41 weeks (exam).**

#### Example # 3

A premature infant is 34.4 weeks by LMP and 33 weeks by exam. The infant's gestational age at birth is **35 weeks (LMP rounded up).**

#### Example # 4

A Healthy term infant is 37.5 weeks by LMP and 40 weeks by exam. The infant's age according to LMP is rounded down to 37 weeks and since the difference between LMP and exam is more than 2 weeks, use exam age. The infant's gestational age at birth is **40 weeks (exam).**

## **D. Recruitment of Subjects**

### **1. Los Angeles, CA**

#### Healthy Term Infants

CHIME information will be provided to parents attending selected Prenatal Care classes at Hollywood Presbyterian Hospital. PNC instructors will read a memo at the third or fourth class which contains a brief description of the study and instructions for interested parents to contact study personnel. Study personnel will describe the study to parents that call and for those who remain interested, follow them until delivery.

- After delivery, a Screening Form will be completed to determine study eligibility.

#### Apnea of Infancy Infants

- At CHLA and LAC, study personnel will complete Screening Forms on all infants admitted with any diagnosis suggestive of a possible life threatening event.

- A Screening Form will be completed for all infants referred to the CHLA Apnea clinic with any diagnosis suggestive of a possible life threatening event.

#### Premature Infants

On a daily basis, study personnel will review a report generated from the Neonatal Information System (NIS) which lists all premature infants at Los Angeles County Hospital (LAC).

- A Screening Form will be initiated on all infants with birth weights of 1750 grams or less and completed at the time a final eligibility decision is possible.

#### Siblings of SIDS

The NIS system at LAC will be used to generate reports identifying all newborns who are subsequent siblings of a SIDS victim.

- Screening Forms will be completed on all infants identified as siblings of SIDS victims.

SIDS parent groups will be informed about the study via newsletters, presentations at local and regional meetings and by individual speaking engagements by CHIME investigators at parent support meetings.

- Screening Forms will be completed on all infants referred to CHIME as subsequent siblings of SIDS victims.

## D. Recruitment of Subjects

### 2. Honolulu, HI

Only infants who reside on Oahu will be screened.

#### Healthy Term Infants

CHIME information will be provided to parents attending selected Prenatal Care classes at Kapiolani and Queens hospitals. A brief description of the study is read by instructors at the third or fourth class and CHIME handouts distributed. Interested parents are asked to sign up on CHIME sign up sheets. Study personnel will collect the names and phone numbers of parents who express interest in participating, contact them to describe the study and for those who remain interested, follow them until delivery.

➤ After delivery, a Screening Form will be completed to determine study eligibility.

In-hospital nursery screening was initiated at KMCWC on July 26, 1994. Charts are reviewed for every baby in the term nursery on the 2<sup>nd</sup> and 3<sup>rd</sup> Tuesday of each month. Form A's are completed for all those infants and eligible infant's families receive a letter of introduction followed by a phone call.

#### Apnea of Infancy Infants

➤ Study personnel will complete a Screening Form for all infants with a diagnosis suggestive of a possible life threatening event who are referred to CHIME by: Kapiolani Home Health Services (KHHS), PMDs, Pediatric ICU attendings, and house staff ward attendings at all participating hospitals.

➤ At KMCWC, Queens, Kaiser and TAMC (TAMC start date 04/06/95), study personnel will complete Screening Forms on all infants admitted with any diagnosis suggestive of a possible life threatening event.

➤ The list of provisional diagnoses includes: apnea, R/O apnea, ALTE, R/O ALTE, choking, breath holding, cyanotic episode, pneumonia, R/O pneumonia, R/O cyanotic heart disease, R/O RSV, seizures, R/O seizures, and dusky episodes

Nursery and pediatric floor screening is done at KMCWC on Monday, Wednesday, and Friday; at Kaiser on Tuesday and Thursday; when TAMC is added, screening will be on Tuesday and Thursday.

Physician and KHHS referrals also are accepted. KHHS notifies CHIME of all infants six months or younger who reside on Oahu who require physician ordered apnea monitoring. CHIME staff screen referrals and complete Form A's appropriately.

#### Premature Infants

Study personnel will check admissions log at Kapiolani daily and visit the nurseries at Kapiolani every Monday, Wednesday and Friday; nurseries at Kaiser are visited either Monday and Thursday, or Tuesday and Friday; at TAMC visits are made every Tuesday and Thursday. Infants with birth weights of 1750 grams or less, with GA of 34 weeks or less who reside on Oahu will be tracked. KMCWC premature infants status will be followed, and the family approached upon baby's transfer to the Intermediate Nursery. TAMC premature infants'

status will be monitored until stable, then the family will be approached. Staff will review potential subject's progress notes, and maintain contact with staff. If at all possible, CHIME staff will attend Discharge Planning at TAMC on Tuesdays and at KMCWC on Thursday. At Queens, Dr. Tinsley will initiate a Form A on every baby with birthweight of 1750 grams or less and forward to CHIME staff for follow-up.

- Screening Form A will be initiated on all infants with birth weights of 1750 grams or less and completed at the time a final eligibility decision is possible.

#### Siblings of SIDS

SIDS parent groups will be informed about the study via newsletters or mailouts. Interested parents will be asked to contact study personnel for further information. Siblings of SIDS victims will also be referred by: PMDs, house staff at both Kapiolani, Queens, Kaiser, TAMC and by KHHS and during routine chart screening in the term and special care nurseries.

- Screening Forms will be completed on all infants referred to CHIME as subsequent siblings of SIDS victims.

## **D. Recruitment of Subjects**

### **3. Chicago, IL**

#### Healthy Term Infants

Investigators will distribute CHIME fact sheet to OB attendings and residents to inform them of the study and generate referrals prenatally. Interested parents will be informed to contact study personnel for further details. Study personnel will call those parents who express interest in participating and describe the study. For those who remain interested, study personnel will follow them until delivery.

- After delivery, a Screening Form will be completed to determine study eligibility.

CHIME information will be provided to parents attending selected Prenatal Care classes. Study personnel will collect the names and phone numbers of parents who express interest in participating, contact the parents to describe the study and for those who remain interested, follow them until delivery.

- After delivery, a Screening Form will be completed to determine study eligibility.

#### Apnea of Infancy Infants

- A Screening Forms will be completed on all infants admitted to Rush-Presbyterian with any diagnosis suggestive of a possible life threatening event.
- A Screening Form will be completed for all infants referred to CHIME as infants with any diagnosis suggestive of a possible life threatening event.

#### Premature Infants

On a daily basis, study personnel will review NICU and Intermediate Care Nursery Admissions for infants with birth weights of 1750 grams or less.

- A Screening Form will be initiated on all these infants and completed at the time a final eligibility decision is possible.

#### Siblings of SIDS

Investigators will distribute the CHIME fact sheet within Rush-Presbyterian and to local PMDs to inform them of the study and generate referrals. SIDS parent groups will be informed about the study via newsletters. All interested parents will be instructed to contact study personnel for further details.

- Screening Forms will be completed on all infants referred to CHIME as subsequent siblings of SIDS victims.

## **D. Recruitment of Subjects**

### **4. Cleveland, OH**

#### Healthy Term Infants

CHIME information will be provided to parents attending Prenatal Care classes at MetroHealth and Rainbow Babies & Children's hospitals. PNC instructors will read a memo at the third or fourth class which contains a brief description of the study and instructions for interested parents to contact study personnel. Study personnel will describe the study to parents that call and for those who remain interested, follow them until delivery.

- After delivery, a Screening Form will be completed to determine study eligibility.

#### Apnea of Infancy Infants

The majority of infants at RB&C with diagnoses suggestive of a possible life threatening event are referred to the Sleep Lab for study.

- A Screening Form will be completed on all infants referred to RB&C's Sleep Lab with a diagnosis suggestive of a possible life threatening event. The Screening Form will be initiated by phone interview and completed at the time a final eligibility decision is possible.

- At MetroHealth, study personnel will complete Screening Forms on all infants admitted with any diagnosis suggestive of a possible life threatening event.

#### Premature Infants

At RB&C, a list of all premature infants in the hospital will be generated by the neonatology department on a weekly basis. At MetroHealth, study personnel will generate a list of all premature infants in the hospital.

- A Screening Form will be initiated on all infants with birth weights of 1750 grams or less and completed at the time a final eligibility decision is possible.

#### Siblings of SIDS

At MetroHealth, it is routine practice in the normal nursery to ask parents about prior SIDS deaths.

- A Screening Form will be completed on all infants in the normal nursery that have been identified as a sibling of a SIDS victim.

Parents will be informed about the study through RB&C's SIDS survival groups. The SIDS counselor will briefly describe the study to parents and instruct interested parents to contact study personnel.

- A Screening Form will be completed on all siblings of SIDS victims whose parents were referred to CHIME by the survival group, as well as, any siblings referred by other sources.

## **D. Recruitment of Subjects**

### **5. Toledo, OH**

#### Healthy Term Infants

CHIME information will be provided to parents attending selected Prenatal Care classes at the Toledo Hospital. Study personnel will collect the names and phone numbers of parents who express interest in participating, contact the parents to describe the study and for those who remain interested, follow them until delivery.

➤ After delivery, a Screening Form will be completed to determine study eligibility.

#### Apnea of Infancy Infants

Investigators will send letters to local PMDs to inform them of the study and generate referrals.

➤ A Screening Form will be completed for all infants referred to Toledo Hospital's Infant Monitor Program with any diagnosis suggestive of a possible life threatening event.

#### Premature Infants

On a daily basis, study personnel will review all admissions to the Toledo Hospital NICU with birth weights of 1750 grams or less. Beginning 11/7/94 St. Rita's Medical Center (Lima, Ohio) and on 12/5/94 the Riverside Hospital were added as screening sites, utilizing the same mechanisms as Toledo Hospital except that screening information is often collected over the phone.

➤ A Screening Form will be initiated on these infants once they attain a weight of 1750 grams. Screening Forms should be completed at the time a final eligibility decision is possible.

#### Siblings of SIDS

SIDS parent groups will be informed about the study via newsletters and presentations at local meetings. Interested parents will be asked to call study personnel for further information.

➤ Screening Forms will be completed on all infants referred to CHIME as subsequent siblings of SIDS victims.

## **E. Screening Form (Form A)**

1.**WHEN** to be completed - at point of contact with potentially eligible subjects. Refer to site specific procedures for greater detail.

2.**WHERE** to obtain information:

Page 1; Section I - from infant's medical record

Page 2; Section IIA+B - Maternal screening interview/chart review

Section IIC - completed by Screener

3.**HOW** to complete form:

Refer to the Coding Instructions for Screening Form A in the **CHIME Coding Manual** and select appropriate group assignment.

4.Obtain **Informed Consent**

### **5.Fax Screening Form**

Fax screening form to DCAC (see address and Fax number below). At the end of each day, the DCAC will fax sites a list of study IDs for each infants enrolled. The first digit of the Study ID will represent the Clinical Site followed by the next available sequential number for that site. When sites receive Study ID, it will then be recorded on the second page of the infant's Screening Form (Form A) and keyed into the CHIME Management Tool.

**Fax Screening Forms** to:

The Data Coordinating & Analysis Center (DCAC):

Namie Kim

B.U. School of Public Health

85 East Newton Street

Suite M802

Boston, MA 02118

**FAX # (617) 638-5066**