

## **XIII. COMPLETION OF MONITORING**

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## **A. Completion of Monitoring**

Form I will be completed by study personnel for each infant who meet any of the following criteria for discontinuing home monitoring:

### **1. Completion of Study Requirements**

Any infant that meets the home monitoring requirements for their specific study group.

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

Home monitoring will be discontinued at 6 months adjusted age unless an infant experiences an ALTE. Infants who experienced an ALTE will be managed as described for Apnea of Infancy group.

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

Home monitoring can be discontinued when the infant has been monitored for at least 3 months without any significant events, including:

1. Been without any reported ALTE (observed by caregiver) for 3 consecutive months

2. In addition, the infant must meet one of the following criteria:

2a. Demonstration of no documented prolonged apneas or sustained bradycardias for 3 months.

2b. Demonstration of consistent decrease in frequency and severity of recorded apneas or bradycardias over 3 months of monitoring and demonstration of the ability to spontaneously recover from apnea and/or bradycardia before the stimulus of auditory alarm. In some cases this may require extension of the alarm limits.

#### **c. Preterm Infants**

Home monitoring can be discontinued when the infant is at least 4 months adjusted age and:

1. Been without any reported ALTE (observed by caregiver) for 3 consecutive months

2. In addition, the infant must meet one of the following criteria:

2a. Demonstration of no documented prolonged apneas or sustained bradycardias for 3 months.

2b. Demonstration of consistent decrease in frequency and severity of recorded apneas or bradycardias over 3 months of monitoring and demonstration of the ability to spontaneously recover from apnea and/or bradycardia before the stimulus of auditory alarm. In some cases this may require extension of the alarm limits.

#### **d. Subsequent Siblings of SIDS Victims**

Home monitoring can be discontinued when the infant is 6 months adjusted age. Families will be allowed to monitor 1 month past the age of death of the previous SIDS victim if it is greater than 6 months and they so choose.

1. In addition, the infant must meet one of the following criteria:

1a. Demonstration of no documented apneas or sustained bradycardias for 3 months.

1b. Demonstration of consistent decrease in frequency and severity of recorded events over 3 months of monitoring and demonstration of the ability to spontaneously recover from apnea and/or bradycardia before the stimulus of auditory alarm. In some cases this may require extension of the alarm limits.

### **2. Early Termination of Monitoring**

If the parent or caregiver decides to (or needs to) stop home monitoring before the criteria for termination are met, complete Form I, but continue to attempt collection of remaining study data (i.e. follow-up visits, etc.)

### **3. Non-Compliance**

A Form I should be completed for any infant with documented monitor nonuse for 1 month or

more over 2 consecutive downloads and for whom compliance enhancement efforts appear futile (see **Section V: Home Monitoring Protocol on further details**).

#### **4.Loss of Contact**

An **Incident Report form (J1)** should be completed if CHIME personnel are unable to contact the parents or caregivers of a study infant for 4 weeks or more. If contact is not made with parents or caregivers for 2 months time, **form I** should also be completed for the infant formally ending his or her home monitoring for the study. Attempts should be made to contact the infant's family, collect remaining study data (i.e. follow-up visits, etc.) and retrieve the CHIME monitor.

#### **5. Death**

Any infant who dies suddenly and unexpectedly during the first year of life, whether or not he/she was using a home monitor at the time of death, will undergo a thorough death scene investigation and post-mortem examination. Each Clinical Site will make arrangements with the local Coroner/Medical Examiner's office for death scene investigations and post-mortem examinations on study infants to be performed in a standardized manner (see **Section XIV: Death Scene Investigation of Study Infants** for further details). The site should immediately notify CHIME's Program Director at NICHD of the infant's death, an **Incident Report Form (J1)** completed and faxed to the DCAC (617-638-5066) and a **Completion of Monitoring form (I)** completed.

#### **6.Alternative Monitoring**

If the parent or caregiver does not wish to stop home monitoring when the criteria of termination are met, and the clinician investigator agrees or is not able to prevent continued home monitoring, the infant will continue home monitoring on a standard monitor, and the study monitor will be retrieved for use on another study infant. A form I must be completed for the infant, documenting the end of home monitoring with the study monitor. Home data will not be obtained after the study monitor has been removed.

## 7. Completion of Monitoring Form (I) (Draft 3/14/95)

On the Completion of Monitoring Form there are 3 dates listed:

- (1) Date monitor placed in the home
- (2) Date monitor retrieved from the home
- (3) Date caregivers instructed to stop using the monitor by CHIME personnel.

All THREE dates need to be completed when an infant ends home monitoring. The only exception is if the infant never home monitored, then only questions 1 and 7 of Form I need to be completed.

The '**Date caregivers instructed to stop using the monitor by CHIME personnel**', refers to:

- 1) the date the caregivers were instructed to stop using the CHIME monitor when study criteria are achieved

**OR**

- 2) for caregivers that wish to end monitoring early, the date the caregiver informs CHIME personnel they no longer wish to home monitor with the CHIME monitor

**OR**

- 3) If study personnel are unable to contact the infant's caregiver(s) over a 2 month period, the infant's home monitoring for the study will officially end. In this case, the '**Date caregivers instructed to stop using the monitor by CHIME personnel**', is the date of the last contact the caregiver had with CHIME personnel. Complete all questions on the Form I except #2 and send the form to the DCAC. As soon as the monitor is retrieved from the infant's home, send the DCAC the date the monitor was retrieved on a Data Correction/Addition log. The '**Reason Monitoring Ended**' would be '**Unable to contact parent(s)/caregiver(s) for 2 months**'.

### **EXAMPLE #1**

A premature infant began monitoring 12/10/94, the day the monitor was placed in the home. At the infant's 56 wk Medical Follow-up visit on 4/23/95, the caregivers are informed by the CHIME research nurse that the infant has successfully completed the home monitoring portion of the protocol and are instructed to stop using the monitor. Since the caregivers brought the monitor to clinic with them, it is returned to CHIME on that same day. On the Form I, (Q#1) the date the monitor was placed in the home is 12/10/94, (Q#2) the date the monitor was retrieved from the home is 4/23/95 and (Q#3) the date caregivers instructed to stop using the monitor by CHIME personnel is also 4/23/95.

## EXAMPLE #2

On 10/2/94 a monitor was placed in a Healthy term infant's home. Two days later, the infant's mother began using the monitor. On 1/20/95, the infant's mother called the site Study Coordinator to request that the monitor be removed from the infant's home and that monitoring be discontinued. The following Wednesday (1/25/95), the vendor made a home visit to remove the monitor from the infant's home. On the Form I, (Q#1) the date the monitor was placed in the home is 10/2/94, (Q#2) the date the monitor was retrieved from the home is 1/25/95 and (Q#3) the date caregivers instructed to stop using the monitor by CHIME personnel is 1/20/95.

## EXAMPLE #3

A sibling of SIDS infant was recruited on 2/16/95 and took the monitor home on 2/17/95. On 2/18 the Coordinator called the infant's home and spoke to the infant's father who reported that the monitor was working beautifully. That was the last time the Coordinator was able to reach the infant's caregivers. After 2 months of unsuccessful weekly phone call attempts, unannounced home visits and unanswered registered letter, on 4/20 the Coordinator completed a Form I for the study infant ending the home monitoring portion of the home monitor and sent it to the DCAC. Three weeks later on 5/1, the vendor finds the infant's family at home (they are in the process of moving!), retrieves the monitor and returns it to the CHIME site. On the Form I, (Q#1) the date monitor placed in the home is 2/17/95, (Q#2) the date the monitor retrieved from the home is 5/01/95 and (Q#3) the date caregivers instructed to stop using monitor by CHIME personnel (or in this case the date of last contact for a family in which you have been unable to contact in 2 months or more) is 2/18/95.