

VI. MEDICAL FOLLOW-UP VISITS

A. Clinical Responsibilities of CHIME Investigators	VI-1
B. Incident Reports	
1. When to complete an Incident Report form	VI-2
2. How to complete an Incident Report form	VI-2
3. Processing of Incident Reports at the DCAC	VI-2
C. Scheduling	VI-3
D. Missed Visits	VI-3
E. Protocol for Administering Questionnaires	VI-4
F. Checking Questionnaires for Completeness	VI-4
G. Procedures to Complete at EVERY Medical Follow-Up	VI-5
H. Additional Procedures to Complete at 1 Month Post-Intake	VI-6
I. Additional Procedures to Complete at the Infants SECOND Medical Follow-Up	VI-6
J. Additional Procedures to Complete at 44 Weeks PCA	VI-6
K. Additional Procedures to Complete at 56 Weeks PCA	VI-7
L. Additional Procedures to Complete at 92 Weeks PCA	VI-7
M. Data Transfer to DCAC	VI-8
Table: Schedule of Medical Follow-Up Visits	VI-9

A. Clinical Responsibilities of CHIME Investigators

CHIME Investigators may serve as the attending physicians and responsible health care professionals for some study infants. The safety, welfare, and optimal clinical care of these infants must remain a high priority. As part of the conduct of the CHIME study, the investigators obtain information about these infants, some of which may be relevant for clinical care. The CHIME investigators have the responsibility to report this clinical information to the appropriate health care provider to ensure optimal clinical care of the patients according to established standards of care and reporting responsibilities. When appropriate, this information may be shared with designated authorities and other relevant care providers, based on the best judgement of the responsible CHIME investigator and in accord with the relevant policies in force at each of the local clinical sites. CHIME investigators are not always the responsible physicians nor do they always have access to complete information on which care can be based. Regardless, when clearly useful information is available it should be given to the responsible physician.

Clinical care issues, when necessary, will take priority over the CHIME research protocol. The specific clinical assessment and intervention decisions will be made by the responsible clinical team at each site, and will not be determined by the CHIME Research Protocol. If the clinical intervention by necessity takes priority over the research protocol, the CHIME Investigator (s) will inform the Data Coordinating and Analysis Center (DCAC) and the NICHD CHIME Research Coordinator through established communications procedures of their actions. The CHIME Investigator will also inform the DCAC and the NICHD CHIME Research Coordinator if it becomes necessary to share clinical information obtained under the CHIME protocol with designated authorities and other relevant care providers.

B. Incident Reports

1. When to complete an Incident Report (J1) form

An Incident Report form must be completed for any potentially harmful incident that occurs to an infant, caregiver, study personnel, or other individuals involving any aspect of the CHIME study protocol. Interruption in home monitoring (> 24 hours), temporary use of a non-study monitor or lack of contact with caregivers for 4 weeks or more must also be documented on an Incident Report. **An Incident Report Form must be completed and FAXED to the DCAC within 48 hours of the incident.**

2. How to complete an Incident Report (J1) form

- 1) Write in the name(s) of all individuals involved in the incident, (Q#1) the date and time of the incident, (Q#2) whether the incident involved equipment, use of a non-study monitor, potential or personal injury of an infant, caregiver, study personnel, vendor or other individual, (Q#3) the location where the incident occurred and (Q#4) the type of the equipment (if any) involved.
- 2) Describe the incident in clear, concise terms (what happened, who was involved, where did it occur, when did it happen and how) (Q#5).
- 3) Describe the investigation of the incident at the site both planned and completed (Q#6). Include details of the investigation such as the type of data obtained, any testing that was done, interviews or home visits made and results.
- 4) Describe all corrective action taken at the site both planned and completed (Q#7). Include instructions given to caregivers, any treatment of injury or equipment replacement.
- 5) A CHIME Investigator **MUST** sign and date page 2 of the Incident Report form **BEFORE** faxing it to the DCAC.
- 6) An Incident Report Form must be completed and FAXED to the DCAC (617-638-5066) **within 48 hours of the incident.**

3. Processing of Incident Reports at the DCAC

For each Incident Report form received by the DCAC, a four digit incident tracking number is assigned. The names of all individuals involved in the incident are removed from the report before copies are faxed to the Project Officer at NICHD (Dr. Marian Willinger) and the CTOC (Dr. Michael Neuman). Some incidents, such as an infant death, may require further review by the CHIME Incident Review Committee (Drs. Lister, Corwin, Hunt, Keens). Copies of the Incident Report will be faxed to committee members for discussion and resolution.

The DCAC tracks the status of each Incident Report using an Incident Follow-up Form (J2). An Incident Report remains 'active' until a final action or resolution has been made, at which time the Incident Report (J1) and the Follow-up Form (J2) are completed and filed. The CTOC and CHIME Engineers assist in evaluating and resolving any Incident Reports which involve technical issues or equipment function.

The Data Safety Monitoring Board is informed of all incidents by Theodore Colton, Sc.D., from the

DRAFT 06/01/95

DCAC, either by periodic reports or at yearly meetings.

Medical Follow-up visits will be scheduled for all infants while on the CHIME monitor, with a final follow-up visit at one year of age. At each visit, the study personnel will update the infant's medical history and review home monitoring procedures with caretakers. Developmental assessments will be performed in conjunction with the infant's 44, 56 and 92 week (PCA) visits. Depending on the individual Site, Medical Follow-up sessions may be conducted at either the Clinical Site or at the caretaker's home. For study infants who discontinue home monitoring early, attempt to complete the infants' remaining developmental assessments (44, 56 and 92 week PCA).

C.Scheduling

All infants will have their **first visit 4 weeks after their monitor start date**. For infants born after 38 weeks gestation, this visit may correspond to one of the visits listed below that are required for developmental testing:

According to Post-Conceptual Age (PCA)

44 weeks (1 month)

56 weeks (4 months)

For preterm births, an additional visit prior to their 44 week PCA visit is required. Infants on monitors beyond 56 weeks PCA will have additional visits every 8 weeks until monitoring is discontinued. The infants' one month post intake, 44 and 56 week Medical Follow-up visits have a 4 week window in which to collect the data, two weeks on either side of the adjusted age (i.e. 42-46 weeks for the 44 week PCA). The 92 week PCA visit has an 8 week window, 4 weeks on either side of the adjusted age (i.e. 88-96 week PCA) in which to collect the data. The CHIME management tool can assist study personnel in scheduling these visits.

D. Missed Visits

If the infant can not be seen for their scheduled Medical Follow-up visit, the Post Enrollment Medical Follow-up form (D) can be completed over the phone. H1, H4 and H6 forms may be mailed to caregivers to complete and return to the site. A medical follow-up visit should be scheduled as soon as possible. **All efforts should be made to keep the interval between visits to no more than 8 weeks.**

Please Note: If a Form D is completed over the phone, write on the cover of the form "**Phone**".

E. Protocol for Administering Questionnaires

At Medical Follow up visits, caregivers should be asked to complete the H1, H4 and H6 questionnaires without assistance from CHIME personnel. The caregiver should have an adequate writing surface to complete the forms. Before handing the caregiver the questionnaires say,

"Now I have some questionnaires for you to fill out yourself. If you have problems with any of the questions, feel free to ask me."

However, encourage the caregiver to read the questionnaire for themselves. If the caregiver is having difficulty understanding the meaning of a word you may offer alternative definitions. Be sensitive to the caregiver's cues. If you learn or suspect that the caregiver can not read, you may add,

"We would like you to fill these out yourself, but if there's any difficulty, I will be glad to read the questions to you. I'll give you a moment to look at the forms, and we can go from there."

However, if the caregiver can read, it is important that they complete the forms themselves. The visit moves faster, the information is more standard, and the information is more private.

F. Checking Questionnaire for Completeness

When the caregiver hands back the H1, H4 or H6 questionnaires, unobtrusively check the form for completeness and that only one answer has been checked for each question. If the caregiver has left something blank, ask them if they intended to do so. If they did not, ask the caregiver if they mind completing the question at this time. If the caregiver refuses to answer the question, code the question as missing (code 9). If the caregiver has circled more than one answer to a question, ask them to choose the one answer they feel best answers the question.

G.Procedures to Complete at EVERY Medical Follow-Up Visit

1.Post-Enrollment Medical Follow-up - Form D

At every Medical Follow-up, the study personnel will update the study infant's medical history by completing a **Post-Enrollment Medical Follow-up Form (Form D)** with the caregiver.

2. H2-Visit, H2-Weekly or H2-Missed form

Each Medical Follow-up visit must be documented by any one of the following forms: an **H2-Weekly, H2-Missed or H2-Visit**.

a. H2-Weekly form

If the infant is currently home monitoring and the H2-Weekly form for the week has not yet been completed over the phone and the infant is scheduled for a Medical follow-up visit during the week, the form should be completed at the time of the Medical Follow-up visit. Complete the cover of the H2-Weekly. Specify the type of contact as a visit and read the scripted questionnaire to the parent or caregiver. Be sure to complete question #12c of the form which refers to solutions and support given at the time of the visit.

b. H2-Missed form

An H2-Missed should be completed when:

- 1) When one or more consecutive H2-Weekly forms have been attempted but unsuccessfully completed, an H2-Missed form must be completed for those weeks.
- 2) When an infant has ended home monitoring but continues to come in for Medical follow-up visits, an H2-Missed must be completed to capture interval medical history; for the time period from the last completed H2-Missed or H2-Weekly to the date of the current Medical Follow-up visit.

For example, say an infant withdraws from the study after monitoring for only one month. The last completed H2-Weekly for this infant is January 1-7, 1995. The infant comes in for her 44 week visit on February 2, 1995. An H2-Missed should be completed for this infant covering the time period of January 8 - February 2, 1995.

- 3) When an infant comes in for his or her 92 week Medical Follow-up visit. An H2-Missed should be completed for the time period since the last H2-Weekly or H2-Missed was completed through the date of the Medical Follow-up visit.

(Please note: For some Pilot infants that did not have H2-Weekly forms completed, the date of last contact should be the date of the infant's last Medical follow-up visit (D form draft 6/28/93).

c. H2-Visit form

If an infant is currently home monitoring and an H2-Weekly is not completed at the time of the Medical follow-up visit, an H2-Visit form must be completed.

3. Monitoring Confidence Scale - H1

At every Medical Follow-up, the caregiver(s) confidence in home monitoring will be evaluated by having them complete the **Monitoring Confidence Scale (Form H1)**.

4. Monitor Satisfaction Scale - H4

At every Medical Follow-up, the caregiver(s) satisfaction with the home monitor will be documented by having them complete the **Monitor Satisfaction Scale (Form H4)**.

H. Additional Procedures to Complete at 1 Month Post-Intake

In addition to the 4 procedures listed in Section E, the following procedures should be completed at the 1 month post-intake Medical Follow-up Visit :

1. Parent Knowledge Evaluation Form - H6

Parent(s) or caregiver(s) should be re-tested, using the Parent Knowledge Evaluation Form (**Form H6**), on their knowledge of home monitoring.

2. Cry Recording

If an infant has not completed his/her second Cry Recording Session at the time of their PSG, it should be completed at 1 month post-intake (see **Section VIII. Cry Recording Protocol** for further details.)

I. Additional Procedures to Complete at Infant's SECOND Medical Follow-Up Visit

The Parent Knowledge Evaluation form (H6) must be completed by caregivers 3 times throughout the study: 1) intake 2) One month post intake and 3) the infant's next Medical follow-up visit after the one month post intake.

1. Parent Knowledge Evaluation Form - H6

Parent(s) or caregiver(s) should be re-tested, using the **Parent Knowledge Evaluation Form (Form H6)**, on their knowledge of home monitoring.

J. Additional Procedures to Complete at 44 WEEKS PCA

In addition to the 4 procedures listed in Section E, the following procedures should be completed at 44 weeks PCA.

1. Feelings About Parenting

Parent(s) or caregiver(s) will be tested on their **Feelings About Parenting** (see **Section XII. PSI Depression Subscale and Feelings About Parenting** for further details.)

2. PSI Depression Sub-Scale

The Parenting Stress Index (PSI) is a family system diagnostic instrument with a primary focus on the parent-child dyad. The **PSI Depression Subscale** used in CHIME consists of the depression and health subscales from the PSI parent domain and measures the emotional availability for parenting of the caregiver. For further details regarding PSI testing see **Section XII: PSI Depression Subscale and Feelings about Parenting**.

3. Bayley Scales of Infant Development - BSID

At 44 weeks PCA, the infant's development will be assessed using the Bayley Scales of Infant Development (BSID), revised 1992 version. For further details regarding BSID testing see **Section IX: Bayley Scales of Infant Development Testing**.

4. Nursing Child Assessment Feeding Scale

Parent-infant interaction will be assessed using the **Nursing Child Assessment Feeding Scale**. See **Section X: Nursing Child Assessment Feeding Scale** for further details.

K. Additional Procedures to Complete at 56 WEEKS PCA

In addition to the 4 procedures listed in Section E, the following procedures should be completed at 56 weeks PCA:

1. Feelings About Parenting

Parent(s) or caregiver(s) will be tested on their **Feelings About Parenting** (see **Section XII. PSI Depression Subscale and Feelings About Parenting** for further details.)

2. PSI Depression Sub-Scale

The Parenting Stress Index (PSI) is a family system diagnostic instrument with a primary focus on the parent-child dyad. The **PSI Depression Subscale** used in CHIME consists of the depression and health subscales from the PSI parent domain and measures the emotional availability for parenting of the caregiver. For further details regarding PSI testing see **Section XII: PSI Depression Subscale and Feelings about Parenting**.

3. Bayley Scales of Infant Development - BSID

At 56 weeks PCA, development will be assessed using the Bayley Scales of Infant Development (BSID), revised 1992 version. For further details regarding BSID testing see **Section IX: Bayley Scales of Infant Development Testing**.

4. Nursing Child Assessment Feeding Scale

Parent-infant interaction will be assessed using the **Nursing Child Assessment Feeding Scale**. See **Section X: Nursing Child Assessment Feeding Scale** for further details.

L. Additional Procedures to Complete at 92 WEEKS PCA Medical Follow-Up

In addition to the 4 procedures listed in Section E, the following procedures should be completed at 92 weeks PCA (one year) Medical Follow-up visit:

1. PSI Depression Sub-Scale

The Parenting Stress Index (PSI) is a family system diagnostic instrument with a primary focus on the parent-child dyad. The **PSI Depression Subscale** used in CHIME consists of the depression and health subscales from the PSI parent domain and measures the emotional availability for parenting of the caregiver. For further details regarding PSI testing see **Section XII: PSI Depression Subscale and Feelings about Parenting**.

2. Bayley Scales of Infant Development - BSID

At 92 weeks PCA (one year), development will be assessed using the Bayley Scales of Infant Development (BSID), revised 1992 version. If the BSID can not be completed at a home visit, it should be performed at the one year Medical Follow-up. For further details regarding BSID testing see **Section IX: Bayley Scales of Infant Development Testing**.

3. Nursing Child Assessment Teaching Scale

The Nursing Child Assessment Teaching Scale (NCATS) is used to assess parent child interaction in a teaching situation. The mother is asked to teach her child some specific task. The teaching situation usually takes from one to five minutes. See **Section XII: Nursing Child Assessment Teaching Scale** for details.

M. Data Transfer to DCAC

Completed questionnaires should be mailed along with other weekly data to the DCAC.

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SCHEDULE OF MEDICAL FOLLOW-UP VISITS

When to complete	What to complete	
Intake*	1) PSG* 2) CRY	3) Parent Knowledge Evaluation (H6) 4) Urine
One month Post-Intake	1) CRY 2) Parent Knowledge Evaluation (H6)	Medical Follow-up: 3) Post-Enrollment Medical Follow-up (D) 4) H2-Visit, H2-Weekly or H2-Missed 5) Monitoring Confidence Scale (H1) 6) Monitor Satisfaction (H4)
Second Medical Follow-up Visit**	1) Parent Knowledge Evaluation (H6)**	Medical Follow-up: 2) Post-Enrollment Medical Follow-up (D) 3) H2-Visit, H2-Weekly or H2-Missed 4) Monitoring Confidence Scale (H1) 5) Monitor Satisfaction (H4)
44 weeks PCA (1 month)	1) Bayley 2) Feeding Scale 3) Feelings about Parenting 4) PSI Sub-scale	Medical Follow-up: 5) Post-Enrollment Medical Follow-up (D) 6) H2-Visit, H2-Weekly or H2-Missed 7) Monitoring Confidence Scale (H1) 8) Monitor Satisfaction (H4)
50 weeks PCA (2.5 months)		Medical Follow-up: 1) Post-Enrollment Medical Follow-up (D) 2) H2-Visit, H2-Weekly or H2-Missed 3) Monitoring Confidence Scale (H1) 4) Monitor Satisfaction (H4)
56 weeks PCA (4 months)	1) Bayley 2) Feeding Scale 3) Feelings about Parenting 4) PSI Sub-scale	Medical Follow-up: 5) Post-Enrollment Medical Follow-up (D) 6) H2-Visit, H2-Weekly or H2-Missed 7) Monitoring Confidence Scale (H1) 8) Monitor Satisfaction (H4)
Medical Follow-up Visits Scheduled every 8 weeks thereafter, while Home Monitored		
1) Post-Enrollment Medical Follow-up (D) 2) H2-Visit, H2-Weekly or H2-Missed 3) Monitoring Confidence Scale (H1) 4) Monitor Satisfaction (H4)		
92 weeks PCA (1 yr)	1) Bayley 2) Teaching Scale 3) PSI Sub-scale	Medical Follow-up: 4) Post-Enrollment Medical Follow-up (D) 5) H2-Visit, H2-Weekly or H2-Missed 6) Monitoring Confidence Scale (H1) 7) Monitor Satisfaction (H4)

*Apnea of Infancy, Premature and Siblings of SIDS infants will have a PSG at intake. DCAC will assign Healthy Term Infants an adjusted age in which to have their PSGs.

** The H6 form must be completed at the second Medical Follow-up visit immediately following the one-month post intake visit which may correspond with any of the visits listed.

DRAFT 06/01/95