

BABY HUG FOLLOW-UP STUDY II
CLINICAL DATA REPORT

PART I: IDENTIFYING INFORMATION

1. Patient's ID Number: _____ 2. Current Clinic: _____
SUBJECT_ID SITE_ID
3. Patient's Letter Code: _____ LETTER_CD
4. Abstraction Date: _____ - _____ - _____ VISIT_DT
Month Day Year

PART II: INTERVAL INFORMATION

1. Visit: _____ M VISIT
2. Interval Start Date: _____ - _____ - _____ INTERVAL_START_DT
Month Day Year
3. Interval End Date: _____ - _____ - _____ INTERVAL_END_DT
Month Day Year
4. Any patient contact during this interval? PATIENT_CONTACT Yes No*
(1) (2)
- *A. If no, reason _____ PATIENT_CONTACT_RSN

*If No, Skip to Part IX.

PART III: HU USE

1. Was the patient prescribed HU at any time during this interval? HU_PRESCRIBED Yes** No*
(1) (2)

*If No, Skip to Part IV.

**A. If yes, what was the:

1. Dose at the first time it was prescribed this interval: _____ . _____ mg/kg
HU_DOSE_WEIGHT

- F. Absolute Neutrophil Count LAST_NEUTROPHIL_CNT _____ . _____ K/mm³ LAST_NEUTROPHIL_NOT_DONE (1) Not Done
- G. Platelet Count LAST_PLATELETS_CNT _____ . _____ K/mm³
- H. Red Blood Cell Count LAST_RBC _____ . _____ M/mm³

4. Were any of the following laboratory values obtained during this interval? LAB_VALUES Yes No*
 (1) (2)

- *A. If No, reason: NO_LAB_REASON
1. Not a routine part of care (1)
 2. Other (2)
 - a. If other, Specify: NOLAB_REASON_SP _____

*If No, Skip to Part V.

B. Creatinine:

1. Date: _____ - _____ - _____ (1) Not Done
CREATININE_DT Month Day Year CREATININE_NOT_DONE

2. Value: _____ . _____ mg/dL CREATININE_VALUE

C. ALT:

1. Date: _____ - _____ - _____ (1) Not Done
ALT_DT Month Day Year ALT_NOT_DONE

2. Value: _____ IU/L ALT_VALUE

D. GGT:

1. Date: _____ - _____ - _____ (1) Not Done
GGT_DT Month Day Year GGT_NOT_DONE

2. Value: _____ u/L GGT_VALUE

ID Number	Visit	Seq

PART V: IMAGING RESULTS

1. Were any TCD's performed during this interval?

Yes No*
 (1) (2) TCD_IMAGE_YN

*If No, Skip to Part V, 2.

A.				B.					
TCD Date				*Results					
				TCD_RESULT2					
1.	____	-	____	-	____	(1)	(2)	(3)	(4)
	Month		Day		Year				
2.	____	-	____	-	____	(1)	(2)	(3)	(4)
	Month		Day		Year				
3.	____	-	____	-	____	(1)	(2)	(3)	(4)
	Month		Day		Year				
4.	____	-	____	-	____	(1)	(2)	(3)	(4)
	Month		Day		Year				
5.	____	-	____	-	____	(1)	(2)	(3)	(4)
	Month		Day		Year				
6.	____	-	____	-	____	(1)	(2)	(3)	(4)
	Month		Day		Year				

*Results

1. Normal (all mean velocities less than 170)
2. Conditional (highest mean velocity 170-199)
3. Abnormal (any mean velocity over 200)
4. Performed per protocol, results unknown

PASSIVE SUBJECTS: If a clinical TCD has been performed, select the one closest to age 10, and send it in for central review

ID Number Visit Seq

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4. Pain

A. Has the child experienced pain (defined as pain lasting four hours or more without other obvious cause for which medication such as ibuprofen, acetaminophen, or acetaminophen with opioid was taken for relief) even if not seen by a medical professional during the interval? PAIN2 Yes* No
(1) (2)

*1. If yes, how many episodes of pain has the patient experienced during this interval? PAIN_EPISODES

5. Surgery

A. Did the patient have at least one surgery during this interval? SURGERY Yes* No
(1) (2)

*1. If yes, identify the type of each surgery and give date:

a. Tonsillectomy, Adenoidectomy or both TONSILLECTOMY_ND
(1) Not Done
 Date: _____ - _____ - _____ TONSILLECTOMY_DT
 Month Day Year

b. Splenectomy (open or aparoscopic) SPLENECTOMY_ND
(1) Not Done
 Date: _____ - _____ - _____ SPLENECTOMY_DT
 Month Day Year

c. Cholecystectomy and/or ERCP CHOLECYSTECTOMY_ND
(1) Not Done
 Date: _____ - _____ - _____ CHOLECYSTECTOMY_DT
 Month Day Year

d. Ear tubes, hernia repair, dental rehabilitation EAR_NOT_DONE
(1) Not Done
 Date: _____ - _____ - _____ EAR_DT
 Month Day Year

e. Other Yes^ No
(1) (2)
SURGERY_OTHER

^1. If other, specify: SURGERY_OTHER_SP

ID Number	Visit	Seq

C. Was iron overload assessed during this interval? Yes* No
(1) (2)
IRONOVL

*If yes,

1. Ferritin (highest value in interval) _____ ng/ml FERRITIN_HIGH
Not done

2. Ferriscan or MRI _____ . _____ gm/gm dn weight of liver FERRISCAN_MRI (1)
FERRISCAN_MRI_ND

3. Liver Bx _____ . _____ gm/gm dn weight of liver LIVER_BX (1)
LIVER_BX_ND

D. Was iron chelation therapy prescribed during this interval? Yes* No
(1) (2)
IRONTHPY

*If yes,

Desferal (Deferioxamine) (1)

Ex Jade (Deferrisirox) (2)

L1 (Deferitronine) (3) IRON_MED

ID Number	Visit	Seq

3. A. Was the spleen reported to be palpable below the costal margin at any time during this interval? SPLEEN_PALPABLE Yes No
(1) (2)

If No, Skip to Part IX.

- B. On what date was it the largest (most centimeters below costal margin): SPLEEN_LARGEST_DT
 _____ - _____ - _____
 Month Day Year

Write the largest value below:

1. Mid-clavicular line: MID_CLAVICULAR MID_CLA_NOTDONE
 _____ . _____ cm below costal margin (1) Not Done
2. Anterior axillary line: ANTEROR_AXILLARY ANT_AXI_NOTDONE
 _____ . _____ cm below costal margin (1) Not Done

- C. Was the child diagnosed with acute splenic sequestration during this interval? DIAG_SPLENIC_SEQU Yes No
(1) (2)

PART IX: COORDINATION

1. Checked for completeness and accuracy:

- A. Certification number: _____ - _____ CERT_NO
- B. Signature: _____ CERT_SIG
- C. General Comments: _____ GEN_CMNT
- _____

ID Number	Visit	Seq