Baby hug Follow-up Study (BHFS)
CLINICAL DATA REPORT

Form 010
Revision 4

Tue Sep 22 10:20:47 EDT 2015

Subject: SUBJECT_ID	Letter Code: LETTER_CD	Visit: VISIT_NBR

1. Visit Date: VISIT_DT

PART II: INTERVAL INFORMATION

1. Visit	VISIT
2. Interval Start Date:	INTERVAL_START_DT
3. Interval End Date:	INTERVAL_END_DT
4. Any patient contact during this interval?	PATIENT_CONTACT
A. If No, reason:	PATIENT_CONTACT_RSN

If No, Skip to Part IX.

PART III: HU USE

1. Was the pateint prescribed HU at any time during this interval?	HU_PRESCRIBED

If No, Skip to Part IV.

A. If yes, what was the:

1. Dose at the first time it was prescribed this interval:	HU_DOSE_WEIGHT

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2. Dose form	HU_DOSE_FORM
2. Was the patient still being prescribed HU at the end of the interval?	HU_INTERVAL_END
A. If yes, what was the:	
1. Dose at the end of the interval	HU_DOSE_WEIGHT2
2. Dose form	HU_DOSE_FORM2
B. If No, what was the date the patient stopped being prescribed HU?	HU_END_DT
3. Did the patient have HU held because of possible drug toxicity during this interval?	HU_TOXICITY
A. If Yes, check all that apply:	
1. Low ANC	LOW_ANC
2. Low Hgb	LOW_HGB
3. Low PHs	LOW_PHS
4. Other bacterial or viral infection	OTHER_INFECTION
5. Other	OTHER_TOXICITY_FTR
a. If Other, specify:	HU_TOXICITY_SP
4. Estimate how many weeks during this interval the patient actually took HU:	HU_TREAT_WEEKS

This is the number of weeks HU was taken minus the number of weeks HU was stopped due to toxicity, if applicable. If there was no toxicity, it is the number of weeks HU was taken in this time period.

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PART IV: BLOOD RESULTS

1. Were any blood specimens collected for clinical reasons during this interval?	BLOOD_COLLECT	
A. If No, reason	BLOOD_COLLECT_REASON	
If No, Skip to Part V.		
2. First CBC in interval:		
A. Date:	FIRST_CBC_DT	
B. Hemoglobin	FIRST_HEMGLOBIN	
C: MCV	FIRST_MCV	
D. Reticulocyte (% of RBC)	FIRST_RETIC_CNT	FIRST_RETIC_NOT_DONE
E. White Blood Cell Count	FIRST_WBC_ACOUNT	
F. Absolute Neutrophil Count	FIRST_NEUTROPHIL_CNT	FIRST_NEUTROPHIL_NOT_DONE
G. Platelet Count	FIRST_PLATELETS_CNT	
H. Red Blood Cell Count	FIRST_RBC	
3. Last CBC in interval:		
A. Date:	LAST_CBC_DT	LAST_CBC_NOT_DONE
B. Hemoglobin	LAST_HEMGLOBIN	
C. MCV	LAST_MCV	
D. Reticulotyte (% of RBC)	LAST_RETIC_CNT	LAST_RETIC_NOT_DONE
E. White Blood Cell Count	LAST_WBC_ACOUNT	
F. Absolute Neutrophil Count	LAST_NEUTROPHIL_CNT	LAST_NEUTROPHIL_NOT_DONE
G. Platelet Count	LAST_PLATELETS_CNT	
H. Red Blood Cell Count	LAST_RBC	

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4. Were any of the following laboratory values obtained during this interval?	LAB_VALUES
*A. If No, reason:	NO_LAB_REASON
1. If Other, specify:	NOLAB_REASON_SP

*If No, Skip to Part V.

B. Creatinine:		
1. Date:	CREATININE_DT	CRATININE_NOT_DONE
2. Value:	CRATININE_VALUE	
C. ALT		
1. Date:	ALT_DT	ALT_NOT_DONE
2. Value:	ALT_VALUE	
D. GGT		
1. Date:	GGT_DT	GGT_NOT_DONE
2. Value:	GGT_VALUE	
E. Fetal Hemoglobin:		
1. Date:	FETAL_HEMOGLOBIN_DT	FETAL_NOT_DONE
2. Value:	FETAL_HEMO_VAL	

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PART V: IMAGING RESULTS

1. Were any TCDs performed during this interval?: **TCD_IMAGE_RESULTS**

If No, skip to Part V, 4

	TCD Date:	TCD Result:
1	TCD_DT	TCD_RESULT

COMPLETE TRANSMITTAL FORM 105 AND FAX ALONG WITH A COPY OF ALL TCD REPORTS TO THE MEDICAL COORDINATING CENTER.

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2. MRI Date — MRI_DT | MRI_NOT_DONE

A. if MRI done, result:

CHECK THE MOST SEVERE RESULT

MRI_RESULTS

1. If Other, specify — MRI_RESULTS_SP

COMPLETE TRANSMITTAL FORM 105 AND FAX ALONG WITH A COPY OF THE REPORT TO THE MEDICAL COORDINATING CENTER.

3. MRA Date — MRA_DT | MRA_NOT_DONE

A. If MRA done, any result abnormal? — MRA_ABNORMAL

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4. CT Date — CT_DT | CT_NOT_DONE

A. If CT done, any result abnormal? — CT_ABNORMAL

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PART VI: OTHER PROCEDURES

1. EEG Date	EEG_DT	EEG_NOT_DONE
A. If EEG done, any result abnormal?	EEG_ABNORMAL	
2. PFTs Date	PFTS_DT	PFTS_NOT_DONE
A. If Pulmonary Function Tests done, any result abnormal?	PFTS_ABNORMAL	
3. Neuropsych Date	NEUROPSYCH_DT	NEUROPSYCH_NOT_DONE
A. If neuropsychology testing done, any result abnormal?	NEUROPSYCH_ABNORMAL	
1. Specify test:	NEUROPSYCH_SP	

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4. Other clinical tests done:	OTHER_TEST
A. If Yes, specify	OTHER_TEST_SP

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PART VII: CLINICAL EVENTS

1. Clinic Visits

A. During this interval how many times was this patient seen in clinic (not ER, day unit, or hospital)?	CLINIC_VISITS

If zero, Skip to Part VII Item 2

B. Enter the number of visits for which the following were the main reasons for each visit in this time period:

1. Routine Clinical Visit (physical examination by sickle cell team)	PERIODIC_CLIN_VIS
2. HU toxicity assessment (blood count check to monitor HU therapy and possible side effects)	HU_TOXICITY_ASSESS4
3. Other clinical service (including follow-up of crisis event and general pediatrics)	OTHER_VISITS
4. Other	OTHER_VISITS_2
a. If Other, specify:	OTHER_VISITS_SP

2. Hospitalization

A. How many times was this patient seen in an ER or day hospital during this interval (in your facility or another):	ER_VISITS

If zero, Skip to Part VII Item 3

B. Reasons for visits:

1. Acute splenic sequestration crisis	ACUTE_SPLENIC_SEQUES
2. Acute chest syndrome	ACUTE_CHEST_SYNDROME
3. Neurologic event (stroke or seizure)	STROKE_SEIZURE
4. Aplastic Crisis	APLASTIC_CRISIS
5. Urinary tract infection	URINARY_TRACT_INFECT
6. Fever or febrile illness including URI/sinusitis/cold/flu	FEVER_FEBRILE

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7. Other acute illness, no fever	NO_FEVER
8. Trauma including broken bones and sprains	TRAUMA
9. Sickle Cell Pain Crisis (including dactylitis)	PAIN
10. Other	OTHER_CRISIS
a. If Other, specify:	OTHER_CRISIS_SP
3. How many times was the patient admitted to the hospital during this interval (in your facility or another)?	HOSPITAL_TIMES

If zero, Skip to Part VII Item 4

A. What was the primary discharge diagnosis for each of these admissions?

1. Neurologic event (stroke or seizure)	DIAGNOSIS_STROKE
2. Acute splenic sequestration crisis	DIAG_SPENIC_SEQUES
3. Acute chect syndrome	DIAGNOSIS_CHEST
4. Aplastic Crisis	DIAGNOSIS_APLASTIC
5. Urinary tract infection	DIAGNOSIS_URINARY
6. Fever or febrile illness including URI/sinusitis/cold/flu	DIAGNOSIS_FEVER
7. Other acute illness, no fever	DIAGNOSIS_NO_FEVER
8. Trauma including broken bones and sprains	DIAGNOSIS_TRAUMA
9. Sickle Cell Pain Crisis (including dactylitis)	DIAGNOSIS_PAIN
10. Surgery (see part VII, item 5 below)	DIAGNOSIS_SURGERY
11. Other:	DIAGNOSIS_OTHER
a. If Other, specify:	DIAGNOSIS_OTHER_SP

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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
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
1. If yes, identify the type of each surgery and give date:	
a. Tonsillectomy, Adenoidectomy or both	TONSILLECTOMY_ND
Date:	TONSILLECTOMY_DT
b. Splenectomy (open or laproscopic)	SPLENECTOMY_NOT_DONE
Date:	SPLENECTOMY_DT
c. Cholecystectomy and/or ERCP	CHOLECYSTECTOMY_ND
Date:	CHOLECYSTECTOMY_DT
d. Ear tubes, hernia repair, dental rehabilitation	EAR_NOT_DONE
Date:	EAR_DT
e. Other	SURGERY_OTHER
1. If Other, specify	SURGERY_OTHER_SP

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6. Transfusion

A. Was the patient on a chronic transfusion program during this interval (meaning scheduled transfusions every two-six weeks for three months or more)?	CHRONIC_TRANSFUSION
1. If yes, what was the main reason for the chronic transfusion program:	CHRONIC_TRANS_REASON
a. If Other, specify:	CHRONIC_TRANS_SP
B. Did the patient receive an episodic transfusion during this interval (meaning a transfusion, scheduled or not that was for a specific problem or to prepare them for surgery)?	EPISODIC_TRANSFUSION
1. If yes, what was the main reason for the episodic transfusion?	EPISODIC_TRANS_RSN
a. If Other, specify:	EPISODIC_TRANS_SP

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PART VIII: PHYSICAL EXAMINATION

If there are more than three sets of collected physical examination data, use the first and last in the sequence and select the one closest in days to the midpoint of the interval. Sickle Cell or Hematology clinic examinations are preferred over ER/hospital/general pediatric visits if there is a choice.

1. Was a physical examination performed during this interval? **PHISICAL_EXAM**

If No, Skip to Part IX

2. Growth Parameters:

A. First Encounter	Date:	FIRST_ENCOUNTER_DT	
1. Height	FIRST_HEIGHT	FIRST_HEIGHT_NOTDONE	
2. Weight	FIRST_WEIGHT	FIRST_WEIGHT_NOTDONE	
3. Head Circumference	FIRST_HEAD_CIRCUM	FIRST_HEAD_NOTDONE	
B. Second Encounter (mid-point)	Date:	SECOND_ENCOUNTER_DT	SECOND_ENCOUNTER_ND

If Not Done, Skip to Part VIII, Item 2C

1. Height	SECOND_HEIGHT	SECOND_HEIGHT_ND	
2. Weight	SECOND_WEIGHT	SECOND_WEIGHT_ND	
3. Head Circumference	SECOND_HEAD_CIRCUM	SECOND_HEAD_NOTDONE	
C. Last or latest Visit	Date:	LAST_ENCOUNTER_DT	LAST_ENCOUNTER_ND

If Not Done, Skip to Part VIII, Item 3

1. Height	LAST_HEIGHT	LAST_HEIGHT_NOTDONE
2. Weight	LAST_WEIGHT	LAST_WEIGHT_NOTDONE
3. Head Circumference	LAST_HEAD_CIRCUM	LAST_HEAD_NOTDONE

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3. A. Was the spleen reported to be palpable below the costal margin at any time during this interval? — SPLEEN_PALPABLE

If No, Skip to Part IX

B. On what date was it the largest (most centimeters below costal margin) — SPLEEN_LARGEST_DT

Write the largest value below:

1. Mid-clavicular line	MID_CLAVICULAR	MID_CLA_NOTDONE
2. Anterior anillary line	ANTEROR_AXILLARY	ANT_AXI_NOTDONE

C. Was the child diagnosed with acute splenic sequestration during this interval? — DIAG_SPLENIC_SEQU

PART IX: COORDINATION

1. Checked for completeness and accuracy:

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