Baby hug Follow-up Study (BHFS)
ENROLLMENT

Form 001
Revision 2

Tue Sep 22 10:14:39 EDT 2015

Subject: SUBJECT_ID	Letter Code: LETTER_CD	Visit: VISIT_NBR

1. Visit Date: VISIT_DT

Part II: Enrollment Information

1. Did this child complete at least 18 mos. of randomized treatment in BABY HUG? If No, Skip to Part III.1.	TREAT_COMPLET (inel)
2. Has informed consent been obtained? If No, Skip to Part III.1.	FOLLOWUP_STUDY
3. Consent Information; A. Consent Date:	CONSENT_DT
B. Consent for data file to include child's information?	DATA_CONSENT
C. Consent for blood and urine specimens to be saved indefinitely?	BLOOD_SAVE_CONSENT
D. Consent for blood and urine specimens to be used for future research on sickle cell disease and related disorders?	BLOOD_FUTURE_CONSENT
4. Follow-up Group	FOLLOWUP_GROUP

Subject: SUBJECT_ID	Letter Code: LETTER_CD	Visit: VISIT_NBR

5. End of randomization - Therapy of choice	
A. Open Label Hydroxyurea?	HYDROXYUREA
If Yes, Complete Form 2 - Patient Treatment Plan	
B. Chronic Transfusion?	CHRONIC_TRANSFUSION
C. Other?	OTHER
1. If yes, specify:	SP

PART III: COORDINATION

1. Checked for completeness and accuracy:	
A. Certification number:	CERT_NO
B. Signature	CERT_SIG
C. General Comments	GEN_CMNT

Baby hug Follow-up Study (BHFS)
PATIENT TREATMENT PLAN

Form 002
Revision 2

Tue Sep 22 10:18:18 EDT 2015

Subject: SUBJECT_ID	Letter Code: LETTER_CD	Visit: VISIT_NBR

1. Visit Date: VISIT_DT

PART II: OPEN LABEL HYDROXYUREA DOSING INFORMATION

1. Date HU Started:	START_DT
2. Dose Started:	DOSE_WEIGHT
3. Dose Form (choose one):	DOSE_FORM

PART III: TREATMENT PLAN

1. A. Is there an ANC below which you will hold open label HU treatment?	ANC_LOW
B. If Yes,	TREAT_DOSE1
1. If Other, then specify:	DOSE_SP1

Baby hug Follow-up Study (BHFS)
PATIENT TREATMENT PLAN

Tue Sep 22 10:18:18 EDT 2015

Subject: SUBJECT_ID	Letter Code: LETTER_CD	Visit: VISIT_NBR

2. A. Is there a platelet count below which your institution will hold open label HU treatment?	PLATELET_LOW
B. If Yes,	TREAT_DOSE2
1. If Other, then specify:	DOSE_SP2
C. Is there a hold that can be started based on spleen size or change in spleen size?	SPLEEN_CHANGE
3. A. Is there a hemoglobin below which your institution will hold open label HU treatment:	HEMOGLOBIN_LOW
If No, Skip to Part III.4A.	
If Yes, choose all that apply	
1. 6 gm/dl or below	HEMO_6GM_DL
2. 5.5 gm/dl or below	HEMO_5_5GM_DL
3. 5 gm/dl or below	HEMO_5GM_DL
4. Percentage below baseline	PCT_BELOW_BASELINE
a. If percentage below baseline, specify percentage	BELOW_BASLINE_PERC
5. Other	HEMO_LOW_OTHER
a. If Other, specify:	HEMO_AMOUNT_SP

Baby hug Follow-up Study (BHFS)
PATIENT TREATMENT PLAN

Tue Sep 22 10:18:18 EDT 2015

Subject: SUBJECT_ID	Letter Code: LETTER_CD	Visit: VISIT_NBR

4. A. Is there a hemoglobin/reticulocyte combination at which your institution will hold open label HU treatment?	**HEMO_RETICULO**
B. If yes,	
1. Hemoglobin of	**HEMO_AMOUNT2**
2. Absolute Reticulocyte of	**RETICULOCYTE_NUM**
If you answered No to 1, 2, 3 and 4, Skip to Part IV.	
5. If your institution holds HU, when will the patient return for the next blood count (choose one)?	**NEXT_COUNT**
1. If Other, then specify:	**NEXT_COUNT_SP**
6. How much HU does your institution prescribe at each blood count check?	**MEDICATION**
A. If Other, then specify:	**MEDICATION_SP**

Baby hug Follow-up Study (BHFS)
PATIENT TREATMENT PLAN

Tue Sep 22 10:18:18 EDT 2015

Subject: SUBJECT_ID	Letter Code: LETTER_CD	Visit: VISIT_NBR

PART IV: COORDINATION

1. Checked for completeness and accuracy:
   - A. Certification number: **CERT_NO**
   - B. Signature **CERT_SIG**
   - C. General Comments **GEN_CMNT**

Baby hug Follow-up Study (BHFS)
STUDY ENTRY

Form 003
Revision 1

Tue Sep 22 10:19:03 EDT 2015

Subject: SUBJECT_ID	Letter Code: LETTER_CD	Visit: VISIT_NBR

1. Visit Date: VISIT_DT

PART II: SPECIMEN COLLECTION

1. Urine or Microalbumin: Creatine(5 ml)
   - A. Label number — **URINE_LABEL** | **URINE_LABEL_ND**
   - B. Date collected — **URINE_DT**
2. Stored Blood sample (5ml EDTA lavender top)
   - A. Label number — **BLOOD_LABEL** | **BLOOD_LABEL_ND**
   - B. Date Collected — **BLOOD_DT**
3. Cystatin C*
   - A. Label number — **CYSTATIN_C_LABEL** | **CYSTATIN_C_ND**
   - B. Date Collected — **CYSTATIN_C_DT**

*Cystatin C should only be collected if a specimen was not obtained upon exit of the BABY HUG Treatment Study. Coordinator should contact the MCC to verify whether or not Cystatin C should be collected.

Baby hug Follow-up Study (BHFS)
STUDY ENTRY

Form 003
Revision 1

Tue Sep 22 10:19:03 EDT 2015

Subject: SUBJECT_ID	Letter Code: LETTER_CD	Visit: VISIT_NBR

PART III: COORDINATION

1. Checked for completeness and accuracy:
   - A. Certification number: **CERT_NO**
   - B. Signature **CERT_SIG**
   - C. General Comments **GEN_CMNT**

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

Subject: SUBJECT_ID	Letter Code: LETTER_CD	Visit: VISIT_NBR

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.

Subject: SUBJECT_ID	Letter Code: LETTER_CD	Visit: VISIT_NBR

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	

Subject: SUBJECT_ID	Letter Code: LETTER_CD	Visit: VISIT_NBR

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	

Subject: SUBJECT_ID	Letter Code: LETTER_CD	Visit: VISIT_NBR

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.

Subject: SUBJECT_ID	Letter Code: LETTER_CD	Visit: VISIT_NBR

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

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

4. CT Date — CT_DT | CT_NOT_DONE

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

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

Subject: SUBJECT_ID	Letter Code: LETTER_CD	Visit: VISIT_NBR

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	

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

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

Subject: SUBJECT_ID	Letter Code: LETTER_CD	Visit: VISIT_NBR

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

Subject: SUBJECT_ID	Letter Code: LETTER_CD	Visit: VISIT_NBR

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

Subject: SUBJECT_ID	Letter Code: LETTER_CD	Visit: VISIT_NBR

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

Subject: SUBJECT_ID	Letter Code: LETTER_CD	Visit: VISIT_NBR

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

Subject: SUBJECT_ID	Letter Code: LETTER_CD	Visit: VISIT_NBR

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

Subject: SUBJECT_ID	Letter Code: LETTER_CD	Visit: VISIT_NBR

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

Baby hug Follow-up Study (BHFS)
48-MONTH OR EXIT LABORATORY TESTS

Form 011
Revision 1

Tue Sep 22 10:21:34 EDT 2015

Subject: SUBJECT_ID	Letter Code: LETTER_CD	Visit: VISIT_NBR

1. Visit Date: VISIT_DT

PART II: SPECIAL TESTS AND PROCEDURES

1. Urine Microalbumin: Creatinine (5 ml):
   - A. Label Number: **URINE_LABEL_NUM** **URINE_LABEL**
   - B. Date Collected: **URINE_DT**
2. Stored Blood Sample (5 ml EDTA lavender top):
   - A. Label Number: **BLOOD_LABEL_NUM** **BLOOD_LABEL**
   - B. Date Collected: **BLOOD_DT**
3. VDJ/HJB (3 ml EDTA lavender top):
   - A. Label Number: **VDJ_LABEL_NUM** **VDJ_LABEL**
   - B. Date Collected: **VDJ_DT**

Baby hug Follow-up Study (BHFS)
48-MONTH OR EXIT LABORATORY TESTS

Tue Sep 22 10:21:34 EDT 2015

Subject: SUBJECT_ID	Letter Code: LETTER_CD	Visit: VISIT_NBR

4. Pitted Cell (0.1 ml EDTA gluteraldehyde):

A. Label Number:	CELL_LABEL_NUM	CELL_LABEL
B. Date Collected:	CELL_DT	

5. Cystatin C (0.5 ml red top):

A. Label Number:	CYSTATIN_LABEL_NUM	CYSTATIN_LABEL
B. Date Collected:	CYSTATIN_DT	

6. Creatinine (0.5 ml red top):

A. Label Number:	CREATININE_LABEL_NUM	CREATININE_LABEL
B. Date Collected:	CREATININE_DT	

PART III: COORDINATION

1. Checked for completeness and accuracy:

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

Baby hug Follow-up Study (BHFS)
EXIT FORM

Form 012
Revision 1

Tue Sep 22 10:22:17 EDT 2015

Subject: SUBJECT_ID	Letter Code: LETTER_CD	Visit: VISIT_NBR

1. Visit Date: VISIT_DT

PART II: END OF TREATMENT

1. End of Follow-up Participation

A. Planned end of follow-up participation **If Yes, skip to Part III.**	END_PARTICIPATION
B. Reason for study exit:	
1. Inactive follow-up status	INACTIVE
2. Permanent relocation to area with no BABY HUG Clinic	RELOCATION
3. Withdrew consent	WITHDRAW
4. Death	DEATH
5. Other condition requiring end of participation	OTHER
a. If Yes, specify:	OTHER_SP
2. Date of last contact with family:	LAST_CONTACT_DT

Baby hug Follow-up Study (BHFS)
EXIT FORM

Form 012
Revision 1

Tue Sep 22 10:22:17 EDT 2015

Subject: SUBJECT_ID	Letter Code: LETTER_CD	Visit: VISIT_NBR

PART III: COORDINATION

1. Checked for completeness and accuracy:
   - A. Certification number: **CERT_NO**
   - B. Signature **CERT_SIG**
   - C. General Comments **GEN_CMNT**

Baby hug Follow-up Study (BHFS)
24 MONTH TRANSCRANIAL (TCD) EXAM

Form 013
Revision 1

Tue Sep 22 10:22:53 EDT 2015

Subject: SUBJECT_ID	Letter Code: LETTER_CD	Visit: VISIT_NBR

1. Visit Date: VISIT_DT

Part II: EQUIPMENT

1. TCD Examiner's last name	RDR46
2. Patient's position during exam	PTNTPOS
A. SPECIFY	POS_SP

Part III: EXAMINATION PERFORMANCE

1. Completeness of exam	COMPEXAM
A. Reason for incomplete exam	INCEXAM
1. Specify	INCEX_SP
B. TCD Label	TCD_LBL

Part IV: COORDINATION

1. Checked for completeness and accuracy:

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

Baby hug Follow-up Study (BHFS)

Form 020

24_MONTH SPECIAL TESTS AND LABORATORY TESTS (Active Patients Only)

Revision 2

Tue Sep 22 10:25:44 EDT 2015

Subject: SUBJECT_ID	Letter Code: LETTER_CD	Visit: VISIT_NBR

1. Visit Date: VISIT_DT

PART II: BLOOD COLLECTION

1. Were blood specimens collected as part of active follow-up?	**BLOOD_COLLECT**	
If No, skip to Part III.		
2. HbF (0.5 ml EDTA lavender top):		
A. Label Number:	**HBF_LABEL**	**HBF_LABEL_ND**
B. Date Collected:	**HBF_DT**	
3. Howell-Jolly Bodies (0.1ml EDTA lavender top):		
A. Label Number:	**HOWELL_LABEL**	**HOWELL_LABEL_ND**
B. Date Collected:	**HOWELL_DT**	

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Subject: SUBJECT_ID	Letter Code: LETTER_CD	Visit: VISIT_NBR

4. Pitted Cell (0.1 ml EDTA lavender top):

A. Label Number:	CELL_LABEL	CELL_LABEL_ND
B. Date Collected:	CELL_DT	

5. Cystatin C (0.5 ml red top):

A. Label Number:	CYSTATIN_LABEL	CYSTATIN_LABEL_ND
B. Date Collected:	CYSTATIN_DT	

6. Creatinine (0.5 ml red top):

A. Label Number:	CREATININE_LABEL	CREATININE_LABEL_ND
B. Date Collected:	CREATININE_DT	

PART III: SPECIAL TESTS AND PROCEDURES

1. Liver/Spleen Scan Performed? LIVER_SCAN

If Yes, record date performed and complete Form 21. A. Date Performed:

Tue Sep 22 10:25:44 EDT 2015

Subject: SUBJECT_ID	Letter Code: LETTER_CD	Visit: VISIT_NBR

2. Abdominal Sonogram Performed?	ABDOMINAL_SONO
If Yes, record date performed and complete Form 23.	
A. Date Performed:	ABDOMINAL_SONO_DT
3. Neuropsychology Testing (WPPSI) Performed?	NEUROPSYCH_TEST
If Yes, record date performed and complete Form 24.	
A. Date Performed:	NEUROPSYCH_DT

PART IV: COORDINATION

1. Checked for completeness and accuracy:	
A. Certification number:	CERT_NO
B. Signature	CERT_SIG
C. General Comments	GEN_CMNT

Baby hug Follow-up Study (BHFS)
LIVER-SPLEEN SCAN PERFORMANCE

Form 021
Revision 1

Tue Sep 22 10:26:53 EDT 2015

Subject: SUBJECT_ID	Letter Code: LETTER_CD	Visit: VISIT_NBR

1. Visit Date: VISIT_DT

PART II: SCAN SPECIFICS

1. Camera manufacturer:	CAMTYPE
2. Camera Model:	CAMMODEL
3. Collimator:	COLLIMAT
4. Supplier of TC-sulfur colloid:	SUPCOLLD
5. Dose injected:	DOSINJ44
6. Time of injection (24-hour clock)	INJ44HR INJ44MN
7. Time imaging started	IMSTRHR IMSTRMN
8. Time imaging completed	IMCOMHR IMCOMMN
9. Camera angle:	CAMANGLE
10. True Posterior imaging time (min:sec)	ANTPOSMN ANTPOSSC
11. Right Posterior Oblique Image Counts:	OBLIMCNT
12. Film Label:	LSSCNLBL
13. Adequecy of imaging (answer both questions)	
A. 400 K Image adequate?	AOI400K
B. Timed Image adequate?	AOITIMED

Baby hug Follow-up Study (BHFS)
LIVER-SPLEEN SCAN PERFORMANCE

Tue Sep 22 10:26:53 EDT 2015

Subject: SUBJECT_ID	Letter Code: LETTER_CD	Visit: VISIT_NBR

Part III: Quantitative Assessment

1. 400K image

A. Anterior View

1. Spleen

a. Total counts	**KASPLTOT**
b. # Pixels in ROI	**KASPLPIX**
c. Counts/pixel	**KASPLCNT**

2. Liver

a. Total counts	**KALIVTOT**
b. # Pixels in ROI	**KALIVPIX**
c. Counts/pixel	**KALIVCNT**

B. Posterior View

1. Spleen

a. Total counts	**KPSPLTOT**
b. # Pixels in ROI	**KPSPLPIX**
c. Counts/pixel	**KPSPLCNT**

2. Liver

a. Total counts	**KPLIVTOT**
b. # Pixels in ROI	**KPLIVPIX**
c. Counts/pixel	**KPLIVCNT**

C. Spleen/Liver Ratio

1. Total counts	**KSLRTTOT**
2. Counts/pixel	**KSLRTCNT**

Baby hug Follow-up Study (BHFS)
LIVER-SPLEEN SCAN PERFORMANCE

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2. Timed image

A. Left Anterior Oblique View

1. Spleen

a. Total counts	**TASPLTOT**
b. # Pixels in ROI	**TASPLPIX**
c. Counts/pixel	**TASPLCNT**

2. Liver

a. Total counts	**TALIVTOT**
b. # Pixels in ROI	**TALIVPIX**
c. Counts/pixel	**TALIVCNT**

B. Right Posterior Oblique View

1. Spleen

a. Total counts	**TPSPLTOT**
b. # Pixels in ROI	**TPSPLPIX**
c. Counts/pixel	**TPSPLCNT**

2. Liver

a. Total counts	**TPLIVTOT**
b. # Pixels in ROI	**TPLIVPIX**
c. Counts/pixel	**TPLIVCNT**

C. Spleen/Liver Ratio

1. Total counts	**TSLRTTOT**
2. Counts/pixel	**TSLRTCNT**

Baby hug Follow-up Study (BHFS)
LIVER-SPLEEN SCAN PERFORMANCE

Form 021
Revision 1

Tue Sep 22 10:26:53 EDT 2015

Subject: SUBJECT_ID	Letter Code: LETTER_CD	Visit: VISIT_NBR

Part IV: Examiner

1. Examiner name:	EXAMINER_NM
2. Signature:	SIGNATURE

PART V: COORDINATION

1. Checked for completeness and accuracy:

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

Baby hug Follow-up Study (BHFS)
DTPA/GFR

Form 022
Revision 2

Tue Sep 22 10:27:38 EDT 2015

Subject: SUBJECT_ID	Letter Code: LETTER_CD	Visit: VISIT_NBR

1. Visit Date: VISIT_DT

PART II: ANTHROPOMETRICS

1. Height	HEIGHT	cm
2. Weight	WEIGHT	kg

PART III: DTPA MEASUREMENTS

1. Standard syringe activity		
A. Pre	STSAPRE	mCi
B. Post	STSAPOST	mCi
C. Standard Activity	STSASTAC	mCi
2. Dose syringe activity		
A. Pre	DSSAPRE	mCi
B. Post	DSSAPOST	mCi
C. Dose Administered	DTPADOSE	mCi
D. Time DTPA administered	DTPAHR	DTPAMN

Baby hug Follow-up Study (BHFS)
DTPA/GFR

Form 022
Revision 2

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Subject: SUBJECT_ID	Letter Code: LETTER_CD	Visit: VISIT_NBR

3. Room (water) background				
A. First count:	ROOMFRST	cpm		
B. Second count:	ROOMSEC	cpm		ROOMSCND
4. Standard				
A. First count:	STNDFRST	cpm		
B. Second count:	STNDSEC	cpm		STNDSCND
5. A. One-hour time (24-hr. clock)	ONEHR	ONEMN		
B. DTPA measurement	ONEDTPA	cpm		ONE_ND
C. Second DTPA measurement	ONEDTPA2	cpm		ONE_ND2
6. A. Two-hour time (24-hr. clock)	TWOHR	TWOMN		
B. DTPA measurement	TWODTPA	cpm		TWO_ND
C. Second DTPA measurement	TWODTPA2	cpm		TWO_ND2
7. A. Four-hour time (24-hr. clock)	FORHR	FORMN		
B. DTPA measurement	FORDTPA	cpm		FOR_ND
C. Second DTPA measurement	FORDTPA2	cpm		FOR_ND2
8. GFR from DTPA				
A. GFR:	GFRDTP_A	ml/min		
B. GFR:	GFRDTP_B	ml/min/m^2		
C. GFR	GFRDTP_C	ml/min/1.73m^2		

Baby hug Follow-up Study (BHFS)
DTPA/GFR

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Subject: SUBJECT_ID	Letter Code: LETTER_CD	Visit: VISIT_NBR

Part IV: TECHNICIAN

1. Technician Name:	EXAMINER_NM
2. Signature:	SIGNATURE

PART V: COORDINATION

1. Checked for completeness and accuracy:

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

Baby hug Follow-up Study (BHFS)
ABDOMINAL SONOGRAM (ULTRASOUND) PERFORMANCE

Form 023
Revision 1

Tue Sep 22 10:28:18 EDT 2015

Subject: SUBJECT_ID	Letter Code: LETTER_CD	Visit: VISIT_NBR

1. Visit Date: VISIT_DT

PART II: EQUIPMENT AND QUALITY

1. Equipment	ABDSEQPT
2. Transducer	ABDSTRNS
3. Quality of study	STATUS45
4. Film label	SONO_LBL

PART III: Sonographer

1. Sonographer's name:	EXAMINER_NM
2. Signature:	SIGNATURE

Baby hug Follow-up Study (BHFS)
ABDOMINAL SONOGRAM (ULTRASOUND) PERFORMANCE

Form 023
Revision 1

Tue Sep 22 10:28:18 EDT 2015

Subject: SUBJECT_ID	Letter Code: LETTER_CD	Visit: VISIT_NBR

PART IV: COORDINATION

1. Checked for completeness and accuracy:

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

Baby hug Follow-up Study (BHFS)
WPPSI FORM

Form 024
Revision 3

Tue Sep 22 10:31:37 EDT 2015

Subject: SUBJECT_ID	Letter Code: LETTER_CD	Visit: VISIT_NBR

1. Visit Date: VISIT_DT

PART II: SUBTEST SCORING

1. Block Design (Discontinue testing after 3 consecutive scores of 0.)

A. Record form Data. Choose one response for each question.

1. 4 Red	BD_1	11. 4 two-color	BD_11
2. 6 Red	BD_2	12. 4 two-color	BD_12
3. 6 Red	BD_3	13. 4 two-color	BD_13
4. 4 Red	BD_4	14. 4 two-color	BD_14
5. 2 Red, 2 White	BD_5	15. 4 two-color	BD_15
6. 4 Red , 2 White	BD_6	16. 4 two-color	BD_16
7. 2 Red, 2 White	BD_7	17. 4 two-color	BD_17
8. 6 Red	BD_8	18. 4 two-color	BD_18
9. 4 Red, 4 White	BD_9	19. 4 two-color	BD_19
10. 4 Red, 4 White	BD_10	20. 4 two-color	BD_20
B. Total Raw Score			BD_SCORE

Baby hug Follow-up Study (BHFS)
WPPSI FORM

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Subject: SUBJECT_ID	Letter Code: LETTER_CD	Visit: VISIT_NBR

2. Information (Discontinue testing after 5 consecutive scores of 0.)

A. Record form Data. Choose one response for each question.

1. Eat	INFO_1	12. Ears	INFO_12	23. Chew	INFO_23
2. Bath	INFO_2	13. Paper	INFO_13	24. Vegetable	INFO_24
3. Drink	INFO_3	14. Bottle	INFO_14	25. Letter	INFO_25
4. Meow	INFO_4	15. Finger	INFO_15	26. Saturday	INFO_26
5. Cut	INFO_5	16. Rainbow	INFO_16	27. Shoes	INFO_27
6. Water	INFO_6	17. Legs	INFO_17	28. Week	INFO_28
7. Nose	INFO_7	18. Animals	INFO_18	29. Seasons	INFO_29
8. Knee	INFO_8	19. Gives milk	INFO_19	30. Opposite	INFO_30
9. Old	INFO_9	20. Rain	INFO_20	31. Bread	INFO_31
10. Write	INFO_10	21. Shines	INFO_21	32. Milk	INFO_32
11. Grass	INFO_11	22. Wheels	INFO_22	33. Ocean	INFO_33
				34. Sun	INFO_34

B. Total Raw Score INFO_SCORE

Baby hug Follow-up Study (BHFS)
WPPSI FORM

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Subject: SUBJECT_ID	Letter Code: LETTER_CD	Visit: VISIT_NBR

3. Matrix Reasoning (Discontinue testing after 4 consecutive scores of 0, or 4 scores of 0 on 5 consecutive items.)

A. Record form Data. Choose one response for each question.

1.	MR_1	11.	MR_11	21.	MR_21
2.	MR_2	12.	MR_12	22.	MR_22
3.	MR_3	13.	MR_13	23.	MR_23
4.	MR_4	14.	MR_14	24.	MR_24
5.	MR_5	15.	MR_15	25.	MR_25
6.	MR_6	16.	MR_16	26.	MR_26
7.	MR_7	17.	MR_17	27.	MR_27
8	MR_8	18.	MR_18	28.	MR_28
9.	MR_9	19.	MR_19	29.	MR_29
10.	MR_10	20.	MR_20		

B. Total Raw Score MR_SCORE

4. Vocabulary (Discontinue testing after 5 consecutive scores of 0.)

A. Record form Data. Choose one response for each question.

1. Car	VOC_1	3. Fork	VOC_3
2. Clock	VOC_2	4. Turtle	VOC_4

Baby hug Follow-up Study (BHFS)
WPPSI FORM

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5. Pumpkin	VOC_5	16. Castle	VOC_16
6. Shoe	VOC_6	17. Glow	VOC_17
7. Telephone	VOC_7	18. Polite	VOC_18
8. Umbrella	VOC_8	19. Holiday	VOC_19
9. Bicycle	VOC_9	20. Swing	VOC_20
10. Candy	VOC_10	21. Double	VOC_21
11. Dog	VOC_11	22. Courage	VOC_22
12. Letter	VOC_12	23. Ancient	VOC_23
13. Train	VOC_13	24. Microscope	VOC_24
14. Leaf	VOC_14	25. Nuisance	VOC_25
15. Hero	VOC_15		
B. Total Raw Score			VOC_SCORE

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Subject: SUBJECT_ID	Letter Code: LETTER_CD	Visit: VISIT_NBR

5. Picture Concepts (Discontinue testing after 4 consecutive scores of 0.)

A. Record form Data. Choose one response for each question.

1.	PCON_1	11.	PCON_11	21.	PCON_21
2.	PCON_2	12.	PCON_12	22.	PCON_22
3.	PCON_3	13.	PCON_13	23.	PCON_23
4.	PCON_4	14.	PCON_14	24.	PCON_24
5.	PCON_5	15.	PCON_15	25.	PCON_25
6.	PCON_6	16.	PCON_16	26.	PCON_26
7.	PCON_7	17.	PCON_17	27.	PCON_27
8.	PCON_8	18.	PCON_18	28.	PCON_28
9.	PCON_9	19.	PCON_19		
10.	PCON_10	20.	PCON_20		

B. Total Raw Score PCON_SCORE

6. Symbol Search (Discontinue testing after 120 seconds.)

A. Total Raw Score SS_SCORE

7. Word Reasoning (Discontinue testing after 5 consecutive scores of 0.)

A. Record form Data. Choose one response for each question.

1.	WR_1	11.	WR_11	21.	WR_21
2.	WR_2	12.	WR_12	22.	WR_22
3.	WR_3	13.	WR_13	23.	WR_23
4.	WR_4	14.	WR_14	24.	WR_24
5.	WR_5	15.	WR_15	25.	WR_25
6.	WR_6	16.	WR_16	26.	WR_26
7.	WR_7	17.	WR_17	27.	WR_27
8.	WR_8	18.	WR_18	28.	WR_28
9.	WR_9	19.	WR_19		
10.	WR_10	20.	WR_20		

B. Total Raw Score WR_SCORE

Baby hug Follow-up Study (BHFS)
WPPSI FORM

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Subject: SUBJECT_ID	Letter Code: LETTER_CD	Visit: VISIT_NBR

8. Coding (Discontinue testing after 120 seconds.)

A. Total Raw Score	COD_SCORE

9. Comprehension (Discontinue testing after 5 consecutive scores of 0.)

A. Record form Data. Choose one response for each question.

1. Stove	CMPHN_1	11. Share	CMPHN_11
2. Street	CMPHN_2	12. Names	CMPHN_12
3. Thank you	CMPHN_3	13. Take turns	CMPHN_13
4. Hands	CMPHN_4	14. On time	CMPHN_14
5. Shoes	CMPHN_5	15. Line	CMPHN_15
6. School	CMPHN_6	16. Permission	CMPHN_16
7. Babysitters	CMPHN_7	17. Water	CMPHN_17
8. Strangers	CMPHN_8	18. Shots	CMPHN_18
9. Home	CMPHN_9	19. Buses and trains	CMPHN_19
10. Tags	CMPHN_10	20. Vote	CMPHN_20

B. Total Raw Score	CMPHN_SCORE

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Subject: SUBJECT_ID	Letter Code: LETTER_CD	Visit: VISIT_NBR

10. Picture Completion (Discontinue testing after 5 consecutive scores of 0.)

A. Record form Data. Choose one response for each question.

1. Boy	PCOMP_1	17. Duck	PCOMP_17
2. Doll	PCOMP_2	18. Lunchbox	PCOMP_18
3. Blocks	PCOMP_3	19. Swings	PCOMP_19
4. Jacket	PCOMP_4	20. Door	PCOMP_20
5. Tricycle	PCOMP_5	21. Braids	PCOMP_21
6. Chair	PCOMP_6	22. Skating	PCOMP_22
7. Rose	PCOMP_7	23. Power lines	PCOMP_23
8. Screws	PCOMP_8	24. Desk	PCOMP_24
9. Apple	PCOMP_9	25. Car	PCOMP_25
10. Clothesline	PCOMP_10	26. Fishing	PCOMP_26
11. Gloves	PCOMP_11	27. Coat	PCOMP_27
12. Kites	PCOMP_12	28. Ponytail	PCOMP_28
13. Boat	PCOMP_13	29. Hand	PCOMP_29
14. Clock	PCOMP_14	30. House	PCOMP_30
15. Ruler	PCOMP_15	31. Clown	PCOMP_31
16. Smile	PCOMP_16	32. Rooster	PCOMP_32

B. Total Raw Score PCOMP_SCORE

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Subject: SUBJECT_ID	Letter Code: LETTER_CD	Visit: VISIT_NBR

11. Similarities (Discontinue testing after 4 consecutive scores of 0.)

A. Record form Data. Choose one response for each question.

1. Red and yellow	SIM_1	13. Mothers and sisters	SIM_13
2. Cookies and ice cream	SIM_2	14. Plates and bowls	SIM_14
3. Juice and milk	SIM_3	15. Circles and squares	SIM_15
4. Socks and shirts	SIM_4	16. Cars and trucks	SIM_16
5. Dogs and cats	SIM_5	17. Ears and noses	SIM_17
6. Apples and oranges	SIM_6	18. Rain and snow	SIM_18
7. Pencils and crayons	SIM_7	19. Buttons and zippers	SIM_19
8. Dolls and balls	SIM_8	20. Happy and sad	SIM_20
9. Two and three	SIM_9	21. Tables and chairs	SIM_21
10. Books and newspapers	SIM_10	22. Sweet and sour	SIM_22
11. Guitars and drums	SIM_11	23. Heavy and light	SIM_23
12. Arms and legs	SIM_12	24. Asleep and awake	SIM_24
B. Total Raw Score			SIM_SCORE

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Subject: SUBJECT_ID	Letter Code: LETTER_CD	Visit: VISIT_NBR

12. Receptive Vocabulary (Discontinue testing after 5 consecutive scores of 0.)

A. Record form Data. Choose one response for each question.

1. Foot	RV_1	20. Curly tail	RV_20
2. Cup	RV_2	21. Cash Register	RV_21
3. Doll	RV_3	22. Telescope	RV_22
4. Butterfly	RV_4	23. Beneath tree	RV_23
5. Giraffe	RV_5	24. Cymbals	RV_24
6. Painting	RV_6	25. Fancy	RV_25
7. Toaster	RV_7	26. Shaggy	RV_26
8. Snail	RV_8	27. Balancing	RV_27
9. Raining	RV_9	28. Bulldozer	RV_28
10. Vacuum Cleaner	RV_10	29. Easel	RV_29
11. Basketball	RV_11	30. Gnawing	RV_30
12. Lamp	RV_12	31. Carousel	RV_31
13. Kicking	RV_13	32. Crouching	RV_32
14. Triangle	RV_14	33. Prancing	RV_33
15. Stirring	RV_15	34. Clenching	RV_34
16. Lying down	RV_16	35. Parallel	RV_35
17. Carrying	RV_17	36. Cylinder	RV_36
18. Desert	RV_18	37. Equivalent	RV_37
19. Paying	RV_19	38. Horizontal	RV_38

B. Total Raw Score RV_SCORE

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13. Object Assembly (Discontinue testing after 3 consecutive scores of 0.)

A. Record form Data. Choose one response for each question.

1. Ball	OA_1
2. Hot dog	OA_2
3. Bird	OA_3
4. Clock	OA_4
5. Car	OA_5
6. Fish	OA_6
7. Bear	OA_7
8. Hand	OA_8
9. House	OA_9
10. Apple	OA_10
11. Dog	OA_11
12. Star	OA_12

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13. Calf	OA_13
14. Tree	OA_14
B. Total Raw Score	OA_SCORE

14. Picture Naming (Discontinue testing after 5 consecutive scores of 0.)

A. Record form Data. Choose one response for each question.

1. Car	PN_1	16. Guitar	PN_16
2. Bear	PN_2	17. Shell	PN_17
3. Banana	PN_3	18. Rake	PN_18
4. Star	PN_4	19. Nail	PN_19
5. Clock	PN_5	20. Lock	PN_20
6. Fork	PN_6	21. Ambulance	PN_21
7. Scissors	PN_7	22. Rhinoceros	PN_22
8. Turtle	PN_8	23. Iron	PN_23
9. Toothbrush	PN_9	24. Pineapple	PN_24
10. Pumpkin	PN_10	25. Teapot	PN_25
11. Ladybug	PN_11	26. Globe	PN_26
12. Broom	PN_12	27. Xylophone	PN_27
13. Whistle	PN_13	28. Thermometer	PN_28
14. Zebra	PN_14	29. Harp	PN_29
15. Kangaroo	PN_15	30. Fire extinguisher	PN_30
B. Total Raw Score			PN_SCORE

15. Child's Age at Testing

Years	AGE_YEARS
Months	AGE_MONTHS
Days	AGE_DAYS

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Subject: SUBJECT_ID	Letter Code: LETTER_CD	Visit: VISIT_NBR

16. Sums of Scaled Scores and Composite Score Conversions (Enter score in each box.)

A. Verbal IQ			
1. Sum of Scaled Score	VIQ_SCALED		
2. Composite Score	VIQ_COMP		
3. Percentile Rank	VIQ_PERCENT		
4. Confidence Interval	VIQ_CONFINT	--	VIQ_CONFINT_HIGH
B. Performance IQ			
1. Sum of Scaled Score	PIQ_SCALED		
2. Composite Score	PIQ_COMP		
3. Percentile Rank	PIQ_PERCENT		
4. Confidence Interval	PIQ_CONFINT	--	PIQ_CONFINT_HIGH
C. Processing Speed			
1. Sum of Scaled Score	PS_SCALED		
2. Composite Score	PS_COMP		
3. Percentile Rank	PS_PERCENT		
4. Confidence Interval	PS_CONFINT	--	PS_CONFINT_HIGH
D. Full Scale IQ			
1. Sum of Scaled Score	FSIQ_SCALED		
2. Composite Score	FSIQ_COMP		
3. Percentile Rank	FSIQ_PERCENT		
4. Confidence Interval	FSIQ_CONFINT	--	FSIQ_CONFINT_HIGH
E. General Language			
1. Sum of Scaled Score	GL_SCALED		
2. Composite Score	GL_COMP		
3. Percentile Rank	GL_PERCENT		
4. Confidence Interval	GL_CONFINT	--	GL_CONFINT_HIGH

Baby hug Follow-up Study (BHFS)
WPPSI FORM

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Subject: SUBJECT_ID	Letter Code: LETTER_CD	Visit: VISIT_NBR

Part III: COORDINATION

1. Checked for completeness and accuracy:
   - A. Coordinator Certification number: **CERT_NO**
   - B. Signature **CERT_SIG**
   - C. Neuropsychologist Name: **NEURO_CET_NO**
   - D. General Comments **GEN_CMNT**

Baby hug Follow-up Study (BHFS)
SERIOUS ADVERSE EVENT (ACTIVE GROUP ONLY)

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5. Admission Date	ADM_DT
6. Discharge Date	DISCH_DT

PART VIII: OUTCOMES

1. Significant new disability	SNEWDISA
2. Persistent new disability	PNEWDISA
3. Permanent new disability	PERMDISA
4. Death	DEATH
A. Date of Death	DEATH_DT
B. Location	DTH_LOC

PART IX: COORDINATION

1. Checked for completeness and accuracy:	
A. Certification number	CERT_NO
B. Signature:	CERT_SIG
C. General Comments:	GEN_CMNT

Baby hug Follow-up Study (BHFS)
SERIOUS ADVERSE EVENT (ACTIVE GROUP ONLY)

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Subject: SUBJECT_ID	Letter Code: LETTER_CD	Visit: VISIT_NBR

PART VI: REPORTABLE TREATMENTS

1. Answer each item	
A. Transfusion	TRANSFUS
1. If yes, complete a. - d. Otherwise, skip to B.	
a. Transfusion Type	TR_TYPE
b. Volume, answer b 1 or 2.	
1. Whole Blood	TRVOLWBL
OR	
2. Packed Red Cells	TRVOLPR2
c. Start Date	TSTRT_DT
d. Stop Date	TSTOP_DT
B. Placement on chronic transfusion therapy	CHRTRAN
C. Splenectomy	SPLCTMY
D. Parenteral antibiotics	PAR_ANTI
E. Dialysis, limited course	DIALYS_L

PART VII: HOSPITALIZATION

1. Hospital Name:	HOSPNAME
2. Hospital City:	HOSPCITY
3. Hospital State:	HOSP_ST
4. Hospital Zip:	HOSP_ZIP

Subject: SUBJECT_ID	Letter Code: LETTER_CD	Visit: VISIT_NBR

H. Seizures	SEIZURE
I. Headache	HEADACHE

5. Results of Imaging Tests

A. MRI of brain	F50MRI
B. CT scan of brain	F50CTBR
C. PET scan of brain	F50PTBR
D. MRA cerebral vasculature	F50MRA
E. Transcranial Doppler	F50TCD
F. Arteriogram	F50ARTGR

PART V: DIAGNOSIS/PROBLEM SEVERITY AND ATTRIBUTION

Complete PART V for each item in PART III checked YES.

	Diagnosis/Problem	Date of Onset	Number of Days	Severity	Attribution to Study Treatment	Diagnosis Unexpected
1	PROBLEM	ONSET_DT	NUMDAYS	SEVERITY	ATTR_TRT	DIAGUNXP

Subject: SUBJECT_ID	Letter Code: LETTER_CD	Visit: VISIT_NBR

B. Spleen size below LCM during SAE	SPLNSIZE_DURING
C. Nadir hemoglobin (in gm/dl)	SPLNHMGL
D. Platelet count at time of nadir hemoglobin (in k/ul)	SPLPTCNT

If PART III, Item 1C is YES, answer 3.
Otherwise, skip to 4.

3. Prolonged Hospitalization

A. Reason.	LONGHOSP_SP

If PART III, Item 1D is YES, answer 4-5.
Otherwise, skip to PART V.

4. (Stroke or TIA) Findings of

A. Loss of consciousness	LOS_CONS
B. Change in mental status	CHG_MENT
C. Loss of or difficulty with speech or vocalization	SPEECH
D. Paralysis or weakness	PARALYS
E. Difficulty with swallowing	DIFFSWAL
F. Difficulty with vision	DIFF_SEE
G. Loss of balance or dizziness	BALANCE

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Subject: SUBJECT_ID	Letter Code: LETTER_CD	Visit: VISIT_NBR

PART III: SAE

1. Please indicate all diagnoses:	
A. Acute chest syndrome	HX_ACS
B. Splenic Sequestration Crisis	HXSPLSEQ
C. Prolonged Hospitalization (greater than 7 days)	LONGHOSP
D. Stroke or TIA	HX_STROKE_TIA
E. Life Threatening Event	LIFE_THREAT_EVT
1. Specify	LIFE_THREAT_EVT_SP
F. Death	HX_DEATH
G. ICU Admission	ICU

PART IV: ADDITIONAL DIAGNOSIS INFORMATION

If PART III, Item 1A is YES, answer 1.
Otherwise, skip to 2.

1. Acute Chest Syndrome	
A. New Infiltrate	ACSNINF
B. O2% Saturation on Room Air at Presentation	ACSSRAP
C. Oxygen Administered (in Liters)	ACSOXADM
D. Mechanical Ventilation	ACSMVENT

If PART III, Item 1B is YES, answer 2.
Otherwise, skip to 3.

2. Splenic Sequestration	
A. Spleen size below LCM prior to SAE	SPLNSIZE_PRIOR

Baby hug Follow-up Study (BHFS)
SERIOUS ADVERSE EVENT (ACTIVE GROUP ONLY)

Form 025
Revision 1

Tue Sep 22 10:32:16 EDT 2015

Subject: SUBJECT_ID	Letter Code: LETTER_CD	Visit: VISIT_NBR

1. Report Date: VISIT_DT

PART II: EVENT PERIOD

1. Date of Event

A. Event Start Date	START_DT
B. Event Ending Date	E_END_DT

2. Qualifying Procedure (Event must have occurred during the 5 days following a 24 month assessment procedure.) Please note all that apply:

A. DTPA/GFR	DTPA_DT	or	DTPA_NA
B. Liver/Spleen Scan	LIVER_SPLEEN_DT	or	LIVER_SPLEEN_NA
C. Abdominal Sonogram	ABD_SONO_DT	or	ABD_SONO_NA
D. WPPSI	WPPSI_DT	or	WPPSI_NA
E. Blood Specimens	BLOOD_SPEC_DT	or	BLOOD_SPEC_NA

Baby hug Follow-up Study (BHFS)
ST. JUDE TRANSMITTAL FORM

Form 101
Revision 3

Tue Sep 22 10:43:56 EDT 2015

1. Visit Date: VISIT_DT

The original printed transmittal form should accompany the specimen(s) to the Core Laboratory. Send the specimen(s) by Federal Express on the day of collection. For HJB and/or VDJ specimens, *place a cold (not frozen) gel pack above and below the styrofoam package* . Fax a copy of this transmittal list with the Federal Express tracking number to Core Laboratory. **Use one transmittal form per patient.**

*For Cystatin C specimens, follow preparation instructions in the MOO (Chapter 4) and ship frozen (separate from HJB and VDJ samples). If unable to spin red tops, ship Cystatin C priority overnight with cold gel pack as indicated for HJB and VDJ.

Clinical Center:	SITE_ID	Date Shipped:	VISIT_DT

Specimen Type	Label Number	Date Collected
Howell-Jolly Bodies	BODIES_LABEL	BODIES_DT
VDJ	VDJ_LABEL	VDJ_DT
Cystatin C*	CYSTATIN_LABEL	CYSTATIN_DT

Comments:	COMMENTS

Send Specimen(s) and transmittal forms to:

Thad Howard
Baylor College of Medicine at Texas Children's Hospital
Ware lab
1102 Bates Feigin Research Bldg. Room 1070.01
Houston, TX 77030

Fax form with Federal Express tracking number to Thad Howard, FAX No. 832-825-4846.

Clinical Center staff member completing form and verifying contents of shipment:

Name:	NAME	Certification Number:	CERT_NO

Federal Express Tracking Number:	TRACK_NUM

BABY HUG FOLLOW-UP STUDY

STEM CELL TRANSPLANT REPORT

PART I: IDENTIFYING INFORMATION

1. Patient's ID Number: [ ][ ][ ][ ] 2. Current Clinic: [ ][ ]

3. Patient's Letter Code: [ ][ ][ ]

4. Visit Date: [ ][ ][ ] - [ ][ ] - [ ][ ][ ][ ]
Month Day Year

PART II: TRANSPLANT INFORMATION

1. Date of Transplant: [ ][ ][ ] - [ ][ ] - [ ][ ][ ][ ]
Month Day Year

2. Location of Transplant Center

_____

3. Reason for Transplant in Sickle Cell Disease

Stroke	(1)
Recurrent Acute Chest Syndrome	(2)
Recurrent Painful Episodes	(3)
Other Sickle Cell Related Cause	(4)*
Other NON Sickle Cell Related Cause	(5)*

*a. Specify _____

4. Type of Graft:

HLA Matched Sibling Bone Marrow	(1)
HLA Matched Sibling Umbilical Cord Blood	(2)
Matched Unrelated Donor	(3)*
Matched Unrelated Umbilical Cord Blood	(4)*
Haplo-Identical Parent*	(5)*

*a. For non-sibling donor, please indicate degree of matching:

6/6	(1)
8/8	(2)
5/6 5-6-7/8	(3)

PART III: TRANSPLANT COMPLICATIONS

1. What is the patient's current status with respect to their transplant? Answer all that apply.

A. Death Date ☐☐☐ ☐☐ ☐☐☐☐ (Month Day Year)

B. Graft Rejection Date ☐☐☐ - ☐☐ - ☐☐☐☐ (Month Day Year)

C. Stable Mixed Chimerism ☐☐☐ - ☐☐ - ☐☐☐☐ (Month Day Year)

D. Cured of Sickle Cell Disease Date ☐☐☐ - ☐☐ - ☐☐☐☐ (Month Day Year)

E. Other (1)

i. If other, please specify: _____

ii. Date: ☐☐☐ - ☐☐ - ☐☐☐☐ (Month Day Year)

^ COMPLETE FORM 25 – SERIOUS ADVERSE EVENT

PART IV: COORDINATOR

1. Checked for completeness and accuracy:

   A. Certification number: ☐☐ - ☐☐

   B. Signature: _____

   C. General Comments: _____

   _____

   _____

BABY HUG FU STUDY

VINELAND SUMMARY

PART I: IDENTIFYING INFORMATION

1. Patient's ID Number: ☐☐☐☐ 2. Current Clinic: ☐☐

3. Patient's Letter Code: ☐☐☐

4. Testing Date: ☐☐☐ - ☐☐ - ☐☐☐☐
Month Day Year

PART II: CAREGIVER CODES:

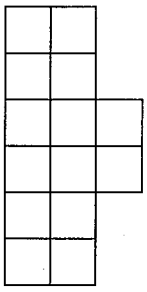
1. Chronological Age: ☐ ☐☐ ☐☐
Years Months Days

2. Caregiver's Relationship to Child:

Mother	(1)
Father	(2)
Grandparent	(3)
Aunt or Uncle	(4)
Foster Parent	(5)
Other	(6)

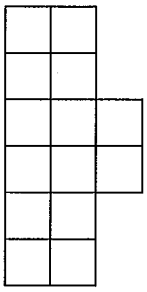
PART III: COMMUNICATIONS DOMAIN

1. Starting Row
2. Ending Row
3. Raw Domain Score
4. Standard Score
5. 95% Conf. Level
6. Percentile Rank



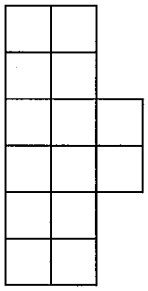
PART IV: DAILY LIVING SKILLS DOMAIN

1. Starting Row
2. Ending Row
3. Raw Domain Score
4. Standard Score
5. 95% Conf. Level
6. Percentile Rank



PART V: SOCIALIZATION DOMAIN

1. Starting Row
2. Ending Row
3. Raw Domain Score
4. Standard Score
5. 95% Conf. Level
6. Percentile Rank



PART VI: MOTOR SKILLS ☐ N/D

If not done, skip to Part VII

1. Starting Row
2. Ending Row
3. Raw Domain Score
4. Standard Score
5. 95% Conf. Level
6. Percentile Rank

PART VII: COORDINATION

1. Checked for completeness and accuracy:
   a. Certification number: ☐☐ - ☐☐
   b. Signature: _____
   c. General Comments:

ID Number ☐☐☐☐ Visit ☐☐☐ - Seq ☐☐

BABY HUG FOLLOW-UP STUDY

LIVER-SPLEEN CENTRAL READING

PART I: IDENTIFYING INFORMATION

1. Patient's ID Number: [ ][ ][ ][ ] 2. Current Clinic: [ ][ ]

3. Patient's Letter Code: [ ][ ][ ]

4. Visit Date: [ ][ ][ ] - [ ][ ] - [ ][ ][ ][ ]
Month Day Year

PART II: LIVER-SPLEEN SCAN QUALITY

1. Reader's Last Name: [ ][ ][ ][ ][ ][ ][ ][ ][ ][ ][ ][ ][ ][ ][ ][ ]

2. Reader Signature: _____

3. Reader Number: [ ][ ]

4. Date of Reading: [ ][ ][ ] - [ ][ ] - [ ][ ][ ][ ]
Month Day Year

5. Film Label Number: [ ][ ][ ][ ][ ]

6. Current Status of this Reading:

Quality adequate and reading complete	(1)
Quality inadequate for reading	(2)*

*A. If inadequate, explain: _____

_____

If Item 6 is 2, Skip to Part IV.

PART III: RESULTS

1. Splenic uptake (answer only one):

A.	Normal	(1)
B.	Present, but decreased	(2)
C.	Absent	(3)
*D.	If decreased,	
	1. < 50% decreased	(1)
	2. > 50% decreased	(2)

PART IV: COORDINATION

1. Checked for completeness and accuracy:

A. Certification number: ☐☐ - ☐☐

B. Signature: _____

C. General Comments: _____

_____

ID Number ☐☐☐☐ Visit ☐☐☐ - Seq ☐☐

BABY HUG FOLLOW-UP STUDY

ABDOMINAL SONOGRAM (ULTRASOUND) CENTRAL READING

PART I: IDENTIFYING INFORMATION

1. Patient's ID Number: [ ][ ][ ][ ] 2. Current Clinic: [ ][ ]

3. Patient's Letter Code: [ ][ ][ ]

4. Procedure Date: [ ][ ][ ] - [ ][ ] - [ ][ ][ ][ ]
Month Day Year

PART II: EQUIPMENT

1. Reader's Last Name: [ ][ ][ ][ ][ ][ ][ ][ ][ ][ ][ ][ ][ ][ ][ ][ ][ ][ ]

2. Reader Signature: _____

3. Reader Number: [ ][ ]

4. Date of Reading: [ ][ ][ ] - [ ][ ] - [ ][ ][ ][ ]
Month Day Year

5. Film Label Number: [ ][ ][ ][ ][ ]

6. Current Status of this Reading:

Quality adequate and reading complete	(1)
Returned for reprocessing	(2)*
Quality inadequate for reading after reprocessing (final)	(3)**

*A. If returned for reprocessing, explain: _____

_____

**B. If inadequate, explain: _____

_____

If 2 or 3, Skip to Part IV.

PART III: RESULTS

	Present	Absent	N/A
1. Gallbladder	(1)	(2)	(3)

If Absent or N/A , Skip to Item 2.

A. If Present
- Normal thin wall (1)
- Thick walled or edema (2)
- Not able to assess (3)

	Minimal	Moderate	Marked	N/D
B. Color Doppler Vascularity	(1)	(2)	(3)	(4)

C. If gallbladder present, answer C1 or C2:

1. Number of Stones [ ][ ]

OR

	Yes
2. Multiple stones not countable	(1)

		N/A
D. Largest stone	[ ][ ] mm	(1)

	Yes	No	N/A
E. Stones Freely Mobile?	(1)	(2)	(3)

F. Dilation	Dilated	Normal	N/A
1. Common bile duct	(1)	(2)	(3)
2. Pancreatic duct	(1)	(2)	(3)
3. Intrahepatic ducts	(1)	(2)	(3)

	Present	Absent	N/A
G. Sludge	(1)	(2)	(3)
H. Pericholecystic fluid	(1)	(2)	(3)

ID Number [ ][ ][ ][ ] Visit [ ][ ][ ] - Seq [ ][ ]

2. Spleen	Present (1)	Absent (2)	N/A (3)

If Absent or N/A, Skip to Item 3.

A. Accessory spleen(s) (1) (2) (3)

B. Cephalocaudad length [ ][ ] . [ ] cm

C. Transverse [ ][ ] . [ ] cm

D. Anterior – Posterior [ ][ ] . [ ] cm

E. Estimated total spleen volume [ ][ ][ ] cu cm (1) N/D

F. Homogeneity

Homogeneous	(1)
Inhomogeneous	(2)*
N/A	(3)

*1. If inhomogeneous, explain: _____

_____

3. Right Kidney	Present (1)	Absent (2)	N/A (3)

If Absent, Skip to Item 4.

A. Estimated volume [ ][ ][ ] cu cm

B. Renal parenchyma	Normal (1)	Abnormal (2)*	N/A (3)

*1. If abnormal, explain: _____

C Echogenicity	(1)	(2)*	(3)

*1. If abnormal, explain: _____

ID Number [ ][ ][ ][ ] Visit [ ][ ][ ] - Seq [ ][ ]

	Present	Absent	N/A
4. Left Kidney	(1)	(2)	(3)

If Absent, Skip to Item 5.

A. Estimated volume [ ][ ][ ] cu cm

	Normal	Abnormal	N/A
B. Renal parenchyma	(1)	(2)*	(3)

*1. If abnormal, explain: _____

C Echogenicity	(1)	(2)*	(3)

*1. If abnormal, explain: _____

	Yes	No	N/A
5. Liver enlarged	(1)	(2)	(3)
6. Any other abnormalities	(1)*	(2)	(3)

*A. If yes, explain: _____

PART IV: COORDINATION

1. Checked for completeness and accuracy:

A. Certification number: [ ][ ] - [ ][ ]

B. Signature: _____

C. General Comments: _____

_____

ID Number [ ][ ][ ][ ] Visit [ ][ ][ ] - Seq [ ][ ]

STEM CELL TRANSPLANT REPORT

Form: FORM_ID - 026 Revision: REVISION - 0 Site: SITE_ID Subject ID: SUBJECT_ID Letter Code: LETTER_CD Visit: VISIT_NBR Seq. #: SEQ_NBR Visit Date: VISIT_DT

PART IV: COORDINATOR

1 Checked for completeness and accuracy

A Certification number CERT_NO

B Signature CERT_SIG

C General Comments GEN_CMNT

Keyer: KEY_CERT Keyed: KEY_DT Modified: MOD_DT Status: EDT_STAT Edited: EDT_DT

STEM CELL TRANSPLANT REPORT

Form: FORM_ID - 026 Revision: REVISION - 0 Site: SITE_ID Subject ID: SUBJECT_ID Letter Code: LETTER_CD Visit: VISIT_NBR Seq. #: SEQ_NBR Visit Date: VISIT_DT

BABY HUG FOLLOW-UP STUDY
STEM CELL TRANSPLANT REPORT

PART II: TRANSPLANT INFORMATION

1 Date of Transplant: TRANSPLANT_DT

2 Location of Transplant Center: TRANSPLANT_CTR

3 Reason for Transplant in Sickle Cell Disease: TRANSPLANT_RN [1=Stroke],[2=Recurrent Acute Chest Syndrome],[3=Recurrent Painful Episodes],[4=Other Sickle Cell Related Cause],[5=Other NON Sickle Cell Related Cause]

*If Other, Specify: RN_SP1

Keyer: KEY_CERT Keyed: KEY_DT Modified: MOD_DT Status: EDT_STAT Edited: EDT_DT

STEM CELL TRANSPLANT REPORT

Form: FORM_ID - 026 Revision: REVISION - 0 Site: SITE_ID Subject ID: SUBJECT_ID Letter Code: LETTER_CD Visit: VISIT_NBR Seq. #: SEQ_NBR Visit Date: VISIT_DT

4 Type of Graft
Cord Blood*],[5=Haplo-Identical Parent*] GRAFT_TP [1=HLA Matched Sibling Bone Marrow],[2=HLA Matched Sibling Umbilical Cord Blood],[3=Matched Unrelated Donor*],[4=Matched Unrelated Umbilical

*a For non-sibling donor, please indicate degree of matching DEGREE_MAT [1=6/6],[2=8/8],[3=5/6 5-6-7/8]

PART III: TRANSPLANT COMPLICATIONS

1 What is the patient's current status with respect to their transplant? (Answer All That Apply)

A Death Date BMT_DEATH_DT

B Graft Rejection Date BMT_GRFT_RJ_DT

C Stable Mixed Chimerism Date BMT_CHIM_DT

D Cured of Sickle Cell Disease Date BMT_CURE_DT

E Other
BMT_OTHER

i If other please specify, BMT_OTH_SP

ii Date BMT_OTH_DT

COMPLETE FORM 25 - SERIOUS ADVERSE EVENT IF ANY DATE IS ENTERED

Keyer: KEY_CERT Keyed: KEY_DT Modified: MOD_DT Status: EDT_STAT Edited: EDT_DT

VINELAND SUMMARY

Form: FORM_ID - 027 Revision: REVISION - 1 Site: SITE_ID Subject ID: SUBJECT_ID Letter Code: LETTER_CD Visit: VISIT_NBR Seq. #: SEQ_NBR Visit Date: VISIT_DT

VINELAND SUMMARY

PART II: CAREGIVER CODES

1 Age (years) CHRAGEYR Years 1 01 Age (months) CHRAGEMN Months 1 02 Age (days) CHRAGEDS Days

2 Caregiver's Relationship to Child CARE41 [1=Mother],[2=Father],[3=Grandparent],[4=Aunt or Uncle],[5=Foster Parent],[6=Other]

Keyer: KEY_CERT Keyed: KEY_DT Modified: MOD_DT Status: EDT_STAT Edited: EDT_DT

VINELAND SUMMARY

Form: FORM_ID - 027 Revision: REVISION - 1 Site: SITE_ID Subject ID: SUBJECT_ID Letter Code: LETTER_CD Visit: VISIT_NBR Seq. #: SEQ_NBR Visit Date: VISIT_DT

PART III: COMMUNICATIONS DOMAIN

1 Starting Row	CDSTROW
2 Ending Row	CDENDROW
3 Raw Domain Score	COMRAW
4 Standard Score	COMSTRD
5 95% Conf Level	COM95CL
6 Percentile Rank	COMPCTL

PART IV: DAILY LIVING SKILLS DOMAIN

1 Starting Row	DDSTROW
2 Ending Row	DDENDROW
3 Raw Domain Score	DLSRAW
4 Standard Score	DLSSTRD
5 95% Conf Level	DLS95CL
6 Percentile Rank	DLSPCTL

PART V: SOCIALIZATION DOMAIN

1 Starting Row	SDSTROW
2 Ending Row	SDENDROW
3 Raw Domain Score	SOCRAW
4 Standard Score	SOCSTRD
5 95% Conf Level	SOC95CL
6 Percentile Rank	SOCPCTL

Keyer: KEY_CERT Keyed: KEY_DT Modified: MOD_DT Status: EDT_STAT Edited: EDT_DT

VINELAND SUMMARY

Form: FORM_ID - 027 Revision: REVISION - 1 Site: SITE_ID Subject ID: SUBJECT_ID Letter Code: LETTER_CD Visit: VISIT_NBR Seq. #: SEQ_NBR Visit Date: VISIT_DT

PART VI: MOTOR SKILLS MOTOR_ND N/D

1 Starting Row	MSSTROW
2 Ending Row	MSENDROW
3 Raw Domain Score	MTSKRAW
4 Standard Score	MTSKSTRD
5 95% Conf Level	MTSK95CL
6 Percentile Rank	MTSKPCTL

PART VII: COORDINATION

1 Checked for completeness and accuracy

a Certification Number	CERT_NO
b Signature	CERT_SIG
c General Comments	GEN_CMNT

Keyer: KEY_CERT Keyed: KEY_DT Modified: MOD_DT Status: EDT_STAT Edited: EDT_DT

LIVER-SPLEEN CENTRAL READING

Form: FORM_ID - 031 Revision: REVISION - 0 Site: SITE_ID Subject ID: SUBJECT_ID Letter Code: LETTER_CD Visit: VISIT_NBR Seq. #: SEQ_NBR Visit Date: VISIT_DT

PART II: LIVER-SPLEEN SCAN QUALITY

1	Reader's Last Name	LSRDRNM	
2	Reader Signature	LSRDRSIG	
3	Reader Number	LSRDRNBR	
4	Date of Reading	LSRD_DT	
5	Film Label Number	LSSCNLBL	
6	Current Status of this Reading	LSSCN_QLTY	[1=1 - Quality adequate and reading complete],[2=2* - Quality inadequate for reading]
*A	If inadequate, explain	QLTY_SP	

If Item 6 is 2, skip to Part IV

Keyer: KEY_CERT Keyed: KEY_DT Modified: MOD_DT Status: EDT_STAT Edited: EDT_DT

LIVER-SPLEEN CENTRAL READING

Form: FORM_ID - 031 Revision: REVISION - 0 Site: SITE_ID Subject ID: SUBJECT_ID Letter Code: LETTER_CD Visit: VISIT_NBR Seq. #: SEQ_NBR Visit Date: VISIT_DT

PART III: RESULTS

1 Splenic uptake (answer only one) SPLUPT [1=A Normal],[2=B Present, but decreased *],[3=C Absent]

D If decreased, SPL_DCRS [1=1 <50% decreased],[2=2 >50% decreased]

PART IV: COORDINATION

1 Checked for completeness and accuracy

A Certification number CERT_NO

B Signature CERT_SIG

C General Comments GEN_CMNT

Keyer: KEY_CERT Keyed: KEY_DT Modified: MOD_DT Status: EDT_STAT Edited: EDT_DT

ABDOMINAL SONOGRAM (ULTRASOUND) CENTRAL READING

Form: FORM_ID - 033 Revision: REVISION - 1 Site: SITE_ID Subject ID: SUBJECT_ID Letter Code: LETTER_CD Visit: VISIT_NBR Seq. #: SEQ_NBR Visit Date: VISIT_DT

PART II: EQUIPMENT

1 Reader's Last Name ABDRDRNM

2 Reader Signature ABDRDRSIG

3 Reader Number ABDRDRNBR

4 Date of Reading ABDRD_DT

5 Film Label Number SONO_LBL

6 Current status of this reading re-processing(final)] ABD_QLTY [1=1 - Quality adequate and reading complete],[2=2 - Returned for processing],[3=3 - Quality inadequate for reading after

*A If returned for reprocessing, explain QLTY2_SP

**B If inadequate, explain QLTY3_SP

If 2 or 3, Skip to Part IV

Keyer: KEY_CERT Keyed: KEY_DT Modified: MOD_DT Status: EDT_STAT Edited: EDT_DT

ABDOMINAL SONOGRAM (ULTRASOUND) CENTRAL READING

Form: FORM_ID - 033 Revision: REVISION - 1 Site: SITE_ID Subject ID: SUBJECT_ID Letter Code: LETTER_CD Visit: VISIT_NBR Seq. #: SEQ_NBR Visit Date: VISIT_DT

PART III: RESULTS

1 Gallbladder GALBLA [1=1 - Present],[2=2 - Absent],[3=3 - N/A]

If Absent or N/A, Skip to item 2

A If Present GBWALL [1=1 - Normal thin wall],[2=2 - Thick walled or edema],[3=3 - Not able to assess]

B Color Doppler vascularity GBCDV [1=1 - Minimal],[2=2 - Moderate],[3=3 - Marked],[4=4 - N/D]

C If gallbladder present, answer C1 or C2

1 Number of stones GBNSTN

OR

2 Multiple stones not countable GBMSTN [1=1 - Yes]

D Largest stone GBLGST mm N/A GBLGSTNA

E Stones freely mobile? GBSFM [1=1 - Yes],[2=2 - No],[3=3 - N/A]

F Dilation

1 Common bile duct GBCBD [1=1 - Dilated],[2=2 - Normal],[3=3 - N/A]

2 Pancreatic duct GBPAND [1=1 - Dilated],[2=2 - Normal],[3=3 - N/A]

3 Intrahepatic ducts GBIHEP [1=1 - Dilated],[2=2 - Normal],[3=3 - N/A]

G Sludge GBSLDG [1=1 - Present],[2=2 - Absent],[3=3 - N/A]

H Pencholecystic fluid GBPRFL [1=1 - Present],[2=2 - Absent],[3=3 - N/A]

Keyer: KEY_CERT Keyed: KEY_DT Modified: MOD_DT Status: EDT_STAT Edited: EDT_DT

ABDOMINAL SONOGRAM (ULTRASOUND) CENTRAL READING

Form: FORM_ID - 033 Revision: REVISION - 1 Site: SITE_ID Subject ID: SUBJECT_ID Letter Code: LETTER_CD Visit: VISIT_NBR Seq. #: SEQ_NBR Visit Date: VISIT_DT

2 Spleen SPLEEN [1=1 - Present],[2=2 - Absent],[3=3 - N/A]

If Absent or N/A, Skip to Item 3

A Accessory spleen(s) ACCSPL [1=1 - Present],[2=2 - Absent],[3=3 - N/A]

B Cephalocaudad length SPLCLN cm

C Transverse SPLTRN cm

D Anterior - Posterior SPLANP cm

E Estimated total spleen volume SPLVOL cu cm N/D SPLVOLND

F Homogeneity SPLHOM [1=1 - Homogeneous],[2=2 - Inhomogeneous],[3=3 - N/A]

*1 If inhomogeneous, explain INHOM_SP

3 Right Kidney RKID [1=1 - Present],[2=2 - Absent],[3=3 - N/A]

If Absent, Skip to Item 4

A Estimated volume RKVOL cu cm

B Renal parenchyma RKRPAR [1=1 - Normal],[2=2* - Abnormal],[3=3 - N/A]

*1 If abnormal, explain RKRPEX

C Echogenicity RKECHO [1=1 - Normal],[2=2* - Abnormal],[3=3 - N/A]

*1 If abnormal, explain RKECEX

Keyer: KEY_CERT Keyed: KEY_DT Modified: MOD_DT Status: EDT_STAT Edited: EDT_DT

ABDOMINAL SONOGRAM (ULTRASOUND) CENTRAL READING

Form: FORM_ID - 033 Revision: REVISION - 1 Site: SITE_ID Subject ID: SUBJECT_ID Letter Code: LETTER_CD Visit: VISIT_NBR Seq. #: SEQ_NBR Visit Date: VISIT_DT

4 Left Kidney LKID [1=1 - Present],[2=2 - Absent],[3=3 - N/A]

If Absent, Skip to Item 5

A Estimated volume LKVOL cu cm

B Renal parenchyma LKRPAR [1=1 - Normal],[2=2* - Abnormal],[3=3 - N/A]

*1 If abnormal, explain LKRPEX

C Echogenicity LKECHO [1=1 - Normal],[2=2* - Abnormal],[3=3 - N/A]

*1 If abnormal, explain LKECEX

5 Liver enlarged LVRENL [1=1 - Yes],[2=2 - No],[3=3 - N/A]

6 Any other abdominal abnormalities ABDABN [1=1 - Yes],[2=2 - No],[3=3 - N/A]

*A If yes, explain ABDABNEX

PART IV: COORDINATION

A Certification number CERT_NO

B Signature CERT_SIG

C General Comment GEN_CMNT

Keyer: KEY_CERT Keyed: KEY_DT Modified: MOD_DT Status: EDT_STAT Edited: EDT_DT