BABY HUG FOLLOW-UP STUDY II

# ENROLLMENT

## PART I: IDENTIFYING INFORMATION

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

## PART II: ENROLLMENT INFORMATION

| | | TREAT_COMPLET_1 | Yes | No |
|---|---|---|---|---|
| 1. | Did this child complete at least 24 mos of follow-up in BABY HUG Follow-up I? | | (1) | (2) (inel) |

If No, Skip to Part III.1.

| | | | Yes | No |
|---|---|---|---|---|
| 2. | Has this child had a stem cell transplant since December 31, 2011? | TRANSPLANT | (1) (inel) | (2) |

If Yes, Skip to Part III.1 and complete Form 26.

| | | | Yes | No |
|---|---|---|---|---|
| 3. | Has informed consent been obtained? | FOLLOWUP_STUDY | (1 ) | (2 ) |

If No, Skip to Part III.1.

4. Consent Information:

   A. Consent Date: ___ ___ ___ - ___ ___ - ___ ___ ___ ___ CONSENT_DT
   Month Day Year

| | | | Yes | No | N/A |
|---|---|---|---|---|---|
| B. | Consent for data file to include child's information? | DATA_CONSENT | (1) | (2) | |
| C. | Consent for blood specimens to be saved indefinitely? | BLOOD_SAVE_CONSENT | (1) | (2) | |
| D. | Consent for urine to be saved indefinitely? | URINE_SAVE_CONSENT | (1) | (2) | |
| E. | Consent for blood samples to be used for future research on sickle cell disease and related disorders? | BLOOD_FUTURE_CONSENT | (1) | (2) | |
| F. | Consent for urine samples to be used for future research on sickle cell disease and related disorders? | URINE_FUTURE_CONSENT | (1) | (2) | |
| G. | Consent for DNA testing to be performed on blood samples? | DNA_CONSENT | (1) | (2) | |
| H. | Was Assent signed? | ASSENT | (1) | (2) | (3) |

| | | | Active | Passive |
|---|---|---|---|---|
| 5. | Follow-up Group: | FOLLOWUP_GROUP | (1) | (2) |

**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 II

**CENTRAL LAB COLLECTION**
**ENTRY/Q12 MONTHS/EXIT**

## PART I: IDENTIFYING INFORMATION

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

## PART II: SPECIMEN COLLECTION

**Please refer to Appendices A and B of the BHFUII Protocol for Lab Collection Requirements.**

1. Urine for Storage: (8-10 ml) (Entry/Exit Only)

   A. Label Number: URINE_STORED_LABEL _____ (1 ) Not Done URINE_STORED_ND

   B. Date Collected: ___ ___ ___ - ___ ___ - ___ ___ ___ ___
   URINE_STORED_DT Month Day Year

   C. Time Collected: ____ ____ : ____ ____ (24-hr clock)
   H H M M
   URINE_STORED_HR URINE_STORED_MN

2. Urine for Microalbumin: Creatinine (1-2 Cryovial ml): (Entry/Exit Only)

   A. Label Number: URINE_LABEL _____ (1 ) Not Done URINE_ND

   B. Date Collected: ___ ___ ___ - ___ ___ - ___ ___ ___ ___
   URINE_DT Month Day Year

   C. Time Collected: ____ ____ : ____ ____ (24-hr clock)
   H H M M
   URINE_COL_HR URINE_COL_MN

3. Stored Blood Sample (5 ml EDTA lavender top) Entry/Exit Only:

   A. Label Number: BLOOD_LABEL _____ (1 ) Not Done BLOOD_ND

   B. Date Collected: ___ ___ ___ - ___ ___ - ___ ___ ___ ___
   BLOOD_DT Month Day Year

   C. Time Collected: ____ ____ : ____ ____ (24-hr clock)
   H H M M
   BLOOD_COL_HR BLOOD_COL_MN

4. Cystatin C (1 ml red top):

   A. Label Number: CYSTATIN_LABEL _____ (1 ) Not Done CYSTATIN_ND

   B. Date Collected: ___ ___ ___ - ___ ___ - ___ ___ ___ ___
   CYSTATIN_DT Month Day Year

   C. Time Collected: ____ ____ : ____ ____ (24-hr clock)
   H H M M
   CYSTATIN_COL_HR CYSTATIN_COL_MN

5. HbF (0.5 ml EDTA lavender top):

   A. Label Number: HBF_LABEL _____ (1 ) Not Done HBF_ND

   B. Date Collected: ___ ___ ___ - ___ ___ - ___ ___ ___ ___
   HBF_DT Month Day Year

   C. Time Collected: ____ ____ : ____ ____ (24-hr clock)
   H H M M
   HBF_COL_HR HBF_COL_MN

6. Creatinine/BUN (4.0 ml red top at 12 mos) (1.0 ml red top at entry/exit):

   A. Label Number: CREATININE_LABEL _____ (1 ) Not Done CREATININE_ND

   B. Date Collected: ___ ___ ___ - ___ ___ - ___ ___ ___ ___
   CREATININE_DT Month Day Year

   C. Time Collected: ____ ____ : ____ ____ (24-hr clock)
   H H M M
   CREATININE_COL_HR CREATININE_COL_MN

7. Pitted Cells (0.1 ml EDTA lavender top w/glutaraldehyde):

   A. Label Number: CELL_LABEL _____ (1 ) Not Done CELL_ND

   B. Date Collected: ___ ___ ___ - ___ ___ - ___ ___ ___ ___
   CELL_DT Month Day Year

   C. Time Prepared: ____ ____ : ____ ____ (24-hr clock)
   H H M M
   CELL_COL_HR CELL_COL_MN

8. HJB/Reticulocytes Micronuclei (1.0 ml EDTA lavender top):

A. Label Number: HJB_LABEL _____ (1 ) Not Done HJB_ND

B. Date Collected: ___ ___ ___ - ___ ___ - ___ ___ ___ ___
HJB_DT Month Day Year

C. Time Collected: ____ ____ : ____ ____ (24-hr clock)
H H M M
HJB_COL_HR HJB_COL_MN

9. VDJ/DNA Extraction/Storage (3.0 ml lavender top): (Entry/Exit Only)

A. Label Number: VDJ_LABEL _____ (1 ) Not Done VDJ_ND

B. Date Collected: ___ ___ ___ - ___ ___ - ___ ___ ___ ___
VDJ_DT Month Day Year

C. Time Collected: ____ ____ : ____ ____ (24-hr clock)
H H M M
VDJ_COL_HR VDJ_COL_MN

**PART III: 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 | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | - | | |

PEDIATRIC HYDROXYUREA CLINICAL TRIAL

**LOCAL LABORATORY RESULTS**

## Active – Entry, Q12 Months, Exit  Passive – Entry, Exit

**PART I: IDENTIFYING INFORMATION**

1. Patient's ID Number: ___ ___ ___ ___ SUBJECT_ID
2. Current Clinic: ___ ___ SITE_ID
3. Patient's Letter Code: ___ ___ ___ LETTER_CD
4. Visit: ___ ___ ___ - 0 0 sequence # VISIT_NBR
5. Visit Date: ___ ___ ___ - ___ ___ - ___ ___ ___ ___ VISIT_DT
   Month Day Year

**PART II: LAB RESULTS**

| | | | | |
|---|---|---|---|---|
| 1. | A. | White Blood Cell Count (WBC) | ___ ___ . ___ K/mm$^3$ | WBC |
| | B. | Red Blood Cell Count (RBC) | ___ . ___ ___ M/mm$^3$ | RBC |
| | C. | Hemoglobin | ___ ___ . ___ g/dL | HB |
| | D. | Hematocrit | ___ ___ . ___ % | PCV |
| | E. | Platelet Count | ___ ___ ___ ___ K/mm$^3$ | PLAT |
| 2. | A. | Differential Type: | (1) Manual (2) Automated | DIFFTYPE |
| | B. | Absolute Neutrophil Count | ___ ___ . ___ ___ K/mm$^3$ | NEUT_CT |
| | C. | Neutrophils (% of WBC) | ___ ___ % | NEUT_PT |
| | D. | Lymphocytes (% of WBC) | ___ ___ % | LYMPH_PT |
| | E. | Monocytes (% of WBC) | ___ ___ % | MONO_PT |
| | F. | Nucleated Red Blood Cells (nRBC)* | ___ ___ | NRBC |
| | | *1. If not 0, corrected WBC Count† | ___ ___ . ___ K/mm$^3$ | CWBC |

G. Reticulocytes (% of RBC) ___ ___ . ___ % RETIC_PT

H. Absolute Reticulocyte count ___ ___ ___ . ___ K/mm$^3$ RETIC_CT

I. MCV ___ ___ ___ . ___ fL MCV

3. A. LDH _____ U/L LDH

B. Bilirubin, Total ___ ___ . ___ Mg/DL T_BILI

C. Bilirubin, Direct ___ ___ . ___ Mg/DL D_BILI

D. ALT _____ U/L ALT

4. A. Urine Osmolality (Active-Entry/Exit Only) _____ mOsm/kg U_OSMO

1. Hours NPO ___ ___ URN_NPO

**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 II

# CLINICAL DATA REPORT

## PART I: IDENTIFYING INFORMATION

1. Patient's ID Number: ___ ___ ___ ___ SUBJECT_ID
2. Current Clinic: ___ ___ 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

| | | Yes | No* |
|---|---|---|---|
| 4. | Any patient contact during this interval? PATIENT_CONTACT | (1 ) | (2 ) |

*A. If no, reason _____ PATIENT_CONTACT_RSN

*If No, Skip to Part IX.

## PART III: HU USE

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

2. Dose form: Liquid Capsules

HU_DOSE_FORM (1 ) (2 )

HU_INTERVAL_END Yes* No**

2. Was the patient still being prescribed HU at the end of the interval? (1 ) (2 )

* A. If **Yes**, what was the:

HU_DOSE_WEIGHT2

1. Dose at the end of the interval: ___ ___ ___ . ___ mg/kg

2. Dose form: Liquid Capsules

HU_DOSE_FORM2 (1 ) (2 )

**B. If **No,** what was the date the patient stopped being prescribed HU?

___ ___ ___ - ___ ___ - ___ ___ ___ ___ HU_END_DT

Month Day Year

3. Did the patient have HU held because of possible drug toxicity during this interval? Yes* No

HU_TOXICITY (1 ) (2 )

*A. If **Yes**, check all that apply:

1. Low ANC (1 ) LOW_ANC
2. Low Hgb (1 ) LOW_HGB
3. Low PHs (1 ) LOW_PHS
4. Other bacterial or viral infection (1 ) OTHER_INFECTION
5. Other (1 ) OTHER_TOXICITY_FTR
   a. 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.**

## PART IV: BLOOD RESULTS

BLOOD_COLLECT

1. Were any blood specimens collected for clinical reasons during this interval? Yes (1 ) No* (2 )

*If NO, reason: _____ BLOOD_COLLECT_REASON

If No, Skip to Part V.

2. First CBC in interval:

A. Date: ___ ___ ___ - ___ ___ - ___ ___ ___ ___ FIRST_CBC_DT
Month Day Year

B. Hemoglobin ___ ___ . ___ gm/dl FIRST_HEMGLOBIN

C. MCV ___ ___ ___ . ___ fL FIRST_MCV

D. Reticulocyte (% of RBC) ___ ___ . ___ % (1 ) Not Done
FIRST_RETIC_CNT FIRST_RETIC_NOT_DONE

E. White Blood Cell Count ___ ___ . ___ K/mm$^3$
FIRST_WBC_ACOUNT

F. Absolute Neutrophil Count ___ ___ . ___ ___ K/mm$^3$ (1 ) Not Done
FIRST_NEUTROPHIL_CNT FIRST_NEUTROPHIL_NOT_DONE

G. Platelet Count ___ ___ ___ ___ K/mm$^3$
FIRST_PLATELETS_CNT

H. Red Blood Cell Count ___ . ___ ___ M/mm$^3$ FIRST_RBC

3. Last CBC in interval:

LAST_CBC_DT LAST_CBC_NOT_DONE

A. Date: ___ ___ ___ - ___ ___ - ___ ___ ___ ___ (1 ) Not Done
Month Day Year

B. Hemoglobin ___ ___ . ___ gm/dl LAST_HEMGLOBIN

C. MCV ___ ___ ___ . ___ fL LAST_MCV
LAST_RETIC_CNT LAST_RETIC_NOT_DONE

D. Reticulocyte (% of RBC) ___ ___ . ___ % (1 ) Not Done
LAST_WBC_ACOUNT

E. White Blood Cell Count ___ ___ . ___ K/mm$^3$

F. Absolute Neutrophil Count LAST_NEUTROPHIL_CNT ___ ___ . ___ ___ K/mm$^3$ LAST_NEUTROPHIL_NOT_DONE (1 ) Not Done

G. Platelet Count ___ ___ ___ ___ K/mm$^3$ LAST_PLATELETS_CNT

H. Red Blood Cell Count ___ . ___ ___ M/mm$^3$ LAST_RBC

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

E. Fetal Hemoglobin:

1. Date: ___ ___ ___ - ___ ___ - ___ ___ ___ ___ (1 ) Not Done
FETAL_HEMOGLOBIN_DT Month Day Year FETAL_NOT_DONE

2. Value: ___ ___ . ___ % FETAL_HEMO_VAL

F. LDH:

1. Date: ___ ___ ___ - ___ ___ - ___ ___ ___ ___ (1 ) Not Done
LDH_DT Month Day Year LDH_NOT_DONE

2. Value: ___ ___ ___ ___ . ___ U/L LDH_VALUE

G. Bilirubin:

1. Date: ___ ___ ___ - ___ ___ - ___ ___ ___ ___ (1 ) Not Done
BILI_DT Month Day Year BILI_NOT_DONE

2. Value: ___ ___ . ___ Mg/DL BILI_VALUE

**PART V: IMAGING RESULTS**

1. Were any TCD's performed during this interval? Yes (1 ) No* (2 ) TCD_IMAGE_YN

*If No, Skip to Part V, 2.

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

*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**

2. MRI Date* ___ ___ ___ - ___ ___ - ___ ___ ___ ___ (1 ) Not Done
MRI_DT Month Day Year MRI_NOT_DONE

| | Yes | No | |
|---|---|---|---|
| A0. Performed per protocol, results unknown | (1 ) | (2 ) | MRI_UNKNOWN |

If Yes, skip to 3.

*A. If MRI done, result:

**CHECK THE MOST SEVERE RESULT** MRI_RESULTS

| | |
|---|---|
| Normal | (1 ) |
| Silent Infarct(s) (gliosis) | (2 ) |
| Stroke (CVA or thrombosis) | (3 ) |
| Hemorrhage (subarachnoid or subdural) | (4 ) |
| Other | (5 )^ |

1. ^If Other, Specify: _____ MRI_RESULTS_SP

**PASSIVE SUBJECTS: If DONE, MRI Performed closest to age 10 should be sent for central review. Complete Form 33 and submit CD to DCC**

3. MRA Date* ___ ___ ___ - ___ ___ - ___ ___ ___ ___ (1 ) Not Done
MRA_DT Month Day Year MRA_NOT_DONE

| | Yes | No | |
|---|---|---|---|
| A0. Performed per protocol, results unknown | (1 ) | (2 ) | MRA_UNKNOWN |

If Yes, skip to 4.

| | | Yes | No |
|---|---|---|---|
| *A. If MRA done, any result abnormal? | MRA_ABNORMAL | (1 ) | (2 ) |

**PASSIVE SUBJECTS: If DONE, MRA Performed closest to age 10 should be sent for central review. Complete Form 33 and submit CD to DCC**

4. PFTs Date* ___ ___ ___ - ___ ___ - ___ ___ ___ ___ (1 ) Not Done
PFT_DT Month Day Year PFT_NOT_DONE

| | | Yes | No |
|---|---|---|---|
| *A. If Pulmonary Function Tests done, any result abnormal? | PFT_ABNORMAL | (1 ) | (2 ) |

**PASSIVE SUBJECTS: Complete Form 31**

5. Cardiac Echo Date* CARDIAC_DT ___ ___ ___ - ___ ___ - ___ ___ ___ ___ (1 ) Not Done CARDIAC_NOT_DONE
Month Day Year

| | | Yes | No |
|---|---|---|---|
| A0. | Performed per protocol, results unknown CARDIAC_UNKNOWN | (1 ) | (2 ) |

If Yes, skip to 6.

| | | Yes | No |
|---|---|---|---|
| *A. | If Cardiac Echo done, any result abnormal? CARDIAC_ABNORMAL | (1 ) | (2 ) |

**PASSIVE SUBJECTS: If DONE, Cardiac Echo Performed closest to age 10 should be sent for central review. Complete Form 32 and submit CD to Echo Core Lab**

6. L/S Scan Date* LIVSP_DT ___ ___ ___ - ___ ___ - ___ ___ ___ ___ (1 ) Not Done LIVSP_NOT_DONE
Month Day Year

| | | Yes | No |
|---|---|---|---|
| A0. | Performed per protocol, results unknown LIVSP_UNKNOWN | (1 ) | (2 ) |

If Yes, skip to 7.

| | | Yes | No |
|---|---|---|---|
| *A. | If L/S Scan done, any result abnormal? LIVSP_ABNORMAL | (1 ) | (2 ) |

**PASSIVE SUBJECTS: If DONE, L/S Scan Performed closest to age 10 should be sent for central review. Complete Form 21 and submit CD to DCC**

7. Abdominal Sonogram Date: ABD_DT ___ ___ ___ - ___ ___ - ___ ___ ___ ___ (1 ) Not Done ABD_NOT_DONE
Month Day Year

| | | Yes | No |
|---|---|---|---|
| A0. | Performed per protocol, results unknown ABD_UNKNOWN | (1 ) | (2 ) |

If Yes, skip to Part VI.

| | | Yes | No |
|---|---|---|---|
| *A. | If Abdominal Sonogram done, any result abnormal? ABD_ABNORMAL | (1 ) | (2 ) |

**PASSIVE SUBJECTS: If DONE, Abdominal Sonogram Performed closest to age 10 should be sent for central review. Complete Form 23 and submit CD to DCC**

**PART VI: OTHER PROCEDURES**

1. EEG Date* EEG_DT ___ ___ ___ - ___ ___ - ___ ___ ___ ___ (Month - Day - Year) (1 ) Not Done EEG_NOT_DONE

| | | Yes | No |
|---|---|---|---|
| *A. | If EEG done, any result abnormal? EEG_ABNORMAL | (1 ) | (2 ) |

2. CT Date* CT_DT ___ ___ ___ - ___ ___ - ___ ___ ___ ___ (Month - Day - Year) (1 ) Not Done CT_NOT_DONE

| | | Yes | No |
|---|---|---|---|
| *A. | If CT done, any result abnormal?: CT_ABNORMAL | (1 ) | (2 ) |

3. Neuropsych Date* NEUROPSYCH_DT ___ ___ ___ - ___ ___ - ___ ___ ___ ___ (Month - Day - Year) (1 ) Not Done NEUROPSYCH_NOT_DONE

| | | NEUROPSYCH_ABNORMAL | Yes^ | No |
|---|---|---|---|---|
| *A. | If neuropsychology testing done, any results abnormal? | | (1 ) | (2 ) |

^1. Specify test: _____ NEUROPSYCH_SP

| | | | Yes* | No |
|---|---|---|---|---|
| 4. | Other clinical tests done: | OTHER_TEST | (1 ) | (2 ) |

*A. If Yes, specify: _____ OTHER_TEST_SP

## 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_ASSESS
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:

| | | | Yes | No |
|---|---|---|---|---|
| 1. | Acute splenic sequestration crisis | ACUTE_SPLENIC_SEQUES | (1 ) | (2 ) |
| 2. | Acute chest syndrome | ACUTE_CHEST_SYNDROME | (1 ) | (2 ) |
| 3. | Neurologic event (stroke or seizure) | STROKE_SEIZURE | (1 ) | (2 ) |
| 4. | Aplastic Crisis | APLASTIC_CRISIS | (1 ) | (2 ) |
| 5. | Urinary tract infection | URINARY_TRACT_INFECT | (1 ) | (2 ) |
| 6. | Fever or febrile illness including URI/sinusitis/cold/fl | FEVER_FEBRILE | (1 ) | (2 ) |

| | | | | |
|---|---|---|---|---|
| 7. | Other acute illness, no fever | NO_FEVER | (1 ) | (2 ) |
| 8. | Trauma including broken bones and sprains | TRAUMA | (1 ) | (2 ) |
| 9. | Sickle Cell Pain Crisis (including dactylitis) | PAIN | (1 ) | (2 ) |
| 10. | Other | OTHER_CRISIS | (1 )* | (2 ) |

*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. Please indicate the number of times the following reasons were the primary discharge diagnosis for each of the above admissions?

| | | | |
|---|---|---|---|
| 1. | Neurologic event (stroke or seizure) | DIAGNOSIS_STROKE | ___ ___ |
| 2. | Acute splenic sequestration crisis | DIAG_SPENIC_SEQUES | ___ ___ |
| 3. | Acute chest 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

4. Pain

PAIN2 Yes* (1) No (2)

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?

PAIN_EPISODES

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

5. Surgery

SURGERY Yes* (1) No (2)

A. Did the patient have at least one surgery during this interval?

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

TONSILLECTOMY_ND

a. Tonsillectomy, Adenoidectomy or both (1) Not Done

Date: ___ ___ ___ - ___ ___ - ___ ___ ___ ___ TONSILLECTOMY_DT
Month Day Year

SPLENECTOMY_ND

b. Splenectomy (open or □aparoscopic) (1) Not Done

Date: ___ ___ ___ - ___ ___ - ___ ___ ___ ___ SPLENECTOMY_DT
Month Day Year

CHOLECYSTECTOMY_ND

c. Cholecystectomy and/or ERCP (1) Not Done

Date: ___ ___ ___ - ___ ___ - ___ ___ ___ ___ CHOLECYSTECTOMY_DT
Month Day Year

EAR_NOT_DONE

d. Ear tubes, hernia repair, dental rehabilitation (1) Not Done

Date: ___ ___ ___ - ___ ___ - ___ ___ ___ ___ EAR_DT
Month Day Year

Yes^ (1) No (2)

e. Other SURGERY_OTHER

^1. If other, specify: SURGERY_OTHER_SP _____

6. Transfusion

CHRONIC_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)? Yes* (1 ) No (2 )

CHRONIC_TRANS_REASON

*1. If yes, what was the main reason for the chronic transfusion program:

| | |
|---|---|
| Stroke (clinical neurologic deficit lasting 24 hours or more) | (1 ) |
| Elevated TCD velocity | (2 ) |
| TIA or other neurologic events | (3 ) |
| Splenic Sequestration | (4 ) |
| Recurrent Acute Chest Syndrome | (5 ) |
| Recurrent Painful Events | (6 ) |
| Other | (7 )^ |

^a. If other, specify: CHRONIC_TRANS_SP _____

B. Did the patient receive one or more episodic transfusion(s) during this interval (meaning a transfusion, scheduled or not that was for a specific problem or to prepare them for surgery)? Yes* (1 ) No (2 )

EPISODIC_TRANSFUSION

*1. If yes, what was the main reason for the episodic transfusion(s)?

EPISODIC_TRANS_RSN

| | |
|---|---|
| Acute Splenic Sequestration | (1 ) |
| Acute Chest Syndrome | (2 ) |
| Neurologic Event or Stroke | (3 ) |
| Aplastic Crisis | (4 ) |
| Peri Operative Preparation | (5 ) |
| Other | (6 )^ |

^a. If other, specify: EPISODIC_TRANS_SP _____

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

*If yes,

1. Ferritin (highest value in interval) ___ ___ ___ ___ ___ ng/ml FERRITIN_HIGH

2. Ferriscan or MRI ___ ___ . ___ gm/gm dn weight of liver FERRISCAN_MRI Not done (1 ) FERRISCAN_MRI_ND

3. Liver Bx ___ ___ . ___ gm/gm dn weight of liver LIVER_BX Not done (1 ) LIVER_BX_ND

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

*If yes,

| | |
|---|---|
| Desferal (Deferioxamine) | (1 ) |
| Ex Jade (Deferrisirox) | (2 ) |
| L1 (Deferitronine) | (3 ) |

IRON_MED

## 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.

PHYSICAL_EXAM Yes No

1. Was a physical examination performed during this interval? (1 ) (2 )

If No, Skip to Part IX.

2. Growth Parameters:

A. First Encounter Date: ___ ___ ___ - ___ ___ - ___ ___ ___ ___
FIRST_ENCOUNTER_DT Month Day Year

FIRST_HEIGHT_NOTDONE
1. Height FIRST_HEIGHT ___ ___ ___ . ___ cm (1 ) Not Done

FIRST_WEIGHT_NOTDONE
2. Weight FIRST_WEIGHT ___ ___ ___ . ___ kg (1 ) Not Done

SECOND_ENCOUNTER_DT SECOND_ENCOUNTER_ND
B. Second Encounter midpoint Date: ___ ___ ___ - ___ ___ - ___ ___ ___ ___ (1 ) Not Done*
Month Day Year

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

SECOND_HEIGHT_ND
1. Height SECOND_HEIGHT ___ ___ ___ . ___ cm (1 ) Not Done

SECOND_WEIGHT_ND
2. Weight SECOND_WEIGHT ___ ___ ___ . ___ kg (1 ) Not Done

LAST_ENCOUNTER_ND
C. Last or latest Visit Date: LAST_ENCOUNTER_DT ___ ___ ___ - ___ ___ - ___ ___ ___ ___ (1 ) Not Done
Month Day Year

*If Not Done, Skip to Part VIII, Item 3.

LAST_HEIGHT_NOTDONE
1. Height LAST_HEIGHT ___ ___ ___ . ___ cm (1 ) Not Done

LAST_WEIGHT_NOTDONE
2. Weight LAST_WEIGHT ___ ___ ___ . ___ kg (1 ) Not Done

SPLEEN_PALPABLE Yes No

3. A. Was the spleen reported to be palpable below the costal margin at any time during this interval? (1 ) (2 )

If No, Skip to Part IX.

SPLEEN_LARGEST_DT

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

Write the largest value below:

MID_CLAVICULAR MID_CLA_NOTDONE

1. Mid-clavicular line: ___ ___ . ___ cm below costal margin (1 ) Not Done

ANTEROR_AXILLARY ANT_AXI_NOTDONE

2. Anterior axillary line: ___ ___ . ___ cm below costal margin (1 ) Not Done

DIAG_SPLENIC_SEQU Yes No

C. Was the child diagnosed with acute splenic sequestration during this interval? (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 | |

BABY HUG FOLLOW-UP STUDY II

# EXIT FORM

## PART I: IDENTIFYING INFORMATION

1. Patient's ID Number: SUBJECT_ID ___ ___ ___ ___ 2. Current Clinic: SITE_ID ___ ___

3. Patient's Letter Code: ___ ___ ___ LETTER_CD

4. Date of Form Submission: VISIT_DT ___ ___ ___ - ___ ___ - ___ ___ ___ ___
Month Day Year

## PART II: END OF TREATMENT

| | | | Yes | No |
|---|---|---|---|---|
| 1. | End of Follow-up Participation | | | |
| | A. Completed Follow-up Study II | END_PARTICIPATION | (1 ) | (2 ) |

**IF YES, GO TO PART III. IF NO, ANSWER IIB 1-6 AND II.2.**

B. Reason for study exit:

| | | | | |
|---|---|---|---|---|
| INACTIVE | 1. Inactive follow-up status | | (1 ) | (2 ) |
| RELOCATION | 2. Permanent relocation to area with no BABY HUG Clinic | | (1 ) | (2 ) |
| WITHDRAW | 3. Withdrew consent | | (1 ) | (2 ) |
| TRANSPLANT | 4. Stem Cell Transplant | **If Yes, complete Form 26.** | (1 ) | (2 ) |
| DEATH | 5. Death | | (1 ) | (2 ) |
| OTHER | 6. Other condition requiring end of participation | | (1 )* | (2 ) |
| | a. *Specify: OTHER_SP _____ | | | |

2. Date of last contact with family: LAST_CONTACT_DT ___ ___ ___ - ___ ___ - ___ ___ ___ ___
Month Day Year

**If participant had stem cell transplant, record the date started conditioning for the transplant as the last contact date.**

| ID Number | | | | Visit | | | Seq | |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | | |

**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 II

# TRANSCRANIAL DOPPLER (TCD) EXAM

## PART I: IDENTIFYING INFORMATION

1. Patient's ID Number: SUBJECT_ID ___ ___ ___ ___ 2. Current Clinic: SITE_ID ___ ___

3. Patient's Letter Code: ___ ___ ___ LETTER_CD

4. Procedure Date: ___ ___ - ___ ___ - ___ ___ ___ ___ VISIT_DT
   Month Day Year

## PART II: EQUIPMENT

1. TCD examiner's last name:

___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ RDR46

2. Patient's position during exam PTNTPOS

| | |
|---|---|
| Sitting | (1) |
| Lying on exam table | (2) |
| Other | (3)* |
| No information available | (4) |

*A. Specify: POS_SP _____

## PART III: EXAMINATION PERFORMANCE

1. Completeness of exam COMPEXAM

| | |
|---|---|
| Attempted, but no data collected | (1)* |
| Started, but aborted with some data | (2)^* |
| Complete exam given | (3)^ |
| No information available | (4) |

ID Number

| | | | |
|---|---|---|---|
| | | | |

*A. Reason for incomplete exam INCEXAM

Patient uncooperative (1)

Other (2)**

**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

_____

_____

ID Number

| | | | |
|---|---|---|---|
| | | | |

BABY HUG FOLLOW-UP STUDY II

# PHYSICAL EXAMINATION

## PART I: IDENTIFYING INFORMATION

1. Patient's ID Number: SUBJECT_ID ___ ___ ___ ___ 2. Current Clinic: SITE_ID ___ ___

3. Patient's Letter Code: ___ ___ ___ LETTER_CD 4. Visit: ___ ___ ___ VISIT_NBR

5. Exam Date:: VISIT_DT ___ ___ - ___ ___ - ___ ___ ___ ___
Month Day Year

## PART II: PHYSICAL EXAMINATION

1. Vital Signs

A. Height in centimeters: ____ ____ ____ . ___ cm HEIGHT

B. Weight in kilograms: ____ ____ . ___ kg WEIGHT

C. Heart rate in beats per minute: ____ ____ ____ bpm HEARTRATE

D. Respiratory rate in breaths per minute: ____ ____ ____ bpm RESP

E. Blood pressure:

1. Measurement BP_SYSTOLIC_1 ____ ____ ____ / BP_DIASTOLIC_1 ____ ____ ____
Systolic Diastolic

F. Oxygen saturation (room air): ____ ____ ____ % $O_2$SAT Not done ( 1 ) $O_2$S_ND

2. Situation where exam performed: SITUATION

| | |
|---|---|
| Scheduled clinic visit when well | (1) |
| Clinic visit when sick | (2) |
| ER visit | (3) |
| Hospitalization at admission | (4) |

3. General

A. Appearance — APPEARANCE

| | |
|---|---|
| Well | (1) |
| Ill or sick appearing | (2) |

B. Eyes — EYE

| | |
|---|---|
| Normal | (1) |
| Sclera jaundiced | (2) |
| Other | (3)* |

*1. Specify: _____ OTHER_EYE

C. Nose — NOSE

| | |
|---|---|
| Normal | (1) |
| Boggy nasal turbinates/congested | (2) |
| Other Abnormal | (3)* |

*1. Specify: _____ OTHER_NOSE

D. Tongue — TONGUE

| | |
|---|---|
| Normal | (1) |
| Abnormal (describe) | (2)* |

*1. Describe: _____ OTHER_TONGUE

E. Throat

1. Tonsils — TONSIL

| | |
|---|---|
| Surgically absent | (1) |
| Tonsils present but not enlarged | (2) |
| Tonsils enlarged | (3)* |

*a. If enlarged: TONSIL_ENL

| | |
|---|---|
| 2+ small, but visible | (1) |
| 3+ > 50% of space filled w/tonsil | (2) |
| 4+ meet in midline | (3) |

| | Yes | No | |
|---|---|---|---|
| 2. Tonsillar Exudate present | (1) | (2) | THROAT_EXUDATE |

F. Neck — NECK

| | | |
|---|---|---|
| No adenopathy | (1) | |
| Small shotty cervical nodes (< 1 cm) | (2) | |
| Enlarged nodes | (3)* | |
| *1. If enlarged, describe largest _____ cm | NECK_NDLGST | |
| *2. Site: | | |
| Right | (1) | NECK_RT |
| Left | (2) | |

G. Chest (check all that apply)

| | | | |
|---|---|---|---|
| 1. | Clear to auscultation (normal) | (1) | CHEST_CLEAR |
| 2. | Retractions | (1) | CHEST_RETRACTIONS |
| 3. | Transmitted upper airway sounds | (1) | CHEST_TRANSAIRWAY |
| 4. | Ronchi or Rales | (1) | CHEST_RONCHI |
| 5. | Wheezing | (1) | CHEST_WHEEZING |
| 6. | Other | (1)* | CHEST_OTHER |
| *a. | Specify: _____ | | CHEST_SPECIFY |

H. Cardiac — CARDIAC

| | |
|---|---|
| S1S2 with no murmur (normal) | (1) |
| S1S2 with systolic ejection murmur (flow murmur) | (2) |
| Other abnormal heart sound or murmur | (3)* |
| *1. Describe: _____ | CARDIAC_OTHER |

I. Abdomen — ABDOMEN

| | |
|---|---|
| Soft (non-tender) | (1) |
| Tender | (2) |
| Rebound and/or Guarding | (3) |

J. Liver — LIVER

| | |
|---|---|
| Not enlarged | (1) |
| Enlarged | (2)* |
| *1. _____cm below right costal margin in midclavicular line | LIVRCM |

K. Spleen — SPLEEN

- Surgically absent (1)
- Not palpable (2)
- Palpable (3)*
  - *1. _____cm below left costal margin in midclavicular line AND — MID_CLAVICULAR
  - *2. _____cm below left costal margin in anterior axillary line — ANTERIOR_AXILLARY

L. Musculoskeletal

1. Hip Range of Motion — MSULSKLTL
   - Normal (1)
   - Abnormal (2)*
     - *a. Describe (include side) _____ — MSUL_ABN

| | Yes | No | |
|---|---|---|---|
| 2. Leg ulcer | (1) | (2) | LGULCER |

M. Neurological Exam - For each Section record only your examiner's overall rating. Refer to worksheets in the MOO for specific testing to be done and form to document subject's responses. ***Maintain worksheet as part of your source documentation.***

1. Behavior/Mental Status — NEUROBEH
   - Normal (1)
   - Deficit with little or no impact on function (2)
   - Abnormal with functional limits or missing function (3)

2. Language — NEUROLANG
   - Normal (1)
   - Deficit with little or no impact on function (2)
   - Abnormal with functional limits or missing function (3)

3. Cranial Nerves — NEUROCN
   - Normal (1)
   - Deficit with little or no impact on function (2)
   - Abnormal with functional limits or missing function (3)

4. Deep Tendon Reflexes NEURODTR
   - Normal (1)
   - Deficit with little or no impact on function (2)
   - Abnormal with functional limits or missing function (3)

5. Motor, Power and Tone NEUROMOT
   - Normal (1)
   - Deficit with little or no impact on function (2)
   - Abnormal with functional limits or missing function (3)

6. Fine Motor Coordination NEUROFMC
   - Normal (1)
   - Deficit with little or no impact on function (2)
   - Abnormal with functional limits or missing function (3)

7. Gait NEUROGAIT
   - Normal (1)
   - Deficit with little or no impact on function (2)
   - Abnormal with functional limits or missing function (3)

N. Tanner Stage (Please see diagrams in MOO)

1. Female
   - A. Breasts _____ I – V F_BRSTS
   - B. Pubic Hair _____ I – V F_P_HAIR

2. Male
   - A. Genitals _____ I – V M_GNTLS
   - B. Pubic Hair _____ I – V M_P_HAIR

**PART III: 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 | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | |

BABY HUG FOLLOW-UP STUDY II

**QUESTIONNAIRE**

## PART I: IDENTIFYING INFORMATION

1. Patient's ID Number: ___ ___ ___ ___ SUBJECT_ID
2. Current Clinic: ___ ___ SITE_ID
3. Patient's Letter Code: ___ ___ ___ LETTER_CD
4. Visit: ___ ___ ___ VISIT_NBR
5. Form Date: ___ ___ ___ - ___ ___ - ___ ___ ___ ___ VISIT_DT
   Month Day Year

This is a composite questionnaire to be done annually on patients. Please ask the questions as they are written and record the responses on this form (this is your source document). Please read ALL of the possible responses before accepting a patient's answer. Ensure that there is privacy during the conversation.

## PART II: SLEEP

Please answer these questions regarding the behavior of your child during sleep and wakefulness. The questions apply to how your child acts in general during the past month, not necessarily during the past few days since these may not have been typical if your child has not been well. A "Y" means "yes," "N" means "no," and "DK" means "don't know."

| | Yes | No | Don't Know (DK) | |
|---|---|---|---|---|
| 1. While sleeping, does your child: | | | | |
| A. snore more than half the time? | (1) | (2) | (3) | SNR_HLFT2 |
| B. always snore? | (1) | (2) | (3) | SNORE2 |
| C. snore loudly? | (1) | (2) | (3) | SNR_LOUD2 |
| D. have heavy or loud breathing? | (1) | (2) | (3) | BRTHLOUD2 |
| E. have trouble breathing, or struggle to breathe? | (1) | (2) | (3) | BRTHTRBL2 |
| 2. Have you ever seen your child stop breathing during the night? | (1) | (2) | (3) | BRTHSTP2 |
| 3. Does your child: | | | | |
| A. tend to breathe through the mouth during the day? | (1) | (2) | (3) | BRTHMTH2 |
| B. have a dry mouth on waking up in the morning? | (1) | (2) | (3) | DRYMTH2 |
| C. occasionally wet the bed? | (1) | (2) | (3) | WETBED2 |
| D. wake up feeling unrefreshed in the morning? | (1) | (2) | (3) | WKPRFRSH2 |
| E. have a problem with sleepiness during the day? | (1) | (2) | (3) | SLP_PROB2 |
| 4. Has a teacher, supervisor or other adult commented that your child appears sleepy during the day? | (1) | (2) | (3) | SLPY_DAY2 |

| | | Yes | No | DON'T KNOW (DK) | |
|---|---|---|---|---|---|
| 5. | Is it hard to wake your child up in the morning? | (1) | (2) | (3) | WKP_HARD2 |
| 6. | Does your child wake up with headaches in the morning? | (1) | (2) | (3) | WKP_HDCH2 |
| 7. | Did your child stop growing at a normal rate at any time since birth? | (1) | (2) | (3) | GROW_STP2 |
| 8. | Is your child overweight? | (1) | (2) | (3) | OVERWGHT2 |
| 9. | This child **often** | | | | |
| | A. Does not seem to listen when spoken to directly | (1) | (2) | (3) | IGNRPPL2 |
| | B. Has difficulty organizing tasks and activities | (1) | (2) | (3) | DIFF_ORG2 |
| | C. Is easily distracted by extraneous stimuli | (1) | (2) | (3) | DISTRACT2 |
| | D. Fidgets with hands or feet or squirms in seat | (1) | (2) | (3) | FIDGET2 |
| | E. Is "on the go" or act as if "driven by a motor" | (1) | (2) | (3) | OVERACT2 |
| | F. Interrupts or intrudes on others (e.g., butt into conversations or games) | (1) | (2) | (3) | INTRDOTH2 |

## PART III: ENURESIS

Now we would like to ask you some questions about bedwetting or 'enuresis'. Please listen to all of the answers offered and then tell me the response that best describes how your child has dealt with this common problem for children with sickle cell disease.

| | | | YES | NO |
|---|---|---|---|---|
| 1. | Has your child wet the bed at night during the last 3 months? | WET_3MON | (1) | (2) |

If No, skip to 4.

2. If your child wet the bed during the last 3 months, how often have they wet the bed: WET_FRQ

| | |
|---|---|
| Rarely | (1) |
| Several times a month (but less than once a week) | (2) |
| 1-2 times per week | (3) |
| 3-5 times per week | (4) |
| Every night or almost every night | (5) |

3. Which of the following have you tried with your child to treat the bedwetting? Has the therapy been successful in stopping bed wetting?

| | | Yes | No | |
|---|---|---|---|---|
| A. | Fluid restriction before bedtime | | | |
| | 1. Tried | (1)* | (2) | FLURES_T |
| | *a. Successful | (1) | (2) | FLURES_S |
| B. | Using pull-ups or diapers when sleeping | | | |
| | 1. Tried | (1)* | (2) | PROT_T |
| | *a. Successful | (1) | (2) | PROT_S |
| C. | Waking them up at night | | | |
| | 1. Tried | (1)* | (2) | WKP_T |
| | *a. Successful | (1) | (2) | WKP_S |

ID Number | Visit | - | Seq

| | | Yes | No | |
|---|---|---|---|---|
| D. | Bell alarm | | | |
| | 1. Tried | (1)* | (2) | ALARM_T |
| | *a. Successful | (1) | (2) | ALARM_S |
| E. | Medication DDAVP (desmopressin) | | | |
| | 1. Tried | (1)* | (2) | DDAVP_T |
| | *a. Successful | (1) | (2) | DDAVP_S |
| F. | Medication Tofranil (imipramine) | | | |
| | 1. Tried | (1)* | (2) | TOFR_T |
| | *a. Successful | (1) | (2) | TOFR_S |
| G. | Therapy or counseling? | | | |
| | 1. Tried | (1)* | (2) | THRPY_T |
| | *a. Successful | (1) | (2) | THRPY_S |

4. After going to bed, has your child ever woken up at night to urinate in the bathroom during the last 3 months? (1) (2) NT_URI

If No, skip to 6.

5. If your child urinates in the bathroom during the night, how often? NTURIFRQ

| | |
|---|---|
| Rarely | (1) |
| Several times month (but less than once a week) | (2) |
| 1-2 times per week | (3) |
| 3-5 times per week | (4) |
| Every night or almost every night | (5) |

| | | Yes | No | |
|---|---|---|---|---|
| 6. | Does your child urinate in his or her clothes during the day? | (1) | (2) | WET_DAY |
| 7. A. | Does your child have an immediate family member (parent, sibling) with history of bedwetting when a child? | (1) | (2) | WTBD_FM |

If No, skip to 8.

| | | Yes | No | |
|---|---|---|---|---|
| B. | Does the family member with bed wetting have sickle cell disease? | (1) | (2) | FM_SCD |
| 8. | Does your child drink any caffeinated beverages (coffee, tea, energy drinks, soda with caffeine) after 4:00 p.m.? | (1) | (2) | DRK_CAFF |
| 9. | Is your child a deep sleeper? | (1) | (2) | DP_SLPER |
| 10. | Does your child have constipation? | (1) | (2) | CONST |

ID Number | Visit | Seq

| | | Yes | No | |
|---|---|---|---|---|
| 11. | Does your child soil their underwear with stool (more than a smear)? | (1) | (2) | SOILY_UW |
| 12. | Does your child have a diagnosis of attention deficit disorder? | (1) | (2) | ATTNDD |
| 13. | Does your child have a diagnosis of developmental delay? | (1) | (2) | DEVDELAY |

**PART IV: ADHERENCE – To be asked of the parent or guardian of patients currently taking Hydroxyurea only**

| | | Yes | No | |
|---|---|---|---|---|
| 1. | Child is taking HU | (1) | (2) | HU |

If No, skip to Part V.

Your child is taking hydroxyurea for their sickle cell anemia. Parents and children have identified several issues about their medication-taking behavior and we are interested in your experiences. There is no right or wrong answer. Please answer each question based on your personal experience with your sickle cell medication – hydroxyurea.

| | | | | |
|---|---|---|---|---|
| A. | Do you sometimes forget to give your child their hydroxyurea? | (1) | (2) | FRGT_HU |
| B. | People sometimes miss taking their medications for reasons other than forgetting. Thinking over the past two weeks, were there any days when your child did not take their hydroxyurea? | (1) | (2) | MISS_HU |
| C. | Have you ever cut back or stopped giving your child hydroxyurea without telling your doctor, because your child felt worse when they took it? | (1) | (2) | STPHU_1 |
| D. | When you travel or leave home, do you sometimes forget to bring along your child's hydroxyurea? | (1) | (2) | HU_TRVL |
| E. | Did your child take their hydroxyurea yesterday? | (1) | (2) | HUYSTRDY |
| F. | When you feel like your child's sickle cell anemia is under control, do you sometimes stop giving your child their hydroxyurea? | (1) | (2) | STPHU_2 |
| G. | Taking hydroxyurea every day is a real inconvenience for some people. Do you ever feel hassled about sticking to your child's sickle cell treatment with hydroxyurea? | (1) | (2) | DIFF_HU |

H. How often do you have difficulty remembering to give your child all of their hydroxyurea? (**Please circle the correct number**) DIFF_FRQ

| | |
|---|---|
| Never/Rarely | (1) |
| Once in a while | (2) |
| Sometimes | (3) |
| Usually | (4) |
| All the time | (5) |

**PART V: PRIAPISM – ask of parents/guardians of MALE patients only (regardless of age)**

| | | Yes | No | |
|---|---|---|---|---|
| 1. | Is the child male? | (1) | (2) | MALE |

If No, skip to Part VI.

A. Have you ever heard the word priapism before? (1) (2) PRIAPWRD

If No, skip to "Read to Patient and Parent."

B. Where have you heard the word priapism before? (Check all that apply)

| | | | |
|---|---|---|---|
| 1. | Doctor or nurse | (1) | SRC_DR |
| 2. | Friend or relative | (1) | SRC_FR |
| 3. | Written information | (1) | SRC_INFO |
| 4. | Other | (1)* | SRC_OTH |
| | *a. Specify: _____ | | SRCOTHSP |

**READ TO PATIENT AND PARENT**: *Priapism is a painful erection of the penis. It may last minutes to hours. It is more common in boys and men with sickle cell disease.*

| | | Yes | No | |
|---|---|---|---|---|
| C. | Has your son ever had a painful unwanted erection of the penis that lasted 30 minutes or more? | (1) | (2) | PRIAP30M |

If No, skip to Part VI.

D. Has your son ever had a painful unwanted erection of the penis that lasted 4 hours or more? (1) (2) PRIAP4HR

For the next two questions, read all of the answers, then ask for one best answer.

E. How many episodes of priapism has your son had in the last year? PRIAPEP1

| | |
|---|---|
| None | (1) |
| One | (2) |
| 2 to 5 | (3) |
| 6 to 20 | (4) |
| More than 20 | (5) |
| Do not know | (6) |

F. How many episodes of priapism did your son have before the last year? PRIAPEP2

| | |
|---|---|
| None | (1) |
| One | (2) |
| 2 to 5 | (3) |
| 6 to 20 | (4) |
| More than 20 | (5) |
| Do not know | (6) |

G. How old was your son when the first episode happened? _____ years old PRIAPAGE

## PART VI: PICA

| | | Yes | No | |
|---|---|---|---|---|
| 1. | Does your child (currently, or in the last 3 months) chew on, but not swallow things that are not food (e.g., pencils, eraser, rim of cup)? | (1) | (2) | PICA_1 |
| 2. | Does your child (currently, or in the last 3 months) chew on and swallow things that are not food (e.g., dirt, foam, hair)? | (1) | (2) | PICA_2 |
| 3. | Have other people (currently, or in the last 3 months) observed your child chewing on or eating non-food items? | (1) | (2) | PICA_OBS |

## PART VII: EDUCATION – SCHOOL QUESTIONNAIRE

1. What is your child's current grade? _____ GRADE

2. What is your child's current age? AGE_YR _____ years _____ Months AGE_MON

| | | Yes | No | |
|---|---|---|---|---|
| 3. | Has your child ever been held back or repeated a grade? | (1) | (2) | RPGRADE |

If No, skip to 4.

A. How many grades? (1) (2) (3 or more) RPTIMES

B. Which grade(s)? (List up to 3 most recent grades) RPGRADE1 _____ RPGRADE2 _____ RPGRADE3 _____

4. Does your child have any accommodations because of learning differences? Check all that apply:

| | | | |
|---|---|---|---|
| A. | Special Education Services | (1) | ACCM_SES |
| B. | 504 plan | (1) | ACCM_504 |
| C. | IEP-individualized education plan | (1) | ACCM_IEP |
| D. | Special tutoring or classes not available to regular students | (1) | ACCM_SPE |
| E. | Other | (1)* | ACCM_OTH |
| | 1. *Describe: _____ | | ACCM_OSP |
| F. | My child does not receive any accommodation for learning differences | (1) | ACCMNONE |

## PART VIII: 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 | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | |

BABY HUG FOLLOW-UP STUDY II

**SPECIAL TESTS (AGE 10)**
**(All Active Subjects)**

## PART I: IDENTIFYING INFORMATION

1. Subject ID Number: SUBJECT_ID ___ ___ ___ ___ 2. Current Clinic: SITE_ID ___ ___

3. Subject Letter Code: ___ ___ ___ LETTER_CD

4. Visit Start Date: VISIT_DT ___ ___ ___ - ___ ___ - ___ ___ ___ ___
Month Day Year

## PART II: SPECIAL TESTS AND PROCEDURES

1. Liver/Spleen Scan Performed? LIVER_SCAN Yes (1 ) No (2 )

**IF YES, RECORD DATE PERFORMED AND COMPLETE FORM 21.**

A. Date Liver/Spleen Scan Performed: LIVER_SCAN_DT ___ ___ ___ - ___ ___ - ___ ___ ___ ___
Month Day Year

2. Abdominal Sonogram Performed? ABDOMINAL_SONO Yes (1 ) No (2 )

**IF YES, RECORD DATE PERFORMED AND COMPLETE FORM 23.**

A. Date Abdominal Sonogram Performed: ABDOMINAL_SONO_DT ___ ___ ___ - ___ ___ - ___ ___ ___ ___
Month Day Year

3. TCD Performed? TCD Yes (1 ) No (2 )

**IF YES, RECORD DATE PERFORMED AND COMPLETE FORM 13.**

A. Date TCD Performed: TCD_DT ___ ___ ___ - ___ ___ - ___ ___ ___ ___
Month Day Year

4. PFT Performed? PFT Yes (1 ) No (2 )

**IF YES, RECORD DATE PERFORMED AND COMPLETE FORM 31.**

A. Date PFT Performed: ___ ___ ___ - ___ ___ - ___ ___ ___ ___
PFT_DT Month Day Year

5. Cardiac Echocardiogram Performed? CARDIAC Yes (1 ) No (2 )

**IF YES, RECORD DATE PERFORMED AND COMPLETE FORM 32.**

A. Date Echocardiogram Performed: ___ ___ ___ - ___ ___ - ___ ___ ___ ___
CARDIAC_DT Month Day Year

6. MRI/MRA Performed? MRIMRA Yes (1 ) No (2 )

**IF YES, RECORD DATE PERFORMED AND COMPLETE FORM 33.**

A. Date MRI/MRA Performed: ___ ___ ___ - ___ ___ - ___ ___ ___ ___
MRIMRA_DT Month Day Year

7. Vineland Performed? VINELAND Yes (1 ) No (2 )

**IF YES, RECORD DATE PERFORMED AND COMPLETE FORM 27.**

A. Date Vineland Performed: ___ ___ ___ - ___ ___ - ___ ___ ___ ___
VINELAND_DT Month Day Year

8. Peds QOL Performed? PEDSQOL Yes (1 ) No (2 )

**IF YES, RECORD DATE PERFORMED AND COMPLETE FORM 29.**

A. Date Peds QOL Performed: ___ ___ ___ - ___ ___ - ___ ___ ___ ___
PEDSQOL_DT Month Day Year

9. Connor CPT II Performed? CONNORCPT2 Yes (1) No (2)

**IF YES, RECORD DATE PERFORMED AND COMPLETE FORM 30.**

A. Date Connor CPT II Performed: ___ ___ ___ - ___ ___ - ___ ___ ___ ___
CONNORCPT2_DT Month Day Year

10. WISC IV Performed? WISC4 Yes (1) No (2)

**IF YES, RECORD DATE PERFORMED AND COMPLETE FORM 28.**

A. Date WISC IV Performed: ___ ___ ___ - ___ ___ - ___ ___ ___ ___
WISC4_DT Month Day Year

## 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 II

# LIVER-SPLEEN SCAN PERFORMANCE

## PART I: IDENTIFYING INFORMATION

1. Patient's ID Number: SUBJECT_ID ___ ___ ___ ___ 2. Current Clinic: SITE_ID ___ ___

3. Patient's Letter Code: ___ ___ ___ LETTER_CD

4. Visit Date VISIT_DT ___ ___ ___ - ___ ___ - ___ ___ ___ ___
Month Day Year

## 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 ___ . ___ mCi
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. Adequacy of Imaging (Answer both questions):

| | | Yes | No |
|---|---|---|---|
| A. | 400 K Image adequate: AOI400K | (1 ) | (2 ) |
| B. | Timed Image adequate: AOITIMED | (1 ) | (2 ) |

## 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 | | . | |

ID Number | | | | | Visit | | | - | Seq | |

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

## PART IV: EXAMINER

1. Examiner's 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 II

# ABDOMINAL SONOGRAM (ULTRASOUND) PERFORMANCE

## PART I: IDENTIFYING INFORMATION

1. Patient's ID Number: SUBJECT_ID ___ ___ ___ ___ 2. Current Clinic: SITE_ID ___ ___

3. Patient's Letter Code: ___ ___ ___ LETTER_CD

4. Visit Date: ___ ___ ___ - ___ ___ - ___ ___ ___ ___
VISIT_DT Month Day Year

## PART II: EQUIPMENT AND QUALITY

1. Equipment: ABDSEQPT _____

2. Transducer: ABDSTRNS _____

3. Quality of Study: STATUS45 Adequate (1 ) Inadequate (2 )

4. Film Label: SONO_LBL

## PART III: SONOGRAPHER

1. Sonographer's Name: EXAMINER_NM _____

2. Signature: SIGNATURE _____

**PART IV: 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

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | - | | |

BABY HUG FOLLOW-UP STUDY II
**SERIOUS ADVERSE EVENT**
**(ACTIVE GROUP ONLY)**

## PART I: IDENTIFYING INFORMATION

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

## PART II: EVENT PERIOD

1. Date of Event
   A. Event Start Date: ___ ___ ___ - ___ ___ - ___ ___ ___ ___ START_DT
   Month Day Year
   B. Event End Date: ___ ___ ___ - ___ ___ - ___ ___ ___ ___ E_END_DT
   Month Day Year
2. Qualifying Procedure (Event must have occurred during the 5 days following an "Active" assessment procedure.) Please note all that apply:
   A. Liver/Spleen Scan LIVER_SPLEEN_DT ___ ___ ___ - ___ ___ - ___ ___ ___ ___ Month Day Year ( 1) N/A LIVER_SPLEEN_NA
   B. Abdominal Sonogram ABD_SONO_DT ___ ___ ___ - ___ ___ - ___ ___ ___ ___ Month Day Year ( 1) N/A ABD_SONO_NA
   C. WISC IV WISC4 ___ ___ ___ - ___ ___ - ___ ___ ___ ___ Month Day Year ( 1) N/A WISC4_NA
   D. Blood Specimens BLOOD_SPEC_DT ___ ___ ___ - ___ ___ - ___ ___ ___ ___ Month Day Year ( 1) N/A BLOOD_SPEC_NA
   E. TCD TCD_DT ___ ___ ___ - ___ ___ - ___ ___ ___ ___ Month Day Year ( 1) N/A TCD_NA
   F. PFT PFT_DT ___ ___ ___ - ___ ___ - ___ ___ ___ ___ Month Day Year ( 1) N/A PFT_NA
   G. Cardiac Echocardiogram CARDIAC_DT ___ ___ ___ - ___ ___ - ___ ___ ___ ___ Month Day Year ( 1) N/A CARDIAC_NA

| | | | | | |
|---|---|---|---|---|---|
| H. | MRI | MRI_DT | ___ ___ ___ - ___ ___ - ___ ___ ___ ___ Month Day Year | ( 1) | N/A MRI_NA |
| I. | MRA | MRA_DT | ___ ___ ___ - ___ ___ - ___ ___ ___ ___ Month Day Year | ( 1) | N/A MRA_NA |
| J. | Vineland | VINELAND_DT | ___ ___ ___ - ___ ___ - ___ ___ ___ ___ Month Day Year | ( 1) | N/A VINELAND_NA |
| K. | Connor CPT II | CONNORCPT2_DT | ___ ___ ___ - ___ ___ - ___ ___ ___ ___ Month Day Year | ( 1) | N/A CONNORCPT2_NA |
| L. | Peds QOL | PEDSQOL_DT | ___ ___ ___ - ___ ___ - ___ ___ ___ ___ Month Day Year | ( 1) | N/A PEDSQOL_NA |

## PART III: SAE

| | | | YES | NO |
|---|---|---|---|---|
| 1. | Please indicate all diagnoses: | | | |
| A. | Acute Chest Syndrome | HX_ACS | (1) | (2) |
| B. | Splenic Sequestration Crisis | HXSPLSEQ | (1) | (2) |
| C. | Prolonged Hospitalization (greater than 7 days) | LONGHOSP | (1) | (2) |
| D. | Stroke or TIA | HX_STROKE_TIA | (1) | (2) |
| E. | Life Threatening Event | LIFE_THREAT_EVT | (1) | (2) |
| | 1. Specify: _____ | LIFE_THREAT_EVT_SP | | |
| F. | Death | HX_DEATH | (1) | (2) |
| G. | ICU Admission | ICU | (1) | (2) |

## PART IV: ADDITIONAL DIAGNOSIS INFORMATION

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

| | | None | 1 Lobe | >1 Lobe | N/A | |
|---|---|---|---|---|---|---|
| 1. | Acute Chest Syndrome | | | | | |
| A. | New Infiltrate | (1) | (2) | (3) | (4) | ACSNINF |
| B. | $O_2$% Saturation on Room Air at Presentation | _____ | _____ | . _____% | | ACSSRAP |
| C. | Oxygen Administered | _____ | _____ | . _____L | | ACSOXADM |
| D. | Mechanical Ventilation | Yes (1) | | No (2) | | ACSMVENT |

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

ID Number

| | | | |
|---|---|---|---|
| | | | |

2. Splenic Sequestration

A. Spleen size below LCM **prior** to SAE SPLNSIZE_PRIOR

| <2 cm | 2-4 cm | 4-6 cm | 6-8 cm | >8 cm |
|---|---|---|---|---|
| (1) | (2) | (3) | (4) | (5) |

B. Spleen size below LCM **during** SAE SPLNSIZE_DURING

| <2 cm | 2-4 cm | 4-6 cm | 6-8 cm | >8 cm |
|---|---|---|---|---|
| (1) | (2) | (3) | (4) | (5) |

C. Nadir hemoglobin ___ ___ . ___ gm/dL SPLNHMGL

D. Platelet count at time of nadir hemoglobin ___ ___ ___ ___ k/µL 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 | | YES | NO | N/A |
|---|---|---|---|---|
| A. Loss of consciousness | LOS_CONS | (1) | (2) | (3) |
| B. Change in mental status | CHG_MENT | (1) | (2) | (3) |
| C. Loss of or difficulty with speech or vocalization | SPEECH | (1) | (2) | (3) |
| D. Paralysis or weakness | PARALYS | (1) | (2) | (3) |
| E. Difficulty with swallowing | DIFFSWAL | (1) | (2) | (3) |
| F. Difficulty with vision | DIFF_SEE | (1) | (2) | (3) |
| G. Loss of balance or dizziness | BALANCE | (1) | (2) | (3) |
| H. Seizures | SEIZURE | (1) | (2) | (3) |
| I. Headache | HEADACHE | (1) | (2) | (3) |

ID Number

| | | | |
|---|---|---|---|
| | | | |

| 5. Results of Imaging Tests | | Normal | Abnormal | Not Done |
|---|---|---|---|---|
| A. MRI of brain | F50MRI | (1) | (2) | (3) |
| B. CT scan of brain | F50CTBR | (1) | (2) | (3) |
| C. PET scan of brain | F50PTBR | (1) | (2) | (3) |
| D. MRA cerebral vasculature | F50MRA | (1) | (2) | (3) |
| E. Transcranial Doppler | F50TCD | (1) | (2) | (3) |
| F. Arteriogram | F50ARTGR | (1) | (2) | (3) |

## PART V: DIAGNOSIS/PROBLEM SEVERITY AND ATTRIBUTION

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

| PROBLEM | ONSET_DT | NUMDAYS | SEVERITY | ATTR_TRT | DIAGUNXP |
|---|---|---|---|---|---|
| 1. Diagnosis/ Problem | 2. Date of Onset | 3. Number of Days | 4. [1]Severity | 5. [2]Attribution to Study Treatment | 6. [3]Diagnosis Unexpected |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |

| [1]Severity | [2]Attribution to Study Test | [3]Diagnosis Unexpected |
|---|---|---|
| 1. Mild | 1. Definite (clearly related) | 1. Yes |
| 2. Moderate | 2. Probably (likely related) | 2. No |
| 3. Severe | 3. Possible (may be related) | 3. N/A |
| 4. Life threatening | 4. Unlikely (doubtfully related) | |
| 5. Disabling | 5. Unrelated (definitely not related) | |
| 6. FATAL | | |
| 7. Unknown | | |

ID Number

| | | | |
|---|---|---|---|
| | | | |

## PART VI: REPORTABLE TREATMENTS

| 1. Answer each item | | YES | NO | N/A |
|---|---|---|---|---|
| A. Transfusion | TRANSFUS | (1) | (2) | (3) |

1. If yes, complete a. – d. Otherwise, skip to B.

a. Transfusion Type: TR_TYPE (1) Simple (2) Exchange

b. Volume, answer b 1 or 2.

1. Whole Blood TRVOLWBL ____ ____ ____ cc

OR

2. Packed Red Cells TRVOLPR2 ____ ____ ____ cc

c. Start Date: TSTRT_DT ___ ___ ___ - ___ ___ - ___ ___ ___ ___
Month Day Year

d. Stop Date: TSTOP_DT ___ ___ ___ - ___ ___ - ___ ___ ___ ___
Month Day Year

| | | YES | NO | N/A |
|---|---|---|---|---|
| B. Placement on chronic transfusion therapy | CHRTRAN | (1) | (2) | (3) |
| C. Splenectomy | SPLCTMY | (1) | (2) | (3) |
| D. Parenteral antibiotics | PAR_ANTI | (1) | (2) | (3) |
| E. Dialysis, limited course | DIALYS_L | (1) | (2) | (3) |

## PART VII: HOSPITALIZATION

1. Hospital Name: _____ HOSPNAME

2. City: _____ HOSPCITY

3. State: ____ ____ HOSP_ST 4. Zip Code: ___ ___ ___ ___ ___ HOSP_ZIP

5. Admission Date: ADM_DT ___ ___ ___ - ___ ___ - ___ ___ ___ ___
Month Day Year

6. Discharge Date: DISCH_DT ___ ___ ___ - ___ ___ - ___ ___ ___ ___
Month Day Year

ID Number

| | | | |
|---|---|---|---|
| | | | |

## PART VIII: OUTCOMES

| | | | YES | NO |
|---|---|---|---|---|
| 1. | Significant new disability | SNEWDISA | (1) | (2) |
| 2. | Persistent new disability | PNEWDISA | (1) | (2) |
| 3. | Permanent new disability | PERMDISA | (1) | (2) |
| 4. | **DEATH** | DEATH | (1) | (2) |

A.. Date of Death: DEATH_DT ___ ___ - ___ ___ - ___ ___ ___ ___
Month Day Year

B. Location: DTH_LOC

1. Inpatient (1)
2. In-Community (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

| | | | |
|---|---|---|---|
| | | | |

BABY HUG FOLLOW-UP STUDY II

# STEM CELL TRANSPLANT REPORT

PLEASE SUBMIT THE FORM 26 AS SOON AFTER THE STEM CELL TRANSPLANT AS POSSIBLE. PART III SHOULD BE FILLED OUT / UPDATED ONE YEAR AFTER THE SURGERY.

## PART I: IDENTIFYING INFORMATION

1. Patient's ID Number: SUBJECT_ID ___ ___ ___ ___ 2. Current Clinic: SITE_ID ___ ___

3. Patient's Letter Code: ___ ___ ___ LETTER_CD

4. Visit Date: VISIT_DT ___ ___ ___ - ___ ___ - ___ ___ ___ ___
Month Day Year

## PART II: TRANSPLANT INFORMATION

1. Date of Transplant: TRANSPLANT_DT ___ ___ ___ - ___ ___ - ___ ___ ___ ___
Month Day Year

A. Date started conditioning for transplant: TPCON_DT ___ ___ ___ - ___ ___ - ___ ___ ___ ___
Month Day Year

2. Location of Transplant Center

TRANSPLANT_LOC
_____

3. Reason for Transplant in Sickle Cell Disease TRANSPLANT_RSN

| | |
|---|---|
| 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 TRANSPLANT_RSN_SP _____

4. Type of Graft: GRAFT_TYPE

| | |
|---|---|
| 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: MATCHING_DEGREE

| | |
|---|---|
| 6/6 | (1) |
| 8/8 | (2) |
| 5/6 or 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
DEATH_DT ___ ___ - ___ ___ - ___ ___ ___ ___
Month Day Year

B. Graft Rejection Date
GRAFTREJ_DT ___ ___ - ___ ___ - ___ ___ ___ ___
Month Day Year

C. Stable Mixed Chimerism
STABLE_DT ___ ___ - ___ ___ - ___ ___ ___ ___
Month Day Year

D. Cured of Sickle Cell Disease Date
CURED_DT ___ ___ - ___ ___ - ___ ___ ___ ___
Month Day Year

E. Other OTHER (1)

i. If other, please specify:
OTHER_SP _____

ii. Date:
OTHER_DT ___ ___ - ___ ___ - ___ ___ ___ ___
Month Day Year

**PART IV: COORDINATOR**

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 II

**VINELAND SUMMARY**

## PART I: IDENTIFYING INFORMATION

1. Patient's ID Number: ___ ___ ___ ___ (SUBJECT_ID) 2. Current Clinic: ___ ___ (SITE_ID)

3. Patient's Letter Code: ___ ___ ___ (LETTER_CD)

4. Testing Date:: (VISIT_DT) ___ ___ ___ - ___ ___ - ___ ___ ___ ___
Month Day Year

## PART II: CAREGIVER CODES

1. Chronological Age: (CHRAGEYR) ____ Years (CHRAGEMN) ____ ____ Months (CHRAGEDS) ____ ____ Days

2. Caregiver's Relationship to Child: (CARE41)

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

## 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 |

**PART VI: MOTOR SKILLS** ☐ **N/D** MOTOR_ND

**If not done, skip to Part VII.**

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

_____

_____

_____

BABY HUG FOLLOW-UP STUDY II

# WISC-IV

## PART I: IDENTIFYING INFORMATION

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

## PART II: TESTING RESULTS

1. Full scale IQ: ___ ___ ___ FAIQ
2. Verbal comprehension composite score: ___ ___ ___ VCI
3. Perceptual reasoning composite score: ___ ___ ___ PRI
4. Working memory composite score: ___ ___ ___ WMI
5. Processing speed composite score: ___ ___ ___ PSI
6. Block design scaled score: ___ ___ BD
7. Similarities scaled score: ___ ___ SI
8. Digit span scaled score: ___ ___ DS
9. Picture concepts scaled score: ___ ___ PC
10. Coding scaled score: ___ ___ CD
11. Vocabulary scaled score: ___ ___ VC
12. Letter-number sequence scaled score: ___ ___ LN
13. Matrix reasoning scaled score: ___ ___ MR
14. Comprehension scaled score: ___ ___ CO
15. Symbol search scaled score: ___ ___ SS

| ID Number | | | | Visit | | | - | Seq | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | |

## PART III: EXAMINER'S INFORMATION

1. Name: _____ EXAMINER_NM

## 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 II

**PedsQL**

## PART I: IDENTIFYING INFORMATION

1. Patient's ID Number: SUBJECT_ID ___ ___ ___ ___ 2. Current Clinic: SITE_ID ___ ___

3. Patient's Letter Code: LETTER_CD ___ ___ ___

4. Visit Date: VISIT_DT ___ ___ ___ - ___ ___ - ___ ___ ___ ___
Month Day Year

## PART II: FAMILY INFORMATION

### RELATIONSHIP

1. What is your relationship to this child (please check and/or circle)?

RLTNSHP

| | |
|---|---|
| Mother, Step Mother, Foster Mother | (1) |
| Father, Step Father, Foster Father | (2) |
| Grandmother | (3) |
| Grandfather | (4) |
| Guardian | (5) |
| Other | (6)* |

*a. If Other, specify: RLTN_SP _____

2. Information about the child.

A. Date of birth: BIRTH_DT ___ ___ ___ - ___ ___ - ___ ___ ___ ___
Month Day Year

B. Child is: SEX Male (1) Female (2)

C. Ethnic Group or Race:

RACE

| | |
|---|---|
| Black, Non-Hispanic | (1) |
| Asian or Pacific Islander | (2) |
| Hispanic | (3) |
| White, Non-Hispanic | (4) |
| Native American or Alaskan Native | (5) |
| Other | (6)* |

*a. If Other, specify: RACE_OTH _____

3. Information about mother:

A. Marital status:

MRTLST_M

| | |
|---|---|
| Single | (1) |
| Married | (2) |
| Separated | (3) |
| Living with someone | (4) |
| Divorced | (5) |
| Widowed | (6) |

B. Highest level of education:

EDU_M

| | |
|---|---|
| 6th grade or less | (1) |
| 7th-9th grade or less | (2) |
| 9th-12th grade or less | (3) |
| High school graduate | (4) |
| Some college or certification course | (5) |
| College graduate | (6) |
| Graduate or Professional Degree | (7) |

C. Occupation or Job Title: _____ JOB_M

4. Information about father:

A. Marital status:

MRTLST_F

| | |
|---|---|
| Single | (1) |
| Married | (2) |
| Separated | (3) |
| Living with someone | (4) |
| Divorced | (5) |
| Widowed | (6) |

B. Highest level of education:

EDU_F

| | |
|---|---|
| 6th grade or less | (1) |
| 7th-9th grade or less | (2) |
| 9th-12th grade or less | (3) |
| High school graduate | (4) |
| Some college or certification course | (5) |
| College graduate | (6) |
| Graduate or Professional Degree | (7) |

C. Occupation or Job Title: _____ JOB_F

5. Impact Scale:

In the past 6 months, has your child…

| | | | Yes | No |
|---|---|---|---|---|
| A. | Had a chronic health condition (defined as a physical or mental health condition that has lasted or is expected to last at least 6 months, and interferes with your child's activities)? | CHC_6M | (1)* | (2) |

*1. If YES, what is the name of your child's chronic health condition? CHC_NAME

_____

In the past 12 months, has your child had…

| | | | Yes | No |
|---|---|---|---|---|
| B. | Any overnight visits to the hospital? | OVNT_12M | (1)* | (2) |

*1. If YES, how many times? OVNT_NUM ___ ___

*2. What was wrong? _____ OVNT_RSN

| | | | Yes | No |
|---|---|---|---|---|
| C. | Any Emergency Room/Urgent Care Visits? | ER_12M | (1)* | (2) |

*1. If YES, how many times? ER_NUM ___ ___

*2. What was wrong? _____ ER_RSN

In the past 30 days…

D. How many days did your child miss from school due to physical or mental health? ABST_30D ___ ___

E. How many days was your child sick in bed or too ill to play? SICK_30D ___ ___

F. How many days did your child need someone to care for him/her due to physical or mental health? CARE_30D ___ ___

| | | | Yes* | No |
|---|---|---|---|---|
| 6. | Does caregiver work outside the home? | WKOTSDHM | | |

**If No, skip to Part III.**

*A. In the past 30 days, how many days have you missed from work due to your child's physical or mental health? MSWK_30D ___ ___

*B. In the past 30 days, has your child's health interfered with…

| | | Never | Almost Never | Some-times | Often | Almost Always | |
|---|---|---|---|---|---|---|---|
| 1. | Your daily routine at work | (0) | (1) | (2) | (3) | (4) | RTN_WK |
| 2. | Your ability to concentrate at work | (0) | (1) | (2) | (3) | (4) | CONC_WK |

## PART III: GENERIC CORE SCALES

1. **Child** Report (Ages 8-12)

In the past one month, how much of a problem has this been for you…

| | | | Never | Almost Never | Some-times | Often | Almost Always | |
|---|---|---|---|---|---|---|---|---|
| A. | About my health and activities (problems with..) | | | | | | | |
| | 1. | It is hard for me to walk more than one block | (0) | (1) | (2) | (3) | (4) | GCRPT_A1 |
| | 2. | It is hard for me to run | (0) | (1) | (2) | (3) | (4) | GCRPT_A2 |
| | 3. | It is hard for me to do sports activity or exercise | (0) | (1) | (2) | (3) | (4) | GCRPT_A3 |
| | 4. | It is hard for me to lift something heavy | (0) | (1) | (2) | (3) | (4) | GCRPT_A4 |
| | 5. | It is hard for me to take a bath or shower by myself | (0) | (1) | (2) | (3) | (4) | GCRPT_A5 |
| | 6. | It is hard for me to do chores around the house | (0) | (1) | (2) | (3) | (4) | GCRPT_A6 |
| | 7. | I hurt or ache | (0) | (1) | (2) | (3) | (4) | GCRPT_A7 |
| | 8. | I have low energy | (0) | (1) | (2) | (3) | (4) | GCRPT_A8 |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| B. | About my feelings (problems with..) | | | | | | | |
| | 1. | I feel afraid or scared | (0) | (1) | (2) | (3) | (4) | GCRPT_B1 |
| | 2. | I feel sad or blue | (0) | (1) | (2) | (3) | (4) | GCRPT_B2 |
| | 3. | I feel angry | (0) | (1) | (2) | (3) | (4) | GCRPT_B3 |
| | 4. | I have trouble sleeping | (0) | (1) | (2) | (3) | (4) | GCRPT_B4 |
| | 5. | I worry about what will happen to me | (0) | (1) | (2) | (3) | (4) | GCRPT_B5 |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| C. | How I get along with others (problems with..) | | | | | | | |
| | 1. | I have trouble getting along with other kids | (0) | (1) | (2) | (3) | (4) | GCRPT_C1 |
| | 2. | Other kids do not want to be my friend | (0) | (1) | (2) | (3) | (4) | GCRPT_C2 |
| | 3. | Other kids tease me | (0) | (1) | (2) | (3) | (4) | GCRPT_C3 |
| | 4. | I cannot do things that other kids my age can do | (0) | (1) | (2) | (3) | (4) | GCRPT_C4 |
| | 5. | It is hard to keep up when I play with other kids | (0) | (1) | (2) | (3) | (4) | GCRPT_C5 |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| D. | About school (problems with..) | | | | | | | |
| | 1. | It is hard to pay attention in class | (0) | (1) | (2) | (3) | (4) | GCRPT_D1 |
| | 2. | I forget things | (0) | (1) | (2) | (3) | (4) | GCRPT_D2 |
| | 3. | I have trouble keeping up with my schoolwork | (0) | (1) | (2) | (3) | (4) | GCRPT_D3 |
| | 4. | I miss school because of not feeling well | (0) | (1) | (2) | (3) | (4) | GCRPT_D4 |
| | 5. | I miss school to go to the doctor or hospital | (0) | (1) | (2) | (3) | (4) | GCRPT_D5 |

ID Number | Visit | Seq

2. **Parent** Report (for Children Ages 8-12)

In the past one month, how much of a problem has your child had with…

| | | | Never | Almost Never | Some-times | Often | Almost Always | |
|---|---|---|---|---|---|---|---|---|
| A. | Physical functioning (problems with..) | | | | | | | |
| | 1. | Walking more than one block | (0) | (1) | (2) | (3) | (4) | GPRPT_A1 |
| | 2. | Running | (0) | (1) | (2) | (3) | (4) | GPRPT_A2 |
| | 3. | Participating in sports activity or exercise | (0) | (1) | (2) | (3) | (4) | GPRPT_A3 |
| | 4. | Lifting something heavy | (0) | (1) | (2) | (3) | (4) | GPRPT_A4 |
| | 5. | Taking a bath or shower by him or herself | (0) | (1) | (2) | (3) | (4) | GPRPT_A5 |
| | 6. | Doing chores around the house | (0) | (1) | (2) | (3) | (4) | GPRPT_A6 |
| | 7. | Having hurts or aches | (0) | (1) | (2) | (3) | (4) | GPRPT_A7 |
| | 8. | Low energy level | (0) | (1) | (2) | (3) | (4) | GPRPT_A8 |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| B. | Emotional functioning (problems with..) | | | | | | | |
| | 1. | Feeling afraid or scared | (0) | (1) | (2) | (3) | (4) | GPRPT_B1 |
| | 2. | Feeling sad or blue | (0) | (1) | (2) | (3) | (4) | GPRPT_B2 |
| | 3. | Feeling angry | (0) | (1) | (2) | (3) | (4) | GPRPT_B3 |
| | 4. | Trouble sleeping | (0) | (1) | (2) | (3) | (4) | GPRPT_B4 |
| | 5. | Worrying about what will happen to him or her | (0) | (1) | (2) | (3) | (4) | GPRPT_B5 |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| C. | Social functioning (problems with..) | | | | | | | |
| | 1. | Getting along with other children | (0) | (1) | (2) | (3) | (4) | GPRPT_C1 |
| | 2. | Other kids not wanting to be his or her friend | (0) | (1) | (2) | (3) | (4) | GPRPT_C2 |
| | 3. | Getting teased by other children | (0) | (1) | (2) | (3) | (4) | GPRPT_C3 |
| | 4. | Not able to do things that other children his or her age can do | (0) | (1) | (2) | (3) | (4) | GPRPT_C4 |
| | 5. | Keeping up when playing with other children | (0) | (1) | (2) | (3) | (4) | GPRPT_C5 |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| D. | School functioning (problems with..) | | | | | | | |
| | 1. | Paying attention in class | (0) | (1) | (2) | (3) | (4) | GPRPT_D1 |
| | 2. | Forgetting things | (0) | (1) | (2) | (3) | (4) | GPRPT_D2 |
| | 3. | Keeping up with schoolwork | (0) | (1) | (2) | (3) | (4) | GPRPT_D3 |
| | 4. | Missing school because of not feeling well | (0) | (1) | (2) | (3) | (4) | GPRPT_D4 |
| | 5. | Missing school to go to the doctor or hospital | (0) | (1) | (2) | (3) | (4) | GPRPT_D5 |

## PART IV: FATIGUE SCALES

1. **Child** Report (Ages 8-12)

In the past one month, how much of a problem has this been for you…

| | | | Never | Almost Never | Some-times | Often | Almost Always | |
|---|---|---|---|---|---|---|---|---|
| A. | General fatigue (problems with..) | | | | | | | |
| | 1. | I feel tired | (0) | (1) | (2) | (3) | (4) | FCRPT_A1 |
| | 2. | I feel physically weak (not strong) | (0) | (1) | (2) | (3) | (4) | FCRPT_A2 |
| | 3. | I feel too tired to do things that I like to do | (0) | (1) | (2) | (3) | (4) | FCRPT_A3 |
| | 4. | I feel too tired to spend time with my friends | (0) | (1) | (2) | (3) | (4) | FCRPT_A4 |
| | 5. | I have trouble finishing things | (0) | (1) | (2) | (3) | (4) | FCRPT_A5 |
| | 6. | I have trouble starting things | (0) | (1) | (2) | (3) | (4) | FCRPT_A6 |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| B. | Sleep/Rest fatigue (problems with..) | | | | | | | |
| | 1. | I sleep a lot | (0) | (1) | (2) | (3) | (4) | FCRPT_B1 |
| | 2. | It is hard for me to sleep through the night | (0) | (1) | (2) | (3) | (4) | FCRPT_B2 |
| | 3. | I feel tired when I wake up in the morning | (0) | (1) | (2) | (3) | (4) | FCRPT_B3 |
| | 4. | I rest a lot | (0) | (1) | (2) | (3) | (4) | FCRPT_B4 |
| | 5. | I take a lot of naps | (0) | (1) | (2) | (3) | (4) | FCRPT_B5 |
| | 6. | I spend a lot of time in bed | (0) | (1) | (2) | (3) | (4) | FCRPT_B6 |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| C. | Cognitive fatigue (problems with..) | | | | | | | |
| | 1. | It is hard for me to keep my attention on things | (0) | (1) | (2) | (3) | (4) | FCRPT_C1 |
| | 2. | It is hard for me to remember what people tell me | (0) | (1) | (2) | (3) | (4) | FCRPT_C2 |
| | 3. | It is hard for me to remember what I just heard | (0) | (1) | (2) | (3) | (4) | FCRPT_C3 |
| | 4. | It is hard for me to think quickly | (0) | (1) | (2) | (3) | (4) | FCRPT_C4 |
| | 5. | I have trouble remembering what I was just thinking | (0) | (1) | (2) | (3) | (4) | FCRPT_C5 |
| | 6. | I have trouble remembering more than one thing at a time | (0) | (1) | (2) | (3) | (4) | FCRPT_C6 |

2. **Parent** Report (Ages 8-12)

In the past one month, how much of a problem has this been for your child…

| | | | Never | Almost Never | Some-times | Often | Almost Always | |
|---|---|---|---|---|---|---|---|---|
| A. | General fatigue (problems with..) | | | | | | | |
| | 1. | Feeling tired | (0) | (1) | (2) | (3) | (4) | FPRPT_A1 |
| | 2. | Feeling physically weak (not strong) | (0) | (1) | (2) | (3) | (4) | FPRPT_A2 |
| | 3. | Feeling too tired to do things that he/she likes to do | (0) | (1) | (2) | (3) | (4) | FPRPT_A3 |
| | 4. | Feeling too tired to spend time with his/her friends | (0) | (1) | (2) | (3) | (4) | FPRPT_A4 |
| | 5. | Trouble finishing things | (0) | (1) | (2) | (3) | (4) | FPRPT_A5 |
| | 6. | Trouble starting things | (0) | (1) | (2) | (3) | (4) | FPRPT_A6 |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| B. | Sleep/Rest fatigue (problems with..) | | | | | | | |
| | 1. | Sleeping a lot | (0) | (1) | (2) | (3) | (4) | FPRPT_B1 |
| | 2. | Difficulty sleeping through the night | (0) | (1) | (2) | (3) | (4) | FPRPT_B2 |
| | 3. | Feeling tired when he/she wakes up in the morning | (0) | (1) | (2) | (3) | (4) | FPRPT_B3 |
| | 4. | Resting a lot | (0) | (1) | (2) | (3) | (4) | FPRPT_B4 |
| | 5. | Taking a lot of naps | (0) | (1) | (2) | (3) | (4) | FPRPT_B5 |
| | 6. | Spending a lot of time in bed | (0) | (1) | (2) | (3) | (4) | FPRPT_B6 |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| C. | Cognitive fatigue (problems with..) | | | | | | | |
| | 1. | Difficulty keeping his/her attention on things | (0) | (1) | (2) | (3) | (4) | FPRPT_C1 |
| | 2. | Difficulty remembering what people tell him/her | (0) | (1) | (2) | (3) | (4) | FPRPT_C2 |
| | 3. | Difficulty remembering what he/she just heard | (0) | (1) | (2) | (3) | (4) | FPRPT_C3 |
| | 4. | Difficulty thinking quickly | (0) | (1) | (2) | (3) | (4) | FPRPT_C4 |
| | 5. | Trouble remembering what he/she was just thinking | (0) | (1) | (2) | (3) | (4) | FPRPT_C5 |
| | 6. | Trouble remembering more than one thing at a time | (0) | (1) | (2) | (3) | (4) | FPRPT_C6 |

## PART V: SICKLE CELL SCALES

1. **Child** Report (Ages 8-12)

In the past one month, how much of a problem has this been for you ...

| | | | Never | Almost Never | Some-times | Often | Almost Always | |
|---|---|---|---|---|---|---|---|---|
| A. | About my pain and hurt (problems with..) | | | | | | | |
| | 1. | I hurt a lot | (0) | (1) | (2) | (3) | (4) | SCRPT_A1 |
| | 2. | I hurt all over my body | (0) | (1) | (2) | (3) | (4) | SCRPT_A2 |
| | 3. | I hurt in my arms | (0) | (1) | (2) | (3) | (4) | SCRPT_A3 |
| | 4. | I hurt in my legs | (0) | (1) | (2) | (3) | (4) | SCRPT_A4 |
| | 5. | I hurt in my stomach | (0) | (1) | (2) | (3) | (4) | SCRPT_A5 |
| | 6. | I hurt in my chest | (0) | (1) | (2) | (3) | (4) | SCRPT_A6 |
| | 7. | I hurt in my back | (0) | (1) | (2) | (3) | (4) | SCRPT_A7 |
| | 8. | I have pain every day | (0) | (1) | (2) | (3) | (4) | SCRPT_A8 |
| | 9. | I have pain so much that I need medicine | (0) | (1) | (2) | (3) | (4) | SCRPT_A9 |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| B. | About my pain impact (problems with..) | | | | | | | |
| | 1. | It is hard for me to do things because I might get pain | (0) | (1) | (2) | (3) | (4) | SCRPT_B1 |
| | 2. | I miss school when I have pain | (0) | (1) | (2) | (3) | (4) | SCRPT_B2 |
| | 3. | It is hard for me to run when I have pain | (0) | (1) | (2) | (3) | (4) | SCRPT_B3 |
| | 4. | It is hard to have fun when I have pain | (0) | (1) | (2) | (3) | (4) | SCRPT_B4 |
| | 5. | I have trouble moving when I have pain | (0) | (1) | (2) | (3) | (4) | SCRPT_B5 |
| | 6. | It is hard to stay standing when I have pain | (0) | (1) | (2) | (3) | (4) | SCRPT_B6 |
| | 7. | It is hard for me to take care of myself when I have pain | (0) | (1) | (2) | (3) | (4) | SCRPT_B7 |
| | 8. | It is hard for me to do what others can do because I might get pain | (0) | (1) | (2) | (3) | (4) | SCRPT_B8 |
| | 9. | I wake up at night when I have pain | (0) | (1) | (2) | (3) | (4) | SCRPT_B9 |
| | 10. | I get tired when I have pain | (0) | (1) | (2) | (3) | (4) | SCRPT_B10 |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| C. | About my pain management and control (problems with..) | | | | | | | |
| | 1. | It is hard for me to manage my pain | (0) | (1) | (2) | (3) | (4) | SCRPT_C1 |
| | 2. | It is hard for me to control my pain | (0) | (1) | (2) | (3) | (4) | SCRPT_C2 |

In the past one month, how much of a problem has this been for you ...

| | | | Never | Almost Never | Some-times | Ofte n | Almost Always | |
|---|---|---|---|---|---|---|---|---|
| D. | About my worrying I (problems with..) | | | | | | | |
| | 1. | I worry that I will have pain | (0) | (1) | (2) | (3) | (4) | SCRPT_D1 |
| | 2. | I worry that others will not know what to do if I have pain | (0) | (1) | (2) | (3) | (4) | SCRPT_D2 |
| | 3. | I worry when I am away from home | (0) | (1) | (2) | (3) | (4) | SCRPT_D3 |
| | 4. | I worry I might have to go to the emergency room | (0) | (1) | (2) | (3) | (4) | SCRPT_D4 |
| | 5. | I worry I might have to stay overnight in the hospital | (0) | (1) | (2) | (3) | (4) | SCRPT_D5 |
| E. | About my worrying II (problems with..) | | | | | | | |
| | 1. | I worry I might have a stroke | (0) | (1) | (2) | (3) | (4) | SCRPT_E1 |
| | 2. | I worry I might have a chest crisis | (0) | (1) | (2) | (3) | (4) | SCRPT_E2 |
| F. | About my emotions (problems with..) | | | | | | | |
| | 1. | I feel mad I have sickle cell disease | (0) | (1) | (2) | (3) | (4) | SCRPT_F1 |
| | 2. | I feel mad when I have pain | (0) | (1) | (2) | (3) | (4) | SCRPT_F2 |
| G. | About my treatment (problems with..) | | | | | | | |
| | 1. | It is hard for me to remember to take my medicine | (0) | (1) | (2) | (3) | (4) | SCRPT_G1 |
| | 2. | I do not like how I feel after I take my medicine | (0) | (1) | (2) | (3) | (4) | SCRPT_G2 |
| | 3. | I do not like the way my medicine tastes | (0) | (1) | (2) | (3) | (4) | SCRPT_G3 |
| | 4. | My medicine makes me sleepy | (0) | (1) | (2) | (3) | (4) | SCRPT_G4 |
| | 5. | I worry about whether my medicine is working | (0) | (1) | (2) | (3) | (4) | SCRPT_G5 |
| | 6. | I worry about whether my treatments are working | (0) | (1) | (2) | (3) | (4) | SCRPT_G6 |
| | 7. | My medicine does not make me feel better | (0) | (1) | (2) | (3) | (4) | SCRPT_G7 |
| H. | About communication I (problems with..) | | | | | | | |
| | 1. | It is hard for me to tell others when I am in pain | (0) | (1) | (2) | (3) | (4) | SCRPT_H1 |
| | 2. | It is hard for me to tell the doctors and nurses how I feel | (0) | (1) | (2) | (3) | (4) | SCRPT_H2 |
| | 3. | It is hard for me to ask the doctors and nurses questions | (0) | (1) | (2) | (3) | (4) | SCRPT_H3 |

ID Number | Visit | - | Seq

| | | | Never | Almost Never | Some-times | Often | Almost Always | |
|---|---|---|---|---|---|---|---|---|
| I. | About communication II (problems with..) | | | | | | | |
| | 1. | It is hard for me when others do not understand about my sickle cell disease | (0) | (1) | (2) | (3) | (4) | SCRPT_I1 |
| | 2. | It is hard for me when others do not understand how much pain I feel | (0) | (1) | (2) | (3) | (4) | SCRPT_I2 |
| | 3. | It is hard for me to tell others I have sickle cell disease | (0) | (1) | (2) | (3) | (4) | SCRPT_I3 |

2. **Parent** Report (Ages 8-12)

In the past one month, how much of a problem has your child had with ...

| | | | Never | Almost Never | Some-times | Often | Almost Always | |
|---|---|---|---|---|---|---|---|---|
| A. | Pain and hurt (problems with..) | | | | | | | |
| | 1. | Hurting a lot | (0) | (1) | (2) | (3) | (4) | SPRPT_A1 |
| | 2. | Hurting all over his/her body | (0) | (1) | (2) | (3) | (4) | SPRPT_A2 |
| | 3. | Hurting in his/her arms | (0) | (1) | (2) | (3) | (4) | SPRPT_A3 |
| | 4. | Hurting in his/her legs | (0) | (1) | (2) | (3) | (4) | SPRPT_A4 |
| | 5. | Hurting in his/her stomach | (0) | (1) | (2) | (3) | (4) | SPRPT_A5 |
| | 6. | Hurting in his/her chest | (0) | (1) | (2) | (3) | (4) | SPRPT_A6 |
| | 7. | Hurting in his/her back | (0) | (1) | (2) | (3) | (4) | SPRPT_A7 |
| | 8. | Having pain every day | (0) | (1) | (2) | (3) | (4) | SPRPT_A8 |
| | 9. | Having so much pain that he/she has to take medicine | (0) | (1) | (2) | (3) | (4) | SPRPT_A9 |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| B. | Pain impact (problems with..) | | | | | | | |
| | 1. | It is hard for him/her to do things because he/she might get pain | (0) | (1) | (2) | (3) | (4) | SPRPT_B1 |
| | 2. | Missing school when he/she has pain | (0) | (1) | (2) | (3) | (4) | SPRPT_B2 |
| | 3. | It is hard for him/her to run when he/she has pain | (0) | (1) | (2) | (3) | (4) | SPRPT_B3 |
| | 4. | It is hard for him/her to have fun when having pain | (0) | (1) | (2) | (3) | (4) | SPRPT_B4 |
| | 5. | Having trouble moving around when he/she has pain | (0) | (1) | (2) | (3) | (4) | SPRPT_B5 |
| | 6. | It is hard for him/her to stay standing when he/she has pain | (0) | (1) | (2) | (3) | (4) | SPRPT_B6 |
| | 7. | It is hard for him/her to take care of himself/herself when he/she has pain | (0) | (1) | (2) | (3) | (4) | SPRPT_B7 |
| | 8. | It is hard for him/her to do what others can do because he/she might get pain | (0) | (1) | (2) | (3) | (4) | SPRPT_B8 |
| | 9. | Waking up at night when he/she has pain | (0) | (1) | (2) | (3) | (4) | SPRPT_B9 |
| | 10. | Getting tired when he/she has pain | (0) | (1) | (2) | (3) | (4) | SPRPT_B10 |

In the past one month, how much of a problem has your child had with ...

| | | | Never | Almost Never | Some-times | Often | Almost Always | |
|---|---|---|---|---|---|---|---|---|
| C. | Pain management and control (problems with..) | | | | | | | |
| | 1. | It is hard for him/her to manage his/her pain | (0) | (1) | (2) | (3) | (4) | SPRPT_C1 |
| | 2. | It is hard for him/her to control his/her pain | (0) | (1) | (2) | (3) | (4) | SPRPT_C2 |
| D. | Worry I (problems with..) | | | | | | | |
| | 1. | Worrying that he/she will have pain | (0) | (1) | (2) | (3) | (4) | SPRPT_D1 |
| | 2. | Worrying that other people will not know what to do if he/she has pain | (0) | (1) | (2) | (3) | (4) | SPRPT_D2 |
| | 3. | Worrying when he/she is away from home | (0) | (1) | (2) | (3) | (4) | SPRPT_D3 |
| | 4. | Worrying he/she might have to go to the emergency room | (0) | (1) | (2) | (3) | (4) | SPRPT_D4 |
| | 5. | Worrying he/she might have to stay overnight in the hospital | (0) | (1) | (2) | (3) | (4) | SPRPT_D5 |
| E. | Worry II (problems with..) | | | | | | | |
| | 1. | Worrying he/she might have a stroke | (0) | (1) | (2) | (3) | (4) | SPRPT_E1 |
| | 2. | Worrying he/she might have a chest crisis | (0) | (1) | (2) | (3) | (4) | SPRPT_E2 |
| F. | Emotions (problems with..) | | | | | | | |
| | 1. | Feeling mad about having sickle cell disease | (0) | (1) | (2) | (3) | (4) | SPRPT_F1 |
| | 2. | Feeling mad when he/she has pain | (0) | (1) | (2) | (3) | (4) | SPRPT_F2 |
| G. | Treatment (problems with..) | | | | | | | |
| | 1. | It is hard for him/her to remember to take his/her medicine | (0) | (1) | (2) | (3) | (4) | SPRPT_G1 |
| | 2. | Not liking how he/she feels after taking medicine | (0) | (1) | (2) | (3) | (4) | SPRPT_G2 |
| | 3. | Not liking the way his/her medicine tastes | (0) | (1) | (2) | (3) | (4) | SPRPT_G3 |
| | 4. | Medicine making him/her sleepy | (0) | (1) | (2) | (3) | (4) | SPRPT_G4 |
| | 5. | Worrying about whether his/her medicine is working | (0) | (1) | (2) | (3) | (4) | SPRPT_G5 |
| | 6. | Worrying about whether his/her treatments are working | (0) | (1) | (2) | (3) | (4) | SPRPT_G6 |
| | 7. | Medicine not making him/her feel better | (0) | (1) | (2) | (3) | (4) | SPRPT_G7 |

ID Number | Visit | - | Seq

In the past one month, how much of a problem has your child had with ...

| | | | Never | Almost Never | Some-times | Often | Almost Always | |
|---|---|---|---|---|---|---|---|---|
| H. | Communication I (problems with..) | | | | | | | |
| | 1. | It is hard for him/her to tell others when he/she is in pain | (0) | (1) | (2) | (3) | (4) | SPRPT_H1 |
| | 2. | It is hard for him/her to tell the doctors and nurses how he/she feels | (0) | (1) | (2) | (3) | (4) | SPRPT_H2 |
| | 3. | It is hard for him/her to ask the doctors and nurses questions | (0) | (1) | (2) | (3) | (4) | SPRPT_H3 |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| I. | Communication II (problems with..) | | | | | | | |
| | 1. | It is hard for him/her when other people do not understand about his/her sickle cell disease | (0) | (1) | (2) | (3) | (4) | SPRPT_I1 |
| | 2. | It is hard for him/her when others do not understand how much pain he/she feels | (0) | (1) | (2) | (3) | (4) | SPRPT_I2 |
| | 3. | It is hard for him/her to tell others that he/she has sickle cell disease | (0) | (1) | (2) | (3) | (4) | SPRPT_I3 |

**PART VI: 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 II

# CONNERS CONTINUOUS PERFORMANCE TEST-II (CPT-II)

## PART I: IDENTIFYING INFORMATION

1. Patient's ID Number: ___ ___ ___ ___ SUBJECT_ID
2. Current Clinic: ___ ___ SITE_ID
3. Patient's Letter Code: ___ ___ ___ LETTER_CD
4. Visit: ___ ___ ___
5. Visit Date: ___ ___ ___ (Month) - ___ ___ (Day) - ___ ___ ___ ___ (Year) VISIT_DT

## PART II: CPT II RESULTS

Guideline
1. Within average range
2. Mildly atypical
3. Markedly atypical

| | Value | T-Score | Percentile | Guideline |
|---|---|---|---|---|
| 1. Omissions | __ __ __ . __ OMI_V | __ __ . __ __ OMI_T | __ __ . __ __ OMI_P | ( 1 ) ( 2 ) ( 3 ) OMI_G |
| 2. Commissions | __ __ __ . __ COMMI_V | __ __ . __ __ COMMI_T | __ __ . __ __ COMMI_P | ( 1 ) ( 2 ) ( 3 ) COMMI_G |
| 3. Hit RT | __ __ __ . __ RT_V | __ __ . __ __ RT_T | __ __ . __ __ RT_P | ( 1 ) ( 2 ) ( 3 ) RT_G |
| 4. Hit RT Std Error | __ __ __ . __ RTSE_V | __ __ . __ __ RTSE_T | __ __ . __ __ RTSE_P | ( 1 ) ( 2 ) ( 3 ) RTSE_G |
| 5. Variability | __ __ __ . __ VARI_V | __ __ . __ __ VARI_T | __ __ . __ __ VARI_P | ( 1 ) ( 2 ) ( 3 ) VARI_G |
| 6. Detectability (d') | __ __ __ . __ DETECT_V | __ __ . __ __ DETECT_T | __ __ . __ __ DETECT_P | ( 1 ) ( 2 ) ( 3 ) DETECT_G |
| 7. Response Style | __ __ __ . __ RESP_V | __ __ . __ __ RESP_T | __ __ . __ __ RESP_P | ( 1 ) ( 2 ) ( 3 ) RESP_G |
| 8. Perservations | __ __ __ . __ PERS_V | __ __ . __ __ PERS_T | __ __ . __ __ PERS_P | ( 1 ) ( 2 ) ( 3 ) PERS_G |
| 9. Hit RT Block Change | __ __ __ . __ RTBCHG_V | __ __ . __ __ RTBCHG_T | __ __ . __ __ RTBCHG_P | ( 1 ) ( 2 ) ( 3 ) RTBCHG_G |
| 10. Hit SE Block Change | __ __ __ . __ SEBCHG_V | __ __ . __ __ SEBCHG_T | __ __ . __ __ SEBCHG_P | ( 1 ) ( 2 ) ( 3 ) SEBCHG_G |
| 11. Hit RT ISI Change | __ __ __ . __ RTICHG_V | __ __ . __ __ RTICHG_T | __ __ . __ __ RTICHG_P | ( 1 ) ( 2 ) ( 3 ) RTICHG_G |
| 12. Hit SE ISI Change | __ __ __ . __ SEICHG_V | __ __ . __ __ SEICHG_T | __ __ . __ __ SEICHG_P | ( 1 ) ( 2 ) ( 3 ) SEICHG_G |

## 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 II

# PULMONARY FUNCTION TESTING

**Do hemoglobin and pulse oximetry along with PFT**

## PART I: IDENTIFYING INFORMATION

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

## PART II: DEMOGRAPHIC INFORMATION

1. Height: ____ ____ ____ . ____ HEIGHT
   (1) inches
   (2) centimeters HT_UNIT

   A. Height is measured by:

   | | | |
   |---|---|---|
   | Standing height | (1) | HT_METHOD |
   | Arm span | (2) | |

2. Weight: ____ ____ ____ WEIGHT
   (1) pounds
   (2) kilograms WT_UNIT

3. With which primary race or ethnicity does the patient identify? PFTRACE

   ***(Check only one)***

   | | |
   |---|---|
   | White (Caucasian) | ( 1 ) |
   | Hispanic | ( 2 ) |
   | African-American | ( 3 ) |
   | Asian or Pacific Islander | ( 4 ) |
   | Other or none of the above | ( 5 ) |
   | *Unknown / undetermined* | ( 6 ) |

4. Does the patient identify with more than one race or ethnicity? MORETHAN_ONERACE

   | | |
   |---|---|
   | Yes | ( 1 ) |
   | No | ( 2 ) |

## PART III: SPIROMETRY

1. Date of spirometry: SPIROMETRY_DT ___ ___ ___ - ___ ___ - ___ ___ ___ ___ (Month - Day - Year) SPIROMETRY_ND Not done ( 1 )

***If spirometry 'Not done', skip to Part V.***

**NOTE: The PFT tech should try to obtain an exhalation effort of ≥ 6 seconds**

2. Pre-bronchodilator spirometry: PRE_BRONCH_SPIROM_ND Not done ( 1 )

***If pre-bronchodilator spirometry 'Not done', skip to 3.***

A. Pre-bronchodilator Results:

0. Was the participant's effort acceptable and reproducible according to ATS guidelines?

| | | |
|---|---|---|
| Yes | (1 ) | PRE_EFFORT |
| No | (2 )* | |
| Questionable | (3 )* | |

*a. If no or questionable, why was effort unacceptable, unreproducible, or questionable?

PRE_EFFORT_SP

_____

_____

| | | | | | Not done | |
|---|---|---|---|---|---|---|
| 1. | $FEV_1$ | PREFEV1 | ____ ____ . ____ ____ | *L (largest)* | ( 1 ) | PREFEV1_ND |
| 2. | FVC | PREFVC | ____ ____ . ____ ____ | *L (largest)* | ( 1 ) | PREFVC_ND |
| 3. | PEFR ($FEF_{max}$) | PREPEFR | ____ ____ ____ . ____ | *L/second (largest)* | ( 1 ) | PREPEFR_ND |
| 4. | FEF 25-75 | PREFEF25 | ____ ____ . ____ ____ | *L/second (from largest $FEV_1$+FVC)* | ( 1 ) | PREFEF25_ND |
| 5. | Ratio ($FEV_1$/ FVC) | PRE_RATIO | ____ . ____ ____ | | ( 1 ) | PRE_RATIOND |

3. Post-bronchodilator:

A. Post-bronchodilator spirometry: POST_BRONCH_SPIROM_ND Not done ( 1 )

***If post-bronchodilator spirometry 'Not done', skip to Part V.***

1. Was the participant's effort acceptable and reproducible according to ATS guidelines?

| | | |
|---|---|---|
| Yes | (1 ) | POST_EFFORT |
| No | (2 )* | |
| Questionable | (3 )* | |

*a. If no or questionable, why was effort unacceptable, unreproducible, or questionable?

POST_EFFORT_SP

_____

_____

B. Bronchodilator: BRONCH

Albuterol 2.5 mg by nebulizer ( 1 )

Other ( 2 )

1. Specify: _____ BRONCH_SP

| | | | | | Not done | |
|---|---|---|---|---|---|---|
| C. | $FEV_1$ | POSTFEV1 | ____ ____ . ____ ____ | *L (largest)* | ( 1 ) | POSTFEV1_ND |
| D. | FVC | POSTFVC | ____ ____ . ____ ____ | *L (largest)* | ( 1 ) | POSTFVC_ND |
| E. | PEFR ($FEF_{max}$) | POSTPEFR | ____ ____ ____ . ____ | *L/second (largest)* | ( 1 ) | POSTPEFR_ND |
| F. | FEF25-75 | POSTFEF25 | ____ ____ . ____ ____ | *L/second (from largest $FEV_1$+FVC)* | ( 1 ) | POSTFEF25_ND |
| G. | Ratio ($FEV_1$/FVC) | POST_RATIO | ____ . ____ ____ | | ( 1 ) | POST_RATIOND |

**PART IV: LUNG VOLUME**

**Record actual Pre-Bronchodilator Measurements**

1. Lung volume: LUNG_VOL2

| | |
|---|---|
| Not done ***(skip to Part V)*** | (1 ) |
| Performed in conformance with BHFUII requirements (i.e., meets ATS guidelines for acceptability) | (2 ) |
| Technique was acceptable with good effort | (3 ) |
| Technique was acceptable with questionable effort | (4 ) |
| Results not interpretable | (5 ) |

A. Was the participant able to perform 3 acceptable maneuvers? LUNG_3MANEU

| | |
|---|---|
| Yes | (1 ) |
| No | (2 ) |

2. Date lung volume performed: LUNG_VOL_DT ___ ___ ___ - ___ ___ - ___ ___ ___ ___
Month Day Year

3. Technique: LUNGV_TECH

| Plethysmography (preferred) | Helium dilution | Nitrogen washout |
|---|---|---|
| (1 ) | (2 ) | (3 ) |

| | | | | Not done | |
|---|---|---|---|---|---|
| 4. TLC | ___ ___ . ___ ___ | *L (mean FRC+MAX IC)* | TLC | (1 ) | TLC_ND |
| 5. Maximum SVC | ___ . ___ ___ | *L* | MAX_SVC | (1 ) | MAX_SVC_ND |
| 6. RV | ___ ___ . ___ ___ | *L (TLC-highest VC)* | RV | (1 ) | RV_ND |
| 7. Mean FRC (TGV) | ___ . ___ ___ | *L (mean from 3 maneuvers)* | MEAN_FRC | (1 ) | MEAN_FRC_ND |

**PART V: DIFFUSING CAPACITY**

1. $D_LCO$: DLCO

| | |
|---|---|
| Not done ***(skip to Part VI)*** | ( 1 ) |
| Performed in conformance with BHFUII requirements | ( 2 ) |
| Not in conformance with BHFUII requirements, but results are clinically interpretable | ( 3 ) |
| Results not interpretable | ( 4 ) |

A. Was the participant's effort acceptable and reproducible according to ATS guidelines? DLCO_EFFORT

| | |
|---|---|
| Yes | (1 ) |
| No | (2 )* |
| Questionable | (3 )* |

*1. If no or questionable, why was effort unacceptable, unreproducible, or questionable?

DLCO_EFFORT_SP

2. Date $D_LCO$ performed: DLCO_DT ___ ___ ___ - ___ ___ - ___ ___ ___ ___
Month Day Year

| | | | | Not done | |
|---|---|---|---|---|---|
| 3. Mean $D_LCO$ (uncorrected for hemoglobin) | ___ ___ . ___ ___ | *mL/min/mmHg* | MEAN_DLCO | ( 1 ) | MEAN_DLCO_ND |
| 4. Hemoglobin | ___ ___ . ___ | *g/dL* | HEMOGLOBIN | ( 1 ) | HEMOGLOBIN_ND |
| 5. Alveolar Volume | ___ ___ . ___ ___ | *L (largest)* | VA | ( 1 ) | VA_ND |

**PART VI: PULSE OXIMETRY**

| | | | Not done | |
|---|---|---|---|---|
| 1. Oxygen saturation (room air): | ____ ____ ____ | % O2SAT | ( 1 ) | O2S_ND |

**PART VII: 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 | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | - | | |

BABY HUG FOLLOW-UP STUDY II

# ECHOCARDIOGRAM PERFORMANCE

## PART I: IDENTIFYING INFORMATION

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

## PART II: GENERAL INFORMATION

**INSTRUCTIONS**

The following information **MUST BE** collected on the day echocardiogram is completed, if an echocardiogram was ever performed for this visit.

1. Date of echocardiogram visit: ECHO ___ ___ ___ - ___ ___ - ___ ___ ___ ___
   Month Day Year
2. Child's date of birth: BIRTH_DT ___ ___ ___ - ___ ___ - ___ ___ ___ ___
   Month Day Year
3. Source indication: SOURCE

| | |
|---|---|
| Routine BABY HUG FU II visit | (1) |
| Abstract from non-BHFU II visit | (2) |

4. Patient state: PT_STATE

| | |
|---|---|
| Relaxed | (1) |
| Tense | (2) |
| Unmanageable | (3) |
| N/A | (4) |

5. Label Number: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ LABEL

| ID Number | | | | Visit | | | - | Seq | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | |

6. Height: ___ ___ ___ . ___ cm HEIGHT

7. Weight: ___ ___ . ___ ___ kg WEIGHT

8. a. Temperature

i. TEMPF ___ ___ ___ . ___ °F **OR** ii. TEMPC ___ ___ . ___ °C

b. Thermometer placement: THERM_PLACE

| | |
|---|---|
| Axillary | (1) |
| Oral | (2) |
| Rectal | (3) |
| Tympanic | (4) |
| N/A | (5) |

9. Heart rate: ___ ___ ___ beat/min HEARTRATE

10. Respiratory rate: ___ ___ ___ breath/min RESP

11. Blood Pressure:

a. Systolic: ___ ___ ___ mm Hg BP_SYSTOLIC

b. Diastolic: ___ ___ ___ mm Hg BP_DIASTOLIC

c. Method: BP_METHOD

| | |
|---|---|
| Dinamap | (1) |
| Doppler | (2) |
| Auscultation | (3) |
| Palpation | (4) |
| N/A | (5) |

12. Were there any illnesses at today's visit? Yes (1) No (2) Unknown (3) ILLNESS

If "Yes," indicate the diagnosis code and site of involvement, where applicable.

| Sequence Number | 13. DX Code | 14. Primary site |
|---|---|---|
| 1 | D-___ ___ ___ ___ P11_DXT | N/A .....1 P11_SITE1_ND<br>S - ___ ___ ___ P11_SITE1 |
| 2 | D-___ ___ ___ ___ | N/A .....1<br>S - ___ ___ ___ |
| **3** | D-___ ___ ___ ___ | N/A .....1<br>S - ___ ___ ___ |
| 4 | D-___ ___ ___ ___ | N/A .....1<br>S - ___ ___ ___ |
| 5 | D-___ ___ ___ ___ | N/A .....1<br>S - ___ ___ ___ |
| 6 | D-___ ___ ___ ___ | N/A .....1<br>S - ___ ___ ___ |

**IF MORE THEN 6 DIAGNOSES ARE REPORTED, USE A PHOTO COPY OF THIS PAGE OR A BLANK PIECE OF PAPER AND LIST THE ADDITIONAL DIAGNOSES.**

## PART III: ECHOCARDIOGRAM STATUS

| | | Yes | No | |
|---|---|---|---|---|
| 1. | Was the echocardiogram completed? | (1) | (2) | ECHO_COMP |

2. Reason(s) that the echocardiogram not completed: **(CHECK ALL THAT APPLY)**

| | | | |
|---|---|---|---|
| a. | Equipment availability | (1) | EQUIP_AVAIL |
| b. | Caretaker objects to participation | (1) | CARETAKER_OBJ |
| c. | Illness of subject, test cancelled by physician | (1) | ILLNESS_SUB |
| d. | Subject developed complications during procedure | (1) | COMPLIC-DURING |
| e. | Other (specify) | (1) | INCOM_OTHER |
| | i. Specify: _____ INCOMP_RSN_SP | | |
| f. | Unknown | (1) | INCOM_UNK |

**IF NOT COMPLETED, GO TO SECTION V**

| | | Yes | No | |
|---|---|---|---|---|
| 3. | Were there any complications from the echocardiogram? | (1)* | (2) | COMPLICATIONS |

a. What were the complications?
*(Specify): _____ COMPLICATION_SP

4. Blood Pressure at the time closest to M-mode:

| | i. First Reading | ii. Second Reading | iii. Third Reading |
|---|---|---|---|
| a. Systolic blood pressure | BP_SYSTOLIC_1ST __ __ __ mm Hg | BP_SYSTOLIC_2ND __ __ __ mm Hg | BP_SYSTOLIC_3RD __ __ __ mm Hg |
| b. Diastolic blood pressure | BP_DIASTOLIC_1ST __ __ __ mm Hg | BP_DIASTOLIC_2ND __ __ __ mm Hg | BP_DIASTOLIC_3RD __ __ __ mm Hg |
| c. Mean blood pressure | BP_MEAN_1ST __ __ __ mm Hg | BP_MEAN_2ND __ __ __ mm Hg | BP_MEAN_3RD __ __ __ mm Hg |

5. Type of echocardiogram material obtained at the time of the echocardiogram:

| | | Yes | No | N/A | |
|---|---|---|---|---|---|
| a. | M-mode strip chart | (1) | (2) | (3) | MMODE_STRIP |
| b. | Doppler strip chart | (1) | (2) | (3) | DOPPLER_STRIP |

**PART IV: ECHOCARDIOGRAM RESULTS**

Items 1 through 17 and 22 through 23 were deliberately eliminated in this revision.

| | | | Yes | No | N/A |
|---|---|---|---|---|---|
| 18. | Are there any cardiovascular abnormalities that were identified during this procedure? | CV_ABNORMAL | (1) | (2) | (3) |

**IF NO OR N/A (RESEARCH ECHOCARDIOGRAM DONE PER PROTOCOL), SKIP TO PART V.**

| | |
|---|---|
| Atrial septal defect, secundum | D-1665 |
| Bicommissural (bicuspid) aortic valve | D-1644 |
| Coronary arteriovenous fistula | D-1662 |
| Mitral stenosis | D-1653 |
| Mitral valve prolapse | D-1654 |
| Patent ductus arteriosus (PDA) | D-1628 |
| Patent formen ovale (PFO) | D-1670 |
| Persistent left superior vena cava | D-1663 |
| Pulmonary valve stenosis | D-1664 |
| Single coronary artery system | D-1667 |
| Subaortic stenosis | D-1657 |
| Supravalvar pulmonary stenosis | D-1667 |
| Total anomalous pulmonary venous return | D-1668 |
| Tricuspid valve prolapse | D-1669 |
| Ventricular septal defect | D-1613 |

If other cardiovascular abnormalities are found, please refer to the cardiac diagnosis code book in the BABY HUG Follow-Up II Procedures Manual, Exhibit 5-4.

If "Yes," indicate the diagnosis code and status, where applicable.

| 19.<br>Sequence Number | 20.<br>DX Code | 21.<br>Status |
|---|---|---|
| 1 | D-___ ___ ___ ___<br>P18_DX1 | New ..... 1<br>Persistent ..... 2<br>P18_STATUS1 |
| 2 | D-___ ___ ___ ___ | New ..... 1<br>Persistent ..... 2 |
| 3 | D-___ ___ ___ ___ | New ..... 1<br>Persistent ..... 2 |
| 4 | D-___ ___ ___ ___ | New ..... 1<br>Persistent ..... 2 |
| 5 | D-___ ___ ___ ___ | New ..... 1<br>Persistent ..... 2 |
| 6 | D-___ ___ ___ ___ | New ..... 1<br>Persistent ..... 2 |

**IF MORE THEN 6 DIAGNOSES ARE REPORTED, USE A PHOTO COPY OF THIS PAGE OR A BLANK PIECE OF PAPER AND LIST THE ADDITIONAL DIAGNOSES.**

## PART V: BRAIN NATRIURETIC PEPTIDE (BNP) TESTING (Performed Locally)

1. BNP Result ___ ___ ___ ng/L BNP

## PART VI: 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 | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | - | | |

BABY HUG FOLLOW-UP STUDY II

# MRI/MRA PERFORMANCE

## PART I: IDENTIFYING INFORMATION

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

## PART II: EQUIPMENT AND QUALITY

1. Equipment: _____ MRIMRA_EQPT
2. MRI Film Label MRI_LBL
3. MRA Film Label MRA_LBL
4. Scan Quality

MRIMRA_QUALITY

| | |
|---|---|
| Excellent | (1) |
| Slight Artifact/Motion, Adequate | (2) |
| Severe Artifact/Motion, Inadequate | (3) |

## PART III: TECHNICIAN INFORMATION

1. Technician Name: _____ TECH_NM
2. Signature: _____ SIGNATURE

| ID Number | | | | Visit | | | - | Seq | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | |

**PART IV: 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 | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | - | | |

BABY HUG FOLLOW-UP STUDY

**LIVER-SPLEEN CENTRAL READING**

## PART I: IDENTIFYING INFORMATION

1. Film Label BH2 ___ ___ ___ ___ ___ SPEC_ID

2. Date read: ___ ___ ___ - ___ ___ - ___ ___ ___ ___ VISIT_DT
   Month Day Year

3. Visit: Y 1 0 VISIT_NBR

## PART II: LIVER-SPLEEN SCAN QUALITY

1. Reader's Last Name: LSRDRNM _____

2. Reader Signature: LSRDRSIG _____

3. Reader Number: ___ ___ ___ ___ LSRDRNBR

4. Current Status of this Reading: LSSCN_QLTY

   Quality adequate and reading complete (1)

   Quality inadequate for reading (2)*

   *A. If inadequate, explain: QLTY_SP _____

_____

_____

If Item 4 is 2, skip to Part IV.

## PART III: RESULTS

1. Splenic uptake (answer only one): SPLUPT

   A. Normal (1)

   B. Present, but decreased (2)*

   C. Absent (3)

   *a. If decreased, SPL_DCRS

      1. < 50% decreased (1)

      2. > 50% decreased (2)

## PART IV: COORDINATION

1. Checked for completeness and accuracy:

   A. Certification number: ___ ___ - ___ ___ CERT_NO

   B. Signature: _____ CERT_SIG

   C. General Comments: _____ GEN_CMNT

_____

Film Label | | | | | |

BABY HUG FOLLOW-UP STUDY II

## ABDOMINAL SONOGRAM (ULTRASOUND) CENTRAL READING

### PART I: IDENTIFYING INFORMATION

1. Film Label BH2 ___ ___ ___ ___ ___ SPEC_ID

2. Date read: ___ ___ ___ - ___ ___ - ___ ___ ___ ___ VISIT_DT
   Month Day Year

3. Visit: Y 1 0 VISIT_NBR

### PART II: EQUIPMENT

ABDRDRNM

1. Reader's Last Name: _____

2. Reader Signature: ABDRDRSIG _____

3. Reader Number: ___ ___ ___ ___ ABDRDRNBR

4. Current Status of this Reading: ABD_QLTY

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

*A. If returned for reprocessing, explain: QLTY1_SP _____

_____

**B. If inadequate, explain: QLTY3_SP _____

_____

If 2 or 3, Skip to Part IV.

## PART III: RESULTS

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

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

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

GBCDV

| | 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 [ ][ ] GBNSTN — If no gallbladder stones, record 00 in C1 and N/A in D and E.

OR

| | Yes | |
|---|---|---|
| 2. Multiple stones not countable | (1 ) | GBMSTN |

| | GBLGST | N/A | GBLGSTNA |
|---|---|---|---|
| D. Largest stone [ ][ ] | mm | (1 ) | |

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

| F. Dilation | Dilated | Normal | N/A | |
|---|---|---|---|---|
| 1. Common bile duct | (1 ) | (2 ) | (3 ) | GBCBD |
| 2. Pancreatic duct | (1 ) | (2 ) | (3 ) | GBPAND |
| 3. Intrahepatic ducts | (1 ) | (2 ) | (3 ) | GBIHEP |

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

Film Label [ ][ ][ ][ ][ ]

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

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

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

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

C. Transverse [ ][ ] . [ ] cm SPLTRN

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

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

F. Homogeneity SPLHOM
- Homogeneous (1)
- Inhomogeneous (2)*
- N/A (3)

*1. If inhomogeneous, explain: INHOM_SP _____

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

If Absent or N/A, Skip to Item 4.

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

B. Renal parenchyma — Normal (1) Abnormal (2)* N/A (3) RKRPAR
*1. If abnormal, explain: RKRPEX _____

C. Echogenicity (1) (2)* (3) RKECHO
*1. If abnormal, explain: RKECEX _____

Film Label [ ][ ][ ][ ][ ]

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

If Absent or N/A, Skip to Item 5.

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

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

*1. If abnormal, explain: _____ LKRPEX

| | | | | | |
|---|---|---|---|---|---|
| C. | Echogenicity | (1 ) | (2 )* | (3 ) | LKECHO |

*1. If abnormal, explain: _____ LKECEX

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

*A. If yes, explain: _____ ABOABNEX

**PART IV: COORDINATION**

1. Checked for completeness and accuracy:

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

B. Signature: _____ CERT_SIG

C. General Comments: _____ GEN_CMNT

_____

Film Label [ ][ ][ ][ ][ ]

BABY HUG FOLLOW-UP STUDY II

**MRA READING**

**PART I: IDENTIFYING INFORMATION**

1. Film Label BH2 ___ ___ ___ ___ ___ SPEC_ID

2. Date read: ___ ___ ___ - ___ ___ - ___ ___ ___ ___ VISIT_DT
   Month Day Year

3. Visit: Y 1 0 VISIT_NBR

**PART II: TO BE COMPLETED BY READER**

1. Reader [Last Name]: _____ MRARDRNM

2. Reader # ___ ___ ___ ___ MRARDRNO

3. SCAN QUALITY (MARK ONE):
   - Excellent (1) MRA_QUAL
   - Slight Artifact/Motion, Adequate (2)
   - Severe Artifact/Motion, Inadequate (3)

4. CURRENT STATUS OF THIS READING
   - Adequate scan, reading complete (1) MRA_STAT
   - Returned for reprocessing (2)
   - Inadequate, reading not completed (3)

**If (2) or (3), SKIP to Part IV.**

**PART III: CENTRAL REVIEW INTERPRETATION** (Answer items 1-8 using the codes below.)

| a. OVERALL RATING | | | b. DESCRIPTION OF ABNORMALITY | | | d. INVOLVED SEGMENTS | | |
|---|---|---|---|---|---|---|---|---|
| 1 | = | Normal | 1 | = | Stenosis, Mild (25% to 50% narrowing) | 1 | = | Supraclinoid |
| 2 | = | Equivocal | 2 | = | Stenosis, Moderate (50% to 75% narrowing) | 2 | = | Pre- or Juxtasellar |
| 3 | = | Abnormal | 3 | = | Stenosis, Severe (75% to 99% narrowing) | 3 | = | Petrous |
| | | | 4 | = | Occlusion | 4 | = | Distal cervical |

| | | OVERALL RATING | DESCRIPTION OF ABNORMALITY (IF OVERALL RATING =3) | LENGTH OF STENOTIC SEGMENT (mm) | INVOLVED SEGMENT (INDICATE ALL THAT APPLY IF RATING =3) | | | |
|---|---|---|---|---|---|---|---|---|
| 1. | Right ICA | a _____ ORRICA | b _____ ABRICA | c _____ LSSRICA | d1 _____ INVSEGR1 | d2 _____ INVSEGR2 | d3 _____ INVSEGR3 | d4 _____ INVSEGR4 |
| 2. | Right MCA | a _____ ORRMCA | b _____ ABRMCA | c _____ LSSRMCA | | | | |
| 3. | Right ACA | a _____ ORRACA | b _____ ABRACA | c _____ LSSRACA | | | | |
| 4. | Left ICA | a _____ ORLICA | b _____ ABLICA | c _____ LSSLICA | d1 _____ INVSEGL1 | d2 _____ INVSEGL2 | d3 _____ INVSEGL3 | d4 _____ INVSEGL4 |
| 5. | Left MCA | a _____ ORLMCA | b _____ ABLMCA | c _____ LSSLMCA | | | | |
| 6. | Left ACA | a _____ ORLACA | b _____ ABLACA | c _____ LSSLACA | | | | |
| 7. | Basilar | a _____ ORBASIL | b _____ ABBASIL | c _____ LSSBASIL | | | | |
| 8. | Overall MRA | a _____ ORMRA | b _____ ABMRA | c _____ LSSMRA | d1 _____ INVSEG1 | d2 _____ INVSEG2 | d3 _____ INVSEG3 | d4 _____ INVSEG4 |

| | | | Right | Left | Both | Not Present |
|---|---|---|---|---|---|---|
| 9. | Collateral Blood Vessels (Mark One): | BLDVSLS | (1) | (2) | (3) | (4) |

Film Label | | | | | |

**PART IV: COORDINATION**

1. To be Completed by Radiology Technician:

   A. Certification number: ___ ___ - ___ ___ CERT_NO

   B. Signature: _____ CERT_SIG

   C. General Comments: GEN_CMNT _____

   _____

Film Label | | | | | |

BABY HUG FOLLOW-UP STUDY II
**MAJOR EVENT**

## PART I: IDENTIFYING INFORMATION

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

## PART II: EVENT PERIOD

1. Date of Event
   A. Event Start Date: ___ ___ - ___ ___ - ___ ___ ___ ___ START_DT
      Month Day Year
   B. Event End Date: ___ ___ - ___ ___ - ___ ___ ___ ___ E_END_DT
      Month Day Year

## PART III: MAJOR EVENT

| 1. Please indicate all diagnoses: | | YES | NO |
|---|---|---|---|
| A. | Acute Chest Syndrome HX_ACS | (1) | (2) |
| B. | Splenic Sequestration Crisis HXSPLSEQ | (1) | (2) |
| C. | Initial or prolonged hospitalization LONGHOSP | (1) | (2) |
| D. | Stroke or TIA HX_STROKE_TIA | (1) | (2) |
| E. | Emergency Room Visit | (1) | (2) |
| F. | Life Threatening LIFE_THREAT_EVT | (1) | (2) |
| G. | Disability or Permanent Damage | (1) | (2) |
| H. | Death HX_DEATH | (1) | (2) |
| I. | ICU Admission ICU | (1) | (2) |
| J. | Pain crisis | (1) | (2) |
| K. | Other | (1) | (2) |

1. Specify: _____

## PART IV: ADDITIONAL DIAGNOSIS INFORMATION

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

1. Acute Chest Syndrome

| | | None | 1 Lobe | >1 Lobe | N/A | |
|---|---|---|---|---|---|---|
| A. | New Infiltrate | (1) | (2) | (3) | (4) | ACSNINF |
| B. | $O_2$% Saturation on Room Air at Presentation | _____ | _____ | . _____% | | ACSSRAP |
| C. | Oxygen Administered | _____ | _____ | . _____L | | ACSOXADM |
| D. | Mechanical Ventilation | Yes (1) | | No (2) | | ACSMVENT |

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

2. Splenic Sequestration

A. Spleen size below LCM **prior** to Major Event SPLNSIZE_PRIOR

| <2 cm | 2-4 cm | 4-6 cm | 6-8 cm | >8 cm |
|---|---|---|---|---|
| (1) | (2) | (3) | (4) | (5) |

B. Spleen size below LCM **during** Major Event SPLNSIZE_DURING

| <2 cm | 2-4 cm | 4-6 cm | 6-8 cm | >8 cm |
|---|---|---|---|---|
| (1) | (2) | (3) | (4) | (5) |

C. Nadir hemoglobin ___ ___ . ___ gm/dL SPLNHMGL

D. Platelet count at time of nadir hemoglobin ___ ___ ___ ___ k/µL 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.

ID Number

| | | | |
|---|---|---|---|
| | | | |

| 4. (Stroke or TIA) Findings of | | YES | NO | N/A |
|---|---|---|---|---|
| A. Loss of consciousness | LOS_CONS | (1) | (2) | (3) |
| B. Change in mental status | CHG_MENT | (1) | (2) | (3) |
| C. Loss of or difficulty with speech or vocalization | SPEECH | (1) | (2) | (3) |
| D. Paralysis or weakness | PARALYS | (1) | (2) | (3) |
| E. Difficulty with swallowing | DIFFSWAL | (1) | (2) | (3) |
| F. Difficulty with vision | DIFF_SEE | (1) | (2) | (3) |
| G. Loss of balance or dizziness | BALANCE | (1) | (2) | (3) |
| H. Seizures | SEIZURE | (1) | (2) | (3) |
| I. Headache | HEADACHE | (1) | (2) | (3) |

| 5. Results of Imaging Tests | | Normal | Abnormal | Not Done |
|---|---|---|---|---|
| A. MRI of brain | F50MRI | (1) | (2) | (3) |
| B. CT scan of brain | F50CTBR | (1) | (2) | (3) |
| C. PET scan of brain | F50PTBR | (1) | (2) | (3) |
| D. MRA cerebral vasculature | F50MRA | (1) | (2) | (3) |
| E. Transcranial Doppler | F50TCD | (1) | (2) | (3) |
| F. Arteriogram | F50ARTGR | (1) | (2) | (3) |
| G. Chest x-ray | | (1) | (2) | (3) |

ID Number

| | | | |
|---|---|---|---|
| | | | |

## PART V: DIAGNOSIS/PROBLEM SEVERITY AND ATTRIBUTION

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

| PROBLEM | ONSET_DT | NUMDAYS | SEVERITY | ATTR_TRT | DIAGUNXP |
|---|---|---|---|---|---|
| 1. Diagnosis/ Problem | 2. Date of Onset | 3. Number of Days | 4. [1]Severity | 5. [2]Attribution to Study Treatment | 6. [3]Diagnosis Unexpected |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |

| [1]Severity | [2]Attribution to Study Test | [3]Diagnosis Unexpected |
|---|---|---|
| 1. Mild | 1. Definite (clearly related) | 1. Yes |
| 2. Moderate | 2. Probably (likely related) | 2. No |
| 3. Severe | 3. Possible (may be related) | 3. N/A |
| 4. Life threatening | 4. Unlikely (doubtfully related) | |
| 5. Disabling | 5. Unrelated (definitely not related) | |
| 6. FATAL | | |
| 7. Unknown | | |

## PART VI: REPORTABLE TREATMENTS

1. Answer each item — YES NO N/A

A. Transfusion — TRANSFUS (1) (2) (3)

1. If yes, complete a. – d. Otherwise, skip to B.

a. Transfusion Type: TR_TYPE (1) Simple (2) Exchange

b. Volume, answer b 1 or 2.

1. Whole Blood — TRVOLWBL _____ _____ _____ cc

OR

2. Packed Red Cells — TRVOLPR2 _____ _____ _____ cc

ID Number

c. Start Date: TSTRT_DT ___ ___ ___ - ___ ___ - ___ ___ ___ ___
Month Day Year

d. Stop Date: TSTOP_DT ___ ___ ___ - ___ ___ - ___ ___ ___ ___
Month Day Year

| | | | YES | NO | N/A |
|---|---|---|---|---|---|
| B. | Placement on chronic transfusion therapy | CHRTRAN | (1) | (2) | (3) |
| C. | Splenectomy | SPLCTMY | (1) | (2) | (3) |
| D. | Parenteral antibiotics | PAR_ANTI | (1) | (2) | (3) |
| E. | Dialysis, limited course | DIALYS_L | (1) | (2) | (3) |
| F. | Antibiotics | | (1) | (2) | (3) |
| G. | Pain medicine | | (1) | (2) | (3) |

## PART VII: HOSPITALIZATION

1. Admission Date: ADM_DT ___ ___ ___ - ___ ___ - ___ ___ ___ ___
Month Day Year

2. Discharge Date: DISCH_DT ___ ___ ___ - ___ ___ - ___ ___ ___ ___
Month Day Year

## PART VIII: OUTCOMES

| | | YES | NO |
|---|---|---|---|
| 1. | Resolved | (1) | (2) |
| 2. | Ongoing | (1) | (2) |

ID Number

## PART IX: COORDINATION

1. Checked for completeness and accuracy:

   A. Certification number: CERT_NO ___ ___ - ___ ___

   B. Signature: _____ CERT_SIG

   C. General Comments:

   GEN_CMNT

   _____

   _____

   _____

**Please Fax the hospital narrative along with this form to the BABY HUG FUP II Data Coordinating Center (DCC) at 443-524-2320.**

ID Number

| | | | |
|---|---|---|---|
| | | | |