STOP II TRIAL
QUARTERLY PROGRESS REPORT FOR RANDOMIZED PATIENTS

*** AFFIX PATIENT LABEL HERE***

A1. Person completing form (Name):_____ (Initials): | | | |

A2. Date of interview (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___

A3. Person interviewed (Choose **ONE** for person providing majority of answers to sections B-D):

☐ 1. Patient ☐ 2. Parent ☐ 3. Legal Guardian ☐ 4. Other → A3.a (specify): _____

A4. Were address and telephone information verified for this patient? ☐ **1. NO** ☐ **2. YES**

QUESTIONS IN SECTIONS B THROUGH D ARE TO BE ANSWERED BY THE PERSON INTERVIEWED; QUESTIONS IN SECTIONS E THROUGH H ARE TO BE ANSWERED BY MEDICAL PERSONNEL.

B. MEDICATIONS

B1. Is the patient currently taking, on a regular basis, any medications prescribed by a physician?

☐ **1. NO** ☐ **2. YES** ↓

B1.a TYPE OF MEDICATION: (CHECK **NO** OR **YES** FOR EACH OF B1.a1-6)	**1. NO**	**2. YES**	**B1.b HOW MANY MONTHS HAS PATIENT BEEN TAKING THE MEDICATION?**
1. Penicillin	☐	☐	1. ☐☐☐
2. Other antibiotic	☐	☐	2. ☐☐☐
		↓ B1.a2.a SPECIFY:_____	
3. Folate	☐	☐	3. ☐☐☐
4. Hydroxyurea	☐	☐	4. ☐☐☐
5. Iron Chelators (Desferoxamine)	☐	☐	5. ☐☐☐
6. Other	☐	☐	6.a ☐☐☐
		↓ B1.a6.a SPECIFY:_____ B1.a6.b SPECIFY:_____	6.b ☐☐☐

☐ ML ☐ DE

C. CLINICAL EVENTS

Since the last quarterly report (or entry interview if this is the first quarterly report) on _____/_____/_____, has the patient been seen by a doctor or nurse for any of the following:

C1.a Event	USE CODES 1. NO 2. YES	C1.b Total # of unique events	C1.c # treated at your institution	C1.d What was the date of the most recent event? (Month/Year)	C1.e Where was patient seen for the most recent event? 1 = STOP II Center 2 = Non-STOP II Center
1. **Stroke/TIA**	☐	☐	☐	__ __/__ __ __ __	☐
*(**PROBE**: An event which a doctor called a stroke or cerebrovascular accident (CVA) which involved loss of consciousness, paralysis, visual, speech, or motor difficulties)*					
2. **New Onset of Seizures**	☐	☐	☐	__ __/__ __ __ __	☐
*(**PROBE**: Any fits or convulsions that were not associated with a stroke or meningitis (brain infection))*					
IF RESPONSE TO C1.a1 or C1.a2 IS YES, SUBMIT NEUROLOGICAL EVENT FORM (FORM 30), NEUROLOGICAL CONSULTANT REPORT (FORM 14), HEAD MRI SCAN (FORM 15), SUPPORTING HOSPITAL SUMMARIES, AND SCANS AND REPORTS FOR ALL IMAGING TESTS PERFORMED					
3. **Meningitis**	☐	☐	☐	__ __/__ __ __ __	☐
*(**PROBE**: Infection of the brain)*					
c1.f3 **IF YES,** Date of discharge	___ ___/___ ___/___ ___ ___ ___				
4. **Head Injury with loss of consciousness**	☐	☐	☐	__ __/__ __ __ __	☐
c1.f4 **IF YES,** Date of discharge	___ ___/___ ___/___ ___ ___ ___				
IF RESPONSE TO C1.a3 or C1.a4 IS YES, SUBMIT NON-NEUROLOGICAL EVENT FORM (FORM 31), AND SCHEDULE NEUROLOGICAL EXAM BY STOP II NEUROLOGIST (COMPLETE FORM 14) AND HEAD MRI SCAN (COMPLETE FORM 15), 2-3 WEEKS AFTER PATIENT'S DISCHARGE FROM HOSPITAL.					
5. **Splenic Sequestration***	☐	☐	☐	__ __/__ __ __ __	☐
*(**PROBE**: Enlargement of the spleen with trapping of blood in it)*					
6. **Aplastic Crisis***	☐	☐	☐	__ __/__ __ __ __	☐
*(**PROBE**: A drop in the blood count which required a transfusion)*					
7. **Hand-Foot Syndrome***	☐	☐	☐	__ __/__ __ __ __	☐
*(**PROBE**: Pain, tenderness, with or without swelling, in the hands and/or feet only)*					
8. **Vaso-occlusive pain event for which the patient was hospitalized***	☐	☐	☐	__ __/__ __ __ __	☐
*(**PROBE**: An acute episode of pain in the arms, legs, back, chest, and/or abdomen, lasting at least two hours for which no other explanation was found)*					

*** IF RESPONSE TO ANY OF C1.a5 – C1.a8 IS YES, COMPLETE A NON-NEUROLOGICAL EVENT (FORM 31) FOR EACH UNIQUE EVENT**

C1.a Event	USE CODES 1. NO 2. YES	C1.b Total # of unique events	C1.c # treated at your institution	C1.d What was the date of the most recent event? (Month/Year)	C1.e Where was patient seen for the most recent event? 1 = STOP II Center 2 = Non-STOP II Center
9. **Fever*** *(**PROBE**: A temperature greater than 101° F (39° C)*	☐	☐	☐	__ __/__ __ __ __	☐
10. **Septicemia*** *(**PROBE**: An infection in the blood stream)*	☐	☐	☐	__ __/__ __ __ __	☐
11. **Acute Chest Syndrome/Pneumonia *** *(**PROBE:** An infection or blockage of blood flow in the lung(s))*	☐	☐	☐	__ __/__ __ __ __	☐
12. **Osteomyelitis*** *(**PROBE**: Infection in the bones)*	☐	☐	☐	__ __/__ __ __ __	☐
13. **Priapism*** *(**PROBE**: A painful, unwanted erection of the penis lasting more than one hour)*	☐	☐	☐	__ __/__ __ __ __	☐
14. **Transfusion reaction** *(**PROBE**: Complication of a transfusion within 2 weeks after the transfusion was given*	☐	☐	☐	__ __/__ __ __ __	☐

IF RESPONSE TO C1.14 IS YES, SUBMIT DELAYED TRANSFUSION REACTION FORM (FORM 32)

15. **Other*** *(**PROBE**: Was the child seen for any Other clinical events? What events?)*

☐ ☐ ☐ __ __/__ __ __ __ ☐

↓

C1.a15.a. IF YES, Specify:

_____

_____

☐☐☐.☐☐ OFFICE USE

☐☐☐.☐☐ OFFICE USE

IF RESPONSE TO C1.a9 - C1.a13 OR C1.a15 IS YES, COMPLETE A NON-NEUROLOGICAL EVENT FORM (FORM 31) FOR EACH UNIQUE EVENT

C2.a Procedure	USE CODES 1. NO 2. YES	C2.b Total # of unique procedures	C2.c # performed at your institution	C2.d What was the date of the most recent procedure? (Month/Year)	C2.e Where was patient seen for the most recent procedure? 1 = STOP II Center 2 = Non-STOP II Center
1. **Transfusion**	☐	☐	☐	__ __/__ __ __ __	☐

*(**PROBE**: Injection of blood into the bloodstream)*

IF RESPONSE TO C2.a1 IS YES, SUBMIT TRANSFUSION FORMS(FORMS 20 AND 21) FOR EACH TRANSFUSION GIVEN

2. **Surgery***

*(**PROBE**: An operation or a medical Procedure requiring general anesthesia)*

☐ ☐ ☐ __ __/__ __ __ __ ☐

↓

C1.a16.a. IF YES, Specify:

_____

_____

☐☐☐ . ☐☐ OFFICE USE

☐☐☐ . ☐☐ OFFICE USE

*** IF RESPONSE TO C2.a2 IS YES, COMPLETE A NON-NEUROLOGICAL EVENT FORM (FORM 31) FOR EACH UNIQUE EVENT**

NOTE: FOR VISITS AT A NON-STOP STUDY SITE, ASK PARENT TO SIGN A MEDICAL RECORD RELEASE FORM FOR EACH UNIQUE EVENT REMEMBER TO SUBMIT MEDICAL RECORD REVIEW FORM (FORM 16R)

D. NEUROLOGICAL SIGNS AND SYMPTOMS

D1. Since the last quarterly report (or entry interview if this is the first quarterly report) on ___ ___/___ ___/___ ___ ___ ___, has the patient complained of headaches?

☐ **1. NO** ☐ **2. YES**

↓

D1.a Is the frequency < 1 per month or ≥ 1 per month?

☐ 1. < 1 per month ☐ 2. ≥ 1 per month

D1.b How long has the patient had them? ☐☐☐ months

D1.c Describe location and type of pain

_____

_____

D2. Since the last report, has (s)he experienced loss of consciousness?

☐ **1. NO** ☐ **2. YES**

↓

D2.a Number of episodes ☐☐

D2.b Date of most recent episode (month/day/year) ___ ___/___ ___/___ ___ ___ ___

D3. Since the last report, has (s)he experienced any episodes of dizziness?

☐ **1. NO** ☐ **2. YES**

↓

D3.a Number of episodes ☐☐

D3.b Date of most recent episode (month/day/year) ___ ___/___ ___/___ ___ ___ ___

D4. Since the last report, has (s)he experienced the following vision difficulties:

D4.a Double vision? ☐ **1. NO** ☐ **2. YES**

D4.b Loss of vision or blind spots? ☐ **1. NO** ☐ **2. YES**

D5. Since the last report, has the child had any unusual or involuntary movements of the face, arms, or legs? ☐ **1. NO** ☐ **2. YES** ↓

D5.a Describe type of movements and duration of episode(s)

_____

_____

_____

D5.b Where did patient exhibit these movements?

(CHECK NO OR YES BOX FOR EACH OF D5.b1 - D5.b6)	1. NO	2. YES	Date of most recent episode (month/year)
1. Left arm	☐	☐ → 1.a	__ __/__ __ __ __
2. Right arm	☐	☐ → 2.a	__ __/__ __ __ __
3. Left leg	☐	☐ → 3.a	__ __/__ __ __ __
4. Right leg	☐	☐ → 4.a	__ __/__ __ __ __
5. Left face	☐	☐ → 5.a	__ __/__ __ __ __
6. Right face	☐	☐ → 6.a	__ __/__ __ __ __

D6. Since the last report, has the patient had any episode of numbness and/or tingling in his arms, legs, or face which lasted for at least an hour?

☐ **1. NO** ☐ **2. YES** ↓

D6.a Location(s) of numbness or tingling

(CHECK NO OR YES BOX FOR EACH OF D6.a1 - D6.a6)	1. NO	2. YES	Date of most recent episode (month/year)
1. Left arm	☐	☐ → 1.a	__ __/__ __ __ __
2. Right arm	☐	☐ → 2.a	__ __/__ __ __ __
3. Left leg	☐	☐ → 3.a	__ __/__ __ __ __
4. Right leg	☐	☐ → 4.a	__ __/__ __ __ __
5. Left face	☐	☐ → 5.a	__ __/__ __ __ __
6. Right face	☐	☐ → 6.a	__ __/__ __ __ __

D7. Since the last report, has the patient had any episodes of weakness in his arms, legs or face?

☐ **1. NO** ☐ **2. YES** ↓

D7.a Location(s) of weakness (CHECK NO OR YES BOX FOR EACH OF D7.a1 - D7.a6)	**1. NO**	**2. YES**	Date of most recent episode (month/year)
1. Left arm	☐	☐ → 1.a	__ __/__ __ __ __
2. Right arm	☐	☐ → 2.a	__ __/__ __ __ __
3. Left leg	☐	☐ → 3.a	__ __/__ __ __ __
4. Right leg	☐	☐ → 4.a	__ __/__ __ __ __
5. Left face	☐	☐ → 5.a	__ __/__ __ __ __
6. Right face	☐	☐ → 6.a	__ __/__ __ __ __

D8. Since the last report, has the patient changed the hand (s)he uses to feed herself/himself?
(***Probe:*** *Did the child use one hand to feed himself/herself previously and now uses the other one?)*

☐ **1. NO** ☐ **2. YES** ↓

D8.a Which hand does (s)he now use to feed herself/himself?

☐ **1. RIGHT** ☐ **2. LEFT**

D9. Since the last report, has the patient had any unexpected difficulty talking or understanding what was said to him/her?

☐ **1. NO** ☐ **2. YES** ↓

D9.a What type of difficulty? (CHECK NO OR YES BOX FOR EACH OF D9.a1 - D9.a3)	**1. NO**	**2. YES**	Date of most recent episode (month/year)
1. Slurring of words	☐	☐ →	1.a __ __/__ __ __ __
2. Difficulty understanding what was said to him/her	☐	☐ →	2.a __ __/__ __ __ __
3. Problems expressing himself/herself	☐	☐ →	3.a __ __/__ __ __ __

D10. Since the last report, has the patient become unable to perform a muscle or language function that (s)he was able to do before?

☐ **1. NO** ☐ **2. YES →** D10.a Explain _____

_____

_____

NOTE: THE PERSON CONDUCTING THE INTERVIEW MUST COMPARE THE RESPONSES TO QUESTIONS IN SECTION D TO RESPONSES GIVEN TO THESE QUESTIONS AT THE PREVIOUS QUARTERLY VISIT BEFORE THE PATIENT IS SEEN BY THE STOP II INVESTIGATOR - SEE SECTION H

E. OTHER MEDICAL CONDITIONS

(QUESTIONS IN SECTIONS E – H TO BE COMPLETED BY MEDICAL PERSONNEL

Since the last quarterly report was the patient **newly** diagnosed with: **(CHECK NO OR YES FOR EACH OF E1 - E17)**	1. NO	2. YES
E1. Leg ulcers	☐	☐
E2. Aseptic necrosis	☐	☐
2.b If Yes, specify location(s) _____		
E3. Sickle cell retinopathy	☐	☐
E4. Chronic lung disease	☐	☐
4.b If Yes, specify type _____		
E5. Asthma	☐	☐
E6. Chronic heart disease	☐	☐
6.b If Yes, specify type: _____		
☐☐☐.☐☐ OFFICE USE		
E7. Chronic liver disease	☐	☐
7.b If Yes, specify type: _____		
☐☐☐.☐☐ OFFICE USE		
E8. Chronic renal disease	☐	☐
8.b If Yes, specify type: _____		
☐☐☐.☐☐ OFFICE USE		
8.c If Yes, is patient receiving dialysis? ☐ 1. NO ☐ 2. YES		
E9. Iron overload	☐	☐
9.b If yes, highest ferritin level (ng/ml) ☐☐☐☐☐		
E10. Diabetes	☐	☐
E11. Rheumatic fever	☐	☐
E12. Tuberculosis	☐	☐
E13. Cancer	☐	☐
13b. If Yes, specify type: _____		
☐☐☐.☐☐ OFFICE USE		
E14. Priapism	☐	☐
E15. Elevated blood lead level (blood lead level ≥ 15 mg/dl?)	☐	☐

Since the last quarterly report was the patient **newly** diagnosed with:

	1. NO	2. YES
E16. New red cell antibody	☐	☐

↓

E16.a. SPECIFY:
a1. _____
a2. _____
a3. _____
a4. _____

E16.b. Date first identified: __ __/__ __/__ __ __ __

IF RESPONSE TO E16 IS YES, ATTACH COPIES OF RESULTS OF INDIRECT (ANTIBODY SCREEN) AND DIRECT ANTIGLOBULIN TESTS AND BLOOD BANK PANEL SHEETS DOCUMENTING IDENTIFICATION OF ANTIBODY (IES) IF NOT SUBMITTED PREVIOUSLY WITH A FORM 20.

E17. Any other chronic medical condition? ☐ ☐

17.a. If Yes, specify type: a1. _____
a2. _____

☐☐☐.☐☐ **OFFICE USE**

☐☐☐.☐☐ **OFFICE USE**

F. VACCINATIONS

F1. Since the last quarterly report, has the patient received Hepatitis B vaccination?

☐ **1. NO** ☐ **2. YES**

↓

F1.a Date of vaccination (Month/Day/Year)
___ ___/___ ___/___ ___ ___ ___

G. GENERAL

G1. Is the patient seen for most of his/her clinical events at a NON-STOP II study site because of third party payment restrictions, distance from clinic, some other reason? ☐ **1. NO** ☐ **2. YES**

H. DETERMINATION OF INTERVAL CHANGE IN PATIENT'S NEUROLOGICAL SYMPTOMS

IN ORDER TO COMPLETE THIS SECTION, RESPONSES TO QUESTIONS D2, D5, D6, D7, D8, D9, AND D10 OF THIS REPORT MUST BE COMPARED TO RESPONSES TO THESE SAME QUESTIONS IN THE PREVIOUS REPORT

H1. Since the last report were any new neurological symptoms reported? . ☐ **1. NO** ☐ **2. YES** ↓

REVIEW RESULTS WITH STOP II INVESTIGATOR

H1.a Did the STOP II Investigator review results of both reports? ☐ **1. NO** → H1a.1 Reason _____

☐ **2. YES** ↓

H1.a2. Did the STOP II Investigator determine that the patient has developed significant new neurological symptoms since the last report?

☐ **1. NO** → H1.a2.a Explain _____

☐ **2. YES** ↓

H1.a2.b Were these "new" symptoms reported on a STOPII Neurological Event Form which was submitted for adjudication since the last quarterly report?

☐ **1. NO** → **COMPLETE AND SUBMIT NEUROLOGICAL EVENT FORM (FORM 30), NEUROLOGICAL CONSULTANT REPORT (FORM 14), MRI AND MRA FORMS (FORM 15 AND 19), SCANS AND REPORTS FOR ALL IMAGING TESTS PERFORMED**

☐ **2. YES** → H1.a2c Date of neurological event recorded on Neurological Event Form (month/day/year) ___ ___/___ ___/___ ___ ___ ___

Signature of Study Coordinator: _____ Date: ___ ___/___ ___/___ ___ ___ ___

I. FOR OFFICE USE

I1.a IAT/DAT Reports Received ☐ **1. NO** ☐ **2. YES** ☐ **-1. NA**

I1.b Blood Bank Panel Sheets Received ☐ **1. NO** ☐ **2. YES** ☐ **-1. NA**