STOP II

ELIGIBILITY QUESTIONNAIRE FOR TCD SCREENING EXAM

(TO DETERMINE ELIGIBILITY FOR TRANSFUSION)

AFFIX PATIENT LABEL HERE

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

A2. Date form completed (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___

B. PATIENT ID INFORMATION

B1. Has a STOP II Form 01A been completed previously for this patient? ☐ **1. NO** ☐ **2. YES**

↓

GO TO SECTION C

B2. Is the birthdate information on the pre-printed patient label provided by the DCC correct? ☐ **1. NO** ☐ **2. YES**

↓

B2.a If NO, list correct birthdate
___ ___/___ ___/___ ___ ___ ___

B3. Is the gender information on the pre-printed patient label provided by the DCC correct? ☐ **1. NO** ☐ **2. YES**

↓

B3.a If NO, check correct gender:

☐ **1. FEMALE**

☐ **2. MALE**

B4. Race

(READ BOLDED SENTENCES TO PARENT/GUARDIAN OR CHILD IF AGE APPROPRIATE AND SHOW CARD WITH CHOICES)

NIH monitors enrollment of minorities to ensure their adequate representation in all research studies funded by NIH. Please identify the race of the child among the following choices [SHOW CARD]:

☐ **1. Black/African American/not Latin origin** ☐ **2. Black/African American/of Latin Origin**

☐ **3. White/not of Latin origin** ☐ **4. White/of Latin origin**

☐ **5. Asian American/Pacific Islander** ☐ **6. Native American/Alaskan Native**

☐ **7. Other** → B4.a SPECIFY: _____

C. INCLUSION/EXCLUSION CRITERIA

C1. Does the patient have a diagnosis of HbSS or HbS/β^0 thalassemia? ☐ **1. NO** ☐ **2. YES**

C2. Is the patient's age in the range of 2 through 16 years? ☐ **1. NO** ☐ **2. YES**

IF THE ANSWER TO EITHER C1 OR C2 IS NO, THE PATIENT IS NOT ELIGIBLE FOR STUDY.
GO TO SECTION D

C3. Does the patient have a prior history of stroke? ☐ **1. NO** ☐ **2. YES**

C4. Has the patient received a bone marrow transplant? ☐ **1. NO** ☐ **2. YES**

IF THE ANSWER TO EITHER C3 OR C4 IS YES, THE PATIENT IS NOT ELIGIBLE FOR STUDY.
GO TO SECTION D

D. ELIGIBILITY DISPOSITION FOR TCD SCREENING

D1. Is the patient eligible for TCD screening?

☐ **1. NO** → **STOP – FORM COMPLETE**

☐ **2. YES** → **CONTINUE TO QUESTION D2**

D2. Has the patient/patient's parent or legal guardian read and signed the informed consent document for TCD screening?

☐ **1. NO** → D2.a Please specify reason: _____ **STOP – FORM COMPLETE**

☐ **2. YES** → **PROCEED WITH TCD EXAMINATION AND COMPLETE TCD EXAM FORM**

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

STOP II

ELIGIBILITY QUESTIONNAIRE FOR PATIENTS ON TRANSFUSION FOR PRIMARY STROKE PREVENTION FOR < 30 MONTHS

AFFIX PATIENT LABEL HERE

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

A2. Date form completed (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___

B. PATIENT ID INFORMATION

B1. Has a STOP II Form 01A or 01B been completed previously for this patient? ☐ **1. NO** ☐ **2. YES**

↓

GO TO SECTION C

B2. Is the birthdate information on the pre-printed patient label provided by the DCC correct? ☐ **1. NO** ☐ **2. YES**

↓

B2.a If NO, list correct birthdate
___ ___/___ ___/___ ___ ___ ___

B3. Is the gender information on the pre-printed patient label provided by the DCC correct? ☐ **1. NO** ☐ **2. YES**

↓

B3.a If NO, check correct gender:

☐ **1. FEMALE**

☐ **2. MALE**

B4. Race

(READ BOLDED SENTENCES TO PARENT/GUARDIAN OR CHILD IF AGE APPROPRIATE AND SHOW CARD WITH CHOICES)

NIH monitors enrollment of minorities to ensure their adequate representation in all research studies funded by NIH. Please identify the race of the child among the following choices [SHOW CARD]:

☐ **1. Black/African American/not Latin origin** ☐ **2. Black/African American/of Latin Origin**

☐ **3. White/not of Latin origin** ☐ **4. White/of Latin origin**

☐ **5. Asian American/Pacific Islander** ☐ **6. Native American/Alaskan Native**

☐ **7. Other** →B4.a. Please specify _____

C. INCLUSION/EXCLUSION CRITERIA

C1. Is the patient a previously STOP randomized patient? ☐ 1. NO ☐ 2. YES

↓

GO TO QUESTION C3

C2. Does the patient have a diagnosis of HbSS or HbS/β^0 thalassemia? ☐ 1. NO ☐ 2. YES

C3. Is the patient's age in the range of 2 through 20 years? ☐ 1. NO ☐ 2. YES

C4. Is the patient currently receiving transfusions for primary stroke prevention? ☐ 1. NO ☐ 2. YES

↓

C4.a Date transfusions started (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___

C4.b. Did the STOP/STOP II TCD Reading Center determine that the patient had 2 abnormal TCDs or 1 abnormal TCD with time averaged maximum mean velocity $\geq$ 220 cm prior to starting transfusions? ☐ 1. NO ☐ 2. YES

IF THE ANSWER TO ANY OF QUESTIONS C2 – C4.b IS NO, THE PATIENT IS NOT ELIGIBLE FOR FOLLOW-UP AS A POTENTIAL CANDIDATE FOR RANDOMIZATION. GO TO SECTION D

C5. Does the patient have a prior history of stroke? ☐ 1. NO ☐ 2. YES

C6. Has the patient received a bone marrow transplant? ☐ 1. NO ☐ 2. YES

IF THE ANSWER TO EITHER C5 OR C6 IS YES, THE PATIENT IS NOT ELIGIBLE FOR STUDY. GO TO SECTION D

D. DETERMINATION OF ELIGIBILITY

D1. Is the patient eligible for follow-up as a potential candidate for randomization?
(Answers to C2 – C4b = YES, Answers to C5 – C6 = NO)

☐ 1. NO → **STOP – FORM COMPLETE**

☐ 2. YES → **CONTINUE TO QUESTION D2**

D2. Has the patient/patient's parent or legal guardian read and signed the informed consent document for follow-up as a potential candidate for randomization?

☐ 1. NO →

D2.a. Please specify reason:

_____

STOP – FORM COMPLETE

☐ 2. YES → **COMPLETE ENTRY FORMS**

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

STOP II

PRE-RANDOMIZATION ELIGIBILITY QUESTIONNAIRE

AFFIX PATIENT LABEL HERE

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

A2. Date form completed (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___

B. PATIENT ID INFORMATION

B1. Has a STOP II Form 01A, B, or C been completed previously for this patient? ☐ **1. NO** ☐ **2. YES**

↓

GO TO SECTION C

B2. Is the birthdate information on the pre-printed patient label provided by the DCC correct? ☐ **1. NO** ☐ **2. YES**

↓

B2.a If NO, list correct birthdate
___ ___/___ ___/___ ___ ___ ___

B3. Is the gender information on the pre-printed patient label provided by the DCC correct? ☐ **1. NO** ☐ **2. YES**

↓

B3.a If NO, check correct gender:

☐ **1. FEMALE**

☐ **2. MALE**

B4. Race

(READ BOLDED SENTENCES TO PARENT/GUARDIAN OR CHILD IF AGE APPROPRIATE AND SHOW CARD WITH CHOICES)

NIH monitors enrollment of minorities to ensure their adequate representation in all research studies funded by NIH. Please identify the race of the child among the following choices [SHOW CARD]:

☐ **1. Black/African American/not Latin origin** ☐ **2. Black/African American/ of Latin Origin**

☐ **3. White/not of Latin origin** ☐ **4. White/of Latin origin**

☐ **5. Asian American/Pacific Islander** ☐ **6. Native American/Alaskan Native**

☐ **7. Other** → B4.a Please specify _____

C. INCLUSION/EXCLUSION CRITERIA

C1. Does the patient have a diagnosis of HbSS or HbS/β^0 thalassemia? ☐ **1. NO** ☐ **2. YES**

C2. Is the patient's age in the range of 4.5 through 20 years? ☐ **1. NO** ☐ **2. YES**

C3. Is the patient currently receiving transfusions for primary stroke prevention? ☐ **1. NO** ☐ **2. YES**

↓

C3.a Was the patient adequately transfused during the last 30 months?
☐ **1. NO**
☐ **2. YES**

↓

C3.a1 Date transfusion started:

___ ___/___ ___/___ ___ ___ ___

C3.a2 Did the STOP/STOP II TCD Reading Center determine that the patient had 2 abnormal TCDs or 1 abnormal TCD with time averaged maximum mean velocity $\geq$ 220 cm prior to starting transfusions?
☐ **1. NO**
☐ **2. YES**

IF THE ANSWER TO ANY OF C1 - C3.a2 IS NO, THE PATIENT IS NOT ELIGIBLE FOR STUDY. GO TO SECTION D

C4. Does the patient have a prior history of stroke? ☐ **1. NO** ☐ **2. YES**

C5. Has the patient received a bone marrow transplant? ☐ **1. NO** ☐ **2. YES**

IF THE ANSWER TO EITHER C4 OR C5 IS YES, THE PATIENT IS NOT ELIGIBLE FOR STUDY. GO TO SECTION D

D. ELIGIBILITY DISPOSITION FOR PRE-RANDOMIZATION EVALUATION

D1. Is the patient eligible for pre-randomization evaluation?
(Answers to questions C1 – C3.a2 = YES,
Answers to questions C4 and C5 = NO)

☐ **1. NO** → **STOP – FORM COMPLETE**

☐ **2. YES**

D2. Has the patient/patient's parent or legal guardian read and signed the informed consent document for pre-randomization evaluation?

☐ **1. NO** →

D2.a Please specify reason:

_____

STOP – FORM COMPLETE

☐ **2. YES** → **PROCEED WITH TCD EXAMINATION AND COMPLETE TCD EXAM FORM**

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

STOP II TRIAL

TRANSCRANIAL DOPPLER (TCD) EXAMINATION FORM

****AFFIX PATIENT LABEL HERE****

SECTIONS A, B and D TO BE COMPLETED BY STUDY COORDINATOR
SECTION C TO BE COMPLETED BY TCD EXAMINER

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

A2. Date form completed (Month/Day/Year) ____ ____/____ ____/____ ____ ____ ____

B. TCD EXAMINATION INFORMATION

B1. Date of examination (Month/Day/Year): ____ ____/____ ____/____ ____ ____ ____

B2. Reason for examination:

- ☐ **1. Routine TCD Screening Examination to determine eligibility for transfusion**
- ☐ **2. Confirmatory TCD Examination to determine eligibility for transfusion**
- ☐ **3. TCD Screening Examination to determine eligibility for randomization**
- ☐ **4. Confirmatory TCD Screening Examination to determine eligibility for randomization**
- ☐ **5. Entry/Quarterly Visit for potential subject**
- ☐ **6. Quarterly or 6 week Follow-up Visit for trial patient**
- ☐ **7. Neurological Event**

↓

B2.a Date of Event (Month/Day/Year) ___ ___/___ ___/___ ___ ___ ___

☐ ML ☐ DE

C. TCD EXAMINATION

SECTION C TO BE COMPLETED BY TCD EXAMINER

C1. Name of examiner: _____ (Initials): | | | |

C2. TCD machine serial number: | |

C3. Examiner comments: _____

SECTION D TO BE COMPLETED BY STUDY COORDINATOR

D. CBC INFORMATION (OPTIONAL)

	1. NO	2. YES
D1. Was a sample for hemoglobin/hematocrit drawn at this visit?		

D1.a. Date drawn (Month/Day/Year) ___ ___/___ ___/___ ___ ___ ___

D1.b. Hemoglobin (g/dl) | | . |

D1.c Hematocrit (%) | | . |

ATTACH INSTITUTIONAL REPORT

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

STOP II

TREATMENT DECISION BY PARENT-GUARDIAN OF NEWLY IDENTIFIED CHILD WITH TWO ABNORMAL TCDS OR ONE ABNORMAL TCD WITH TAMM VELOCITY ≥ 220 CM/SEC

****AFFIX PATIENT LABEL HERE****

A1. Person completing form (Name) _____ (Initials): [ ] [ ] [ ]

A2. Date form completed (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___

B. TREATMENT DECISION

B1. Did the parent/guardian elect to place child on transfusion for primary stroke prevention?

[ ] **1. NO** →

B1.a Reason:

- [ ] **1. Concerns about transfusion safety**
- [ ] **2. Difficulty participating in program/ anticipated compliance problems**
- [ ] **3. Family/patient not convinced that transfusion is needed**
- [ ] **4. Other:** _____

_____

[ ] **2. YES** →

COMPLETE STOP II ELIGIBILITY QUESTIONNAIRE (FORM 01B)

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

STOP II
Randomized Patients

SIGNED ACKNOWLEDGEMENT OF NEW INFORMATION ABOUT THE STOP II STUDY

PATIENT ID # _____

ACROSTIC _____

BIRTHDATE: _____

The above STOP II Randomized patient was given a copy of the 11/22/04 "Acknowledgement of New Information about the STOP II Study" on ___ ___ / ___ ___ / ___ ___ ___ ___.

☐ The Parent/Legal Guardian of the patient signed the 11/22/04 "Acknowledgement of New Information about the STOP II Study" on ___ ___ / ___ ___ / ___ ___ ___ ___ ☐ Check here if not signed because of subject's age

☐ The Patient signed the 11/22/04 "Acknowledgement of New Information About the STOP II Study" on ___ ___ / ___ ___ / ___ ___ ___ ___ ☐ Check here if not signed because of subject's age

Comments (optional):
_____

_____

_____

Signature of STOP II Principal Investigator _____

Date form completed: ___ ___ / ___ ___ / ___ ___ ___ ___

Fax completed form to: Dianne Gallagher • Fax Number: 617-923-4176

Date received at DCC: ___ ___ / ___ ___ / ___ ___ ___ ___

STOP II

TREATMENT DECISION AFTER TRIAL END

AFFIX PATIENT LABEL HERE

A1. Person completing form (Name): _____ ___ ___ ___
PRINT FULL NAME INITIALS

A2. Date of form completion ___ ___ / ___ ___ / ___ ___ ___ ___
M M D D Y Y Y Y

B. TREATMENT BEFORE AND AFTER TRIAL END ON MM/DD/YY

B1. On [MM/DD/YY], was the patient receiving regular transfusions?

NO ..... 1 (**GO TO B1a**) YES ..... 2 (**SKIP TO B1b**)

a. After the trial end, the treatment decision for this patient was to

RESTART TRANSFUSIONS.....1

REMAIN OFF OF TRANSFUSIONS 2

SKIP TO C1

b. After the trial end, the treatment decision for this patient was to

CONTINUE TRANSFUSIONS.....1

DISCONTINUE TRANSFUSIONS.....2

C. OTHER TREATMENT

C1. On MM/DD/YY, was the patient receiving hydroxyurea?

NO ..... 1 YES 2

C2. Is the patient currently receiving hydroxyurea?

NO ..... 1 (**SKIP TO C3**) YES 2

a. Date hydroxyurea started ___ ___ / ___ ___ / ___ ___ ___ ___
M M D D Y Y Y Y

C3. Is the patient currently receiving chelation?

NO.....1 YES.....2

STOP II TRIAL

TRIAL RANDOMIZATION FORM

****AFFIX PATIENT LABEL HERE*****

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

A2. Date form completed (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___

******PLEASE ANSWER NO OR YES TO EACH OF THE QUESTIONS IN SECTIONS B & C******

B. INCLUSION CRITERIA

	1. NO	2. YES
B1. Was the patient randomized in the STOP Trial?	☐	☐ → GO TO B4
B2. Was the diagnosis of HbSS or HbS/β^0 thalassemia confirmed?	☐	☐
B3. Has the DCC confirmed that the patient had two TCD examinations with flow velocities ≥ 200 cm/second or one exam with velocity ≥ 220 cm/second determined by the STOP/STOP II TCD Reading Center before starting transfusions?	☐	☐
B4. Is the patient's age in the range of 4.5 through 20 years?	☐	☐
B5. Has the STOP II DCC confirmed compliance with transfusion for ≥ 30 months as specified in the research protocol?	☐	☐
B6. Did the patient have two normal TCD exams as determined by the STOP/STOP II TCD Reading Center, at least two weeks apart, while on transfusion with the most recent one being within 4 months of today's date?	☐	☐

IF THE ANSWER TO ANY OF QUESTIONS B2-B6 IS NO, THE PATIENT IS NOT ELIGIBLE FOR RANDOMIZATION. GO TO SECTION D

C. EXCLUSION CRITERIA

	1. NO	2. YES
C1. Does the patient have a prior history of clinical stroke adjudicated by the STOP or STOP II Endpoint Adjudication Panel?	☐	☐
C2. Does the patient have evidence on MRA of moderate to severe intracranial arterial disease as determined by the STOP II MR Review Panel?	☐	☐
C3. Is the patient participating in any study involving treatments which might confound the interpretation of the results of STOP II?	☐	☐

C3.a. **IF YES**, specify study _____

☐ ML ☐ DE

	1. NO	2. YES
C4. Is the patient receiving clinical treatment which might confound the interpretation of the results of STOP II?	☐	☐
C4.a. **IF YES**, specify treatment _____		
C5. Does the patient have any other medical condition which would preclude discontinuation of transfusion?	☐	☐
C5.a. **IF YES**, specify condition _____		
C6. Does the patient have any medical condition that would prevent continuation of transfusion?	☐	☐
C6.a. **IF YES**, specify condition _____		

IF THE ANSWER TO ANY OF THE QUESTIONS IN SECTION C IS YES, THE PATIENT IS NOT ELIGIBLE FOR RANDOMIZATION. GO TO SECTION D

D. DETERMINATION OF RANDOMIZATION ELIGIBILITY

D1. Is the patient eligible for randomization?

☐ **1. NO** → **STOP - FORM COMPLETE**

☐ **2. YES** → **CONTINUE TO QUESTION D2**

D2. Has the patient/patient's parent or legal guardian read and signed the informed consent document for randomization?

☐ **1. NO** →

D2.a. **Please specify reason:**

☐ **1. Fear of stroke**

☐ **2. Other** → D2.a1. Specify _____

STOP - FORM COMPLETE

☐ **2. YES** →

D2.b. Has the patient/patient's parent or legal guardian agreed to allow serum and DNA samples to be collected, stored, and used for sickle cell research?

☐ **1. NO**

☐ **2. YES**

E. RANDOMIZATION (ELIGIBLE PATIENTS ONLY) – TO BE COMPLETED AT TIME OF CALL TO DCC TO RANDOMIZE PATIENTS

E1. Was eligibility confirmed by the CAC and DCC Principal Investigators?
(YES to questions B2 – B6, and NO to all questions in Section C)

☐ **1. NO** → **STOP - FORM COMPLETE**

☐ **2. YES** → **CONTINUE TO QUESTION E2**

E2. Date Patient Randomized ___ ___/___ ___/___ ___ ___ ___

E3. Trial Group Assigned ☐ **1. Continuation of Transfusion** ☐ **2. Discontinuation of Transfusion**

E4. Confirmation Number ☐☐☐☐

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

STOP II

INTAKE HISTORY FORM FOR PATIENTS ENROLLED AS POTENTIALS OR 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 I 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 ☐☐☐
		↓	6.b ☐☐☐
		B1.a6.a SPECIFY:_____ B1.a6.b SPECIFY: _____	

☐ ML ☐ DE

C. CLINICAL EVENT HISTORY

C1. Has the patient had 2 or more episodes of Acute Chest Syndrome (pneumonia) in the past year? ☐ **1. NO** ☐ **2. YES**

(**PROBE:** An infection or blockage of blood flow in the lungs)

C2. How many times was the patient hospitalized for sickle cell painful episodes in the last 2 years? ☐☐

(**PROBE:** Pain in the bones of arms, legs, or vertebrae**)**

C3.a Has the patient ever been seen by a doctor for any of the following events?			C3.b **What was date of recent event (month/year)**	C3.c **Where seen for most recent event? 1 = STOP II Center 2 = Non-STOP II Center**
1. Meningitis	☐ **1. NO**	☐ **2. YES** →	___ ___/___ ___ ___ ___	☐
(PROBE: Infection of the brain**)**				
2. Splenic Sequestration	☐ **1. NO**	☐ **2. YES** →	___ ___/___ ___ ___ ___	☐
(PROBE: Enlargement of the spleen with trapping of blood in it)				
3. Aplastic Crisis	☐ **1. NO**	☐ **2. YES** →	___ ___/___ ___ ___ ___	☐
(PROBE: A drop in the blood count which required a transfusion)				
4. Hand-Foot Syndrome	☐ **1. NO**	☐ **2. YES** →	___ ___/___ ___ ___ ___	☐
(PROBE: Pain, tenderness, with or without swelling, in the hands and/or feet only)				
5. Septicemia	☐ **1. NO**	☐ **2. YES** →	___ ___/___ ___ ___ ___	☐
(PROBE: An infection in the blood stream**)**				
6. Osteomyelitis	☐ **1. NO**	☐ **2. YES** →	___ ___/___ ___ ___ ___	☐
(PROBE: Infection in the bones)				
7. Priapism	☐ **1. NO**	☐ **2. YES** →	___ ___/___ ___ ___ ___	☐
(PROBE: A painful, unwanted erection of the penis lasting more than one hour)				
8. Transfusion Reaction	☐ **1. NO**	☐ **2. YES** →	___ ___/___ ___ ___ ___	☐
(PROBE: Complication of a transfusion within 2 weeks after the transfusion was given)				

C4. Has the patient had any of the following surgical procedures?

a. Splenectomy	☐ **1. NO**	☐ **2. YES** →	C4.a1 Date: (month/year) ___ ___/___ ___ ___ ___
b. Liver Biopsy	☐ **1. NO**	☐ **2. YES** →	C4.b1 Date: (month/year) ___ ___/___ ___ ___ ___
			C4.b2 Date: (month/year) ___ ___/___ ___ ___ ___
			C4.b3 Date: (month/year) ___ ___/___ ___ ___ ___

C5. Does the patient currently have a portacath? ☐ **1. NO** ☐ **2. YES**

D. FAMILY HISTORY OF STROKE

D1. Have any of the following members of the child's family ever had a stroke?

a. Mother ☐ 1. NO ☐ 2. YES ☐ 3. DON'T KNOW

b. Father ☐ 1. NO ☐ 2. YES ☐ 3. DON'T KNOW

c. Brothers ☐ 1. NO ☐ 2. YES ☐ 3. DON'T KNOW ☐ 4. NA - no brothers

↓

c1. # of brothers who had stroke ☐☐

d. Sisters ☐ 1. NO ☐ 2. YES ☐ 3. DON'T KNOW ☐ 4. NA - no sisters

↓

d1. # of sisters who had stroke ☐☐

*******SECTIONS E THROUGH I TO BE COMPLETED BY MEDICAL PERSONNEL*******

E. OTHER MEDICAL CONDITIONS

Does the patient currently carry the diagnosis of: **(CHECK NO OR YES FOR E1 - E19)**	1. NO	2. YES	Year of diagnosis
E1. Leg ulcers	☐	☐ →	1.a ☐☐☐☐
E2. Aseptic necrosis	☐	☐ →	2.a ☐☐☐☐
2.b If Yes, specify location(s) _____			
E3. Sickle cell retinopathy	☐	☐ →	3.a ☐☐☐☐
E4. Chronic lung disease	☐	☐ →	4.a ☐☐☐☐
4.b If Yes, specify type _____			
4.b1 ☐☐☐.☐☐ **OFFICE USE**			
E5. Asthma	☐	☐ →	5.a ☐☐☐☐
E6. Chronic heart disease	☐	☐ →	6.a ☐☐☐☐
6.b If Yes, specify type: _____			
6.b1 ☐☐☐.☐☐ **OFFICE USE**			
E7. Chronic liver disease	☐	☐ →	7.a ☐☐☐☐
7.b If Yes, specify type: _____			
7.b1 ☐☐☐.☐☐ **OFFICE USE**			
E8. Chronic renal disease	☐	☐ →	8.a ☐☐☐☐
8.b If Yes, specify type: _____			
8.b1 ☐☐☐.☐☐ **OFFICE USE**			
8.c If Yes, is patient receiving dialysis?	☐ 1. NO	☐ 2. YES	

	1. NO	2. YES	Year of diagnosis
E9. Iron overload	☐	☐ →	9.a ☐☐☐☐
9.b If yes, highest ferritin level (ng/ml) ☐☐☐☐☐			
E10. Diabetes	☐	☐ →	10.a ☐☐☐☐
E11. Rheumatic fever	☐	☐ →	11.a ☐☐☐☐
E12. Tuberculosis	☐	☐ →	12.a ☐☐☐☐
E13. Cancer	☐	☐ →	13.a ☐☐☐☐
13.b If Yes, specify type: _____			
13.b1 ☐☐☐.☐☐ OFFICE USE			
E14. Priapism	☐	☐ →	14.a ☐☐☐☐
E15. Elevated blood lead level (blood lead level ≥ 15 mg/dl?)	☐	☐ →	15.a ☐☐☐☐
E16. Hepatitis B	☐	☐ →	16.a ☐☐☐☐
E17. Hepatitis C	☐	☐ →	17.a ☐☐☐☐
E18. HIV	☐	☐ →	18.a ☐☐☐☐
E19. Any other chronic medical condition?	☐	☐	
19.b If Yes, specify type: _____			19.b1 ☐☐☐☐
19.b2 ☐☐☐.☐☐ OFFICE USE			
19.c If Yes, specify type: _____			19.c1 ☐☐☐☐
19.c2 ☐☐☐.☐☐ OFFICE USE			

F. RED CELL PHENOTYPING (COMPLETION NOT REQUIRED FOR PATIENTS RANDOMIZED IN STOP)

F1. Was the patient randomized in STOP? ☐ **1. NO** ☐ **2. YES →** **GO TO SECTION G**

F2.a. ABO Blood Group

☐ **1. A** ☐ **2. B** ☐ **3. AB** ☐ **4. O**

F2.b Rh Antigens	1. ABSENT	2. PRESENT
1. D	☐	☐
2. C	☐	☐
3. E	☐	☐
4. e	☐	☐
5. c	☐	☐
6. f	☐	☐
7. V	☐	☐

F2.c Kell Antigens	1. ABSENT	2. PRESENT
1. K (Kell)	☐	☐
2. k	☐	☐
3. Js^a	☐	☐
4. Js^b	☐	☐
5. Kp^a	☐	☐
6. Kp^b	☐	☐
F2.d Duffy Antigens		
1. Fy^a	☐	☐
2. Fy^b	☐	☐
F2.e Kidd Antigens		
1. Jk^a	☐	☐
2. Jk^b	☐	☐
F2.f Lewis Antigens		
1. Le^a	☐	☐
2. Le^b	☐	☐
F2.g Lutheran Antigens		
1. Lu^a	☐	☐
2. Lu^b	☐	☐
3. Lu^3	☐	☐
F2.h P Antigens		
1. P_1	☐	☐
F2.i MNS Antigens		
1. M	☐	☐
2. N	☐	☐
3. S	☐	☐
4. s	☐	☐
5. U	☐	☐

***** ATTACH RED CELL PHENOTYPE REPORT ******

G. RED CELL ANTIBODIES AND TRANSFUSION COMPLICATIONS

G1. Is the patient known by your blood bank to have any of the following red cell antibodies?

(CHECK NO OR YES FOR EACH OF G1 a - l)

	1.NO	2. YES	G2. Date first identified
a. anti-D	☐	☐ →	___ ___/___ ___/___ ___ ___ ___
b. anti-C	☐	☐ →	___ ___/___ ___/___ ___ ___ ___
c. anti-E	☐	☐ →	___ ___/___ ___/___ ___ ___ ___
d. anti-M	☐	☐ →	___ ___/___ ___/___ ___ ___ ___
e. anti-S	☐	☐ →	___ ___/___ ___/___ ___ ___ ___
f. anti-K (Kell)	☐	☐ →	___ ___/___ ___/___ ___ ___ ___
g. anti-Fy^a	☐	☐ →	___ ___/___ ___/___ ___ ___ ___
h. anti-Fy^b	☐	☐ →	___ ___/___ ___/___ ___ ___ ___
i. anti-Jk^b	☐	☐ →	___ ___/___ ___/___ ___ ___ ___
j. anti-Le^a	☐	☐ →	___ ___/___ ___/___ ___ ___ ___
k. anti-Le^b	☐	☐ →	___ ___/___ ___/___ ___ ___ ___
l. Other	☐	☐ ↓	

List Antibody:		Date first identified:	
G1.l1	_____	G1.l1.a	___ ___/___ ___/___ ___ ___ ___
G1.l2	_____	G1.l2.a	___ ___/___ ___/___ ___ ___ ___
G1.l3	_____	G1.l3.a	___ ___/___ ___/___ ___ ___ ___

G3. Has the patient ever had a transfusion reaction? ☐ **1. NO** ☐ **2. YES** ☐ **3. DON'T KNOW**

↓

G3.a Describe

_____

_____

_____

H. VACCINATIONS

H1. Has the patient received Hepatitis B vaccination?

☐ **1. NO** ☐ **2. YES**

↓

H1.a Date of most recent vaccination (Month/Day/Year)

___ ___/___ ___/___ ____ ___ ___

I. GENERAL

I1. 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**

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

SECTION J. FOR OFFICE USE

J1. Local red cell phenotyping report received?

☐ **1. NO**

☐ **2. YES**

☐ **-1. NA**

STOP II

PHYSICAL EXAMINATION

AFFIX PATIENT'S LABEL HERE

A1. Person performing physical examination (Name): _____ (Initials): | | | |

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

B. MEASUREMENTS

B1. Height (cm): | | | | . | |

B2. Weight (kg): | | | | . | |

B3. Blood Pressure (Supine, before blood drawing): a. | | | | Systolic b. | | | | Diastolic

B4. Pulse (beats/min): | | |

B5. Respiration rate/min: | | |

B6. Temperature (°C): | | . | |

C. PHYSICAL EXAMINATION

C1. General Appearance ☐ **1. NORMAL** ☐ **2. ABNORMAL** → a. Describe _____

C2. Eyes ☐ **1. NORMAL** ☐ **2. ABNORMAL** → a. Describe _____

C3. Ears ☐ **1. NORMAL** ☐ **2. ABNORMAL** → a. Describe _____

C4. Nose/Throat/Mouth ☐ **1. NORMAL** ☐ **2. ABNORMAL** → a. Describe _____

b. Tonsils ☐ **1. NORMAL** ☐ **2. ENLARGED** ☐ **3. ABSENT**

C5. Lungs	**1. ABSENT**	**2. PRESENT**
a. Rales	☐	☐
b. Rhonchi	☐	☐
c. Wheezing	☐	☐
d. Mouth Breathing	☐	☐
e. Other lung/respiratory abnormality	☐	☐ → e1. Specify _____

☐ ML ☐ DE

C6. Heart — **1. ABSENT** **2. PRESENT**

a. Rhythm abnormality ☐ ☐ → a1. Specify type:_____

b. Heart murmur ☐ ☐ → b1. Specify type:_____

c. Other abnormality ☐ ☐ → c1. Specify type:_____

C7. Abdomen ☐ **1. NORMAL** ☐ **2. ABNORMAL** → a. Describe _____

C8. Spleen ☐ **1. NOT ENLARGED** ☐ **2. ENLARGED** ☐ **3. N/A: S/P splenectomy**

↓

C8.a Distance below LCM at MCL (cm) ☐☐ . ☐

C9. Liver ☐ **1. NOT ENLARGED** ☐ **2. ENLARGED**

a. Tenderness ☐ **1. ABSENT** ☐ **2. PRESENT**

C10. Extremities

	1. NO	**2. YES**
a. Pain or limitation of motion in		
1. Right hip?	☐	☐
2. Left hip?	☐	☐
3. Right shoulder?	☐	☐
4. Left shoulder?	☐	☐

b. Leg ulcer ☐ **1. ABSENT** ☐ **2. PRESENT** → b1. ☐ **1. RIGHT** ☐ **2. LEFT** ☐ **3. BOTH**

c. Lower extremity edema ☐ **1. ABSENT** ☐ **2. PRESENT** → c1. ☐ **1. RIGHT** ☐ **2. LEFT** ☐ **3. BOTH**

C11. Skin ☐ **1. NORMAL** ☐ **2. ABNORMAL** → a. Describe _____

C12. Lymph nodes enlarged? ☐ **1. NO** ☐ **2. YES** → a. Specify _____

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

STOP II TRIAL
CORE LABORATORY FORM

AFFIX PATIENT LABEL HERE

A1. On-site person completing page 1 of form: _____ (Initials): | | | |

A2. Date samples shipped (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___

A3. Reason for Collection:

☐ **1. Baseline Visit** ☐ **2. Quarterly Visit**

☐ **3. Annual Visit** ☐ **4. Exit from study**

☐ **5. Transfusion →** A3.a Date of Transfusion (Month/Day/Year): ___ ___/___ ___/___ ___ ___ __

For Office Use A3.a1 | | | |

☐ **6. Neurological Event →** A3.b Date of Event (Month/Day/Year): ___ ___/___ ___/___ ___ ___ __

B. SPECIMENS:

Type of Visit	Specimens Required (# in parentheses = # of tubes required) Routine Hematology (Lavender Top)	Serum Chemistries (Red Top)	Serum Repository (Red Top)
Trial Entry	(2) 5 ml	(2) 5 ml*	(1) 5 ml
Quarterly	(1) 5 ml		(1) 5 ml
Annual	(1) 5 ml	(1) 5 ml*	(1) 5 ml
Exit from study	(1) 5 ml	(1) 5 ml*	(1) 5 ml
Transfusion (pre)	(1) 5 ml		
Neurological Event	(1) 5 ml		(1) 5 ml

*** Will also be used for infection panel**

Amount and type of tube	*To be completed by Study Coordinator* Date blood Drawn	# of tubes Enclosed	*For Core Lab use* # of tubes received In good condition
B1. 5 ml lavender-top tube	a. ___ ___/___ ___/___ ___ ___ ___	b. _____	c. _____
B2. 5 ml red-top tube	a. ___ ___/___ ___/___ ___ ___ ___	b. _____	c. _____

C. TRANSFUSION STATUS

C1. Has patient been transfused during the last 4 months? ☐ **1. NO** ☐ **2. YES** ↓

C1.a Date of Last Transfusion: ___ ___/___ ___/___ ___ ___ ___

☐ ML ☐ DE

D. LABORATORY TEST RESULTS (To be completed by MCG Core Lab)

D1. Core Lab person completing form: _____ (Initials): [ ] [ ] [ ]

D2. Date shipment received (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___

D3. Date Core Lab sections completed (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___

D4. Hemoglobin Analysis:

a. % S [ ][ ] . [ ]
b. % F [ ][ ] . [ ]
c. %A_2 [ ] . [ ]
d. %A [ ][ ] . [ ]
e. % other [ ][ ] . [ ]

↓

D4.e1. **SPECIFY:** _____

f. Hemoglobin Phenotype

[ ] **1. SS** [ ] **2. Sβ^o thal** [ ] **3. Other** → D4.f1. **SPECIFY:** _____

D5. CBC

			Reference Range
a.	White Cell Count (x 10 ^{9}/l) (uncorrected for nRBCs)	[ ][ ] . [ ]	3.5 - 22.5
b.	Red Cell Count (x10^{12}/l)	[ ] . [ ][ ]	1.5 - 5
c.	Hemoglobin (g/dl)	[ ][ ] . [ ]	5 - 12
d.	Hematocrit (%)	[ ][ ] . [ ]	14 - 36
e.	Mean Cell Volume (fl)	[ ][ ][ ]	60 - 110
f.	Mean Cell Hemoglobin (pg)	[ ][ ] . [ ]	22 - 35
g.	Mean Cell Hemoglobin Concentration (g/dl)	[ ][ ] . [ ]	
h.	RDW (%)	[ ][ ] . [ ]	

D6. Reticulocyte Count (%) [ ][ ] . [ ] 0 - 30

D7. Platelet Count (x10^9/l) [ ][ ][ ][ ] 100 - 750

D8. WBC Differential/Nucleated RBCs

a. PMN (%) ☐☐

b. Bands (%) ☐☐

c. Lymphocytes (%) ☐☐

d. Monocytes (%) ☐☐

e. Eosinophils (%) ☐☐

f. Basophils (%) ☐☐

g. Other (includes atypical cells, myelocytes, metamyelocytes) (%) ☐☐

h. Nucleated Red Blood Cells (/100 WBC) ☐☐☐

D9. Serum Ferritin (ng/ml) ☐☐☐☐☐

D10. Serum chemistries

		Reference Range
a. ALT (SGPT) (U/l)	☐☐☐☐	0 - 75
b. GGT (U/l)	☐☐☐☐	12 - 89
c. LDH (U/l)	☐☐☐☐	50 - 1000
d. Total Bilirubin (mg/dl)	☐☐.☐	.5 - 10
e. Direct Bilirubin (mg/dl)	☐☐.☐	0 - 1.0

D11. β^S Haplotype: _____

D12. Number α Genes: ☐

D13. Infection Panel:

a. Hepatitis B Surface Antibody ☐ **1. NEGATIVE** ☐ **2. POSITIVE**

b. Hepatitis C Antibody ☐ **1. NEGATIVE** ☐ **2. POSITIVE**

D14. Serum repository sample received ☐ **1. NO** ☐ **2. YES**

STOP II
LOCAL LABORATORY FORM FOR NON-RANDOMIZED PATIENTS RECEIVING TRANSFUSIONS

AFFIX PATIENT LABEL

HERE

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

A2. Date form completed (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___

A3. Reason for Completion:

☐ **1. Entry Visit** ☐ **2. Quarterly Visit** For Office Use

☐ **3. Pre-transfusion →** A3.a Date of Transfusion (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___ A3.a1 | | | |

B. TESTS REQUIRED

Test Required

Type of Visit:	CBC	HBS	Ferritin	Liver Profile
Entry	X	X	X	X
Quarterly	X	X	X	X
Transfusion (pre)	X	X		

B1. Date Blood Drawn for CBC (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___ ☐ -1. **NOT DONE**

B2. Date Blood Drawn for Hemoglobin S (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___ ☐ -1. **NOT DONE**

B3. Date Blood Drawn for Ferritin (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___ ☐ -1. **NOT DONE**

B4. Date Blood Drawn for Liver Profile (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___ ☐ -1. **NOT DONE**

C. TRANSFUSION STATUS

C1. Has patient been transfused during the last 4 months? ☐ **1. NO** ☐ **2. YES**

↓

C1.a Date of Last Transfusion: ___ ___/___ ___/___ ___ ___ ___

D. LABORATORY TEST RESULTS

D1. Hemoglobin Analysis:

a. % S | | | . |

D2. CBC

		Reference Range
a.	White Cell Count (x 10 ^{9}/l) (uncorrected for nRBCs)	3.5 - 22.5
b.	Red Cell Count (x10^{12}/l)	1.5 - 5
c.	Hemoglobin (g/dl)	5 - 12
d.	Hematocrit (%)	14 - 36
e.	Mean Cell Volume (fl)	60 - 110
f.	Mean Cell Hemoglobin (pg)	22 - 35
g.	Mean Cell Hemoglobin Concentration (g/dl)	
h.	RDW (%)	

D3. Serum Ferritin (ng/ml)

D4. Serum chemistries

		Reference Range
a.	ALT (SGPT) (U/l)	0 - 75
b.	GGT (U/l)	12 - 89
c.	LDH (U/l)	50 - 1000
d.	Total Bilirubin (mg/dl)	.5 - 10
e.	Direct Bilirubin (mg/dl)	0 - 1.0

ATTACH LABORATORY REPORTS FOR ALL TESTS PERFORMED

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

E. FOR OFFICE USE

E1. Local CBC report received	**1. NO**	**2. YES**	**-1. NOT APPLICABLE**
E2. Hemoglobin analysis report received	**1. NO**	**2. YES**	**-1. NOT APPLICABLE**
E3. Serum ferritin report received	**1. NO**	**2. YES**	**-1. NOT APPLICABLE**
E4. Liver profile report received	**1. NO**	**2. YES**	**-1. NOT APPLICABLE**

STOP II TRIAL
NEUROLOGICAL CONSULTANT REPORT

AFFIX PATIENT LABEL

HERE

A1. Name of Examiner: _____ (Initials): | | | |

A2. Date and time of interview (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___ A2.a Time:____:____

A2.b ☐ **1. A.M.** ☐ **2. P.M.**

A3. Patient is: ☐ **1. Male** ☐ **2. Female** A4. Patients age: | | Years

A5. Type of exam

☐ **1. BASELINE →** **GO TO SECTION C**

☐ **2. ANNUAL →** **GO TO SECTION C**

☐ **3. NEUROLOGICAL EVENT →** **GO TO SECTION B**

☐ **4. POST-MENINGITIS →**

A5.a Date of event (month/day/year): ___ ___/___ ___/___ ___ ___ ___

A5.b Date of discharge(month/day/year): ___ ___/___ ___/___ ___ ___ ___

GO TO SECTION C

☐ **5. POST-HEAD INJURY →**

A5.c Date of event (month/day/year): ___ ___/___ ___/___ ___ ___ ___

A5.d Date of discharge(month/day/year): ___ ___/___ ___/___ ___ ___ ___

GO TO SECTION C

B EVENT HISTORY

B1. Person interviewed (Choose **ONE** for person providing majority of answers to questions in Section B):

☐ **1. Patient** ☐ **2. Parent** ☐ **3. Legal Guardian** ☐ **4. Other →** B1.a (specify): _____

B2. Did person interviewed witness the event? ☐ **1. NO** ☐ **2. YES**

PERSON INTERVIEWED SHOULD ANSWER QUESTIONS B3 - B10

B3. Why did the patient come to the hospital?

_____

_____

_____

_____

☐ ML ☐ DE

B4. Describe the development of symptoms in detail:

_____

_____

_____

_____

B5. Specific date and time of onset: (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___ B5.a Time:____:____

B5.b ☐ **1. A.M.** ☐ **2. P.M.**

B6. How long did symptoms last? _____

B7. Has patient had these symptoms before? ☐ **1. NO** ☐ **2. YES**

B8. Was the patient also experiencing a pain crisis or medical illness? ☐ **1. NO** ☐ **2. YES**

↓

B8.a Specify type of event**:**

_____

_____

_____

B9. Did the patient experience any of the following symptoms?

		1. NO	**2. YES**	**GIVE DETAILS IF YES**
B9.a	Alteration of Level of Consciousness	☐	☐	B9.a1. _____
B9.b	Headache	☐	☐	B9.b1. _____
B9.c	Hemiparesis or other weakness	☐	☐	B9.c1. _____

↓

LOCATION		**RIGHT**			**LEFT**		
B9.c2.	Face	☐ **1. NO**	☐ **2. YES**	a.	☐ **1. NO**	☐ **2. YES**
B9.c3.	Arm	☐ **1. NO**	☐ **2. YES**	b.	☐ **1. NO**	☐ **2. YES**
B9.c4.	Leg	☐ **1. NO**	☐ **2. YES**	c.	☐ **1. NO**	☐ **2. YES**

B9.d	Loss of vision	☐	☐	B9.d1. _____
B9.e	Alteration of speech	☐	☐	B9.e1. _____
B9.f	Clumsiness	☐	☐	B9.f1. _____
B9.g	Possible seizure	☐	☐	B9.g1. _____

B9. (cont'd) Did the patient experience any of the following symptoms?

	1. NO	2. YES	GIVE DETAILS IF YES
B9.h Numbness or other sensory disturbance	☐	☐ ↓	B9.h1. _____

LOCATION		RIGHT			LEFT		
B9.h2.	Face	☐ 1. NO	☐ 2. YES	a.	☐ 1. NO	☐ 2. YES	
B9.h3.	Arm	☐ 1. NO	☐ 2. YES	b.	☐ 1. NO	☐ 2. YES	
B9.h4.	Leg	☐ 1. NO	☐ 2. YES	c.	☐ 1. NO	☐ 2. YES	

	1. NO	2. YES
B9.i Abnormal Movements	☐	☐ ↓

B9.i1. **GIVE DETAILS** _____

_____

B10. PLEASE PROVIDE ANY OTHER INFORMATION THAT MAY HELP DETERMINE THE NATURE OF THE EVENT:

_____

_____

_____

C. GENERAL PHYSICAL EXAM

C1. Record Vital Signs and Measurements:

C1.a Pulse (beats/minute) ☐☐☐

C1.b Respirations (breaths/minute) ☐☐☐

C1.c Blood Pressure (mmHg) (sys/dia) c1. ☐☐☐ / c2. ☐☐☐

C1.d Temperature (C°) ☐☐☐ . ☐

C1.e Height (cm) ☐☐☐ . ☐

C1.f Weight (kg) ☐☐☐ . ☐

C1.g Head Circumference (cm) ☐☐ . ☐ (Measure at baseline and annual visits)

C2. Is the patient right or left handed? ☐ **1. Right** ☐ **2. Left** ☐ **3. Ambidexterous** ☐ **4. Undetermined**

C3. Assess condition of the following:	1. NORMAL	2. ABNORMAL	GIVE DETAILS IF ABNORMAL
C3.a Skin	☐	☐	C3.a1 _____
C3.b Head and Neck	☐	☐	C3.b1 _____
C3.c Chest	☐	☐	C3.c1 _____
C3.d Spine	☐	☐	C3.d1 _____
C3.e Abdomen	☐	☐	C3.e1 _____

C3.f Cardiovascular:	1. ABSENT	2. PRESENT	GIVE DETAILS IF PRESENT
C3.f1 Murmurs:	☐	☐	C3.f1.a _____
C3.f2 Arrhythmias	☐	☐	C3.f2.a_____

D. NEUROLOGICAL EXAMINATION

D1. Level of Consciousness ☐ **1. NORMAL** ☐ **2. ABNORMAL**

↓

D1.a
- ☐ **1. Lethargy**
- ☐ **2. Stupor**
- ☐ **3. Coma**
- ☐ **4. Other:** D1.a1 specify_____

EXAMINER: MARK ANY ITEMS "NA" IF NOT APPLICABLE DUE TO AGE, OR "NE" IF NOT EVALUABLE DUE TO PHYSICAL/MENTAL CAPABILITY, OR LACK OF COOPERATION, AND EXPLAIN IN THE COMMENTS SECTION. OTHERWISE PLEASE ANSWER ALL ITEMS.

D2. **NAMING TO CONFRONTATION** **(SHOW PATIENT DRAWINGS ON PAGE 11)**

(check if response correct)

- Clock ☐
- Pencil ☐
- Skateboard ☐
- Shirt ☐
- Ball ☐
- Bicycle ☐

D2.a Total Correct: ☐ ☐ **-8. NE** ☐ **-1. NA**

D2.b Is naming appropriate for age? ☐ **-8. NE** ☐ **1. NO** ☐ **2. YES**

EXAMINER: MARK ANY ITEMS "NA" IF NOT APPLICABLE DUE TO AGE, OR "NE" IF NOT EVALUABLE DUE TO PHYSICAL/MENTAL CAPABILITY, OR LACK OF COOPERATION, AND EXPLAIN IN THE COMMENTS SECTION. OTHERWISE PLEASE ANSWER ALL ITEMS.

D3. **COMPREHENSION**

(check if response correct)
Ask patient to:

1. Close your eyes ☐
2. Touch your nose ☐
3. Point to the floor and then point to the ceiling ☐

D3.a Total Correct: ☐ ☐ **-8. NE** ☐ **-1. NA**

D3.b Is comprehension appropriate for age? ☐ **-8. NE** ☐ **1. NO** ☐ **2. YES**

D4. **REPETITION**

(check if response correct)
Ask patient to repeat:

1. Stop. ☐
2. Stop and go. ☐
3. If it rains we play inside ☐
4. The President lives in Washington ☐

D4.a Total Correct: ☐ ☐ **-8. NE** ☐ **-1. NA**

D4.b Is comprehension appropriate for age? ☐ **-8. NE** ☐ **1. NO** ☐ **2. YES**

D5. **READING** **(SHOW PATIENT SENTENCES ON PAGE 12)**

(check if response correct)
Ask patient to read:

1. Stop. ☐
2. See the dog run. ☐
3. Little children like to play outdoors ☐

D5.a Total Correct: ☐ ☐ **-8. NE** ☐ **-1. NA**

D5.b Is reading appropriate for age? ☐ **-8. NE** ☐ **1. NO** ☐ **2. YES**

D6. **WRITING** **(SPACES PROVIDED ON PAGE 13)**

(check if response correct)
Ask patient to write:

1. The patient's signature ☐
2. Cat ☐
3. The cat is black ☐

D6.a Total Correct: ☐ ☐ **-8. NE** ☐ **-1. NA**

D6.b Is writing appropriate for age? ☐ **-8. NE** ☐ **1. NO** ☐ **2. YES**

EXAMINER: MARK ANY ITEMS "NA" IF NOT APPLICABLE DUE TO AGE, OR "NE" IF NOT EVALUABLE DUE TO PHYSICAL/MENTAL CAPABILITY, OR LACK OF COOPERATION, AND EXPLAIN IN THE COMMENTS SECTION. OTHERWISE PLEASE ANSWER ALL ITEMS.

D7. **RIGHT/LEFT ORIENTATION**

(check if response correct)
Ask patient to:

1. Show me your left hand ☐
2. Show me your right hand ☐

D7.a Total Correct: ☐ ☐ **-8. NE** ☐ **-1. NA**

D7.b Is right/left orientation appropriate for age? ☐ **-8. NE** ☐ **1. NO** ☐ **2. YES**

D8. **DRAWING** **(SHOW PATIENT DRAWINGS ON PAGE 14)**

(check if response is correct)
Ask patient to copy:

1. Circle ☐
2. Triangle ☐
3. Maltese cross ☐
4. Bisecting lines ☐

D8.a Total Correct: ☐ ☐ **-8. NE** ☐ **-1. NA**

D8.b Is drawing appropriate for age? ☐ **-8. NE** ☐ **1. NO** ☐ **2. YES**

D9. SUMMARIZE THE ABNORMALITIES/COMMENTS:

_____

_____

_____

_____

EXAMINER: ANSWER NE IF NOT EVALUABLE DUE TO PHYSICAL/MENTAL CAPABILITY OR LACK OF COOPERATION, AND EXPLAIN IN THE COMMENTS SECTION. PLEASE ANSWER ALL ITEMS.

D10. CRANIAL NERVES:

D10.a Visual fields to confrontation ☐ **-8. NE** ☐ **1. NORMAL** ☐ **2. ABNORMAL →** **B10.a1 GIVE DETAILS IF ABNORMAL**

_____

_____

D10.b Papilledema ☐ **-8. NE** ☐ **1. ABSENT** ☐ **2. PRESENT**

EXAMINER: MARK ANY ITEMS "NE" IF NOT EVALUABLE DUE TO PHYSICAL/MENTAL CAPABILITY OR LACK OF COOPERATION, AND EXPLAIN IN THE COMMENTS SECTION. OTHERWISE PLEASE ANSWER ALL ITEMS.

	-8. NE	1. NORMAL	2. ABNORMAL	GIVE DETAILS IF ABNORMAL
CRANIAL NERVES III, IV, VI				
D10.c Pupils	☐	☐	☐	→c1. _____
D10.d Extra Ocular Movements	☐	☐	☐	→d1. _____
D10.e Gaze	☐	☐	☐	→e1. _____
CRANIAL NERVES V.	-8. NE	1. NORMAL	2. ABNORMAL	GIVE DETAILS IF ABNORMAL
D10.f Facial Sensation	☐	☐	☐	→f1. _____
D10.g. Corneal Reflexes	☐	☐	☐	→g1. _____
CRANIAL NERVE VII	-8. NE	1. NORMAL	2. WEAK	GIVE DETAILS IF WEAK
D10.h Facial Strength				
D10.h1 Right Lower Face	☐	☐	☐	→h1.a _____
D10.h2 Right Upper Face	☐	☐	☐	→h2.a _____
D10.h3 Left Lower Face	☐	☐	☐	→h3.a _____
D10.h4 Left Upper Face	☐	☐	☐	→h4.a _____
CRANIAL NERVES VIII	-8. NE	1. NORMAL	2. ABNORMAL	GIVE DETAILS IF ABNORMAL
D10.i Hearing	☐	☐	☐	→i1. _____
CRANIAL NERVES IX, X				
D10.j Gag	☐	☐	☐	→j1. _____
D10.k Palate elevation	☐	☐	☐	→k1. _____
CRANIAL NERVE XI				
D10.l Trapezius strength	☐	☐	☐	→l1. _____
CRANIAL NERVE XII				
D10.m Tongue strength	☐	☐	☐	→m1. _____

D10.n Dysarthria ☐ -8. NE ☐ 1. ABSENT ☐ 2. MILD ☐ 3. MODERATE ☐ 4. SEVERE

D11. MOTOR FUNCTION - TONE

	-8. NE	1. NORMAL	2. INCREASED	3. DECREASED
D11.a Right arm	☐	☐	☐	☐
D11.b Right leg	☐	☐	☐	☐
D11.c Left arm	☐	☐	☐	☐
D11.d Left Leg	☐	☐	☐	☐

11.e DESCRIBE ANY ABNORMAL MOVEMENTS:

EXAMINER: MARK ANY ITEMS "NA" IF NOT APPLICABLE DUE TO AGE, OR "NE" IF NOT EVALUABLE DUE TO PHYSICAL/MENTAL CAPABILITY, OR LACK OF COOPERATION, AND EXPLAIN IN THE COMMENTS SECTION. OTHERWISE PLEASE ANSWER ALL ITEMS.

D12. STRENGTH (Circle Appropriate MRC Grade*)

D12.a Right arm	12a.p proximal	**NE**	**0**	**1**	**2**	**3**	**4**	**5**
	12a.d distal	**NE**	**0**	**1**	**2**	**3**	**4**	**5**
D12.b Right leg	12b.p. proximal	**NE**	**0**	**1**	**2**	**3**	**4**	**5**
	12b.d distal	**NE**	**0**	**1**	**2**	**3**	**4**	**5**
D12.c Left arm	12c.p proximal	**NE**	**0**	**1**	**2**	**3**	**4**	**5**
	12c.d distal	**NE**	**0**	**1**	**2**	**3**	**4**	**5**
D12.d Left Leg	12d.p proximal	**NE**	**0**	**1**	**2**	**3**	**4**	**5**
	12d.d distal	**NE**	**0**	**1**	**2**	**3**	**4**	**5**

MRC GRADE

0 = No contraction
1 = Flicker or trace of contraction
2 = Active movement, with gravity eliminated
3 = Active movement against gravity
4 = Active movement against gravity and resistance
5 = Normal power

D12.e Can the patient hop on the left foot? ☐ **-1. NA** ☐ **-8 NE** ☐ **1. NO** ☐ **2. YES**

D12.f Can the patient hop on the right foot? ☐ **-1. NA** ☐ **-8 NE** ☐ **1. NO** ☐ **2. YES**

D12.g Can the patient walk on tip toes? ☐ **-1. NA** ☐ **-8 NE** ☐ **1. NO** ☐ **2. YES**

↓

D12.g1. **IF NO**, the problem is with which foot? ☐ **1. RIGHT** ☐ **2. LEFT** ☐ **3. BOTH**

D12.h Can the patient walk on heels? ☐ **-1. NA** ☐ **-8 NE** ☐ **1. NO** ☐ **2. YES**

↓

D12.h1. **IF NO**, the problem is with which foot? ☐ **1. RIGHT** ☐ **2. LEFT** ☐ **3. BOTH**

D13. IF ANY MOTOR ITEMS ARE NOT EVALUABLE, EXPLAIN WHY:

EXAMINER: MARK ANY ITEMS "NA" IF NOT APPLICABLE DUE TO AGE, OR "NE" IF NOT EVALUABLE DUE TO PHYSICAL/MENTAL CAPABILITY, OR LACK OF COOPERATION, AND EXPLAIN IN THE COMMENTS SECTION. OTHERWISE PLEASE ANSWER ALL ITEMS.

D14. TENDON REFLEXES

Circle response:

		RIGHT							LEFT					
D14.a	Knee Jerk	**NE**	**0**	**1**	**2**	**3**	**4**	a1.	**NE**	**0**	**1**	**2**	**3**	**4**
D14.b	Ankle Jerk	**NE**	**0**	**1**	**2**	**3**	**4**	b1.	**NE**	**0**	**1**	**2**	**3**	**4**
D14.c	Biceps Jerk	**NE**	**0**	**1**	**2**	**3**	**4**	c1.	**NE**	**0**	**1**	**2**	**3**	**4**
D14.d	Triceps Jerk	**NE**	**0**	**1**	**2**	**3**	**4**	d1.	**NE**	**0**	**1**	**2**	**3**	**4**
D14.e	Brachioradialis	**NE**	**0**	**1**	**2**	**3**	**4**	e1.	**NE**	**0**	**1**	**2**	**3**	**4**

D14.f. Plantar Responses:

D14.f1. Right ☐ **-8. NE** ☐ **1. NORMAL** ☐ **2. ABNORMAL**

D14.f2. Left ☐ **-8. NE** ☐ **1. NORMAL** ☐ **2. ABNORMAL**

D15. COORDINATION

D15.a Gait ☐ **-1. NA** ☐ **-8. NE** ☐ **1. NORMAL** ☐ **2. ABNORMAI**

D15.b Can the patient balance on the left foot? ☐ **-1. NA** ☐ **-8. NE** ☐ **1. NO** ☐ **2. YES**

D15.c Can the patient balance on the right foot? ☐ **-1. NA** ☐ **-8. NE** ☐ **1. NO** ☐ **2. YES**

D15.d The fine motor coordination of the left hand is ☐ **-1. NA** ☐ **-8. NE** ☐ **1. NORMAL** ☐ **2. ABNORMAI**

D15.e The fine motor coordination of the right hand is ☐ **-1. NA** ☐ **-8. NE** ☐ **1. NORMAL** ☐ **2. ABNORMAI**

D15.f Appendicular Ataxia?

D15.f1. Right Arm ☐ **-8. NE** ☐ **1. ABSENT** ☐ **2. PRESENT**

D15.f2. Right Leg ☐ **-8. NE** ☐ **1. ABSENT** ☐ **2. PRESENT**

D15.f3. Left Arm ☐ **-8. NE** ☐ **1. ABSENT** ☐ **2. PRESENT**

D15.f4. Left Leg ☐ **-8. NE** ☐ **1. ABSENT** ☐ **2. PRESENT**

D15.g DESCRIBE ANY ABNORMALITIES WITH COORDINATION:

EXAMINER: MARK ANY ITEMS "NA" IF NOT APPLICABLE DUE TO AGE, OR "NE" IF NOT EVALUABLE DUE TO PHYSICAL/MENTAL CAPABILITY, OR LACK OF COOPERATION, AND EXPLAIN IN THE COMMENTS SECTION. OTHERWISE PLEASE ANSWER ALL ITEMS.

D16. SENSATION

	Light Touch	Pinprick
D16.a Right Arm	☐ -1. NA ☐ -8. NE ☐ 1. Normal ☐ 2. Abnormal	a1. ☐ -8. NE ☐ 1. Normal ☐ 2. Abnormal
D16.b Right Leg	☐ -1. NA ☐ -8. NE ☐ 1. Normal ☐ 2. Abnormal	b1. ☐ -8. NE ☐ 1. Normal ☐ 2. Abnormal
D16.c Left Arm	☐ -1. NA ☐ -8. NE ☐ 1. Normal ☐ 2. Abnormal	c1. ☐ -8. NE ☐ 1. Normal ☐ 2. Abnormal
D16.d Left Leg	☐ -1. NA ☐ -8. NE ☐ 1. Normal ☐ 2. Abnormal	d1. ☐ -8. NE ☐ 1. Normal ☐ 2. Abnormal
D16.e Right Face	☐ -1. NA ☐ -8. NE ☐ 1. Normal ☐ 2. Abnormal	e1. ☐ -8. NE ☐ 1. Normal ☐ 2. Abnormal
D16.f Right Trunk	☐ -1. NA ☐ -8. NE ☐ 1. Normal ☐ 2. Abnormal	f1. ☐ -8. NE ☐ 1. Normal ☐ 2. Abnormal
D16.g Left Face	☐ -1. NA ☐ -8. NE ☐ 1. Normal ☐ 2. Abnormal	g1. ☐ -8. NE ☐ 1. Normal ☐ 2. Abnormal
D16.h Left Trunk	☐ -1. NA ☐ -8. NE ☐ 1. Normal ☐ 2. Abnormal	h1. ☐ -8. NE ☐ 1. Normal ☐ 2. Abnormal

	Vibration	Proprioception
D16.a2. Right Arm	☐ -1. NA ☐ -8. NE ☐ 1. Normal ☐ 2. Abnormal	a3. ☐ -1. NA ☐ -8. NE ☐ 1. Normal ☐ 2. Abnormal
D16.b2. Right Leg	☐ -1. NA ☐ -8. NE ☐ 1. Normal ☐ 2. Abnormal	b3. ☐ -1. NA ☐ -8. NE ☐ 1. Normal ☐ 2. Abnormal
D16.c2. Left Arm	☐ -1. NA ☐ -8. NE ☐ 1. Normal ☐ 2. Abnormal	c3. ☐ -1. NA ☐ -8. NE ☐ 1. Normal ☐ 2. Abnormal
D16.d2. Left Leg	☐ -1. NA ☐ -8. NE ☐ 1. Normal ☐ 2. Abnormal	d3. ☐ -1. NA ☐ -8. NE ☐ 1. Normal ☐ 2. Abnormal

D16.i If sensation is not evaluable, explain why:

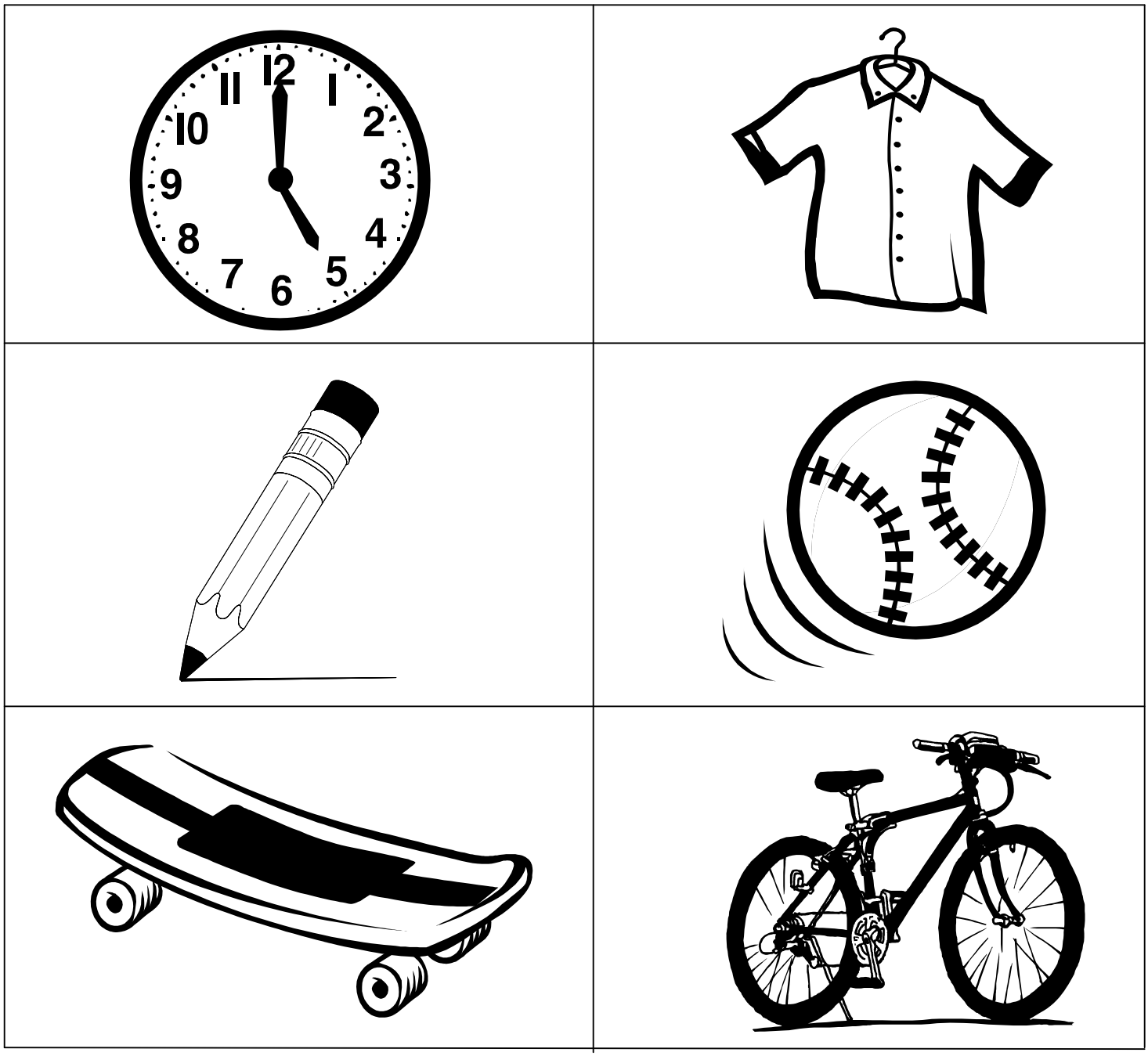
D. EXAMINERS ASSESSMENT - FOR EVENT ONLY:

D17. Was this event a stroke (pick one)?

- ☐ **1. Definitely yes**
- ☐ **2. Probably yes**
- ☐ **3. Unclear**
- ☐ **4. Probably not**
- ☐ **5. Definitely not**

D2. Naming to Confrontation

Ask patient to identify:



D5. Reading

Ask the patient to read:

1. Stop.

2. See the dog run.

3. Little children like to play outdoors.

D6. Writing

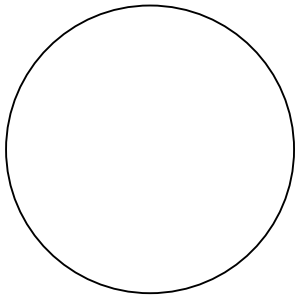
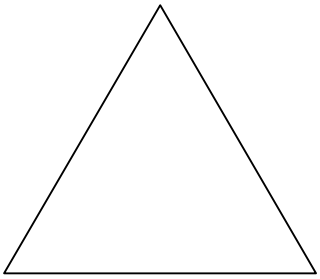
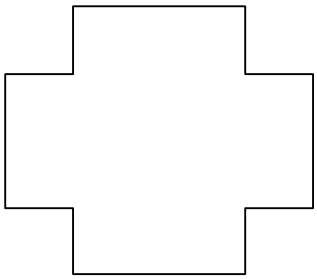
1. _____

2. _____

3. _____

D7. Drawing

Ask patient to copy these drawings:

	
	
	
Ask patient to place an “X” in the middle of these lines: 	

STOP II TRIAL
HEAD MRI SCAN

AFFIX PATIENT LABEL

HERE

SECTION A TO BE COMPLETED BY STOP II NEURORADIOLOGIST

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

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

A3. Was the patient's MRI data copied to a STOP II optical disk? ☐ **1. NO** ☐ **2. YES**

↓

A3.a What is the file name of the patient's MR study on the STOP II Optical Disk?

_____

A4. Was DWI performed (<u>required</u> only for suspected neurological events)? ☐ **1. NO** ☐ **2. YES** ☐ **-1 N/A**

A5. Is the MRI study adequate for interpretation? ☐ **1. NO** ☐ **2. YES**

↓

A5.a. Reason
- ☐ 1. Incomplete Study
- ☐ 2. Motion Artifact
- ☐ 3. Other

↓

A5.b Specify:_____

_____

RESCHEDULE STUDY WITHIN 2 WEEKS

A6. Is there evidence for any of the following?

A6.a. Aneurysm ☐ 1. NO ☐ 2. YES

↓

A6.a1. Location: _____

A6.b. Arteriovenous malformation ☐ 1. NO ☐ 2. YES

↓

A6.b1. Location: _____

A6.c. Tumor ☐ 1. NO ☐ 2. YES

↓

A6.c1. Location: _____

****IF THE ANSWER TO ANY OF QUESTIONS A6.a. – A6.c. IS YES, PLEASE CONTACT CENTER INVESTIGATOR ****

☐ ML ☐ DE

SECTION B TO BE COMPLETED BY STUDY COORDINATOR

B1. Reason for MRI procedure:

☐ 1. Pre-Randomization Study ☐ 2. Routine Follow-up Study

☐ 3. Exit from Study ☐ 4. TCD Endpoint or 3 inadequate TCD exams by at least 2 examiners

☐ 5. New Neurological Event

↓

B1.a. Date of event (Month/Day Year) ___ ___/___ ___/___ ___ ___ ___

B1.b. Type of event:

☐ 1. TIA

☐ 2. Cerebral Infarction

☐ 3. Intracranial Hemorrhage →B1.b1. Type ☐ 1. Intraparenchymal ☐ 2. Subarachnoid ☐ 3. Intraventricular

☐ 4. Other: → B1.b2. Specify: _____

☐ 6. Post-meningitis event → B1.c. Date of event (Month/Day/Year) ___ ___/___ ___/___ ___ ___ ___

B1.d. Date of discharge from hospital (Month/Day/Year) ___ ___/___ ___/___ ___ ___ ___

☐ 7. Post-head injury event → B1.e. Date of event (Month/Day/Year) ___ ___/___ ___/___ ___ ___ ___

B1.f. Date of discharge from hospital (Month/Day/Year) ___ ___/___ ___/___ ___ ___ ___

B2. Date optical disk with MRI study sent to the STOP II Data Coordinating Center (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___

SECTION C TO BE COMPLETED BY DCC DATA MANAGER

C1. Is this MRI scan being compared to a previous scan? ☐ 1. NO ☐ 2. YES

↓

Which Scan(s)?
C.1.a. Pre-randomization scan dated ___ ___/___ ___/___ ___ ___ ___
C.1.b. Previous scan dated ___ ___/___ ___/___ ___ ___ ___

C2. Are event CT scans enclosed? ☐ 1. NO ☐ 2. YES

↓

C2.a. Date of CT scan (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___
C2.b. Date of neurological event (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___

C3. Type of neurological event:

☐ 1. TIA
☐ 2. Cerebral Infarction
☐ 3. Intracranial Hemorrhage → C3.a. Type
  ☐ 1. Intraparenchymal
  ☐ 2. Subarachnoid
  ☐ 3. Intraventricular
☐ 4. Other: → C3.b Specify: _____

C4. Reason event CT scan enclosed for review (CHECK ALL APPLICABLE):

☐ 1. MRI was not performed
☐ 2. Patient had an intracranial hemorrhage
☐ 3. Other: → C4.a Specify: _____

SECTIONS D - J TO BE COMPLETED BY READERS

D1. Readers: a. (Name): _____ (Initials): | | | |

b. (Name): _____ (Initials): | | | |

D2 Date read (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___

D3. Study acceptable for interpretation? ☐ 1. NO ☐ 2. YES

↓

D3.a. Reason: _____

_____

D4. **SCAN QUALITY (CHECK ONE):**

☐ 1. Excellent

☐ 2. Slight Artifact/Motion, Adequate

☐ 3. Severe Artifact/Motion, Inadequate

D5. **DWI**

D5.a Are DWI films available for review for this study? ☐ **1. NO**

☐ **2. YES**

E1. ATROPHY (CHECK ONE):

☐ 1. No atrophy ☐ 2. Atrophy ☐ 3. Equivocal

Type of atrophy:

E2. GENERAL: ☐ 1. NO ☐ 2. YES

- a. Sulcal ☐ 1. NO ☐ 2. YES
- b. Ventricular ☐ 1. NO ☐ 2. YES
- c. Level of severity ☐ 1. MILD ☐ 2. MODERATE ☐ 3. SEVERE

E3. FOCAL: ☐ 1. NO ☐ 2. YES

- a. Sulcal ☐ 1. NO ☐ 2. YES
- b. Ventricular ☐ 1. NO ☐ 2. YES
- c. Specify Area(s): c1. _____

USE THE FOLLOWING CODES FOR QUESTIONS E4 AND E5

CODES
A. IMPROVED
B. SAME
C. NEW
D. WORSE
E. CANNOT DETERMINE
F. N/A

	a. Pre-randomization Study	**b. Previous Study**
E4. Status of *Generalized* atrophy compared to: **(Enter Code)**	☐	☐
E5. Status of *Focal* atrophy compared to: **(Enter Code)**	☐	☐

If NEW, specify new area(s):

a1. _____ b1. _____

a2. _____ b2. _____

a3. _____ b3. _____

F. DISCRETE FINDINGS (COMPLETE TABLE FOR UP TO 7 LESIONS USING THE CODES BELOW)

SIDE:	TYPE:	SIZE:	LOCATION:	STATUS:
R = Right L = Left	H = Hemorrhage I = Infarct HI = Hemorrhagic Infarct	0 = Small (punctate) (few mm) 1 = Medium (ovoid) (0.5 - 1.5 cm) 2 = Large (geographic) (≥ 1.5 cm)	0 = Frontal 1 = Temporal 2 = Parietal 3 = Occipital 4 = Basal ganglia or Thalamic (caudate, putamen, globus pallidus) 5 = Cortex 6 = Capsular/Corona 7 = Deep white matter or periventricular 8 = Brain stem 9 = Cerebellum 10 = Subarachnoid 11 = Intraventricular	A = Improved B = Same (no progression) C = NEW lesion D = Worse (progression) E = Cannot determine F = N/A

	a.	b.	c.	d.	e.	f.	g.	h.	i.
				LOCATION(S)				STATUS COMPARED TO	
LESION NUMBER	SIDE	TYPE	SIZE	1	2	3	4	Pre-rand. Study	Previous Study
1.									
2.									
3.									
4.									
5.									
6.									
7.									

G. VASCULATURE (COMPLETE THE TABLE USING THE FOLLOWING CODES):

DESCRIPTION CODES:
0 = NOT SEEN (Technically)
1 = VISUALIZED - PATENT
2 = OCCLUDED

	a. RIGHT	b. LEFT
G1. Internal carotid: cavernous		
G2. Internal carotid: supraclinoid		
G3. MCA		
G4. ACA		
G5. PCA		
G6. Basilar		

G7. Collateral Blood Vessels **(CHECK ONE):** ☐ 1. RIGHT ☐ 2. LEFT ☐ 3. BOTH ☐ 4. NOT PRESENT

USE THE CODES TO THE RIGHT FOR QUESTION G8

CODES
A. IMPROVED
B. SAME
C. NEW
D. WORSE
E. CANNOT DETERMINE
F. N/A

	a. Pre-rand. Study	b. Previous Study
G8. Status of vasculature compared to: **(Enter Code)**		

H1. BONY CHANGES (CHECK ONE):

☐ 1. Normal ☐ 2. Diffuse thickening ☐ 3. Focal abnormality

↓

H1.a. Specify: _____

_____

_____

USE THE CODES TO THE RIGHT FOR QUESTION H2

CODES
A. IMPROVED
B. SAME
C. NEW
D. WORSE
E. CANNOT DETERMINE
F. N/A

		a. Pre-rand. Study	b. Previous Study
H2. Status of bony changes compared to:	**(Enter Code)**		

I. COMMENTS:

J. EVENT CT SCANS

J1. Were CT films reviewed? ☐ 1. NO → **FORM COMPLETE** ☐ 2. YES → **CONTINUE TO J2**

J2. ATROPHY ON CT SCAN (CHECK ONE):

☐ 1. No atrophy ☐ 2. Atrophy ☐ 3. Equivocal

Type of atrophy:

a1. GENERAL: ☐ 1. NO ☐ 2. YES

a. Sulcal	☐ 1. NO	☐ 2. YES	
b. Ventricular	☐ 1. NO	☐ 2. YES	
c. Level of severity	☐ 1. MILD	☐ 2. MODERATE	☐ 3. SEVERE

a2. FOCAL: ☐ 1. NO ☐ 2. YES

a. Sulcal	☐ 1. NO	☐ 2. YES
b. Ventricular	☐ 1. NO	☐ 2. YES

c. Specify Area(s): c1. _____

J3. Does the CT scan show evidence of intracranial hemorrhage? ☐ 1. NO ☐ 2. YES

Type:	**1. NO**	**2. YES**
a. Subarachnoid	☐	☐
b. Intraventricular	☐	☐
c. Subdural	☐	☐
d. Epidural	☐	☐
e. Intraparenchymal	☐	☐

J4. DISCRETE FINDINGS ON CT SCAN (COMPLETE TABLE FOR UP TO 7 LESIONS USING THE CODES BELOW)

SIDE:	TYPE:	SIZE:	LOCATION:	STATUS:
R = Right L = Left	H = Hemorrhage I = Infarct HI = Hemorrhagic Infarct	0 = Small (Punctate) (few mm) 1 = Medium (ovoid) (0.5 - 1.5 cm) 2 = Large (geographic) (≥ 1.5 cm)	0 = Frontal 1 = Temporal 2 = Parietal 3 = Occipital 4 = Basal ganglia or Thalamic (caudate, putamen, globus pallidus) 5 = Cortex 6 = Capsular/Corona 7 = Deep white matter or periventricular 8 = Brain stem 9 = Cerebellum 10 = Subarachnoid 11 = Intraventricular	A = Acute B = Subacute C = Chronic

	a.	b.	c.	d.	e.	f.	g.	h.
				LOCATION(S)				
LESION NUMBER	SIDE	TYPE	SIZE	1	2	3	4	STATUS
1.								
2.								
3.								
4.								
5.								
6.								
7.								

STOP II TRIAL

EVENT CT SCAN

AFFIX PATIENT'S LABEL HERE

SUBMIT THIS FORM AND FOUR COPIES (ORIGINALS IF AVAILABLE) OF EACH CT FILM OF HEAD ONLY IF:

1) **CT SCAN (BUT NO MRI) WAS PERFORMED FOLLOWING A NEUROLOGICAL EVENT**
2) **PATIENT HAD AN INTRACRANIAL HEMORRHAGE**
3) **PRINCIPAL INVESTIGATOR FEELS CT SCAN IS CRITICAL TO UNDERSTANDING THE EVENT**

THIS FORM IS TO BE COMPLETED BY PRINCIPAL INVESTIGATOR OR STUDY COORDINATOR

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

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

A3. Date of Neurological Event for which CT scan was performed (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___

A4. Reason CT films submitted **(CHECK NO OR YES FOR EACH OF a THROUGH c)**

a. Was an MRI performed? ☐ **1. NO** ☐ **2. YES**

↓

A4.a1. **IF NO**, specify reason
_____

b. Did the patient have an intracranial hemorrhage? ☐ **1. NO** ☐ **2. YES**

c. Did the Principal Investigator request a review? ☐ **1. NO** ☐ **2. YES**

↓

A4.c1. **IF YES**, specify reason
_____

☐ ML ☐ DE

SECTIONS B - C TO BE COMPLETED BY READERS (F15J)

B1. Readers: a. (Name): _____ (Initials): | | | |

b. (Name): _____ (Initials): | | | |

B2 Date read (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___

B3. Study acceptable for interpretation? ☐ 1. NO ☐ 2. YES

↓

B3.a. Reason: _____

_____

B4. **SCAN QUALITY (CHECK ONE):**

☐ 1. Excellent

☐ 2. Slight Artifact/Motion, Adequate

☐ 3. Severe Artifact/Motion, Inadequate

C1. ATROPHY ON CT SCAN (CHECK ONE):

☐ 1. No atrophy ☐ 2. Atrophy ☐ 3. Equivocal

Type of atrophy:

a1. GENERAL: ☐ 1. NO ☐ 2. YES

a. Sulcal	☐ 1. NO	☐ 2. YES	
b. Ventricular	☐ 1. NO	☐ 2. YES	
c. Level of severity	☐ 1. MILD	☐ 2. MODERATE	☐ 3. SEVERE

a2. FOCAL: ☐ 1. NO ☐ 2. YES

a. Sulcal	☐ 1. NO	☐ 2. YES
b. Ventricular	☐ 1. NO	☐ 2. YES

c. Specify Area(s): c1. _____

C2. Does the CT scan show evidence of intracranial hemorrhage? ☐ 1. NO ☐ 2. YES

Type:	1. NO	2. YES
a. Subarachnoid	☐	☐
b. Intraventricular	☐	☐
c. Subdural	☐	☐
d. Epidural	☐	☐
e. Intraparenchymal	☐	☐

C3. DISCRETE FINDINGS ON CT SCAN (COMPLETE TABLE FOR UP TO 7 LESIONS USING THE CODES BELOW)

SIDE:	TYPE:	SIZE:	LOCATION:	STATUS:
R = Right L = Left	H = Hemorrhage I = Infarct HI = Hemorrhagic Infarct	0 = Small (Punctate) (few mm) 1 = Medium (ovoid) (0.5 - 1.5 cm) 2 = Large (geographic) (≥ 1.5 cm)	0 = Frontal 1 = Temporal 2 = Parietal 3 = Occipital 4 = Basal ganglia or Thalamic (caudate, putamen, globus pallidus) 5 = Cortex 6 = Capsular/Corona 7 = Deep white matter or periventricular 8 = Brain stem 9 = Cerebellum 10 = Subarachnoid 11 = Intraventricular	A = Acute B = Subacute C = Chronic

	a.	b.	c.	d.	e.	f.	g.	h.
				LOCATION(S)				
LESION NUMBER	SIDE	TYPE	SIZE	1	2	3	4	STATUS
1.								
2.								
3.								
4.								
5.								
6.								
7.								

C4. COMMENTS:

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**

STOP II TRIAL
QUARTERLY PROGRESS REPORT FOR NON-RANDOMIZED PATIENTS RECEIVING TRANSFUSIONS

*** 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-F):

☐ 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 G 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 QUASI-ADJUDICATION NEUROLOGICAL EVENT FORM Q30, NEUROLOGICAL EVALUATION REPORT, MRI REPORT, CT SCAN REPORT (IF DONE), AND SUPPORTING HOSPITAL SUMMARIES					
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	___ ___/___ ___/___ ___ ___ ___				
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)*					

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*	☐	☐	☐	__ __/__ __ __ __	☐
15. **Other*** *(**PROBE**: Was the child seen for any other clinical events? What events?)*	☐	☐	☐	__ __/__ __ __ __	_____

↓

C1.a15.a. IF YES, Specify:

_____

_____

☐☐☐.☐☐ OFFICE USE

☐☐☐.☐☐ OFFICE USE

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)*	☐	☐	☐	__ __/__ __ __ __	☐
2. **Surgery*** *(**PROBE**: An operation or a medical procedure requiring general anesthesia)*	☐	☐	☐	__ __/__ __ __ __	☐

↓

C2.a2.a. IF YES, Specify:

_____

_____

☐☐☐.☐☐ OFFICE USE

☐☐☐.☐☐ OFFICE USE

C3. Does the patient currently have a portacath? ☐ **1. NO** ☐ **2. YES**

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

D. NEUROLOGICAL SIGNS AND SYMPTOMS

D1. Has the patient developed a new neurologic problem, been hospitalized for a neurological event, or been seen by a neurologist because of a new neurologic problem?

☐ **1. NO** ☐ **2. YES**

D1.a. Please give brief details:

_____

_____

_____

E. OTHER MEDICAL CONDITIONS

(SECTIONS E – G 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	☐	☐

	1. NO	2. YES
E12. Tuberculosis	☐	☐
E13. Cancer	☐	☐

13b. If Yes, specify type: _____

☐☐☐.☐☐ OFFICE USE

E14. Priapism	☐	☐
E15. Elevated blood lead level (blood lead level ≥ 15 mg/dl?)	☐	☐
E16. New red cell antibody	☐	☐

↓

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

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

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

STOP II TRIAL

QUARTERLY MEDICAL RECORD REVIEW

AFFIX PATIENT'S LABEL HERE

THIS FORM IS TO BE COMPLETED AS SOON AS POSSIBLE AFTER EACH QUARTERLY PROGRESS REPORT IS COMPLETED. PLEASE REVIEW MEDICAL RECORDS FOR THE TIME PERIOD COVERED BY THE QUARTERLY PROGRESS REPORT IN ORDER TO CORROBORATE THE OCCURRENCE/NON-OCCURRENCE OF EVENTS LISTED ON PAGES 2 AND 3 OF THE QUARTERLY PROGRESS REPORT. IF THE PATIENT WAS SEEN FOR AN EVENT AT A NON-STOP II STUDY SITE, MEDICAL RECORDS FROM THAT SITE SHOULD ALSO BE CHECKED AND/OR APPROPRIATE MEDICAL PERSONNEL CONTACTED. PLEASE MAKE SURE TO COMPLETE THE APPROPRIATE STOP II STUDY EVENT FORM*:

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

A2. Date form completed (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___

A3. Date Quarterly Progress Report completed (Month/Day/Year) ___ ___/___ ___/___ ___ ___ ___

A4. STOP II Patient group: ☐ **1. POTENTIAL CANDIDATE** ☐ **2. RANDOMIZED PATIENT**

B. DOCUMENTATION OF CLINICAL EVENTS

During the period covered in the Quarterly Progress Report, indicate if the occurrence of each of the following events was documented by medical records and/or medical personnel:

Event	Event Documented	# of Events	Date of Event	Where was patient seen for event? **1 = STOP II Center 2 = Non-STOP II Center**	Was STOP II event form* completed? (see below)
	1. NO	**2. YES**			**1. NO** **2. YES**
B1. Stroke	☐	☐ → a. ☐	b. __ __/__ __/__ __ __ __	c. ☐	d. ☐ ☐
			e. __ __/__ __/__ __ __ __	f. ☐	g. ☐ ☐
B2. TIA	☐	☐ → a. ☐	b. __ __/__ __/__ __ __ __	c. ☐	d. ☐ ☐
			e. __ __/__ __/__ __ __ __	f. ☐	g. ☐ ☐
B3. Seizures	☐	☐ → a. ☐	b. __ __/__ __/__ __ __ __	c. ☐	d. ☐ ☐
			e. __ __/__ __/__ __ __ __	f. ☐	g. ☐ ☐
B4. Splenic Sequestration	☐	☐ → a. ☐	b. __ __/__ __/__ __ __ __	c. ☐	d. ☐ ☐
			e. __ __/__ __/__ __ __ __	f. ☐	g. ☐ ☐

FOR A RANDOMIZED PATIENT:
*** Complete FORM 30 for each documented neurological event (stroke, TIA, or seizures)**
*** Complete FORMS 20 and 21 for each documented transfusion**
*** Complete FORM 32 for each documented delayed transfusion reaction**
*** Complete FORM 31 for all other types of documented clinical events**
FOR A POTENTIAL CANDIDATE:
*** Complete FORM Q30 for each documented neurological event**

☐ ML ☐ DE

Event	Event Documented		# of Events	Date of Event	Where was patient seen for event? 1 = STOP II Center 2 = Non-STOP II Center	Was STOP II event form* completed?	
	1. NO	**2. YES**				**1. NO**	**2. YES**
B5. Aplastic Crisis	☐	☐ → a.	☐	b. __ __/__ __/__ __ __ __	c. ☐	d. ☐	☐
				e. __ __/__ __/__ __ __ __	f. ☐	g. ☐	☐
B6. Hand-Foot Syndrome	☐	☐ → a.	☐	b. __ __/__ __/__ __ __ __	c. ☐	d. ☐	☐
				e. __ __/__ __/__ __ __ __	f. ☐	g. ☐	☐
B7. Vaso-occlusive pain event for which patient was hospitalized	☐	☐ → a.	☐	b. __ __/__ __/__ __ __ __	c. ☐	d. ☐	☐
				e. __ __/__ __/__ __ __ __	f. ☐	g. ☐	☐
				h. __ __/__ __/__ __ __ __	i. ☐	j. ☐	☐
				k. __ __/__ __/__ __ __ __	l. ☐	m. ☐	☐
B8. Fever ≥ 101°F (39°C)	☐	☐ → a.	☐	b. __ __/__ __/__ __ __ __	c. ☐	d. ☐	☐
				e. __ __/__ __/__ __ __ __	f. ☐	g. ☐	☐
				h. __ __/__ __/__ __ __ __	i. ☐	j. ☐	☐
				k. __ __/__ __/__ __ __ __	l. ☐	m. ☐	☐
B9. Septicemia	☐	☐ → a.	☐	b. __ __/__ __/__ __ __ __	c. ☐	d. ☐	☐
				e. __ __/__ __/__ __ __ __	f. ☐	g. ☐	☐
				h. __ __/__ __/__ __ __ __	i. ☐	j. ☐	☐
B10. Pneumonia/ Acute Chest Syndrome	☐	☐ → a.	☐	b. __ __/__ __/__ __ __ __	c. ☐	d. ☐	☐
				e. __ __/__ __/__ __ __ __	f. ☐	g. ☐	☐
				h. __ __/__ __/__ __ __ __	i. ☐	j. ☐	☐
				k. __ __/__ __/__ __ __ __	l. ☐	o. ☐	☐

FOR A RANDOMIZED PATIENT:
*** Complete FORM 30 for each documented neurological event (stroke, TIA, or seizures)**
*** Complete FORMS 20 and 21 for each documented transfusion**
*** Complete FORM 32 for each documented delayed transfusion reaction**
*** Complete FORM 31 for all other types of documented clinical events**
FOR A POTENTIAL CANDIDATE:
*** Complete FORM Q30 for each documented neurological event**

Event	Event Documented **1. NO 2. YES**	# of Events	Date of Event	Where was patient seen for event? **1 = STOP II Center** **2 = Non-STOP II Center**	Was STOP II event form* completed? **1. NO 2. YES**
B11. Meningitis or Encephalitis	☐ ☐ →	a. ☐	b. __ __/__ __/__ __ __ __	c. ☐	d. ☐ ☐
			e. __ __/__ __/__ __ __ __	f. ☐	g. ☐ ☐
B12. Osteomyelitis	☐ ☐ →	a. ☐	b. __ __/__ __/__ __ __ __	c. ☐	d. ☐ ☐
			e. __ __/__ __/__ __ __ __	f. ☐	g. ☐ ☐
B13. Priapism	☐ ☐ →	a. ☐	b. __ __/__ __/__ __ __ __	c. ☐	d. ☐ ☐
			e. __ __/__ __/__ __ __ __	f. ☐	g. ☐ ☐
B14. Transfusion Reaction	☐ ☐ →	a. ☐	b. __ __/__ __/__ __ __ __	c. ☐	d. ☐ ☐
			e. __ __/__ __/__ __ __ __	f. ☐	g. ☐ ☐
B15. Other	☐ ☐ →	a. ☐			

IF YES, specify event(s) below

a.1 _____	b.1 __ __/__ __/__ __ __ __	c.1 ☐	d.1 ☐ ☐
a.2 _____	b.2 __ __/__ __/__ __ __ __	c.2 ☐	d.2 ☐ ☐
a.3 _____	b.3 __ __/__ __/__ __ __ __	c.3 ☐	d.3 ☐ ☐

B16. Transfusion	☐ ☐ → a. ☐	b. __ __/__ __/__ __ __ __	c. ☐ d. ☐ ☐
		e. __ __/__ __/__ __ __ __	f. ☐ g. ☐ ☐
		h. __ __/__ __/__ __ __ __	i. ☐ j. ☐ ☐
		k. __ __/__ __/__ __ __ __	l. ☐ m. ☐ ☐
		n. __ __/__ __/__ __ __ __	o. ☐ p. ☐ ☐
B17. Surgery	☐ ☐ → a. ☐		

IF YES, specify surgical procedures below

a.1 _____	b.1 __ __/__ __/__ __ __ __	c.1 ☐	d.1 ☐ ☐
a.2 _____	b.2 __ __/__ __/__ __ __ __	c.2 ☐	d.2 ☐ ☐
a.3 _____	b.3 __ __/__ __/__ __ __ __	c.3 ☐	d.3 ☐ ☐

FOR A RANDOMIZED PATIENT:
*** Complete FORM 30 for each documented neurological event (stroke, TIA, or seizures)**
*** Complete FORMS 20 and 21 for each documented transfusion**
*** Complete FORM 32 for each documented delayed transfusion reaction**
*** Complete FORM 31 for all other types of documented clinical events**
FOR A POTENTIAL CANDIDATE:
*** Complete FORM Q30 for each documented neurological event**

STOP II TRIAL

MISSED FOLLOW-UP VISIT FOR POTENTIAL OR RANDOMIZED PATIENTS

****AFFIX PATIENT LABEL HERE****

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

A2. Date form completed (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___

B1. Did patient miss a quarterly visit? ☐ **1. NO** ☐ **2. YES**
B1.a **IF YES**, reason_____

B2. Did patient miss a TCD exam? ☐ **1. NO** ☐ **2. YES**
B2.a **IF YES**, reason_____

B3. Did patient withdraw consent to continue follow-up in study? ☐ **1. NO** ☐ **2. YES**
B3.a **IF YES**, reason_____

B4. Was patient lost to follow-up (address and telephone number unknown)? ☐ **1. NO** ☐ **2. YES**

B5. Did patient die? ☐ **1. NO** ☐ **2. YES**

↓

B5.a Date of death (month/day/year): ___ ___/___ ___/___ ___ ___ ___

COMPLETE CAUSE OF DEATH FORM

☐ ML ☐ DE

STOP II TRIAL

REASON FOR OVERDUE TCD EXAM VISIT FOR RANDOMIZED PATIENT

****AFFIX PATIENT LABEL HERE****

A. OVERDUE TCD EXAM IDENTIFIER INFORMATION

A1. Person completing form (Initials) [ ] [ ] [ ]

A2. Date form completed (Month/Day/Year) ___ ___/___ ___/___ ___ ___ ___

A3. TCD exam number of overdue TCD EX- ___ ___ ___

A4. Is this the first Form 18T submitted for this exam number?

NO .....1 (**SKIP TO B1.b**)

YES 2

B. REASON FOR OVERDUE OR MISSED TCD EXAM

B1. Was a TCD exam scheduled?

NO..... 1

YES..... 2 (**SKIP TO Q. B1.b**)

B1.a. Reason that TCD exam was not scheduled

PATIENT LOST-TO -FOLLOW-UP.....1 **[STOP- FORM COMPLETE]**

PATIENT REFUSING 2

PATIENT MOVED .....3 [**STOP – FORM COMPLETE]**

PATIENT ILL.....4

TCD EXAMINER NOT AVAILABLE TO PERFORM STUDY 5

OTHER 99

B1.a1. If OTHER, specify _____

_____

(**GO TO Q. B.2**)

B1.b. Number of missed TCD exam visits for this exam number that were not previously reported: ____

a. Date of Scheduled TCD Exam Visit	b. Reason TCD Exam Visit was Missed (See code list below)	c. Specify reason if "Other"
1. ___ ___ / ___ ___ / ___ ___ ___ ___ M M D D Y Y Y Y	___ ___	
2. ___ ___ / ___ ___ / ___ ___ ___ ___ M M D D Y Y Y Y	___ ___	
3. ___ ___ / ___ ___ / ___ ___ ___ ___ M M D D Y Y Y Y	___ ___	
4. ___ ___ / ___ ___ / ___ ___ ___ ___ M M D D Y Y Y Y	___ ___	

Reason for Missed TCD Exam Visit Code List **(Enter code for primary reason patient missed TCD exam visit)**
01 Patient did not show up for scheduled visit
02 Patient was ill or experiencing or recovering from an acute event on the date of the scheduled visit
03 Patient lost to follow-up
04 Patient moved
05 TCD examiner was not available to perform TCD
06 TCD machine malfunction
99 Other (if Other, specify reason in Column c)

B2. Has the patient been scheduled/rescheduled for a TCD exam visit?

NO..... 1

YES..... 2

B2.a Date of next scheduled TCD exam visit (Month/Day/Year):

__ __ / __ __ / __ __ __ __

STOP II TRIAL
MRA SCAN

AFFIX PATIENT LABEL

HERE

SECTION A TO BE COMPLETED BY STOP II NEURORADIOLOGIST

A1. Person completing form (Name): _____ (Initials): [ ][ ][ ]

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

A3. Was the patient's MRA data copied to a STOP II optical disk? [ ] **1. NO** [ ] **2. YES**

↓

A3.a What is the file name of the patient's MR study on the STOP II optical disk?

_____

A4. Is the MRA study adequate for interpretation? [ ] **1. NO** [ ] **2. YES**

↓

A4.a. Reason:

[ ] 1. Incomplete Study [ ] 2. Motion Artifact [ ] 3. Other → A4.b Specify:_____

RESCHEDULE STUDY WITHIN 2 WEEKS _____

A5. Name of Imaging Center: _____

A6. Machine/Model: _____

A7. Echo Time (ms): [ ] . [ ]

A8. Matrix: [ ][ ][ ] **X** [ ][ ][ ]

A9. Field-of-View (range: 6 - 20 cm):

a. [ ][ ] (if square)

b. [ ][ ] **X** [ ][ ] (if rectangular)

[ ] ML [ ] DE

SECTION B TO BE COMPLETED BY STUDY COORDINATOR

B1. Reason for MRA procedure:

1. Pre-Randomization Study
2. Routine Follow-up Study
3. Exit from Study
4. TCD Endpoint or 3 inadequate TCD exams by at least 2 examiners
5. New Neurological Event

↓

B1.a. Date of event (Month/Day Year) ___ ___/___ ___/___ ___ ___ ___

B1.b. Type of event:

1. TIA
2. Cerebral Infarction
3. Intracranial Hemorrhage → B1.b1. Type 1. Intraparenchymal 2. Subarachnoid 3. Intraventricular
4. Other: B1.b2. Specify: _____

6. Post-meningitis event → B1.c. Date of event (Month/Day/Year) ___ ___/___ ___/___ ___ ___ ___

B1.d. Date of discharge from hospital (Month/Day/Year) ___ ___/___ ___/___ ___ ___ ___

7. Post-head injury event → B1.e. Date of event (Month/Day/Year) ___ ___/___ ___/___ ___ ___ ___

B1.f. Date of discharge from hospital (Month/Day/Year) ___ ___/___ ___/___ ___ ___ ___

B2. Date optical disk with MRA study sent to the STOP II Data Coordinating Center (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___

SECTION C TO BE COMPLETED BY DCC DATA MANAGER

C1. Is this MRA scan being compared to a previous scan? ☐ **1. NO** ☐ **2. YES**

↓

Which Scan(s)?

C1.a. Pre-randomization study dated ___ ___/___ ___/___ ___ ___ ___

C1.b. Previous scan dated ___ ___/___ ___/___ ___ ___ ___

SECTIONS D - F TO BE COMPLETED BY READERS

D1. Readers: a. (Name): _____ (Initials): | | | |

b. (Name): _____ (Initials): | | | |

D2. Date read (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___

D3. Study acceptable for interpretation? ☐ **1. NO** ☐ **2. YES**

↓

D3.a. Reason: _____

_____

D4. Scan Quality (check one):

☐ 1. Excellent

☐ 2. Slight Artifact/Motion, Adequate

☐ 3. Severe Artifact/Motion, Inadequate

D5. Are the following available for review?

	1. NO	**2. YES**
a. Source images	☐	☐
b. Targeted MIP images	☐	☐
c. Unsegmented paraxial images	☐	☐

E. CENTRAL REVIEW INTERPRETATION (COMPLETE TABLE FOR MRA USING THE CODES BELOW)

a. RATING	b. STATUS
1 = NORMAL 2 = STENOSIS, MILD 3 = STENOSIS, MODERATE 4 = STENOSIS, SEVERE 5 = OCCLUSION 6 = NOT ASSESSABLE 7 = DEPHASING ARTIFACT, LIKELY NORMAL	A = IMPROVED B = SAME (NO PROGRESSION) C = WORSE (PROGRESSION) D = CANNOT DETERMINE E = N/A

		RATING	STATUS COMPARED TO Pre-rand. Study	STATUS COMPARED TO Previous Study
E1.	RIGHT ICA	a. ☐	b1. ☐	b2. ☐
E2.	RIGHT MCA	a. ☐	b1. ☐	b2. ☐
E3.	RIGHT ACA	a. ☐	b1. ☐	b2. ☐
E4.	RIGHT PCA	a. ☐	b1. ☐	b2. ☐
E5.	LEFT ICA	a. ☐	b1. ☐	b2. ☐
E6.	LEFT MCA	a. ☐	b1. ☐	b2. ☐
E7.	LEFT ACA	a. ☐	b1. ☐	b2. ☐
E8.	LEFT PCA	a. ☐	b1. ☐	b2. ☐
E9.	BASILAR	a. ☐	b1. ☐	b2. ☐

		1. NORMAL	2. SMALL	3. NOT VISUALIZED		
E10.a	RIGHT PCoA	☐	☐	☐	b1. ☐	b2. ☐
E11.a	LEFT PCoA	☐	☐	☐	b1. ☐	b2. ☐

		1. GOOD	2. POOR	3. INDETERMINATE		
E12.a	Robustness of R. hemisphere blood flow	☐	☐	☐	b1. ☐	b2. ☐
E13.a	Robustness of L. hemisphere blood flow	☐	☐	☐	b1. ☐	b2. ☐

F. COMMENTS:

STOP II TRIAL

TRANSFUSION FORM

*** AFFIX PATIENT LABEL HERE ***

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

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

A3. Reason for this transfusion:

- ☐ **1. STOP II TRIAL Transfusion for Primary Stroke Prevention**
- ☐ **2. Acute Anemic Episode**
- ☐ **3. Acute Chest Event**
- ☐ **4. CVA**
- ☐ **5. Surgery**
- ☐ **6. Priapism**
- ☐ **7. Other Reason (SPECIFY):** A3.a _____

A4. Date of most recent prior transfusion: ___ ___/___ ___/___ ___ ___ ___ ☐ **UNKNOWN**

B. PHYSICAL EXAMINATION PRIOR TO TRANSFUSION

B1. Weight (kg) | | | | . |

B2. Blood pressure (supine) (Sys/Dia) a. | | | / b. | | |

B3. Spleen size (distance below LCM at MCL) | | cm

B4. Physical Examination ☐ **1. NORMAL** ☐ **2. ABNORMAL** ↓

B4.a **List Abnormalities**

_____

_____

_____

C. TRANSFUSION SUMMARY

C1. Total number of units transfused | | → **COMPLETE FORM 21 FOR EACH** ↓

C1.a Total mL in | | | |

C2. Time transfusion started | | : | | C2.a ☐ **1. AM** ☐ **2. PM**

C3. Time transfusion stopped | | : | | C3.a ☐ **1. AM** ☐ **2. PM**

C4. Was total planned volume given? ☐ **1. NO** ☐ **2. YES** ↓

C4.a Reason: _____

☐ **ML** ☐ **DE**

D. PRE-TRANSFUSION LABORATORY TEST RESULTS:

D1. CBC *

D1.a Date blood drawn (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___

D1.b Hemoglobin (g/dl) ☐☐ . ☐

D1.c Hematocrit (%) ☐☐ . ☐

D1.d White Cell Count (x 10 ^{9}/l) (corrected for nRBCs) ☐☐ . ☐

D2. Reticulocyte Count (%) ☐☐ . ☐

D3. Platelet Count (x10^{9}/l) ☐☐☐☐

D4. Hemoglobin Analysis*

D4.a Date blood drawn (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___

D4.b % HbS ☐☐

ATTACH COPIES OF LOCAL LABORATORY REPORTS

D5. Antiglobulin Tests

D5.a Date blood drawn (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___

D5.b Direct Antiglobulin Test (DAT) ☐ **1. NEGATIVE** ☐ **2. POSITIVE**

D5.c Indirect Antiglobulin Test (IAT) ☐ **1. NEGATIVE** ☐ **2. POSITIVE**

ATTACH COPY OF ANTIGLOBULIN TEST RESULTS REPORT

IF BOTH D5.b AND D5.c ARE NEGATIVE, GO TO E1

IF EITHER D5.b OR D5.c IS POSITIVE, CONTINUE TO D5.d

***NOTE: A pre-transfusion sample for hb, hct, and hemoglobin analysis by the Core Lab must also be drawn for patients randomized to the Transfusion arm.**

D5.d Antibodies			D5.e Newly Identified?	
	1. NO	**2. YES**	**1. NO**	**2. YES**
1. Anti - D	☐	☐ →	☐	☐
2. Anti - C	☐	☐ →	☐	☐
3. Anti - E	☐	☐ →	☐	☐
4. Anti - e	☐	☐ →	☐	☐
5. Anti - c	☐	☐ →	☐	☐
6. Anti - f	☐	☐ →	☐	☐
7. Anti - V	☐	☐ →	☐	☐
8. Anti - M	☐	☐ →	☐	☐
9. Anti - N	☐	☐ →	☐	☐
10. Anti - S	☐	☐ →	☐	☐
11. Anti - s	☐	☐ →	☐	☐
12. Anti - U	☐	☐ →	☐	☐
13. Anti - Kp^a	☐	☐ →	☐	☐
14. Anti - Kp^b	☐	☐ →	☐	☐
15. Anti - Js^a	☐	☐ →	☐	☐
16. Anti - Js^b	☐	☐ →	☐	☐
17. Anti - K (Kell)	☐	☐ →	☐	☐
18. Anti - k	☐	☐ →	☐	☐
19. Anti - Fy^a	☐	☐ →	☐	☐
20. Anti - Fy^b	☐	☐ →	☐	☐
21. Anti - Jk^a	☐	☐ →	☐	☐
22. Anti - Jk^b	☐	☐ →	☐	☐
23. Anti - Le^a	☐	☐ →	☐	☐
24. Anti - Le^b	☐	☐ →	☐	☐
25. Anti - P_1	☐	☐ →	☐	☐
26. Anti - I	☐	☐ →	☐	☐
27. Anti - Other → D5.d27.a Specify_____	☐	☐ →	☐	☐

IF THE RESPONSE TO ANY OF D5.e1-27 IS YES, SEND SPECIMEN TO REFERENCE LAB FOR CONFIRMATION.

D5.f Date specimen sent to reference lab (Month/Day/Year) :__ __/__ __ /__ __ __ __ ☐ **-1. NOT SENT**

↓

D5.f.1 Reason:

_____

_____

E. COMPLICATIONS

E1. Were any of the following transfusion complications noted <u>during</u> the transfusion visit? ☐ 1. NO ☐ 2. YES

		1. NO	2. YES	1 Time Complication Detected		2	3 Time Complication Resolved		4	
E1.a	Hemolytic immediate	☐	☐ →	__:__	☐ 1. AM ☐ 2. PM		__:__	☐ 1. AM ☐ 2. PM		
E1.b	Febrile, nonhemolytic (fever, chills)	☐	☐ →	__:__	☐ 1. AM ☐ 2. PM		__:__	☐ 1. AM ☐ 2. PM		
E1.c	Severe anaphylaxis (dyspnea, chest constriction, cyanosis, pulse variations, convulsions)	☐	☐ →	__:__	☐ 1. AM ☐ 2. PM		__:__	☐ 1. AM ☐ 2. PM		
E1.d	Other allergic reactions (redness of skin, Itching, urticaria)	☐	☐ →	__:__	☐ 1. AM ☐ 2. PM		__:__	☐ 1. AM ☐ 2. PM		
E1.e	Fluid overload	☐	☐ →	__:__	☐ 1. AM ☐ 2. PM		__:__	☐ 1. AM ☐ 2. PM		
E1.f	Hypertension (increase of >=30 mm Hg over baseline BP)	☐	☐ →	__:__	☐ 1. AM ☐ 2. PM		__:__	☐ 1. AM ☐ 2. PM		
E1.g	Other	☐	☐ → ↓	__:__	☐ 1. AM ☐ 2. PM		__:__	☐ 1. AM ☐ 2. PM		

SPECIFY:

E1.g5 _____

IF PATIENT HAD AN IMMEDIATE HEMOLYTIC TRANSFUSION REACTION, COMPLETE QUESTION E2; OTHERWISE GO TO QUESTION E4

E2. Antiglobulin Tests

E2.a Time sample collected ☐☐:☐☐ a1. ☐ 1. AM ☐ 2. PM

E2.b Direct Antiglobulin Test (DAT) ☐ 1. NEGATIVE ☐ 2. POSITIVE

E2.c Indirect Antiglobulin Test (IAT) ☐ 1. NEGATIVE ☐ 2. POSITIVE

ATTACH COPY OF ANTIGLOBULIN TEST RESULTS REPORT

IF BOTH E2.b AND E2.c ARE NEGATIVE, GO TO E4

IF EITHER E2.b OR E2.c IS POSITIVE, CONTINUE TO E2.d

E2.d Antibodies				E2.e Newly Identified?	
	1. NO	**2. YES**		**1. NO**	**2. YES**
1. Anti - D	☐	☐	→	☐	☐
2. Anti - C	☐	☐	→	☐	☐
3. Anti - E	☐	☐	→	☐	☐
4. Anti - e	☐	☐	→	☐	☐
5. Anti - c	☐	☐	→	☐	☐
6. Anti - f	☐	☐	→	☐	☐
7. Anti - V	☐	☐	→	☐	☐
8. Anti - M	☐	☐	→	☐	☐
9. Anti - N	☐	☐	→	☐	☐
10. Anti - S	☐	☐	→	☐	☐
11. Anti - s	☐	☐	→	☐	☐
12. Anti - U	☐	☐	→	☐	☐
13. Anti - Kp^a	☐	☐	→	☐	☐
14. Anti - Kp^b	☐	☐	→	☐	☐
15. Anti - Js^a	☐	☐	→	☐	☐
16. Anti - Js^b	☐	☐	→	☐	☐
17. Anti - K (Kell)	☐	☐	→	☐	☐
18. Anti - k	☐	☐	→	☐	☐
19. Anti - Fy^a	☐	☐	→	☐	☐
20. Anti - Fy^b	☐	☐	→	☐	☐
21. Anti - Jk^a	☐	☐	→	☐	☐
22. Anti - Jk^b	☐	☐	→	☐	☐
23. Anti - Le^a	☐	☐	→	☐	☐
24. Anti - Le^b	☐	☐	→	☐	☐
25. Anti - P_1	☐	☐	→	☐	☐
26. Anti - I	☐	☐	→	☐	☐
27. Anti - Other → E2.d27.a Specify_____	☐	☐	→	☐	☐

IF RESPONSE TO ANY OF E2.e1-27 IS YES, SEND SPECIMEN TO REFERENCE LAB FOR CONFIRMATION.

E3. Date specimen sent to reference lab (Month/Day/Year) :__ __/__ __ /__ __ __ __ ☐ **-1. NOT SENT**

↓

E3.a Reason:

_____

_____

E4. Describe pertinent details of each complication and its management

ATTACH TRANSFUSION SUMMARY NOTES

E5. Was patient hospitalized because of a complication from this transfusion?

☐ **1. NO** ☐ **2. YES →**

E5.a Date of admission (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___

E5.b Date of discharge (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___

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

F. FOR OFFICE USE:

F1. Local hematology laboratory reports received:	☐ **1. NO**	☐ **2. YES**	
F2. Blood Bank antiglobulin test report received:	☐ **1. NO**	☐ **2. YES**	
F3. Blood Bank Panel sheets received:	☐ **1. NO**	☐ **2. YES**	☐ **-1. NA**
F4. Transfusion notes received:	☐ **1. NO**	☐ **2. YES**	
F5. Reference lab report received:	☐ **1. NO**	☐ **2. YES**	☐ **-1. NA**

STOP II TRIAL
BLOOD UNIT FORM

****AFFIX PATIENT LABEL HERE****

COMPLETE SEPARATE FORM FOR <u>EACH UNIT</u> GIVEN DURING A TRANSFUSION VISIT

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

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

A3. Unit Number: _____

B1. Blood Product:

☐ 1. HbS negative packed red cells

☐ 2. HbS negative packed red cells reconstituted with →

B1.a

- ☐ **1. saline**
- ☐ **2. albumin**
- ☐ **3. plasma**
- ☐ **4. other** → B1.b Specify: _____

☐ 3. Other → B1.c Specify: _____

B2. Was the unit NEGATIVE for the following antigens?	**1. NO**	**2. YES**
B2.a C	☐	☐
B2.b E	☐	☐
B2.c Kell	☐	☐

B3. Was the unit known to be negative for any other antigens? ☐ ☐ ↓

SPECIFY ANTIGEN(S):

B3.a1 _____

B3.a2 _____

B3.a3 _____

B3.a4 _____

☐ ML ☐ DE

B4. Was a Third Generation Leukodepletion Filter used? ☐ **1. NO** ☐ **2. YES**

B4.a Filtering Process:

- ☐ A **PRESTORAGE LEUKODEPLETION**
- ☐ B **LEUKODEPLETION IN BLOOD BANK**
- ☐ C **BEDSIDE FILTRATION**
- ☐ D **OTHER**

D1. If other, specify: _____

C. TRANSFUSION TYPE AND DELIVERY

C1. Type of transfusion for this unit:

C1.a **Simple** ☐ **1. NO** ☐ **2. YES** → C1.a1 Number of mL in ☐☐☐☐

C1.b **Exchange** ☐ **1. NO** ☐ **2. YES** → C1.b1 Total mL in: ☐☐☐☐

C1.b2 Total mL out: ☐☐☐☐

C1.b3 Method ☐ **1. Manual** ☐ **2. Red Cell Pheresis**

C1.b3.a Delivery

- ☐ **1. Intermittent**
- ☐ **2. Continuous**

C1.b4 Hematocrit of

a. blood transfused (%) ☐☐.☐ ☐ **-1. NOT AVAILABLE**

b. blood removed (%) ☐☐.☐ ☐ **-1. NOT AVAILABLE**

ATTACH COPY OF THE TRANSFUSION TAG FOR THIS BLOOD UNIT.

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

D. FOR OFFICE USE

D1. Transfusion tag received: ☐ **1.NO** ☐ **2.YES** ☐ ML ☐ DE

STOP II
TRANSFUSION HISTORY LOG FOR PATIENTS ON TRANSFUSION FOR PRIMARY STROKE PREVENTION WHO WERE NOT STOP RANDOMIZED PATIENTS

****AFFIX PATIENT LABEL HERE****

A1. Person completing log (Name): _____ (Initials): ☐☐☐

A2. Date form completed (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___

B. TRANSFUSION HISTORY SECTION

B1. Date Transfusion Started (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___

B2. Reason for Transfusions:

☐ **1. PRIMARY STROKE PREVENTION**

☐ **2. OTHER→** B2.a. Specify: _____ _____

B3. Is Patient Receiving Chelation? ☐ **1. NO** ☐ **2. YES→**B3.a Date Started ___ ___/___ ___/___ ___ ___ ___

B4. Transfusion Visits Since Chronic Transfusion Program Started (List most recent transfusion first):

	a. Date of Transfusion	Pre-transfusion b. %Hb S	c. Ferritin (ng/ml)	d. Date Blood Drawn	e. OFFICE USE
1.	__ __/__ __/__ __ __ __	☐☐	☐☐☐☐☐	__ __/__ __/__ __ __ __	☐
2.	__ __/__ __/__ __ __ __	☐☐	☐☐☐☐☐	__ __/__ __/__ __ __ __	☐
3.	__ __/__ __/__ __ __ __	☐☐	☐☐☐☐☐	__ __/__ __/__ __ __ __	☐
4.	__ __/__ __/__ __ __ __	☐☐	☐☐☐☐☐	__ __/__ __/__ __ __ __	☐
5.	__ __/__ __/__ __ __ __	☐☐	☐☐☐☐☐	__ __/__ __/__ __ __ __	☐
6.	__ __/__ __/__ __ __ __	☐☐	☐☐☐☐☐	__ __/__ __/__ __ __ __	☐
7.	__ __/__ __/__ __ __ __	☐☐	☐☐☐☐☐	__ __/__ __/__ __ __ __	☐
8.	__ __/__ __/__ __ __ __	☐☐	☐☐☐☐☐	__ __/__ __/__ __ __ __	☐

☐ ML ☐ DE

B4. Transfusion Visits Since Chronic Transfusion Program Started (continued):

	a. Date of Transfusion	Pre-transfusion b. %Hb S	Pre-transfusion c. Ferritin (ng/ml)	Pre-transfusion d. Date Blood Drawn	e. OFFICE USE
9.	__ __/__ __/__ __ __ __			__ __/__ __/__ __ __ __	
10.	__ __/__ __/__ __ __ __			__ __/__ __/__ __ __ __	
11.	__ __/__ __/__ __ __ __			__ __/__ __/__ __ __ __	
12.	__ __/__ __/__ __ __ __			__ __/__ __/__ __ __ __	
13.	__ __/__ __/__ __ __ __			__ __/__ __/__ __ __ __	
14.	__ __/__ __/__ __ __ __			__ __/__ __/__ __ __ __	
15.	__ __/__ __/__ __ __ __			__ __/__ __/__ __ __ __	
16.	__ __/__ __/__ __ __ __			__ __/__ __/__ __ __ __	
17.	__ __/__ __/__ __ __ __			__ __/__ __/__ __ __ __	
18.	__ __/__ __/__ __ __ __			__ __/__ __/__ __ __ __	
19.	__ __/__ __/__ __ __ __			__ __/__ __/__ __ __ __	
20.	__ __/__ __/__ __ __ __			__ __/__ __/__ __ __ __	
21.	__ __/__ __/__ __ __ __			__ __/__ __/__ __ __ __	
22.	__ __/__ __/__ __ __ __			__ __/__ __/__ __ __ __	
23.	__ __/__ __/__ __ __ __			__ __/__ __/__ __ __ __	
24.	__ __/__ __/__ __ __ __			__ __/__ __/__ __ __ __	
25.	__ __/__ __/__ __ __ __			__ __/__ __/__ __ __ __	
26.	__ __/__ __/__ __ __ __			__ __/__ __/__ __ __ __	
27.	__ __/__ __/__ __ __ __			__ __/__ __/__ __ __ __	
28.	__ __/__ __/__ __ __ __			__ __/__ __/__ __ __ __	
29.	__ __/__ __/__ __ __ __			__ __/__ __/__ __ __ __	
30.	__ __/__ __/__ __ __ __			__ __/__ __/__ __ __ __	

B4. Transfusion Visits Since Chronic Transfusion Program Started (continued):

	a. Date of Transfusion	Pre-transfusion b. %Hb S	Pre-transfusion c. Ferritin (ng/ml)	Pre-transfusion d. Date Blood Drawn	e. OFFICE USE
31.	__ __/__ __/__ __ __ __			__ __/__ __/__ __ __ __	
32.	__ __/__ __/__ __ __ __			__ __/__ __/__ __ __ __	
33.	__ __/__ __/__ __ __ __			__ __/__ __/__ __ __ __	
34.	__ __/__ __/__ __ __ __			__ __/__ __/__ __ __ __	
35.	__ __/__ __/__ __ __ __			__ __/__ __/__ __ __ __	
36.	__ __/__ __/__ __ __ __			__ __/__ __/__ __ __ __	
37.	__ __/__ __/__ __ __ __			__ __/__ __/__ __ __ __	
38.	__ __/__ __/__ __ __ __			__ __/__ __/__ __ __ __	
39.	__ __/__ __/__ __ __ __			__ __/__ __/__ __ __ __	
40.	__ __/__ __/__ __ __ __			__ __/__ __/__ __ __ __	
41.	__ __/__ __/__ __ __ __			__ __/__ __/__ __ __ __	
42.	__ __/__ __/__ __ __ __			__ __/__ __/__ __ __ __	
43.	__ __/__ __/__ __ __ __			__ __/__ __/__ __ __ __	
44.	__ __/__ __/__ __ __ __			__ __/__ __/__ __ __ __	
45.	__ __/__ __/__ __ __ __			__ __/__ __/__ __ __ __	
46.	__ __/__ __/__ __ __ __			__ __/__ __/__ __ __ __	
47.	__ __/__ __/__ __ __ __			__ __/__ __/__ __ __ __	
48.	__ __/__ __/__ __ __ __			__ __/__ __/__ __ __ __	
49.	__ __/__ __/__ __ __ __			__ __/__ __/__ __ __ __	
50.	__ __/__ __/__ __ __ __			__ __/__ __/__ __ __ __	

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

STOP II TRIAL

CHELATION QUESTIONNAIRE FOR STOP II RANDOMIZED PATIENTS

****AFFIX PATIENT LABEL HERE****

Section A: KEY IDENTIFYING INFORMATION

A1. Person completing form _____ ___ ___ ___
PRINT FULL NAME INITIALS

A2. Date form completed ___ ___ / ___ ___ / ___ ___ ___ ___
M M D D Y Y Y Y

Section B: CHELATION PRESCRIPTION INFORMATION

B1. Is patient currently being chelated? NO .....1 YES .....2 UNKNOWN....-8
IF NO, SKIP TO SECTION D **IF UNKNOWN, SKIP TO SECTION D**

B2. Current prescription for chelation

a. Dose ___ ___ ___ mg/kg/day

b. Frequency ___ days/week

c. Method of delivery

SUBCUTANEOUS 1
INTRAVENOUS 2
INTRAMUSCULAR 3

d. Where administered

AT HOME.....1
IN CLINIC (OUTPATIENT) 2
IN HOSPITAL (INPATIENT) 3
OTHER 9

1. If OTHER, specify

_____

_____

☐ ML ☐ DE

Section C: CURRENT PATIENT COMPLIANCE IN CHELATION PROGRAM

C1. Rate the degree of compliance <u>at this time</u>

HIGH 1
MODERATE 2
POOR.....3
UNKNOWN.....-8

COMPLETE SECTION D ONLY IF THE PATIENT IS NOT BEING CHELATED CURRENTLY OR THE PATIENT'S CURRENT CHELATION STATUS IS UNKNOWN.

Section D: PAST HISTORY OF CHELATION

D1. Did patient ever receive chelation therapy? NO .....1 YES.....2

a. If YES, most recent date discontinued

___ ___ / ___ ___ / ___ ___ ___ ___
M M D D Y Y Y Y

Section E: COMMENTS

E1. Do you want to add any additional comments about the patient's current or past chelation treatment? NO .....1 YES.....2

a. If YES, please **PRINT** comments in space provided below:

_____

_____

_____

_____

_____

FAX COMPLETED FORM TO TAMMI MANSOLF, STOP II DCC, BY FRIDAY, FEBRUARY 21, 2003

617-923-4176

STOP II
TRANSFUSION HISTORY LOG FOR PRE-STOP II TRANSFUSIONS THAT ARE NOT IN FOXPRO OR ADEPT FOR STOP RANDOMIZED PATIENTS
[Forms 20A & 21 completed]

****AFFIX PATIENT LABEL HERE****

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

A2. Date form completed (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___

B. TRANSFUSION HISTORY SECTION

List Transfusion Visits Recorded on STOP Form 20A That Are Not in FOXPRO or ADEPT:

	a. Date of Transfusion	b. Foxpro TR Number	c. Pre-Transfusion HbS (%)	d. Date Blood Drawn	e. OFFICE USE
1.	___ ___ / ___ ___ / ___ ___ ___ ___	__ __	___ ___	___ ___ / ___ ___ / ___ ___ ___ ___	__ __
2.	___ ___ / ___ ___ / ___ ___ ___ ___	__ __	___ ___	___ ___ / ___ ___ / ___ ___ ___ ___	__ __
3.	___ ___ / ___ ___ / ___ ___ ___ ___	__ __	___ ___	___ ___ / ___ ___ / ___ ___ ___ ___	__ __
4.	___ ___ / ___ ___ / ___ ___ ___ ___	__ __	___ ___	___ ___ / ___ ___ / ___ ___ ___ ___	__ __
5.	___ ___ / ___ ___ / ___ ___ ___ ___	__ __	___ ___	___ ___ / ___ ___ / ___ ___ ___ ___	__ __
6.	___ ___ / ___ ___ / ___ ___ ___ ___	__ __	___ ___	___ ___ / ___ ___ / ___ ___ ___ ___	__ __
7.	___ ___ / ___ ___ / ___ ___ ___ ___	__ __	___ ___	___ ___ / ___ ___ / ___ ___ ___ ___	__ __
8.	___ ___ / ___ ___ / ___ ___ ___ ___	__ __	___ ___	___ ___ / ___ ___ / ___ ___ ___ ___	__ __
9.	___ ___ / ___ ___ / ___ ___ ___ ___	__ __	___ ___	___ ___ / ___ ___ / ___ ___ ___ ___	__ __
10.	___ ___ / ___ ___ / ___ ___ ___ ___	__ __	___ ___	___ ___ / ___ ___ / ___ ___ ___ ___	__ __

	a. Date of Transfusion	b. Foxpro TR Number	c. Pre-Transfusion HbS (%)	d. Date Blood Drawn	e. OFFICE USE
11.	___ ___ / ___ ___ / ___ ___ ___ ___	__ __	___ ___	___ ___ / ___ ___ / ___ ___ ___ ___	__ __
12.	___ ___ / ___ ___ / ___ ___ ___ ___	__ __	___ ___	___ ___ / ___ ___ / ___ ___ ___ ___	__ __
13.	___ ___ / ___ ___ / ___ ___ ___ ___	__ __	___ ___	___ ___ / ___ ___ / ___ ___ ___ ___	__ __
14.	___ ___ / ___ ___ / ___ ___ ___ ___	__ __	___ ___	___ ___ / ___ ___ / ___ ___ ___ ___	__ __
15.	___ ___ / ___ ___ / ___ ___ ___ ___	__ __	___ ___	___ ___ / ___ ___ / ___ ___ ___ ___	__ __
16.	___ ___ / ___ ___ / ___ ___ ___ ___	__ __	___ ___	___ ___ / ___ ___ / ___ ___ ___ ___	__ __
17.	___ ___ / ___ ___ / ___ ___ ___ ___	__ __	___ ___	___ ___ / ___ ___ / ___ ___ ___ ___	__ __
18.	___ ___ / ___ ___ / ___ ___ ___ ___	__ __	___ ___	___ ___ / ___ ___ / ___ ___ ___ ___	__ __
19.	___ ___ / ___ ___ / ___ ___ ___ ___	__ __	___ ___	___ ___ / ___ ___ / ___ ___ ___ ___	__ __
20.	___ ___ / ___ ___ / ___ ___ ___ ___	__ __	___ ___	___ ___ / ___ ___ / ___ ___ ___ ___	__ __
21.	___ ___ / ___ ___ / ___ ___ ___ ___	__ __	___ ___	___ ___ / ___ ___ / ___ ___ ___ ___	__ __
22.	___ ___ / ___ ___ / ___ ___ ___ ___	__ __	___ ___	___ ___ / ___ ___ / ___ ___ ___ ___	__ __
23.	___ ___ / ___ ___ / ___ ___ ___ ___	__ __	___ ___	___ ___ / ___ ___ / ___ ___ ___ ___	__ __
24.	___ ___ / ___ ___ / ___ ___ ___ ___	__ __	___ ___	___ ___ / ___ ___ / ___ ___ ___ ___	__ __
25.	___ ___ / ___ ___ / ___ ___ ___ ___	__ __	___ ___	___ ___ / ___ ___ / ___ ___ ___ ___	__ __
26.	___ ___ / ___ ___ / ___ ___ ___ ___	__ __	___ ___	___ ___ / ___ ___ / ___ ___ ___ ___	__ __
27.	___ ___ / ___ ___ / ___ ___ ___ ___	__ __	___ ___	___ ___ / ___ ___ / ___ ___ ___ ___	__ __
28.	___ ___ / ___ ___ / ___ ___ ___ ___	__ __	___ ___	___ ___ / ___ ___ / ___ ___ ___ ___	__ __
29.	___ ___ / ___ ___ / ___ ___ ___ ___	__ __	___ ___	___ ___ / ___ ___ / ___ ___ ___ ___	__ __
30.	___ ___ / ___ ___ / ___ ___ ___ ___	__ __	___ ___	___ ___ / ___ ___ / ___ ___ ___ ___	__ __

STOP II TRIAL

NEUROLOGICAL EVENT FORM

AFFIX PATIENT LABEL HERE

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

A2. Date of neurological event (Month/Day/Year): ____ ____/____ ____/____ ____ ____ ____

B. PRESENTATION

B1. Where was the patient first seen for this event?

☐ **1. STOP II Center** → B1.a. ☐☐

☐ **2. Other** → B1.b _____

B2. Were signs or symptoms first reported at a quarterly visit? ☐ **1. NO** ☐ **2. YES**

↓

B2.a Date of Quarterly Progress Report (Month/Day/Year): ____ ____/____ ____/____ ____ ____ ____

B3. What signs or symptoms occurred?

(CHECK NO OR YES BOX FOR EACH OF B3.a-l)

	1. NO	**2. YES**	
B3.a Loss of consciousness	☐	☐	
B3.b Change in mental status	☐	☐	
B3.c Loss of or difficulty with speech	☐	☐	
B3.d Paralysis or weakness	☐	☐	→ B3.d1 SIDE: ☐ **1. RIGHT** ☐ **2. LEFT** ☐ **3. BOTH**
B3.e Difficulty with swallowing	☐	☐	
B3.f Difficulty with vision	☐	☐	→ B3.f1 SIDE: ☐ **1. RIGHT** ☐ **2. LEFT** ☐ **3. BOTH**
B3.g Loss of balance or dizziness	☐	☐	
B3.h Seizure	☐	☐	
B3.i Headache	☐	☐	→ B3.i1 LOCATION: ☐ **1. DIFFUSE** ☐ **2. FOCAL**
			↓ B3.i1a SPECIFY: _____
B3.j New sensory disturbance	☐	☐	→ B3.j1 SIDE: ☐ **1. RIGHT** ☐ **2. LEFT** ☐ **3. BOTH**
B3.k Change in behavior	☐	☐	
B3.l Change in gait or coordination	☐	☐	

☐ ML ☐ DE

B4. Was patient hospitalized for this event?

☐ **1. NO** ☐ **2. YES →**

B4.a Date of Hospital Admission (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___

B4.b Date of Hospital Discharge (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___

B4.c Where was patient hospitalized? _____

_____

C. HISTORY

C1. Person interviewed **(SELECT PERSON PROVIDING MAJORITY OF RESPONSES)**

☐ **1. Patient** ☐ **2. Parent** ☐ **3. Other** → C1.a Specify: _____

C2. Did person interviewed witness suspected event? ☐ **1. NO** ☐ **2. YES**

C3. Did the patient experience any of the following during the two weeks prior to the neurological event?

(CHECK NO OR YES BOX FOR EACH OF C3.a - i)	**1. NO**	**2. YES**	**3. DON'T KNOW**
C3.a Acute febrile event	☐	☐	☐
C3.b Painful event	☐	☐	☐
C3.c Acute Chest Syndrome	☐	☐	☐
C3.d Acute anemia	☐	☐	☐
C3.e General anesthesia	☐	☐	☐
C3.f Priapism	☐	☐	☐
C3.g Head injury with loss of consciousness	☐	☐	☐
C3.h Transfusion	☐	☐	☐

↓

COMPLETE TRANSFUSION FORM

C3.i Other	☐	☐	☐

↓

C3.i1 Specify _____

_____

C4. DESCRIBE PERTINENT CLINICAL DETAILS OF CLINICAL EVENTS WHICH OCCURRED WITHIN THE TWO WEEKS PRECEDING THE NEUROLOGICAL EVENT

_____

_____

**** COMPLETE A NEUROLOGICAL EVENT FORM FOR EACH EVENT (C3.a – f OR C3.i) FOR WHICH "YES" IS CHECKED"**

D. RESULTS OF IMAGING AND ULTRASOUND TESTS PERFORMED TO EVALUATE <u>THIS EVENT</u>: (CHECK APPROPRIATE BOX FOR EACH OF D1 - 7)

D1. MRI of brain ☐ **1. NOT DONE** ☐ **2. DONE**

↓

D1.a Date performed (month/day/year): ___ ___/___ ___/___ ___ ___ ___

D1.b Was DWI performed? ☐ **1. NO** ☐ **2. YES**

D2. CT scan of brain ☐ **1. NOT DONE** ☐ **2. DONE**

↓

D2.a Date performed (month/day/year): ___ ___/___ ___/___ ___ ___ ___

D3. PET scan of brain ☐ **1. NOT DONE** ☐ **2. DONE**

↓

D3.a Date performed (month/day/year): ___ ___/___ ___/___ ___ ___ ___

D4. MRA of brain ☐ **1. NOT DONE** ☐ **2. DONE**

↓

D4.a Date performed (month/day/year): ___ ___/___ ___/___ ___ ___ ___

D5. Arteriogram ☐ **1. NOT DONE** ☐ **2. DONE**

↓

D5.a Date performed (month/day/year): ___ ___/___ ___/___ ___ ___ ___

D6. Transcranial Doppler ☐ **1. NOT DONE** ☐ **2. DONE**

↓

D6.a Date performed (month/day/year): ___ ___/___ ___/___ ___ ___ ___

D7. Other → D7.a Specify_____

☐ **1. NOT DONE** ☐ **2. DONE**

↓

D7.b Date performed (month/day/year): ___ ___/___ ___/___ ___ ___ ___

**** ATTACH REPORTS FOR ALL IMAGING AND ULTRASOUND TESTS PERFORMED ****
**** SEND FORMS 15 AND 19 AND STOP II OPTICAL DISK WITH MRI, DWI, AND MRA DATA TO DCC ****
**** IF TCD WAS PERFORMED, SEND TCD IMAGE FILE AND FORM 2 TO DCC****

E. NEUROLOGICAL EVALUATION

E1. Was a neurological evaluation performed by the STOP Neurology Consultant?

☐ **1. NO →** **SCHEDULE EVALUATION BY STOP NEUROLOGY CONSULTANT**

☐ **2. YES →** E1.a Date of exam (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___

SEND STOP NEUROLOGICAL CONSULTANT REPORT TO THE DCC

F. MANAGEMENT AND COMPLICATIONS

F1. Were there other events associated with this neurological event? ☐ **1. NO** ☐ **2. YES**

COMPLETE A SEPARATE NON-NEUROLOGICAL EVENT FORM FOR EACH UNIQUE ASSOCIATED EVENT

F2. Was the patient transfused for this neurological event ? ☐ **1. NO** ☐ **2. YES**

COMPLETE TRANSFUSION FORM

F3. Did the patient die as a complication of this event ? ☐ **1. NO** ☐ **2. YES**

COMPLETE CAUSE OF DEATH FORM

G. FINAL LOCAL DIAGNOSIS

G1. Type of neurological event:

☐ **1. Cerebral Infarction** ☐ **2. Intracranial Hemorrhage** ☐ **3. TIA** ☐ **4. Seizure** ☐ **5. Other** ↓

G1.a Specify: _____

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

H. FOR OFFICE USE

H1. Imaging/ultrasound reports received:	☐ **1. NO**	☐ **2. YES**
H2. Optical disk with MR data received:	☐ **1. NO**	☐ **2. YES**
H3. Imaging films received:	☐ **1. NO**	☐ **2. YES**
H4. TCD received:	☐ **1. NO**	☐ **2. YES**

STOP II TRIAL

NON-NEUROLOGICAL EVENT FORM

AFFIX PATIENT LABEL HERE

INSTRUCTIONS

COMPLETE THIS FORM WHENEVER THE PATIENT IS SEEN IN THE EMERGENCY ROOM OR CLINIC OR IS HOSPITALIZED FOR A CLINICAL EVENT WHICH IS NOT A STROKE, TIA, SEIZURE, OR DELAYED TRANSFUSION REACTION.
A SEPARATE EVENT FORM SHOULD BE COMPLETED FOR EACH EVENT TYPE.

IF THE PATIENT IS SEEN FOR A SUSPECTED STROKE, TIA, OR SEIZURES, COMPLETE THE NEUROLOGICAL EVENT FORM.

IF THE PATIENT IS SEEN FOR A DELAYED TRANSFUSION REACTION, COMPLETE THE DELAYED TRANSFUSION REACTION FORM.

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

A2. Date form completed (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___

A3. Date of event (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___

A4. Event name (see choices below):_____ | | | |
OFFICE USE

OFFICE USE | | | | . | |

OFFICE USE | | | | . | |

Code	Type of Event	Code	Type of Event	Code	Type of Event
010	**Vasoocclusive Pain**	061	**Splenic Sequestration**	111	**New Aseptic Necrosis, Shoulder**
020	**Acute Chest Syndrome (with new pulmonary infiltrate)**	062	**Aplastic Crisis**	120	**Urinary Tract Infection**
030	**Fever without source**	063	**Other anemia (SPECIFY TYPE)**	121	**Hematuria**
041	**Sepsis**	070	**Cholecystitis or cholelithiasis**	122	**Proteinuria**
042	**Meningitis**	080	**Priapism**	123	**Renal Insufficiency**
043	**Osteomyelitis**	090	**Surgery (SPECIFY TYPE)**	124	**Other Renal Complication (SPECIFY TYPE)**
044	**Other Infection (SPECIFY TYPE)**	100	**New Leg Ulcer**	130	**Head Injury with loss of consciousness**
060	**Acute Anemia (unspecified)**	110	**New Aseptic Necrosis, Hip**	160	**Other event (SPECIFY TYPE)**

A5. Has the patient been seen for the same type of event within the week preceding this visit?

☐ **1. NO** ☐ **2. YES →**

A5.a Do the present history, symptoms, and/or physical exam indicate that this event is a continuation of the previous event?

☐ **1. NO** ☐ **2. YES** ☐ **9. DK**

☐ ML ☐ DE

A6. Was the patient admitted to the hospital ***because of this event***?

☐ **1. NO** ☐ **2. YES →**

A6.a Date of hospital admission (Month/Day/Year) ___ ___/___ ___/___ ___ ___ ___

A6.b Date of hospital discharge (Month/Day/Year) ___ ___/___ ___/___ ___ ___ ___

B. LABORATORY STUDIES FOR SUSPECTED INFECTIONS

B1. Were samples for any cultures obtained? ☐ **1. NO** ☐ **2. YES**

B1.a CULTURE	**B1.b RESULTS** 1. NEGATIVE	2. POSITIVE	**B1.c SPECIFY ORGANISM**
1. _____ →	☐	☐ → _____	☐☐☐☐ OFFICE USE
2. _____ →	☐	☐ → _____	☐☐☐☐ OFFICE USE
3. _____ →	☐	☐ → _____	☐☐☐☐ OFFICE USE
4. _____ →	☐	☐ → _____	☐☐☐☐ OFFICE USE

B2. Were any serological studies performed? ☐ **1. NO** ☐ **2. YES**

B2.a. Were the results of any of these studies positive? ☐ **1. NO** ☐ **2. YES**

B2.b. Were any of the results indicative of an **<u>acute</u>** infection?

☐ **1. NO** ☐ **2. YES** ☐ **3. DON'T KNOW**

B2.b1 What was the infectious agent?_____

B2.b2 What was the evidence that this was an acute infection?

_____

_____

_____

C. MANAGEMENT AND COMPLICATIONS

C1. Were there other events associated with this event? ☐ **1. NO** ☐ **2. YES**

↓

COMPLETE SEPARATE EVENT FORM FOR EACH EVENT TYPE

C2. Did the patient require ventilator support? ☐ **1. NO** ☐ **2. YES**

↓

C2.a Number of days ☐☐

C3. Was the patient transfused for this event? ☐ **1. NO** ☐ **2. YES**

↓

COMPLETE TRANSFUSION FORMS

C4. Did patient die as a result of this event? ☐ **1. NO** ☐ **2. YES**

↓

COMPLETE CAUSE OF DEATH FORM

IF THIS FORM IS BEING COMPLETED FOR EITHER A MENINGITIS OR A HEAD INJURY EVENT, AN MRI AND NEUROLOGICAL EXAMINATION BY THE STOP NEUROLOGICAL CONSULTANT MUST BE PERFORMED 3-4 WEEKS AFTER HOSPITAL DISCHARGE. FORMS 14 AND 15 MUST BE COMPLETED AT THAT TIME.

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

STOP II TRIAL

DELAYED TRANSFUSION REACTION FORM

AFFIX PATIENT LABEL HERE

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

A2. Date form completed (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___

A3. Date of transfusion reaction (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___

B. TRANSFUSION HISTORY

B1. Date of most recent transfusion preceding date of transfusion reaction (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___

B2. Were STOP II Transfusion Forms completed for this transfusion? ☐ 1. NO ☐ 2. YES

↓

COMPLETE TRANSFUSION FORMS

C. TYPE OF REACTION

	1. NO	2. YES
C1. Delayed hemolytic	☐	☐
C2. Febrile, nonhemolytic (fever, chills)	☐	☐
C3. Severe anaphylaxis (dyspnea, chest constriction, cyanosis, pulse variations, convulsions)	☐	☐
C4. Mild anaphylasis (redness of skin, itching, urticaria)	☐	☐
C5. Fluid overload	☐	☐
C6. Hypertension	☐	☐
C7. Other	☐	☐

↓

C7.a Specify_____

C8. DESCRIBE PERTINENT CLINICAL DETAILS OF THE REACTION:

☐ ML ☐ DE

D. LABORATORY TESTS

D1. Antiglobulin Test

☐ **1. NOT DONE** →

D1.a Specify reason:

GO TO D2

☐ **2. DONE**

↓

D1.b Date of test (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___

D1.c Direct ☐ **1. NEGATIVE** ☐ **2. POSITIVE**

D1.d Indirect ☐ **1. NEGATIVE** ☐ **2. POSITIVE**

IF BOTH D1.c AND D1.d ARE NEGATIVE, GO TO D3

IF EITHER D1.c OR D1.d ARE POSITIVE, CONTINUE TO D1.e

D1.e Antibodies			D1.f Newly Identified?	
	1. NO	**2. YES**	**1. NO**	**2. YES**
1. Anti - D	☐	☐ →	☐	☐
2. Anti - C	☐	☐ →	☐	☐
3. Anti - E	☐	☐ →	☐	☐
4. Anti - e	☐	☐ →	☐	☐
5. Anti - c	☐	☐ →	☐	☐
6. Anti - f	☐	☐ →	☐	☐
7. Anti - V	☐	☐ →	☐	☐
8. Anti - M	☐	☐ →	☐	☐
9. Anti - N	☐	☐ →	☐	☐
10. Anti - S	☐	☐ →	☐	☐
11. Anti - s	☐	☐ →	☐	☐
12. Anti - U	☐	☐ →	☐	☐
13. Anti - Kp^a	☐	☐ →	☐	☐
14. Anti - Kp^b	☐	☐ →	☐	☐
15. Anti - Js^a	☐	☐ →	☐	☐
16. Anti - Js^b	☐	☐ →	☐	☐
17. Anti - K (Kell)	☐	☐ →	☐	☐
18. Anti - k	☐	☐ →	☐	☐
19. Anti - Fy^a	☐	☐ →	☐	☐
20. Anti - Fy^b	☐	☐ →	☐	☐
21. Anti - Jk^a	☐	☐ →	☐	☐
22. Anti - Jk^b	☐	☐ →	☐	☐

D1.e Antibodies			D1.f Newly Identified?	
	1. NO	**2. YES**	**1. NO**	**2. YES**
23. Anti - Le^a	☐	☐ →	☐	☐
24. Anti - Le^b	☐	☐ →	☐	☐
25. Anti - P_1	☐	☐ →	☐	☐
26. Anti - I	☐	☐ →	☐	☐
27. Anti - Other → D5.e27.a Specify_____	☐	☐ →	☐	☐

IF THE RESPONSE TO ANY OF D1.f1-27 IS YES, SEND SPECIMEN TO REFERENCE LAB FOR CONFIRMATION

D2. Date specimen sent to reference lab (Month/Day/Year) : __ __/__ __ /__ __ __ __ ☐ **-1. NOT SENT**

↓

D2.a Reason:

_____

_____

D3. CBC ☐ **1. NOT DONE** ☐ **2. DONE**

↓ **GO TO D4**

D3.a. Date of test (Month/Day/Year) ___ ___/___ ___/___ ___ ___ ___

D3.b. Hemoglobin (g/dl) ☐☐.☐

D3.c Hematocrit (%) ☐☐.☐

D4. Serum Chemistries ☐ **1. NOT DONE** ☐ **2. DONE**

↓ **GO TO D5**

D4.a Date of test (Month/Day/Year) ___ ___/___ ___/___ ___ ___ ___

D4.b Total bilirubin ☐☐.☐

D4.c Direct bilirubin ☐☐.☐

D4.d LDH ☐☐☐☐

D5. Urinalysis ☐ **1. NOT DONE** ☐ **2. DONE**

↓ **GO TO SECTION E**

D5.a Date of test (Month/Day/Year) ___ ___/___ ___/___ ___ ___ ___

D5.b Hemoglobin ☐ **1. NEG** ☐ **2. TRACE** ☐ **3. 1+** ☐ **4. 2+** ☐ **5. 3+** ☐ **6. 4+**

D5.c Number of Red Cells per HPF ☐☐☐☐

****ATTACH LABORATORY OR BLOOD BANK REPORTS FOR EACH OF THE ABOVE TESTS THAT WERE PERFORMED****

E. MANAGEMENT AND OUTCOME

E1. Was the patient admitted to the hospital because of the reaction?

☐ 1. NO ☐ 2. YES →

E1.a Date of hospital admission (Month/Day/Year) ___ ___/___ ___/___ ___ ___ ___

E1.b Date of hospital discharge (Month/Day/Year) ___ ___/___ ___/___ ___ ___ ___

E2. What types of treatment did the patient receive?

	1. NO	2. YES	
E2.a Hydration	☐	☐	
E2.b Transfusion	☐	☐	→ **COMPLETE TRANSFUSION FORM**
E2.c Other	☐	☐	

↓

E2.c1 Specify _____

E3. Did patient die? ☐ 1. NO ☐ 2. YES

↓

COMPLETE CAUSE OF DEATH FORM

****ATTACH CLINIC/ER NOTES (AND HOSPITAL DISCHARGE SUMMARY IF PATIENT WAS HOSPITALIZED)****

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

F. FOR OFFICE USE:

F1. CBC report received	☐ 1. NO	☐ 2. YES	☐ -1. NA
F2. Blood Bank antiglobulin report received:	☐ 1. NO	☐ 2. YES	☐ -1. NA
F3. Blood Bank panel sheets received:	☐ 1. NO	☐ 2. YES	☐ -1. NA
F4. Reference lab report received:	☐ 1. NO	☐ 2. YES	☐ -1. NA
F5. Serum chemistries report received:	☐ 1. NO	☐ 2. YES	☐ -1. NA
F6. Urinalysis report received:	☐ 1. NO	☐ 2. YES	☐ -1. NA
F7. Clinic/ER notes received:	☐ 1. NO	☐ 2. YES	
F8. Hospital discharge summary received:	☐ 1. NO	☐ 2. YES	

STOP II TRIAL

OUTCOME OF HOSPITALIZATION FOR STROKE, MENINGITIS, OR HEAD INJURY

****AFFIX PATIENT LABEL HERE****

A1. Person completing form (Name):_____ (Initials): [ ] [ ] [ ]

A2. Reason for hospitalization:

- [ ] 1. Neurological Event (stroke) → **COMPLETE FORM 30**
- [ ] 2. Meningitis → **COMPLETE FORM 31**
- [ ] 3. Head Injury → **COMPLETE FORM 31**

A3.a. Date of first hospital admission for event (Month/Day/Year): ___ ___ / ___ ___ / ___ ___ ___ ___

b. Date of hospital discharge (Month/Day/Year): ___ ___ / ___ ___ / ___ ___ ___ ___

c. Name and address of hospital _____

_____

_____

B. DISCHARGE STATUS

B1. Patient discharged to:

- [ ] 1. Home
- [ ] 2. Rehabilitation center
- [ ] 3. Chronic care facility
- [ ] 4. Died during hospitalization

↓

COMPLETE FORM 40

B2. Disability status at discharge (Modified Rankin Disability Scale):

- [ ] 1. No symptoms
- [ ] 2. Symptoms but no disability (no interference with daily activities)
- [ ] 3. Mild-moderate disability (mostly independent functioning and some interference with daily activities)
- [ ] 4. Major disability (requires help with most or all activities; has limited mobility)

B2.a. Name and Title of person who determined disability status:

_____

_____

C. COMPLICATIONS DURING HOSPITALIZATION (Please answer all items):

	1. NO	2. YES
C1. Recurrent Stroke	☐	☐
C2. Seizure	☐	☐
C3. Brain edema with worsening of symptoms	☐	☐
C4. Infection	☐	☐

↓

a. Bacterial	☐ **1. NO**	☐ **2. YES**	→ **COMPLETE FORM 31**
b. Viral	☐ **1. NO**	☐ **2. YES**	→ **COMPLETE FORM 31**
c. Other type of infection	☐ **1. NO**	☐ **2. YES**	→ **COMPLETE FORM 31**

↓

c1. Specify Type: _____

Signature of Study Coordinator:

Date: ___ ___ / ___ ___ / ___ ___ ___ ___

STOP II TRIAL

CAUSE OF DEATH FORM

AFFIX PATIENT'S LABEL HERE

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

A2. Date of Clinic's notification of the death (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___

A3. Date of death (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___

A4. Place of Death:

Address:

Number _____ Street _____ | |

a. City _____ b. County _____ c. State

A5. This is the address of

- ☐ 1. A STOP Hospital — A5.a STOP Center code # | |
- ☐ 2. A non-STOP Hospital * → **GO TO A5.b**
- ☐ 3. A chronic care facility* → **GO TO A5.b**
- ☐ 4. The patient's home
- ☐ 5. Other → **GO TO A5.b**

A5.b Specify Name:_____

☐ ML ☐ DE

A6. If the place of death was a hospital, what was the time of death in relationship to the time of the patient's presentation at the hospital?

☐ 1. Pronounced dead on arrival at hospital

☐ 2. Died in emergency room or within 24 hours of admission

☐ 3. Died more than 24 hours after admission

↓

A6.a Date of admission Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___

A6.b Admitting diagnosis:

OFFICE USE

a. _____ ☐☐☐.☐☐

b. _____ ☐☐☐.☐☐

c. _____ ☐☐☐.☐☐

d. _____ ☐☐☐.☐☐

* **Obtain signed RELEASE OF INFORMATION form from next of kin and request records**

****ATTACH HOSPITALIZATION SUMMARY**** ☐

OFFICE USE

B1. Is a copy of the death certificate available?

☐ **1. NO** ☐ **2. YES**

↓

The cause of death as reported on the Death Certificate was:

OFFICE USE

a. immediate _____ ☐☐☐.☐☐

b. due to _____ ☐☐☐.☐☐

c. due to _____ ☐☐☐.☐☐

Other significant conditions reported on the Death Certificate were:

OFFICE USE

d. _____ ☐☐☐.☐☐

e. _____ ☐☐☐.☐☐

f. _____ ☐☐☐.☐☐

****ATTACH A COPY OF THE DEATH CERTIFICATE**** ☐

OFFICE USE

B2. The information regarding the circumstances surrounding the death was obtained from:
(CHECK NO OR YES FOR EACH OF a - d)

	1. NO	**2. YES**
a. Member of immediate family	☐	☐
b. Medical Personnel	☐	☐
c. Medical Records	☐	☐
d. Other	☐	☐

a1. Specify _____

d1. Specify _____

B3. Was an autopsy performed?

☐ **1. NO**

☐ **2. YES →** **ATTACH A COPY OF THE COMPLETE REPORT**

☐ **9. DK**

☐ **OFFICE USE**

C1. Classification of cause of death by STOP II Center Investigator

☐ **1. NEUROLOGICAL EVENT →**

C1.a Type

- ☐ **1. Cerebral Infarction**
- ☐ **2. Intracranial Hemorrhage**

C1.b Specify type _____

- ☐ **3. Other →** C1.c Specify _____

☐ **2. OTHER →** C1.d Specify _____

☐ **3. UNKNOWN – SUDDEN DEATH (EXPLAIN BELOW)**

☐ **4. UNKNOWN - NO INFORMATION**

Continue to C2

C2. STOP II Investigator's summary of sequence of events and/or circumstances surrounding the patient's death

****ATTACH COPIES OF DEATH CERTIFICATE, AUTOPSY REPORT, AND HOSPITAL SUMMARY WHEN AVAILABLE****
SUBMIT APPROPRIATE STOP EVENT FORMS FOR EACH EVENT SURROUNDING THE PATIENT'S DEATH:

FORM 30 FOR NEUROLOGICAL EVENT
FORM 31 FOR EACH NON-NEUROLOGICAL EVENT
FORMS 20 AND 21 FOR EACH TRANSFUSION
FORM 32 FOR DELAYED TRANSFUSION REACTION

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

STOP II TRIAL
ENDPOINT ADJUDICATION DECISION

A1. Patient ID # ☐☐ - ☐☐☐ - ☐

A2. ACROSTIC ☐☐☐☐☐

A3 Date of neurological event (Month/Day/Year): ___ ___ / ___ ___ / ___ ___ ___ ___

B. SUMMARY AND CONSENSUS FOR NEW STROKE

Individual assessments: Did patient have a new stroke?

1. Reviewer #1 _____ (Initials) ☐☐☐ ☐ **1. NO** ☐ **2. YES**
2. Reviewer #2 _____ (Initials) ☐☐☐ ☐ **1. NO** ☐ **2. YES**
3. Reviewer #3 _____ (Initials) ☐☐☐ ☐ **1. NO** ☐ **2. YES**

C. SUMMARY OF TELECONFERENCE (If applicable):

D. GROUP CONSENSUS FOR NEW STROKE

D1. Is the group consensus that the patient had a new stroke?

☐ **1. NO** ↓

D1.a If NO, type of event:

- ☐ 1. TIA
- ☐ 2. Seizure
- ☐ 3. Migraine
- ☐ 4. Non-CNS event: Specify _____
- ☐ 5. Other: Specify _____
- ☐ 6. Cannot determine

☐ **2. YES** ↓

D1.b If YES, type:

- ☐ 1. Infarction
- ☐ 2. Intraparenchymal Hemorrhage
- ☐ 3. Subarachnoid Hemorrhage
- ☐ 4. Intraventricular Hemorrhage

Signature of Endpoint Adjudication Panel Chair: _____ Date ___ ___ / ___ ___ / ___ ___ ___ ___

Fax completed report to: Dianne Gallagher
New England Research Institutes
FAX #: (617) 923-4176

☐ ML ☐ DE

STOP II TRIAL

QUASI-ADJUDICATION NEUROLOGICAL EVENT FORM

AFFIX PATIENT LABEL HERE

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

A2. Date of neurological event (Month/Day/Year): ____ ____/____ ____/____ ____ ____ ____

B. PRESENTATION

B1. Where was the patient first seen for this event?
☐ **1. STOP II Center** → B1.a. Center # ☐☐
☐ **2. Other** → B1.b _____

B2. Were signs or symptoms first reported at a quarterly visit? ☐ **1. NO** ☐ **2. YES**

↓

B2.a Date of Quarterly Progress Report (Month/Day/Year): ____ ____/____ ____/____ ____ ____ ____

B3. What signs or symptoms occurred?

(CHECK NO OR YES BOX FOR EACH OF B3.a-l)

	1. NO	**2. YES**	
B3.a Loss of consciousness	☐	☐	
B3.b Change in mental status	☐	☐	
B3.c Loss of or difficulty with speech	☐	☐	
B3.d Paralysis or weakness	☐	☐	→ B3.d1 SIDE: ☐ **1. RIGHT** ☐ **2. LEFT** ☐ **3. BOTH**
B3.e Difficulty with swallowing	☐	☐	
B3.f Difficulty with vision	☐	☐	→ B3.f1 SIDE: ☐ **1. RIGHT** ☐ **2. LEFT** ☐ **3. BOTH**
B3.g Loss of balance or dizziness	☐	☐	
B3.h Seizure	☐	☐	
B3.i Headache	☐	☐	→ B3.i1 LOCATION: ☐ **1. DIFFUSE** ☐ **2. FOCAL**
			↓ B3.i1a SPECIFY: _____
B3.j New sensory disturbance	☐	☐	→ B3.j1 SIDE: ☐ **1. RIGHT** ☐ **2. LEFT** ☐ **3. BOTH**
B3.k Change in behavior	☐	☐	
B3.l Change in gait or coordination	☐	☐	

B4. Was patient hospitalized for this event?

☐ **1. NO** ☐ **2. YES** →

B4.a Date of Hospital Admission (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___

B4.b Date of Hospital Discharge (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___

B4.c Where was patient hospitalized? _____

_____

C. HISTORY

C1. Person interviewed **(SELECT PERSON PROVIDING MAJORITY OF RESPONSES)**

☐ **1. Patient** ☐ **2. Parent** ☐ **3. Other** → C1.a Specify: _____

C2. Did person interviewed witness suspected event? ☐ **1. NO** ☐ **2. YES**

C3. Did the patient experience any of the following during the two weeks prior to the neurological event?

(CHECK NO OR YES BOX FOR EACH OF C3.a - i)	**1. NO**	**2. YES**	**3. DON'T KNOW**
C3.a Acute febrile event	☐	☐	☐
C3.b Painful event	☐	☐	☐
C3.c Acute Chest Syndrome	☐	☐	☐
C3.d Acute anemia	☐	☐	☐
C3.e General anesthesia	☐	☐	☐
C3.f Priapism	☐	☐	☐
C3.g Head injury with loss of consciousness	☐	☐	☐
C3.h Transfusion	☐	☐	☐
C3.i Other	☐	☐	☐

↓

C3.i1 Specify _____

_____

C4. DESCRIBE PERTINENT CLINICAL DETAILS OF CLINICAL EVENTS WHICH OCCURRED WITHIN THE TWO WEEKS PRECEDING THE NEUROLOGICAL EVENT

_____

_____

D. RESULTS OF IMAGING AND ULTRASOUND TESTS PERFORMED TO EVALUATE <u>THIS EVENT</u>: (CHECK APPROPRIATE BOX FOR EACH OF D1 - 7)

D1. MRI of brain ☐ **1. NOT DONE** ☐ **2. DONE**

↓

D1.a Date performed (month/day/year): ___ ___/___ ___/___ ___ ___ ___

D1.b Was DWI performed? ☐ **1. NO** ☐ **2. YES**

D2. CT scan of brain ☐ **1. NOT DONE** ☐ **2. DONE**

↓

D2.a Date performed (month/day/year): ___ ___/___ ___/___ ___ ___ ___

D3. PET scan of brain ☐ **1. NOT DONE** ☐ **2. DONE**

↓

D3.a Date performed (month/day/year): ___ ___/___ ___/___ ___ ___ ___

D4. MRA of brain ☐ **1. NOT DONE** ☐ **2. DONE**

↓

D4.a Date performed (month/day/year): ___ ___/___ ___/___ ___ ___ ___

D5. Arteriogram ☐ **1. NOT DONE** ☐ **2. DONE**

↓

D5.a Date performed (month/day/year): ___ ___/___ ___/___ ___ ___ ___

D6. Transcranial Doppler ☐ **1. NOT DONE** ☐ **2. DONE**

↓

D6.a Date performed (month/day/year): ___ ___/___ ___/___ ___ ___ ___

D7. Other → D7.a Specify_____

☐ **1. NOT DONE** ☐ **2. DONE**

↓

D7.b Date performed (month/day/year): ___ ___/___ ___/___ ___ ___ ___

ATTACH COPIES OF LOCAL REPORTS FOR ALL IMAGING STUDIES COMPLETED

E. NEUROLOGICAL EVALUATION

E1. Was a neurological evaluation performed by the STOP II Neurology Consultant?

☐ **1. NO**

☐ **2. YES →** E1.a Date of exam (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___

F. MANAGEMENT AND COMPLICATIONS

F1. Were there other events associated with this neurological event? ☐ **1. NO** ☐ **2. YES**

F2. Was the patient transfused for this neurological event ? ☐ **1. NO** ☐ **2. YES**

F3. Did the patient die as a complication of this event ? ☐ **1. NO** ☐ **2. YES**

G. FINAL LOCAL DIAGNOSIS

G1. Type of neurological event:

☐ **1. Cerebral Infarction** ☐ **2. Intracranial Hemorrhage** ☐ **3. TIA** ☐ **4. Seizure** ☐ **5. Other** ↓

G1.a Specify: _____

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

H. FOR OFFICE USE

H1. Imaging/ultrasound reports received: ☐ **1. NO** ☐ **2. YES**

H2. TCD received: ☐ **1. NO** ☐ **2. YES** ☐ **-1. NA (Not Done)**

STOP II TRIAL
QUASI-ADJUDICATION CONSENSUS

****AFFIX PATIENT LABEL HERE****

A1. Patient ID # ☐☐ - ☐☐☐ - ☐

A2. ACROSTIC ☐☐☐☐☐

A3 Date of neurological event (Month/Day/Year): ___ ___ / ___ ___ / ___ ___ ___ ___

B. SUMMARY AND CONSENSUS FOR NEW STROKE

Individual assessments: Did patient have a new stroke?

1. Reviewer #1 _____ (Initials) ☐☐☐ ☐ **1. NO** ☐ **2. YES**
2. Reviewer #2 _____ (Initials) ☐☐☐ ☐ **1. NO** ☐ **2. YES**
3. Reviewer #3 _____ (Initials) ☐☐☐ ☐ **1. NO** ☐ **2. YES**

C. SUMMARY OF TELECONFERENCE (If applicable):

D. GROUP CONSENSUS FOR NEW STROKE

D1. Is the group consensus that the patient had a new stroke?

☐ **1. NO** ↓

D1.a If NO, type of event:

- ☐ 1. TIA
- ☐ 2. Seizure
- ☐ 3. Migraine
- ☐ 4. Non-CNS event: Specify _____
- ☐ 5. Other: Specify _____
- ☐ 6. Cannot determine

☐ **2. YES** ↓

D1.b If YES, type:

- ☐ 1. Infarction
- ☐ 2. Intraparenchymal Hemorrhage
- ☐ 3. Subarachnoid Hemorrhage
- ☐ 4. Intraventricular Hemorrhage

Signature of Endpoint Adjudication Panel Chair: _____ Date ___ ___ / ___ ___ / ___ ___ ___ ___

Fax completed report to: Dianne Gallagher
New England Research Institutes
FAX #: (617) 926-1142

Optimizing Primary Stroke Prevention in Children with Sickle Cell Anemia
Patient Roster for STOP II

1.	Patient ID:		__ __ __ __ __ __
2.	Acrostic:		__ __ __ __ __
3.	Line number:		__ __
4.	Date of birth:		__ __ / __ __ / __ __ __ __
5.	Gender:		1. FEMALE 2. MALE
6.	Hemoglobin Diagnosis:		1. SS 2. HbS β^0 Thalassemia
7.	Has diagnosis been confirmed?		1. NO 2. YES
8.	Are there other siblings on the roster?		1. NO 2. YES
	a. Sibling ID #1:		__ __ __ __ __ __
	b. Sibling ID #2:		__ __ __ __ __ __
	c. Sibling ID #3:		__ __ __ __ __ __
	d. Sibling ID #4:		__ __ __ __ __ __
9.	Is patient expected to be screened in STOP II?		1. NO, NOT ELIGIBLE 2. NO 3. YES
10.	Is the patient on transfusion for primary stroke prevention?		1. NO 2. YES
11.	Begin Date of transfusions:		__ __ / __ __ / __ __ __ __
12.	End Date of transfusions:		__ __ / __ __ / __ __ __ __
13.	Old STOP ID number of patient:		__ __ __ __ __ __
15.	Did patient enroll as a Potential patient?		1. NO 2. YES
16.	Did patient discontinue f/u as a Potential patient?		1. NO 2. YES
		a. Date discontinued:	__ __ / __ __ / __ __ __ __
		b. Reason discontinued:	_____
17.	Comments: _____		