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: ___ ___/___ ___/___ ___ ___ __