

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 ≥ 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

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**PROCEED WITH TCD EXAMINATION
AND COMPLETE TCD EXAM FORM**

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