

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/β⁰ 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 ≥ 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?

1. NO →

STOP – FORM COMPLETE

(Answers to C2 – C4b = YES, Answers to C5 – C6 = NO)

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: ____/____/____