S13r0 Randomization Eligibility Form

Patient's Identification Number _____

Visit date: _____

Correction?
☐ Yes
☐ No

Section I: If any of these items are No, the patient is not eligible for randomization.

1. Patient must have sickle cell anemia (hemoglobin SS) or sickle beta thalassemia (hemoglobin S beta), as confirmed at the local institution.
☐ Yes
☐ No

2. Patient must have a documented silent cerebral infarct approved by the Neurology Committee.
☐ Yes
☐ No

3. Randomization informed consent, with assent, in accordance with institutional policies (institutional IRB/Ethics Committee approval) and government guidelines, must be signed by the patient's legally-authorized guardian acknowledging written consent to join the study. When suitable, patient will be requested to give his/her assent to join the study.
☐ Yes
☐ No

Section II: If any of these items are Yes, patient is not eligible for randomization.

4. Patient with a history of a focal neurologic event lasting more than 24 hours with medical documentation or a history of prior overt stroke.
☐ Yes
☐ No

5. Patient who has a TCD study with a time-averaged mean velocity equal to or greater than 200 cm/sec verified by the study radiologist or a TCD that is undetermined.
☐ Yes
☐ No

6. Patient whose pre-randomization MRI (2nd MRI immediately prior to randomization) shows progressive silent infarct lesions or additional silent infarct lesions.
☐ Yes
☐ No

7. Patient with other neurological problems, such as neurofibromatosis, lead poisoning, seizures, or tuberous sclerosis.
☐ Yes
☐ No

8. Patient with HIV infection.
☐ Yes
☐ No

9. Patient who is pregnant or lactating.
☐ Yes
☐ No

10. Patient who received treatment with anti-sickling drugs or hydroxyurea within 3 months or anticipates receiving anti-sickling drugs or hydroxyurea during the course of study.
☐ Yes
☐ No

Patient with abnormal kidney function (creatinine > 2X upper limit of normal).
☐ Yes
☐ No

12. Patient on chronic blood transfusion therapy for any reason.
- ☐ Yes
- ☐ No

13. Patient whose family is judged not likely to be compliant by hematologist and local coordinator, based on previous compliance in clinical appointments and following advice. Specifically, a patient whose family has missed at least two appointments without notification within 12 months prior to the trial, or whose parents have been reported for medical or educational neglect, is not eligible for this trial.
- ☐ Yes
- ☐ No

14. Patient unable to receive blood transfusion because of alloimmunization.
- ☐ Yes
- ☐ No

15. Patient who has (or anticipates receiving) permanent (or semi-permanent) metallic structures attached to their body (e.g., braces on teeth, body piercings), which his/her physician feels will interfere with the MRI of the head to assess the presence of silent cerebral infarct, should not be referred for screening MRI. EXCEPTION: If the screening MRI is interpretable, and the metallic structures do not interfere with quality of the MRI, the patient remains eligible.
- ☐ Yes
- ☐ No

16. Patient with sibling who has been randomly assigned in the SIT Trial.
- ☐ Yes
- ☐ No

Summary

17. is this patient eligible for randomization?
- ☐ Yes
- ☐ No

Staff ID #: _____

PI Signature: _____