

S00r0 Screening 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 screening.

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 be 6 through 12 years of age (i.e., must have attained their 6th, but not their 13th birthday). Yes
 No
3. Screening 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, the patient is not eligible for screening.

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 with neurological problems, such as neurofibromatosis, lead poisoning, seizures, or tuberous sclerosis. Yes
 No
6. Patient with HIV infection. Yes
 No
7. Patient who is pregnant or lactating. Yes
 No
8. Patient who received treatment with anti-sickling drugs or hydroxyurea within 3 months, or anticipate receiving anti-sickling drugs or hydroxyurea during the course of the study. Yes
 No
9. Patient on chronic blood transfusion therapy for any reason. Yes
 No
10. 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

11. Patient unable to receive blood transfusion because of alloimmunization. Yes No

12. 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

13. Patient with sibling who has been randomly assigned in the SIT Trial. Yes No

Summary

14. Is this patient eligible for screening? Yes No

Staff I.D. #: _____

P.I. ID #: _____