

ELIGIBILITY SCREENING I

PART I: IDENTIFYING INFORMATION

1. Patient's ID Number: ID
2. Current Clinic: SITE
3. Patient's Letter Code: INITS
4. Visit: VISIT - sequence # SEQNO
5. Visit Date: - - VIS_DT
- Month Day Year

PART II: INCLUSION CRITERIA

- | | Yes | No |
|---|---------------|---------------|
| 1. Diagnosis of Hb-SS or Hb S-beta-0-thal?
DIAGHBSS | (1) | (2)
(INEL) |
| 2. A. Date of Birth: <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/>
Month Day Year BIRTH_DT | | |
| B. Is the child between 9 and 17 months of age inclusive?
AGEINCL4 | (1) | (2)
(HOLD) |
| <div style="border: 1px solid black; padding: 2px; width: fit-content; margin-bottom: 10px;">If <u>NO</u>, answer Item 2C.</div> | | |
| C. Will the child be between 9 and 17 months of age inclusive, during the study recruitment period?
WILL1217 | (1)
(HOLD) | (2)
(INEL) |
| 3. Has informed consent been obtained?
CONSNT04 | (1) | (2)
(HOLD) |
| 4. Has HIPAA authorization form been obtained?
HIPAA04 | (1) | (2)
(HOLD) |
| 5. Does the family have telephone service for contact as required?
PHONE04 | (1) | (2)
(HOLD) |

PART III: EXCLUSION CRITERIA

- | | | Yes | No |
|-------|---|---------------|-----------------|
| 1. A. | Splenectomy?SPLENCBL | (1)
(INEL) | (2) |
| B. | Chronic transfusion program? CHRTRFBL | (1)
(INEL) | (2) |
| C. | Transfusion within last 2 months? TRN2MO04 | (1)
(HOLD) | (2) |
| 1. | If yes, Date <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> | | TRN04_DT |
| | Month Day Year | | |
| D. | Known hereditary persistence of Hb-F? HERPHFBL | (1)
(INEL) | (2) |
| E. | Stroke or Grade III/IV intracranial STROKEBL | (1)
(INEL) | (2) |
| F. | Malignancy? MALIGBL | (1)
(INEL) | (2) |
| G. | Cerebral palsy and/or mental retardation? ... PALSYBL | (1)
(INEL) | (2) |
| H. | Other condition or severe chronic illness? OTHCHRBL | (1)
(INEL) | (2) |
| I. | S-beta+ thalassemia? SBTHALBL | (1)
(INEL) | (2) |
| J. | Previous or current hydroxyurea therapy? ... PRVHUBL | (1)
(INEL) | (2) |
| K. | Other antisickling agent, previous or current? ANTISKBL | (1)
(INEL) | (2) |
| L. | Current participation in other intervention TRIALSBL | (1)
(INEL) | (2) |

PART IV: SIBLING INFORMATION

- | | | | |
|----|---|-------------|-----------|
| 1. | Does the child have a sibling either enrolled or in screening in BABY HUG? SIB_ENR | Yes
(1)* | No
(2) |
|----|---|-------------|-----------|

*A. If yes, what is the sibling's Patient ID? **SIBLING**

PART V: COORDINATION

1. Checked for completeness and accuracy:

- | | | |
|----|---|-----------------|
| A. | Certification number: <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> | CERT_NO |
| B. | Signature: _____ | CERT_SIG |
| C. | General Comments: | GEN_CMNT |

ID Number	Visit	Seq
<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	- <input type="text"/> <input type="text"/>