STOP II

INTAKE HISTORY FORM FOR PATIENTS ENROLLED AS POTENTIALS OR RANDOMIZED PATIENTS

***** AFFIX PATIENT LABEL HERE *****

A1. Person completing form (Name):_____ (Initials): | | | |

A2. Date of interview (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___

A3. Person interviewed (Choose **ONE** for person providing majority of answers to sections B-D):

☐ **1. Patient** ☐ **2. Parent** ☐ **3. Legal Guardian** ☐ **4. Other** → A3.a (specify): _____

A4. Were address and telephone information verified for this patient? ☐ **1. NO** ☐ **2. YES**

QUESTIONS IN SECTIONS B THROUGH D ARE TO BE ANSWERED BY THE PERSON INTERVIEWED; QUESTIONS IN SECTIONS E THROUGH I ARE TO BE ANSWERED BY MEDICAL PERSONNEL.

B. MEDICATIONS

B1. Is the patient currently taking, on a regular basis, any medications prescribed by a physician?

☐ **1. NO** ☐ **2. YES** ↓

B1.a TYPE OF MEDICATION: (CHECK **NO** OR **YES** FOR EACH OF B1.a1-6)	**1. NO**	**2. YES**	**B1.b HOW MANY MONTHS HAS PATIENT BEEN TAKING THE MEDICATION?**
1. Penicillin	☐	☐	1. ☐☐☐
2. Other antibiotic	☐	☐	2. ☐☐☐
		↓ B1.a2.a SPECIFY:_____	
3. Folate	☐	☐	3. ☐☐☐
4. Hydroxyurea	☐	☐	4. ☐☐☐
5. Iron Chelators (Desferoxamine)	☐	☐	5. ☐☐☐
6. Other	☐	☐	6.a ☐☐☐
		↓	6.b ☐☐☐
		B1.a6.a SPECIFY:_____ B1.a6.b SPECIFY: _____	

☐ ML ☐ DE

C. CLINICAL EVENT HISTORY

C1. Has the patient had 2 or more episodes of Acute Chest Syndrome (pneumonia) in the past year? ☐ **1. NO** ☐ **2. YES**

(**PROBE:** An infection or blockage of blood flow in the lungs)

C2. How many times was the patient hospitalized for sickle cell painful episodes in the last 2 years? ☐☐

(**PROBE:** Pain in the bones of arms, legs, or vertebrae**)**

C3.a Has the patient ever been seen by a doctor for any of the following events?			C3.b **What was date of recent event (month/year)**	C3.c **Where seen for most recent event? 1 = STOP II Center 2 = Non-STOP II Center**
1. Meningitis	☐ **1. NO**	☐ **2. YES** →	___ ___/___ ___ ___ ___	☐
(PROBE: Infection of the brain**)**				
2. Splenic Sequestration	☐ **1. NO**	☐ **2. YES** →	___ ___/___ ___ ___ ___	☐
(PROBE: Enlargement of the spleen with trapping of blood in it)				
3. Aplastic Crisis	☐ **1. NO**	☐ **2. YES** →	___ ___/___ ___ ___ ___	☐
(PROBE: A drop in the blood count which required a transfusion)				
4. Hand-Foot Syndrome	☐ **1. NO**	☐ **2. YES** →	___ ___/___ ___ ___ ___	☐
(PROBE: Pain, tenderness, with or without swelling, in the hands and/or feet only)				
5. Septicemia	☐ **1. NO**	☐ **2. YES** →	___ ___/___ ___ ___ ___	☐
(PROBE: An infection in the blood stream**)**				
6. Osteomyelitis	☐ **1. NO**	☐ **2. YES** →	___ ___/___ ___ ___ ___	☐
(PROBE: Infection in the bones)				
7. Priapism	☐ **1. NO**	☐ **2. YES** →	___ ___/___ ___ ___ ___	☐
(PROBE: A painful, unwanted erection of the penis lasting more than one hour)				
8. Transfusion Reaction	☐ **1. NO**	☐ **2. YES** →	___ ___/___ ___ ___ ___	☐
(PROBE: Complication of a transfusion within 2 weeks after the transfusion was given)				

C4. Has the patient had any of the following surgical procedures?

a. Splenectomy	☐ **1. NO**	☐ **2. YES** →	C4.a1 Date: (month/year) ___ ___/___ ___ ___ ___
b. Liver Biopsy	☐ **1. NO**	☐ **2. YES** →	C4.b1 Date: (month/year) ___ ___/___ ___ ___ ___
			C4.b2 Date: (month/year) ___ ___/___ ___ ___ ___
			C4.b3 Date: (month/year) ___ ___/___ ___ ___ ___

C5. Does the patient currently have a portacath? ☐ **1. NO** ☐ **2. YES**

D. FAMILY HISTORY OF STROKE

D1. Have any of the following members of the child's family ever had a stroke?

a. Mother ☐ 1. NO ☐ 2. YES ☐ 3. DON'T KNOW

b. Father ☐ 1. NO ☐ 2. YES ☐ 3. DON'T KNOW

c. Brothers ☐ 1. NO ☐ 2. YES ☐ 3. DON'T KNOW ☐ 4. NA - no brothers

↓

c1. # of brothers who had stroke ☐☐

d. Sisters ☐ 1. NO ☐ 2. YES ☐ 3. DON'T KNOW ☐ 4. NA - no sisters

↓

d1. # of sisters who had stroke ☐☐

*******SECTIONS E THROUGH I TO BE COMPLETED BY MEDICAL PERSONNEL*******

E. OTHER MEDICAL CONDITIONS

Does the patient currently carry the diagnosis of: **(CHECK NO OR YES FOR E1 - E19)**	1. NO	2. YES	Year of diagnosis
E1. Leg ulcers	☐	☐ →	1.a ☐☐☐☐
E2. Aseptic necrosis	☐	☐ →	2.a ☐☐☐☐
2.b If Yes, specify location(s) _____			
E3. Sickle cell retinopathy	☐	☐ →	3.a ☐☐☐☐
E4. Chronic lung disease	☐	☐ →	4.a ☐☐☐☐
4.b If Yes, specify type _____			
4.b1 ☐☐☐.☐☐ **OFFICE USE**			
E5. Asthma	☐	☐ →	5.a ☐☐☐☐
E6. Chronic heart disease	☐	☐ →	6.a ☐☐☐☐
6.b If Yes, specify type: _____			
6.b1 ☐☐☐.☐☐ **OFFICE USE**			
E7. Chronic liver disease	☐	☐ →	7.a ☐☐☐☐
7.b If Yes, specify type: _____			
7.b1 ☐☐☐.☐☐ **OFFICE USE**			
E8. Chronic renal disease	☐	☐ →	8.a ☐☐☐☐
8.b If Yes, specify type: _____			
8.b1 ☐☐☐.☐☐ **OFFICE USE**			
8.c If Yes, is patient receiving dialysis?	☐ 1. NO	☐ 2. YES	

	1. NO	2. YES	Year of diagnosis
E9. Iron overload	☐	☐ →	9.a ☐☐☐☐
9.b If yes, highest ferritin level (ng/ml) ☐☐☐☐☐			
E10. Diabetes	☐	☐ →	10.a ☐☐☐☐
E11. Rheumatic fever	☐	☐ →	11.a ☐☐☐☐
E12. Tuberculosis	☐	☐ →	12.a ☐☐☐☐
E13. Cancer	☐	☐ →	13.a ☐☐☐☐
13.b If Yes, specify type: _____			
13.b1 ☐☐☐.☐☐ OFFICE USE			
E14. Priapism	☐	☐ →	14.a ☐☐☐☐
E15. Elevated blood lead level (blood lead level ≥ 15 mg/dl?)	☐	☐ →	15.a ☐☐☐☐
E16. Hepatitis B	☐	☐ →	16.a ☐☐☐☐
E17. Hepatitis C	☐	☐ →	17.a ☐☐☐☐
E18. HIV	☐	☐ →	18.a ☐☐☐☐
E19. Any other chronic medical condition?	☐	☐	
19.b If Yes, specify type: _____			19.b1 ☐☐☐☐
19.b2 ☐☐☐.☐☐ OFFICE USE			
19.c If Yes, specify type: _____			19.c1 ☐☐☐☐
19.c2 ☐☐☐.☐☐ OFFICE USE			

F. RED CELL PHENOTYPING (COMPLETION NOT REQUIRED FOR PATIENTS RANDOMIZED IN STOP)

F1. Was the patient randomized in STOP? ☐ **1. NO** ☐ **2. YES →** **GO TO SECTION G**

F2.a. ABO Blood Group

☐ **1. A** ☐ **2. B** ☐ **3. AB** ☐ **4. O**

F2.b Rh Antigens	1. ABSENT	2. PRESENT
1. D	☐	☐
2. C	☐	☐
3. E	☐	☐
4. e	☐	☐
5. c	☐	☐
6. f	☐	☐
7. V	☐	☐

F2.c Kell Antigens	1. ABSENT	2. PRESENT
1. K (Kell)	☐	☐
2. k	☐	☐
3. Js^a	☐	☐
4. Js^b	☐	☐
5. Kp^a	☐	☐
6. Kp^b	☐	☐
F2.d Duffy Antigens		
1. Fy^a	☐	☐
2. Fy^b	☐	☐
F2.e Kidd Antigens		
1. Jk^a	☐	☐
2. Jk^b	☐	☐
F2.f Lewis Antigens		
1. Le^a	☐	☐
2. Le^b	☐	☐
F2.g Lutheran Antigens		
1. Lu^a	☐	☐
2. Lu^b	☐	☐
3. Lu^3	☐	☐
F2.h P Antigens		
1. P_1	☐	☐
F2.i MNS Antigens		
1. M	☐	☐
2. N	☐	☐
3. S	☐	☐
4. s	☐	☐
5. U	☐	☐

***** ATTACH RED CELL PHENOTYPE REPORT ******

G. RED CELL ANTIBODIES AND TRANSFUSION COMPLICATIONS

G1. Is the patient known by your blood bank to have any of the following red cell antibodies?

(CHECK NO OR YES FOR EACH OF G1 a - l)

	1.NO	2. YES	G2. Date first identified
a. anti-D	☐	☐ →	___ ___/___ ___/___ ___ ___ ___
b. anti-C	☐	☐ →	___ ___/___ ___/___ ___ ___ ___
c. anti-E	☐	☐ →	___ ___/___ ___/___ ___ ___ ___
d. anti-M	☐	☐ →	___ ___/___ ___/___ ___ ___ ___
e. anti-S	☐	☐ →	___ ___/___ ___/___ ___ ___ ___
f. anti-K (Kell)	☐	☐ →	___ ___/___ ___/___ ___ ___ ___
g. anti-Fy^a	☐	☐ →	___ ___/___ ___/___ ___ ___ ___
h. anti-Fy^b	☐	☐ →	___ ___/___ ___/___ ___ ___ ___
i. anti-Jk^b	☐	☐ →	___ ___/___ ___/___ ___ ___ ___
j. anti-Le^a	☐	☐ →	___ ___/___ ___/___ ___ ___ ___
k. anti-Le^b	☐	☐ →	___ ___/___ ___/___ ___ ___ ___
l. Other	☐	☐ ↓	

List Antibody:		Date first identified:	
G1.l1	_____	G1.l1.a	___ ___/___ ___/___ ___ ___ ___
G1.l2	_____	G1.l2.a	___ ___/___ ___/___ ___ ___ ___
G1.l3	_____	G1.l3.a	___ ___/___ ___/___ ___ ___ ___

G3. Has the patient ever had a transfusion reaction? ☐ **1. NO** ☐ **2. YES** ☐ **3. DON'T KNOW**

↓

G3.a Describe

_____

_____

_____

H. VACCINATIONS

H1. Has the patient received Hepatitis B vaccination?

☐ **1. NO** ☐ **2. YES**

↓

H1.a Date of most recent vaccination (Month/Day/Year)

___ ___/___ ___/___ ____ ___ ___

I. GENERAL

I1. Is the patient seen for most of his/her clinical events at a NON-STOP II study site because of third party payment restrictions, distance from clinic, some other reason? ☐ **1. NO** ☐ **2. YES**

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

SECTION J. FOR OFFICE USE

J1. Local red cell phenotyping report received?

☐ **1. NO**

☐ **2. YES**

☐ **-1. NA**