REAL Medical Record Abstraction Form – v1.0

Subject ID

This form should be completed using data abstracted from the medical record. Follow the instructions for each question to determine how far in the record to look back.

DATE OF CONSENT: |___|___|-|___|___|-|___|___|___|___|
Month Day Year

DATE THIS FORM COMPLETED: |___|___|-|___|___|-|___|___|___|___|
Month Day Year

1. Confirmed enrollment diagnosis: (CHECK ONLY ONE). DIAGNOSIS MUST BE SUPPORTED BY SOURCE DOCUMENTATION.

Diagnosis	
a. Hb SS or sickle cell anemia	☐
b. Hb SC disease	☐
c. Hb S beta^0 thalassemia	☐
d. Hb S beta$^+$ thalassemia	☐

Diagnosis	
e. Hb S hereditary persistence of fetal Hb (S/HPFH)	☐
f. Hb SE	☐
g. Hb SD	☐
h. Hb SO	☐

a. What was the basis for diagnosis?
- ☐ Newborn screening
- ☐ Hemoglobin fractionation
- ☐ Hemoglobin electrophoresis
- ☐ DNA sequencing

2. Approximate age of first diagnosis (physician confirmed): _____ AGE In YEARS **OR** ☐ NEWBORN SCREENING **OR** ☐ UNKNOWN

3. Has the subject ever been evaluated for curative gene therapy? ☐ Yes ☐ No

4. Most recent test results for alpha-thalassemia?
- ☐ Yes—single alpha globin gene deleted
- ☐ Yes—two alpha globin genes deleted
- ☐ Yes––negative
- ☐ No—not evaluated
- ☐ Unknown

Basic Measurements (most recent)	Not in Record	Measurements	Date (mm/yyyy)	Steady state?
5. Height	☐	|___|___|___| CM		Y N
6. Weight	☐	|___|___|___|.|___| KG		Y N
7. Temperature	☐	|___|___|.|___| Celsius		Y N
8. Heart Rate	☐	|___|___|___| BEATS/MINUTE		Y N
9. Respiration Rate	☐	|___|___|___| BREATHS/MINUTE		Y N
10. Oxygen saturation (SpO_2)	☐	|___|___|___| %		Y N
11. Blood Pressure	☐	|___|___|___| / |___|___|___| ON ANTI-HYPERTENSIVE MEDS? ☐ Yes ☐ No		Y N

12. Has the subject ever used hydroxyurea? YES NO (if NO skip to Endari question)

13. Is the subject currently taking hydroxyurea? ☐ Yes ☐ No

a. Start date (mm/yyyy) |__|__|-|__|__|__|__|

b. Stop/last date (mm/yyyy) |__|__|-|__|__|__|__| ☐ Currently using

14. Has the subject ever taken Endari ☐ Yes ☐ No ➔ **GO TO Q16**

a. Start date (mm/yyyy) |__|__|-|__|__|__|__|

b. Stop/last date (mm/yyyy) |__|__|-|__|__|__|__| ☐ Currently using

c. Total duration of use _____ ☐ Months or ☐ Years ☐ Unknown

d. Current dose _____ Mg/kg or _ Mg

15. Has the subject ever taken Adakveo? ☐ Yes ☐ No ➔ **GO TO Q18**

a. Start date (mm/yyyy) |__|__|-|__|__|__|__|

b. Stop/last date (mm/yyyy) |__|__|-|__|__|__|__| ☐ Currently using

c. Total duration of use _____ ☐ Months or ☐ Years ☐ Unknown

d. Current dose _____ __ Mg/kg or __ Mg

16. Has the subject ever taken Oxbryta? ☐ Yes ☐ No ➔ **GO TO Q20**

a. Start date (mm/yyyy) |__|__|-|__|__|__|__|

b. Stop/last date (mm/yyyy) |__|__|-|__|__|__|__| ☐ Currently using

c. Total duration of use _____ ☐ Months or ☐ Years ☐ Unknown

d. Current dose _____ Mg/kg or _ Mg

20. Does the subject currently take pain medicines? ☐ Yes ☐ No ➔ **GO TO Q21**

What pain medicines does the subject currently take?
On the list below, check the box next to the name of the pain medicines the subject takes (even if not every day).

- ❒ Acetaminophen & Codeine (TylenolCodeine #3 or #4)
- ❒ Acetaminophen & Oxycodone (Percocet, Endocet)
- ❒ Acetaminophen & Hydrocodone (Vicodin, Norco, Lortab)
- ❒ Acetaminophen (Tylenol)
- ❒ Amitriptyline/Elavil
- ❒ Aspirin (any brand)
- ❒ Aspirin, Caffeine & Codeine (Ascomp-Codeine)
- ❒ Buprenorphine/Belbuca/Butrans
- ❒ Celecoxib (Celebrex)
- ❒ Diclofenac/Voltaren/Cambia/Solaraze
- ❒ Esomeprazole (Nexium)
- ❒ Excedrin
- ❒ Fentanyl (Duragesic)
- ❒ Gabapentin (Neurontin)
- ❒ Hydromorphone (Exalgo ER, Dilaudid)
- ❒ Ibuprofen (Motrin, Advil)
- ❒ Ketorolac/Toradol
- ❒ Magnesium salicylic acid (Durasal)
- ❒ Meperidine (Demerol)
- ❒ Methadone (Dolophine)
- ❒ Morphine sulfate (MS Contin, Kadian)
- ❒ Morphine and Naltrexone (Embeda, MS IR)
- ❒ Naproxen (Aleve, Naprosyn)
- ❒ Oxycodone (Oxycontin, Roxicodone)
- ❒ Oxymorphone (Opana)
- ❒ Pentazocine/Talwin
- ❒ Pregabalin (Lyrica)
- ❒ Promethazine/Phenergan with Codeine
- ❒ Tapentadol/Nucynta
- ❒ Tramadol
- ❒ Venlafaxine/Effexor
- ❒ Medical marijuana/Cannabis
- ❒ Topical/Skin cream for pain (all types)
- ❒ Other pain medications (specify below)

_____

21. Please list all OTHER medications the subject is **currently** taking. ☐ NONE CURRENTLY BEING USED

Name of Medication	Name of Medication
a.	k.
b.	l.
c.	m.
d.	n.
e.	o.
f.	p.
g.	q.
h.	r.
i.	s.
j.	t.

SCD Complications **Indicate whether the subject has ever had a diagnosis of each condition and the date of the most recently diagnosed episode**	NO	YES	Most recent dx (age or date)		Condition currently under treatment
			Age	Date mm/yyyy	
Musculoskeletal					
24. Avascular necrosis *(check all that apply)*	☐	☐			
a. Hip	☐	☐			
b. Shoulder	☐	☐			
c. Knee	☐	☐			
d. Other location, specify _____	☐	☐			
Genitourinary					
25. Chronic kidney disease	☐	☐			
26. End stage renal disease *(if yes, complete Renal form)*	☐	☐			
a. Kidney transplant	☐	☐			
b. Kidney transplant rejection	☐	☐			
27. Priapism	☐	☐			
Nervous system					
28. Stroke (*check all that apply*)	☐	☐			
a. Ischemic	☐	☐			
b. Hemorrhagic	☐	☐			
c. Transient ischemic attack (TIA)	☐	☐			
d. Silent	☐	☐			
29. Intracranial bleeding	☐	☐			
Cardiovascular					
30. Pulmonary arterial hypertension	☐	☐			
a. Mean pulmonary artery pressure > or = to 25 mm Hg	☐	☐			
b. Tricuspid regurgitation velocity (TRV) > or = to 3.0 m/sec	☐	☐			
31. Left ventricular dysfunction	☐	☐			
Respiratory					
32. Acute chest syndrome	☐	☐			
33. Asthma	☐	☐			
Digestive					
34. Gallstones/cholelithiasis, cholecystitis	☐	☐			
35. Splenomegaly *(check all that apply)*	☐	☐			

a. PRBC transfusion given for splenomegaly? □ Yes □ No					
b. Splenic sequestration	□	□			
# sequestration episodes in past 12 months _____					
c. Splenic infarcts, symptomatic	□	□			
d. Hypersplenism	□	□			
e. Splenectomy	□	□			
Other Autoimmune/Inflammatory					
36. Deep vein thrombosis (DVT)	□	□			
a. Pulmonary embolism	□	□			
b. Venous thromboembolism (VTE)	□	□			
37. Lupus	□	□			
38. Rheumatoid arthritis	□	□			
39. Gout	□	□			
40. Sarcoidosis	□	□			
Other Conditions					
41. Multi-organ failure *(check all that apply)*	□	□			
a. ICU	□	□			
b. Intubation	□	□			
c. Simple transfusion	□	□			
d. Exchange transfusion	□	□			
e. Hemodialysis	□	□			
f. Peritoneal dialysis	□	□			
42. Pneumococcal sepsis	□	□			
43. Skin ulcers	□	□			
44. Retinopathy	□	□			
45. Diabetes mellitus	□	□			
46. Iron overload (liver iron content > 3 mg/g of dry weight liver on MRI or serum ferritin above 1,000 ng/dL for >3 separate measurements or >18 PRBCs)	□	□			
47. Chronic refractory pain	□	□			
48. Seizure disorder	□	□			
49. Anxiety	□	□			
50. Depression	□	□			
51. Other psychiatric disorder, specify:	□	□			
52. Other major health condition, specify:	□	□			
Liver Conditions					
53. Liver cirrhosis	□	□			
54. Intrahepatic cholelithiasis	□	□			
55. Hepatitis B	□	□			
56. Hepatitis C	□	□			
57. Hepatic sequestration	□	□			
58. Hepatomegaly	□	□			
59. Bridging fibrosis	□	□			

60. Has the subject ever been diagnosed with a primary cancer?

- ☐ Yes
- ☐ No ➔ GO TO Q61
- ☐ Don't know ➔ GO TO Q61

a. CANCER TYPE AND LOCATION_____

b. CANCER STAGE_____

c. DATE OF DIAGNOSIS (MM/YYY): |___|___| |___|___|___|___|

61. What kind of health insurance or health care coverage does the subject currently have? (Choose all that apply.)

- ☐ None
- ☐ Private health insurance
- ☐ Medicare
- ☐ Medicaid, Medical Assistance (MA), the Children's Health Insurance Program (CHIP), or any kind of state or government-sponsored assistance
- ☐ TRICARE or other military health care, including VA health care
- ☐ Support from Charities or Donations
- ☐ Other type of health insurance, specify:_____

Name of Abstractor: _____ PI review and sign-off: _____