Form 101 v1: Inclusion Criteria

Q01	Date of birth *Derived from Subject Enrollment Form Q06.* *Year of birth must be between 1996-2014 to be eligible.*		___ ___ - ___ ___ ___ - ___ ___ ___ ___ dd-mmm-yyyy
Q02	Sickle Cell Anemia subject identified through ICD-9/ICD-10 *Q02 must be yes to be eligible.*		0 No 0 Yes
Q03	Subject has been seen more than 2 times in either inpatient or outpatient setting at the institution between 2012-2016 *Q03 must be yes to be eligible.*		0 No 0 Yes
Q04	*If Q03 = 'Yes'*	Source of information	0 EMR 0 Administrative database 0 Center database 0 Other, specify: _____
Qc	General comments		

Name of person who collected data:

If this is a source document, sign/date here:

DISPLACE	Subject:	Visit:

Form 114 v2: Concomitant Medication Log

Enter any iron chelation, chronic aspirin, anti-coagulation, or hydroxyurea prescribed for the subject from January 1, 2012 to December 31, 2016. Start a new row to enter new medications or dose changes.

Q01	Concomitant medication prescribed within the calendar year				O No O Yes					
	QA. Medication type	*If QA is not hydroxyurea* QB. Name of medication	QH. Dose	QC. Reason for medication	QD. Date started dd-mmm-yyyy	QE. Status	QF. Date stopped dd-mmm-yyyy	*If QA= hydroxyurea and QE = stopped* QI. Reason stopped	*If QI = Other* QJ. Other reason stopped	QG. Notes
Q02-1	O Iron chelation O Chronic aspirin O Anti-coagulation O Hydroxyurea					O Continuing O Stopped O Unknown		O Not adherent O Side effects O Started CRCT O Unknown O Other		
Q02-2	O Iron chelation O Chronic aspirin O Anti-coagulation O Hydroxyurea					O Continuing O Stopped O Unknown		O Not adherent O Side effects O Started CRCT O Unknown O Other		
Q02-3	O Iron chelation O Chronic aspirin O Anti-coagulation O Hydroxyurea					O Continuing O Stopped O Unknown		O Not adherent O Side effects O Started CRCT O Unknown O Other		
Q02-4	O Iron chelation O Chronic aspirin O Anti-coagulation O Hydroxyurea					O Continuing O Stopped O Unknown		O Not adherent O Side effects O Started CRCT O Unknown O Other		
Qc	General comments									

Name of person who collected data:

If this is a source document, sign/date here:

Form 117 v1: Vital Signs

Enter the vital signs collected closest to or on the date that the TCD was completed within the calendar year.
If TCD did not occur for any reason, enter the vital signs closest to the scheduled TCD. If multiple TCDs occurred within that calendar year, only enter the vital signs for the first completed TCD.

Qa	Data collected	0 No 0 Yes
Qb	Date of assessment	___ ___ - ___ ___ ___ - ___ ___ ___ ___ dd-mmm-yyyy
Q01	Heart rate	_____ beats / min
Q02	Systolic blood pressure	_____ mmHg
Q03	Diastolic blood pressure	_____ mmHg
Q04	Oxygen saturation (SpO_2)	_____ %
Q05	Weight	_____ kg
Q06	Height	_____ cm
Qc	General comments	

Name of person who collected data:

If this is a source document, sign/date here:

Form 126 v3: End of Retrospective Study

Q01		Primary reason for study termination	0 Retrospective study completed 0 Lost to follow-up 0 Death 0 Other , specify: _____
Q03	*If Q01 is 'Lost to follow-up'*	Date subject was last known to be alive	___ ___ - ___ ___ ___ - ___ ___ ___ ___ dd-mmm-yyyy
Q06	*If Q01 is 'Death'*	Date of death	___ ___ - ___ ___ ___ - ___ ___ ___ ___ dd-mmm-yyyy
Q10	*If Q01 is 'Death'*	Cause of death	
Q11		Date subject was last seen at site	___ ___ - ___ ___ ___ - ___ ___ ___ ___ dd-mmm-yyyy
Q12		Eligible for prospective study *Derived from Form 101 Q01 and current date.*	0 No 0 Yes
Q13	*If subject is ≥ 18 years old*	Receiving adult care *As of 01-Jan-2017.*	0 No 0 Yes 0 Unknown
Q14	*If Q13 is 'Yes'*	Location of care *As of 01-Jan-2017.*	0 New hospital system 0 Same hospital system
A site team member must review and affirm that all case report forms have been completed for this study participant.			
Q15		All subject data have been entered for this subject	0 No 0 Yes
		Signature of site PI *Not for data entry.*	
Qc		General comments	

Name of person who collected data:

If this is a source document, sign/date here:

Form 501 v1: Diagnosis

Q01	Basis for diagnosis	O Newborn screening O Hemoglobin fractionation O Hemoglobin electrophoresis O DNA sequencing
Q02	Diagnosis	O Hb SS or sickle cell anemia O Hb S beta^0 thalassemia O Hb S + Hb FH O Hb SE O Hb SD O Hb SO
Q03	Alpha-thalassemia results	O Not done O Single alpha globin gene detected O Two alpha globin genes detected O Negative
Qc	General comments	

Name of person who collected data:

If this is a source document, sign/date here:

Form 502 v1: Developmental Screening and Neurocognitive Assessment

Q01		Developmental screening outside of primary care visit	0 No 0 Yes 0 Unknown
Q02	*If Q01 = 'Yes'*	Date of first developmental screening	___ ___ - ___ ___ ___ - ___ ___ ___ ___ dd-mmm-yyyy
Q03	*If Q01 = 'Yes'*	Reason for developmental screening	0 School-related issue 0 Parental concern 0 MRI Abnormality 0 TCD Abnormality 0 Behavioral issue 0 Other, specify: _____
Q04		Neurocognitive assessment	0 No 0 Yes 0 Unknown
Q05	*If Q04= 'Yes'*	Date of first neurocognitive assessment	___ ___ - ___ ___ ___ - ___ ___ ___ ___ dd-mmm-yyyy
Q06	*If Q04= 'Yes'*	Reason for neurocognitive assessment	0 School-related issue 0 Parental concern 0 MRI Abnormality 0 TCD Abnormality 0 Behavioral issue 0 Other, specify: _____
Qc		General comments	

Name of person who collected data:

If this is a source document, sign/date here:

Form 503 v1: Sickle Cell Disease Complications

At the Subject Registration visit, include all complications/diagnoses occurring prior to the registration visit.
For subsequent years, include complications/diagnoses occurring within that calendar year.

Q01	Subject experienced a neurological complication *Neurological complications are ischemic stroke, hemorrhagic stroke, transient ischemic attack, silent stroke, and intracranial bleeding.* *If yes, complete table below.*	0 No 0 Yes
	QA. Neurological complication	QB. Start date of neurological complication dd-mmm-yyyy
Q02-1	0 Ischemic stroke 0 Hemorrhagic stroke 0 Transient ischemic attack 0 Silent stroke 0 Intracranial bleeding	___ ___ - ___ ___ ___ - ___ ___ ___ ___
Q02-2	0 Ischemic stroke 0 Hemorrhagic stroke 0 Transient ischemic attack 0 Silent stroke 0 Intracranial bleeding	___ ___ - ___ ___ ___ - ___ ___ ___ ___
Q02-3	0 Ischemic stroke 0 Hemorrhagic stroke 0 Transient ischemic attack 0 Silent stroke 0 Intracranial bleeding	___ ___ - ___ ___ ___ - ___ ___ ___ ___
Q02-4	0 Ischemic stroke 0 Hemorrhagic stroke 0 Transient ischemic attack 0 Silent stroke 0 Intracranial bleeding	___ ___ - ___ ___ ___ - ___ ___ ___ ___

Name of person who collected data:

If this is a source document, sign/date here:

Form 503 v1: Sickle Cell Disease Complications

Indicate if the subject was diagnosed with any of the following during this calendar year.

Q03		Asthma	0 No 0 Yes
Q04	*If Q03 = 'Yes'*	Date of asthma diagnosis	___ ___ - ___ ___ ___ - ___ ___ ___ ___ dd-mmm-yyyy
Q05		Hypertension	0 No 0 Yes
Q06	*If Q05 = 'Yes'*	Date of hypertension diagnosis	___ ___ - ___ ___ ___ - ___ ___ ___ ___ dd-mmm-yyyy
Q07		Type of treatment	
Q08		Gallstones/cholelithiasis	0 No 0 Yes
Q09	*If Q08 = 'Yes'*	Date of gallstones/cholelithiasis diagnosis	___ ___ - ___ ___ ___ - ___ ___ ___ ___ dd-mmm-yyyy
Q10		Cholecystitis	0 No 0 Yes
Q11	*If Q10 = 'Yes'*	Date of cholecystitis diagnosis	___ ___ - ___ ___ ___ - ___ ___ ___ ___ dd-mmm-yyyy
Q12		Splenomegaly	0 No 0 Yes
Q13	*If Q12 = 'Yes'*	Splenomegaly	0 Splenic sequestration, alone 0 Splenectomy, alone 0 Splenic sequestration and splenectomy
Q14	*If Q13 <> 'Splenic Sequestration, alone'*	Date of splenectomy	___ ___ - ___ ___ ___ - ___ ___ ___ ___ dd-mmm-yyyy
Q15		Pneumococcal sepsis	0 No 0 Yes
Q16	*If Q15 = 'Yes'*	Date of pneumococcal sepsis	___ ___ - ___ ___ ___ - ___ ___ ___ ___ dd-mmm-yyyy
Q17		Other sepsis	0 No 0 Yes
Q18	*If Q17 = 'Yes'*	Date of other sepsis	___ ___ - ___ ___ ___ - ___ ___ ___ ___ dd-mmm-yyyy
Q19	*If Q17 = 'Yes'*	Microbial cause	
Qc		General comments	

Name of person who collected data:

If this is a source document, sign/date here:

Form 504 v3: Transcranial Doppler

At the Subject Registration visit, include all Transcranial Doppler testing occurring prior to the registration visit.
For subsequent years, include any Transcranial Doppler testing within that calendar year.

Q01		TCD testing attempted	O No O Yes
Q02	*If Q01 = 'Yes'*	Date of TCD testing	___ ___ - ___ ___ ___ - ___ ___ ___ ___ dd-mmm-yyyy
Q03		Type of TCD	O TCD O TCDimaging O Unknown
Q04		TCD completed at study hospital	O No O Yes
Q05		TCD results	O Low O Normal O High - Conditional O Abnormal O Inadequate
Q06	*If Q04 = 'Yes'*	TCD done at same time as another clinic appointment	O No O Yes
Q07	*If Q05 <> 'Normal'*	Repeated TCD	O No O Yes
Q08	*If Q07 = 'Yes'*	Date of repeated TCD	___ ___ - ___ ___ ___ - ___ ___ ___ ___ dd-mmm-yyyy

Name of person who collected data:

If this is a source document, sign/date here:

Form 504 v3: Transcranial Doppler

Q09	*If Q01 = 'No'*	Reason original TCD testing was not completed *Refer only to original TCD not repeated TCD.*	O Lost to follow-up O Machine not functional or available O Appointment was canceled O Patient was no show to appointment O Parent refused O Unknown O Other, specify: _____
Q10		More than one missed TCD appointment	O No O Yes O Unknown
Q11	*If Q05 = 'Abnormal'*	Recommended hydroxyurea	O No O Yes
Q12		Recommended CRCT	O No O Yes
Q13		Recommended bone marrow/hematopoietic stem cell transplant	O No O Yes
Q14	*If Q13 = 'No'*	Reason BMT/HSCT was not recommended	
Q15	*If Q13 = 'Yes'*	Received BMT/HSCT	O No O Yes
Q16	*If Q15 = 'No'*	Reason BMT/HSCT was not received	O No full matches—sibling or non-sibling O Family did not want to pursue O Insurance would not cover O Unknown O Other, specify: _____
Q17	*If Q15 = 'Yes'*	Date of BMT/HSCT	___ ___ - ___ ___ ___ - ___ ___ ___ ___ dd-mmm-yyyy
Q18		Type of BMT/HSCT	O Matching sibling O Unrelated donor O Haplo-identical O Mis-matched unrelated donor
Q19		Type of chemotherapy	O Myeloablative O Non-myeloablative O Reduced intensity O Unknown
Q20		TCD Upload *Upload de-identified imaging report.*	
Qc		General comments	

Name of person who collected data:

If this is a source document, sign/date here:

Form 505 v1: Chronic Red Cell Transfusion

At the Subject Registration visit, include all CRCT treatment occurring prior to the registration visit.
For subsequent years, include CRCT treatment occurring within that calendar year.

Q01	Chronic Red Cell Transfusion Therapy recommended		0 No 0 Yes
Q02	*If Q01 = 'Yes'*	CRCT Indication	0 Abnormal TCD 0 Stroke 0 Acute chest syndrome 0 Chronic pain 0 Other, specify: _____
Q03		Type of CRCT	0 Simple 0 Manual exchange 0 Auto-exchange
Q04		Receiving CRCT	0 Less than 5 times per year 0 5-9 times per year 0 More than 9 times per year
Q05	*If Q04 = 'Less than 5 times per year'*	Reason subject not receiving CRCT	0 Lost to follow-up 0 Missed appointment 0 Parent refused 0 Insurance issue 0 Allo-immunization 0 Other, specify: _____
Q06	*If Q04 = '5-9 times per year or more than 9 times per year'*	Date started CRCT	___ ___ - ___ ___ ___ - ___ ___ ___ ___ dd-mmm-yyyy
Qc		General comments	

Name of person who collected data:

If this is a source document, sign/date here:

DISPLACE	Subject:	Visit:

Form 506 v3: Brain Imaging

At the Subject Registration visit, complete a CRF for any brain imaging occurring prior to the registration visit. For subsequent years, complete a CRF for any brain imaging occurring within that calendar year. Add additional CRFs as needed.

Qa		Data collected	O No O Yes
Q01		Image type	O MRI O MRA O MRV O CT
Q02		Date of image	___ ___ - ___ ___ ___ - ___ ___ ___ ___ dd-mmm-yyyy
Q03	*If Q01 = MRI*	MRI abnormality	O None O Ischemic stroke O Silent stroke O IVH O AH O Other, specify: _____
Q04	*If Q01 = MRA*	MRA abnormality	O None O AH O Aneurysm O Moyamoya O Other, specify: _____
Q05	*If Q01 = MRV*	MRV abnormality	O None O Sinus Venous Thrombosis
Q06	*If Q01 = CT*	CT abnormality	O None O Ischemic stroke O IVH O AH O Other, specify: _____
Q07		Imaging report *Upload de-identified imaging report.*	
Qc		General comments	

Name of person who collected data:

If this is a source document, sign/date here:

DISPLACE	Subject:	Visit:

Form 509 v2: Echocardiogram

At the Subject Registration visit, complete a CRF for any echocardiograms occurring prior to the registration visit . For subsequent years, complete a CRF for any echocardiograms occurring within that calendar year.

Qa		Data collected	0 No 0 Yes
Q01		Echocardiogram performed	0 No 0 Yes
Q02	*If Q01 = 'Yes'*	Date echocardiogram performed	___ ___ - ___ ___ ___ - ___ ___ ___ ___ dd-mmm-yyyy
Q03		Abnormality	
Q04		Echocardiogram upload *Upload de-identified echocardiogram report.*	
Qc		General comments	

Name of person who collected data:

If this is a source document, sign/date here:

DISPLACE	Subject:	Visit:

Form 510 v1: Demographics

Q01	Zip code	_____
Q02	Insurance type *Check all that apply.*	☐ Medicaid ☐ CHIP ☐ TRICARE or other military health care (includes VA) ☐ Private health Insurance ☐ Local Program ☐ No Insurance ☐ Unknown
Q03	Primary caregiver	0 Parent 0 Grandparent 0 Foster parent/ guardian 0 Unknown 0 Other, specify: _____
Qc	General comments	

Name of person who collected data:

If this is a source document, sign/date here:

DISPLACE	Subject:	Visit:

Form 511 v1: Hydroxyurea

At the 2012 visit, enter any hydroxyurea prescribed within that calendar year.

For subsequent years, the hydroxyurea previously entered as 'continuing' will be propagated to the next visit in WebDCU™. Indicate if any hydroxyurea is continuing, stopped, or not assessed. Start a new row to enter dose changes.

Q01	Hydroxyurea prescribed within the calendar year			0 No 0 Yes				
	QA. Medication name	QB. Daily dose mg	QC. Date started dd-mmm-yyyy	QD. Status	QE. Date stopped dd-mmm-yyyy	QF. Reason stopped	*If QF=Other* QG. Other reason stopped	QH. Notes
Q02-1	Hydroxyurea			0 Continuing 0 Stopped 0 Not assessed		0 Not adherent 0 Side effects 0 Started CRCT 0 Unknown 0 Other		
Q02-2	Hydroxyurea			0 Continuing 0 Stopped 0 Not assessed		0 Not adherent 0 Side effects 0 Started CRCT 0 Unknown 0 Other		
Q02-3	Hydroxyurea			0 Continuing 0 Stopped 0 Not assessed		0 Not adherent 0 Side effects 0 Started CRCT 0 Unknown 0 Other		
Qc	General comments							

Name of person who collected data:

If this is a source document, sign/date here:

DISPLACE	Subject:	Visit:

Form 515 v2: Labs

Enter the labs collected closest to or on the date that the TCD was completed within the calendar year.
If TCD did not occur for any reason, enter the labs closest to the scheduled TCD. If multiple TCDs occurred within that calendar year, only enter the labs for the first completed TCD.

Qa	Data collected	0 No 0 Yes
Q01	Date of blood draw	___ ___- ___ ___ ___ - ___ ___ ___ ___ dd-mmm-yyyy
Q02	White blood cell count	_____ $x10^3$ / mm^3
Q03	Red blood cell count	_____ $x10^6$ / mm^3
Q04	Hemoglobin	_____ g / dL
Q05	Hematocrit	_____ %
Q06	Mean corpuscular volume	_____ $micrometer^3$
Q07	Platelet count	_____ $10^3/mm^3$
Q08	Neutrophils (segmented and banded together)	_____ %
Q09	Absolute reticulocytes	_____ 10^3/microliter
Q10	Percent reticulocytes	_____ %
Q11	Ferritin	_____ ng/mL
Qc	General comments	

Name of person who collected data:

If this is a source document, sign/date here:

DISPLACE	Subject:	Visit:

Subject Enrollment

Q01	Site	
Q02	Subject ID *Assigned by WebDCU.*	
Q03	Gender	0 Male 0 Female
Q04	Ethnicity	0 Hispanic or Latino 0 Not Hispanic or Latino 0 Unknown
Q05	Race *Check all that apply.*	☐ American Indian or Alaska Native ☐ Asian ☐ Black or African American ☐ Native Hawaiian or Other Pacific Islander ☐ White ☐ Unknown
Q06	Date of birth *Year of birth must be between 1996-2014 to be eligible.*	___ ___ - ___ ___ ___ - ___ ___ ___ ___ dd-mmm-yyyy
Qc	General comments	

Name of person who collected data:

If this is a source document, sign/date here: