

CRF Completion Guidelines

CSCC Collaborative Data Project (C-Data) Protocol

This document contains the basic CRF only. Other required and supplemental forms can be found on the CSCC website under Study:C-Data:Case Report Forms.

General Information

This is an Electronic Data Capture System. All information is to be entered via the CSCC's EDC website (<https://www.rhoworld.com/sickle>). To enter the system:

- Login with userid and password. Leave this page open in order to log out when you are finished.
- Click on "Comprehensive Sickle Cell Centers"
- Choose "C-Data" from the studies listed on the right side of the screen.
- Click on "Data Entry -> C-Data" under "EDC Links".
- Select a subject ID number (or add a new subject).
- **If adding a new subject, PLEASE remember to print out the CSCC Registration form with the subject's assigned CSCC ID#. The registration form is to be filed with the subject's medical record.**
- Select the visit for which data is to be entered at that time from the "Forms" menu.
- Remember to log out of EDC and on the CSCC "Study: C-Data" page!

Header Information:

- ➔ The subject ID and site header information will be automatically displayed.
- ➔ Most pages ask for the date the form was completed. This is the date the paper form was completed, not the date the form was entered into the EDC system.
- ➔ Most pages also ask for the initials of the person completing the form. This is for the initials of the person completing the paper form, not the person entering the form into the EDC system.

Dates:

- ➔ Dates should be recorded in the following format: **dd/mmm/yy** (i.e., 28/SEP/05). Record leading zeros where applicable.
- ➔ If a complete date is unknown, record the date part(s) that are known, and leave the unknown date parts blank.

Numeric Fields:

- ➔ Rounding rules: If the number of digits to the right of the decimal in any value are greater than the number of boxes available for data entry of the number, then any "extra" digits in the decimal should be dropped and the value rounded to the correct number of places. Example: A lab value for hemoglobin of 7.06 gm/dL will be entered as 7.1gm/dL.

Yes, No, and Unknown:

- Check “Yes” if the patient has ever had the procedure (condition, etc.).
- Check “No” if there is no evidence in the medical record AND the patient has only been seen at your site.
- Check “Unknown” if there is a reasonable degree of uncertainty. For example, if the patient was seen at other sites and it cannot be determined for certain that the procedure (condition, etc.) was not done.

Comments for page:

- A “Comments for page:” text box will be located at the bottom of each EDC screen and on the last page of each interview form.
- Record any additional information pertinent to a particular CRF page at the bottom of that page in the space provided.

To indicate that information is not available or that a block of information on a CRF page was not collected:

- Leave the fields blank and record the reason why the particular set of data was not collected in the “Comments for page:” field at the bottom of the page.

Corrections to data:

- Open the page in the EDC system where the data was originally entered. Find the field and change the entry. Only an authorized member of the investigator’s staff may make corrections to data. Click the [Update] button at the bottom of the screen in order to submit corrections to the database.

Printing:

- Open the page in the EDC system that you would like to print. Click the [Print] button at the bottom of the screen in order to print. Pages must be printed individually at this time.

Source documentation (autopsy report, Quality of Life instruments, etc.):

- Store all original study-related materials (case report forms, lab reports, quality of life instruments, etc.) in the subject’s research record. Send copies to Rho or the DSMB when requested. Delete or completely mark out subject identifiers on all study materials. Be sure that the subject ID number is present.
- If a case report form was completed on paper before entering the data into the EDC system, store that case report form in the subject’s research record.

Enrollment Form

CRF & Guidelines

Item	Instructions
Date of Birth	Record the patient's date of birth in dd/mmm/yyyy format (i.e., 25/SEP/1970), as determined from the patient's medical record.
Gender	Check the appropriate gender, as determined from the patient's medical record.
Diagnosis	<ul style="list-style-type: none"> • Check only one box for the diagnosis of this patient, as determined from the patient's medical record. • If "S Other" is checked, please specify diagnosis.
Enrollment	<ul style="list-style-type: none"> • Check the appropriate time of enrollment to indicate whether the patient was enrolled during a clinic visit or at a special event planned to enroll patients. • If Clinical Encounter is selected, an Encounter Form should be filled out for this event. • Only patients seen regularly within your center should be enrolled. Avoid enrolling one time drop-in patients, if possible.
Informed Consent/Authorization	Record the date that the patient (or the parent/guardian of the patient) signed the informed consent/authorization in dd/mmm/yy format (i.e, 25/SEP/04).
Date of Clinical Encounter	<ul style="list-style-type: none"> • Record the most recent clinical encounter of this patient in dd/mmm/yy format. • If the patient enrolled during a <i>clinical encounter</i>, enter this date. • If the patient enrolled during a <i>special study enrollment visit</i>, enter the date of the most recent clinical encounter prior to the study enrollment visit.

Comprehensive Sickle Cell Centers	<h1 style="text-align: center;">Enrollment Form</h1>	<h2 style="text-align: center;">Enrollment</h2>
<p style="text-align: center;">Protocol # 2</p> <p style="text-align: center;">Collaborative Data Project</p>	<p>Date Form Completed: <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> Day Month Year</p> <p>Form Completed by: <input type="text"/> <input type="text"/> <input type="text"/></p>	<p>CSCC ID: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/></p> <p>Center code: <input type="text"/> <input type="text"/> <input type="text"/></p> <p>Hospital code: <input type="text"/> <input type="text"/> <input type="text"/></p>

Date of Birth: / /
Day Month Year

Gender: Male
 Female

Diagnosis SS SC sβ⁺ sβ⁰
(choose one) S Other, specify _____

Did this patient enroll at time of a: Clinical Encounter
(clinical encounter includes a visit such as a routine follow-up, transfusion, research study, medications, acute visit, ED visit or hospital admission)

OR

Special Study enrollment visit for Patient Database

Date patient signed Informed Consent/Authorization: / /
Day Month Year

Date of most recent clinical encounter: / /
(Including enrollment encounter, if applicable) Day Month Year

Medical History Form Part I

CRF & Guidelines

All items on Page 1 should be determined from the patient’s medical record unless otherwise noted (i.e., participation in research study).

Item	Instructions
<p>Date patient first seen</p>	<ul style="list-style-type: none"> Record the date the patient was first seen <i>in your center</i> (not just hospital) in dd/mmm/yy format. <p>Remote sites should leave this field blank and enter “Remote Site” in the “Comments for page:” field at the bottom of the page.</p>
<p>Weight</p>	<ul style="list-style-type: none"> Record the most recent weight in pounds (lb) or kilograms (kg). Be sure to mark the appropriate unit. Weight should be measured with the patient standing still, wearing light clothing (such as a paper exam gown), and with no shoes. <i>If it is unknown whether or not the patient was measured this way, please remember for future annual visits.</i>
<p>Height</p>	<ul style="list-style-type: none"> Record the most recent height in inches (in) or centimeters (cm). Be sure to mark the appropriate unit. Height should be measured with the patient standing straight, with no shoes, and arms positioned at the side. Height should be measured at the top of the head, not the top of the hairstyle. <i>If it is unknown whether or not the patient was measured this way, please remember for future annual visits.</i>
<p>Date of measurement</p>	<p>Record the most recent dates of measurement in dd/mmm/yy format for both height and weight. Dates may be the same or different.</p>
<p>Currently in research study</p>	<ul style="list-style-type: none"> Check “Yes” or “No” to indicate if the patient is currently participating in a research study <u>or</u> if they have participated in a CSCC study that has been completed. This should be determined primarily by medical records and secondarily by patient/parent interview. If Yes, be sure to check each study that the patient is currently participating in <u>and</u> any CSCC study that has been completed. If “Within-Center Study” or “Other Study” is marked, be sure to specify the study name. <p>Arginine, Neuropsych, Hydroxyurea-Magnesium, and Priapism are multi-center CSCC studies.</p> <p>Within-Center Study is a CSCC study only enrolling at hospitals within the same CSCC center.</p> <p>Other study is any non-CSCC study.</p> <p>REMINDER: There are no restrictions on participation in C-Data. However, there may be restrictions in other studies that would prohibit participation in C-Data. Please consult the inclusion/exclusion criteria for other studies in which this patient is currently enrolled.</p>

Information needed to complete page 2 should come primarily from the patient's medical records and secondarily from patient/parent interview.

Item	Instructions
<p>Surgical History</p>	<ul style="list-style-type: none"> • Check "Yes" if the patient has ever had this procedure. • Check "No" if there is no reference to the surgery in the medical record AND the patient has only been seen at your site. • Check "Unknown" if there is a reasonable degree of uncertainty. For example, if the patient was seen at other sites and it cannot be determined for certain that the procedure was not done. • If Yes is checked, provide the 4-digit year (i.e., 1999). If the patient has had the same surgery more than once, record the most recent surgery. • For Hip Replacement and Permanent Indwelling Line, specify either "1 Time" or ">1 Time". • For "Other" categories, be sure to specify the name of the procedure and provide the year.

The information needed to complete page 3 should be determined primarily by medical records and secondarily by patient/parent interview.

Item	Instructions
Medical Conditions	<ul style="list-style-type: none">• Check “Yes” if the patient has ever been diagnosed with the condition.• Check “No” if there is no reference to the condition in the medical record AND the patient has only been seen at your site.• Check “Unknown” if there is a reasonable degree of uncertainty. For example, if the patient was seen at other sites and it cannot be determined for certain that the condition was never present.• If Ever is checked, provide the 4-digit year (i.e., 1999). If the patient has been diagnosed with a condition more than once, record the year of the <i>first</i> diagnosis.• For Cardiac Failure, if Yes is checked, specify “Left”, “Right”, or “Unknown”.

Protocol # 2

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Date Form Completed: / /
Day Month Year

Form Completed by:

CSCC ID:

Center code:

Hospital code:

Has this patient ever had or ever been diagnosed with....

Yes	Year of First Diagnosis	No	Unknown	
<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	Acute Chest Syndrome or Pneumonia
<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	Aplastic Episode
<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	Asthma/Reactive Airway Disease
<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	Avascular Necrosis, Hip(s)
<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	Avascular Necrosis, Shoulder(s)
<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	Avascular Necrosis, Spine
<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	Bacteremia/Sepsis
<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	Cardiac Failure <i>If yes:</i> <input type="checkbox"/> Left <input type="checkbox"/> Right <input type="checkbox"/> Unknown
<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	Central Nervous System Disease, Abnormal TCD
<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	Central Nervous System Disease, Stroke, Ischemic
<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	Central Nervous System Disease, Stroke, Hemorrhagic
<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	Central Nervous System Disease, Seizure
<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	Central Nervous System Disease, Silent Infarct
<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	Central Nervous System Disease, TIA
<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	Dactylitis (Hand Foot Syndrome)
<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	Gall Bladder Disease
<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	Hypertension, chronic, requiring treatment
<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	Leg Ulcer
<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	Liver Disease, Hepatitis, Viral
<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	Liver Disease, Hepatic Sequestration/ Sickle-Hepatopathy/ Intrahepatic Sickling
<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	Liver Disease, Hepatic Fibrosis/Cirrhosis

The information needed to complete page 4 should be determined primarily by medical records and secondarily by patient/parent interview.

Item	Instructions
Medical Conditions	<ul style="list-style-type: none"> • Check “Yes” if the patient has ever been diagnosed with the condition. • Check “No” if there is no reference to the condition in the medical record AND the patient has only been seen at your site. • Check “Unknown” if there is a reasonable degree of uncertainty. For example, if the patient was seen at other sites and it cannot be determined for certain that the condition was never present. • If Ever is checked, provide the 4-digit year (i.e., 1999). If the patient has been diagnosed with a condition more than once, record the year of the <i>first</i> diagnosis.

Protocol # 2

**Collaborative
Data Project**

Date Form Completed: / /
Day Month Year

Form Completed by:

CSCC ID:

Center code:

Hospital code:

Yes	Year of First Diagnosis	No	Unknown	
<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	Liver Disease, Iron Overload
<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	Lung Disease, Pulmonary Fibrosis
<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	Lung Disease, Pulmonary Hypertension
<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	Meningitis
<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	Osteomyelitis
<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	Pain Crisis
<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	Priapism
<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	Renal Disease, Acute Renal Failure
<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	Renal Disease, Chronic Renal Failure
<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	Renal Disease, Proteinuria
<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	Renal Disease, Transplant
<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	Retinopathy
<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	Splenic Sequestration

The information needed to complete page 5 should be determined primarily by medical records and secondarily by patient/parent interview.

Item	Instructions
Medications	<ul style="list-style-type: none">• Check “Yes” if the patient has ever used the selected medication.• Check “No” if there is no reference to the selected medication being used in the medical record AND the patient has only been seen at your site.• Check “Unknown” if there is a reasonable degree of uncertainty. For example, if the patient was seen at other sites and it cannot be determined for certain that the selected medications were never used.
Other Anti-Sickling Agents, Other oral iron chelator medications, Antidepressants, Anticonvulsants, and Other Alternative Therapies	If Yes is checked for either time period, specify the medication used in the specify column and in the appropriate field for the time period.

The information needed to complete page 6 should be determined primarily by medical records and secondarily by patient/parent interview.

Item	Instructions
<p>Transfusion in the past year</p>	<ul style="list-style-type: none"> • Check “Yes” or “No” to indicate if the patient has or has not received a transfusion <i>in the past 12 months</i>. Check “Unknown” if this information is not known. • If Yes, check the category that includes the number of <u>transfusions</u> received <i>in the past 12 months</i>.
<p>Transfusion prior to the past year</p>	<ul style="list-style-type: none"> • Check “Yes” or “No” to indicate if the patient has or has not received a transfusion <i>prior to the past 12 months</i>. Check “Unknown” if this information is not known. • If Yes, check the category that includes the number of <u>transfusions</u> received <i>prior to the past 12 months</i>.
<p>Iron overload assessment</p>	<ul style="list-style-type: none"> • Check “Yes” or “No” to indicate if the patient has or has not <i>ever</i> had iron overload assessed. Check “Unknown” if this information is not known. • If Yes, record results for the <i>most recent</i> assessments. • For Liver Biopsy, Ferritin, and SQUID*, record the correct response, the result in the units specified, and the date in dd/mmm/yy format. <p>* Superconducting QUantum Interference Device</p>
<p>Iron chelation therapy</p>	<ul style="list-style-type: none"> • Check “Yes” or “No” to indicate if the patient has or has not <i>ever</i> received iron chelation therapy. Check “Unknown” if this information is not known. • If Yes, be sure to check the type of therapy or indicate if type of therapy is unknown.

Protocol # 2

**Collaborative
Data Project**

Date Form Completed: / /
Day Month Year

Form Completed by:

CSCC ID:

Center code:

Hospital code:

Did this patient receive a transfusion in the past year? Yes No Unknown

If yes, how would you describe this patient's transfusion history in the past year?

Number of transfusions: 1-5 6-20 21-99 100+

Did this patient receive a transfusion prior to the past year? Yes No Unknown

If yes, how would you describe this patient's transfusion history prior to the past year?

Number of transfusions: 1-5 6-20 21-99 100+

Was iron overload ever assessed? Yes No Unknown

If yes, enter results of most recent assessments:

	Yes	No	Unknown	Result	Date
					dd / mmm / yy
Liver Biopsy:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____	___ / ___ / ___
				mg Fe/g Dry Weight	
Ferritin:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____	___ / ___ / ___
				µg/L	
SQUID:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____	___ / ___ / ___
				mg Fe/g Dry Weight	

Did this patient ever receive iron chelation therapy? Yes No Unknown

If yes, Desferal Oral Unknown

The information needed to complete page 7 should be determined primarily by medical records and secondarily by patient/parent interview.

Item	Instructions
<p>RBC antibodies</p>	<ul style="list-style-type: none"> • Check “Yes” or “No” to indicate if the patient has or has not ever had RBC antibodies documented. Check “Unknown” if this information is not known. • If Yes, check all the antibodies that are reported as being present. • If RBC antibody documented is not one of the available choices, please check “Other”. Specification of “Other” is not necessary. • <i>Do not record antibodies that are suspected but not documented.</i>
<p>Selected Diagnostic Tests</p>	<ul style="list-style-type: none"> • Record information on the most recent diagnostic tests performed on this patient during <i>the past 12 months</i>. • Record information on the most recent diagnostic tests performed on this patient during the <i>2 years prior to the past 12 months</i> in the following row. • For each row, check “Yes” or “No” to indicate whether or not a test was performed. Check “Unk” if this information is not known. <p>If Yes,</p> <ul style="list-style-type: none"> • Record the most recent test date in dd/mmm/yy format. • Check “Normal”, “Abnormal”, or “Equivocal” to indicate the result of the most recent test. If any part of the test is abnormal, the whole test should be marked abnormal. • To record a Transcranial Doppler (TCD) with conditional results, check “Equivocal”. • Record any comments relevant to the test in the comments field.

Protocol # 2

**Collaborative
Data Project**

Date Form Completed: / /
Day Month Year

Form Completed by:

CSCC ID:

Center code:

Hospital code:

Has this patient ever had RBC antibodies documented? Yes No Unknown

If yes, check all that were present/positive:

- | | | | | | |
|----------------------------|------------------------------|------------------------------|------------------------------|--|--|
| <input type="checkbox"/> c | <input type="checkbox"/> E | <input type="checkbox"/> Fyb | <input type="checkbox"/> k | <input type="checkbox"/> Leb | <input type="checkbox"/> Cold antibody |
| <input type="checkbox"/> C | <input type="checkbox"/> e | <input type="checkbox"/> Jka | <input type="checkbox"/> K | <input type="checkbox"/> M | <input type="checkbox"/> Unknown |
| <input type="checkbox"/> D | <input type="checkbox"/> Fya | <input type="checkbox"/> Jkb | <input type="checkbox"/> Lea | <input type="checkbox"/> Warm autoantibody | <input type="checkbox"/> Other |

Selected Diagnostic Tests - Provide information on the most recent diagnostic tests performed on this patient in the **past year** and the most recent test performed in the **2 years prior to the past year**.

Test	Performed			Test Date dd / mmm / yy	Most Recent Result			Comments (reason for test, etc.)
	Yes	No	Unk		Normal	Abnormal	Equivocal	
MRI, Head – in past year	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	__ / __ / __	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
MRI, Head – in 2 years prior to past year	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	__ / __ / __	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
MRA, Head – in past year	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	__ / __ / __	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
MRA, Head – in 2 years prior to past year	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	__ / __ / __	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Transcranial Doppler (TCD) - in past year	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	__ / __ / __	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Transcranial Doppler (TCD), in 2 years prior to past year	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	__ / __ / __	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Echocardiogram – in past year	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	__ / __ / __	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Echocardiogram -- in 2 years prior to past year	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	__ / __ / __	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Pulmonary Function Testing – in past year	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	__ / __ / __	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Pulmonary Function Testing – in 2 years prior to past year	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	__ / __ / __	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
EKG – in past year	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	__ / __ / __	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
EKG – in 2 years prior to past year	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	__ / __ / __	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

The information needed to complete page 8 should be determined primarily by medical records and secondarily by patient/parent interview.

Item	Instructions
	<p>Review the patient's medical records for labs recorded within the last 2 years. DO NOT record labs that:</p> <ul style="list-style-type: none"> • Were performed less than 2 months after a transfusion • Were performed less than 2 months after a hospitalization • May have been affected by a clinical event such as parvovirus <p>The labs recorded may not be the most recent labs in the patient's chart per the criteria listed above.</p>
<p>Does this patient have labs recorded during the last 2 years that meet the criteria described above?</p>	<ul style="list-style-type: none"> • Check "Yes" if the patient has labs recorded during a time when the patient has not been transfused, hospitalized, or had a clinical event which may have affected these labs, in the 2 months prior to having labs drawn. • Check "No" if the patient only has labs recorded in his/her medical record that were performed during the 2 months after a transfusion, hospitalization, or during a time in which another clinical event may have affected these labs. • If Yes is checked, please fill in the lab data for Hgb, WBC, and Platelets. • If No is checked, skip the lab data.
<p>Lab tests</p>	<p>For lab test that meet the criteria, record:</p> <ul style="list-style-type: none"> • Date of specimen • Result (in the units provided) • Comment, if appropriate or needed • If it is possible that a medication could have affected the lab result(s), record the name of the medication in the comments field.

The information needed to complete page 9 should be determined primarily by medical records and secondarily by patient/parent interview.

Item	Instructions
<p>Hospital Admissions</p>	<p>For all hospital admissions (do not include Emergency Department visits) that occurred during the past 2 years and at any hospital associated with your center:</p> <ul style="list-style-type: none"> Record the admission and discharge dates in dd/mmm/yy format. Select at least one appropriate discharge diagnosis from the drop-down box. Up to three (3) of the most important diagnoses may be selected. Due to the lack of standard definitions, please select each symptom within one diagnosis separately. For example, if a patient is diagnosed with ACS, fever will not be assumed to also be present. ACS and Fever should be selected separately. <p>Remote sites should list all known hospitalizations that have occurred during the past 2 years at their site and enter "Remote Site" in the "Comments for page:" field (EDC) at the bottom of the page.</p>
<p>Admissions at other institutions</p>	<ul style="list-style-type: none"> Check "Yes" if you think that the patient has had other hospital admissions that occurred at hospitals not associated with your center and are NOT listed above. Check "No" if there is no reference to other admissions in the medical record AND you know that the patient has only been seen at your site. Check "Unknown" if the patient was seen at other sites AND it cannot be determined for certain from the patient's medical record that other admissions did NOT occur. The answer to this question is not to be obtained from the patient. This question should be based on the opinion of a practitioner or study coordinator at the site after reviewing the patient's medical records and considering their medical history. You are not expected to obtain any information from hospitals outside of your center in order to complete this form.

Use the Hospital Admissions Worksheet provided to record multiple hospital admissions. Print double-sided to display the complete list of symptoms/diagnoses on the back of the worksheet.

Comprehensive Sickle Cell Centers	Medical History Form Part I Hospital Admissions	Clinical Data Page: 9 of 10
Protocol # 2 Collaborative Data Project	Date Form Completed: <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <div style="text-align: center; margin-left: 100px;">Day Month Year</div> Form Completed by: <input type="text"/> <input type="text"/> <input type="text"/>	CSCC ID: <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"/> <input type="text"/> <input type="text"/> <input type="text"/> Center code: <input type="text"/> <input type="text"/> <input type="text"/> Hospital code: <input type="text"/> <input type="text"/> <input type="text"/>

List all Hospital Admissions during the **past 2 years**. If possible, identify the primary discharge diagnoses.

Date Admitted (dd/mmm/yy)	Date Discharged (dd/mmm/yy)	Most Important Discharge Diagnoses (up to 3) <i>Select all that apply</i>						
__ / __ / __	__ / __ / __	<p style="text-align: center;">drop-down box:</p> <table border="1" style="width:100%; border-collapse: collapse;"> <tr><td>Acute Chest Syndrome or Pneumonia</td></tr> <tr><td>Aplastic Episode</td></tr> <tr><td>Asthma/Reactive airway disease</td></tr> <tr><td>Avascular Necrosis</td></tr> <tr><td>Bacteremia/Sepsis</td></tr> <tr><td>Other</td></tr> </table>	Acute Chest Syndrome or Pneumonia	Aplastic Episode	Asthma/Reactive airway disease	Avascular Necrosis	Bacteremia/Sepsis	Other
Acute Chest Syndrome or Pneumonia								
Aplastic Episode								
Asthma/Reactive airway disease								
Avascular Necrosis								
Bacteremia/Sepsis								
Other								
__ / __ / __	__ / __ / __	drop-down box						
__ / __ / __	__ / __ / __	drop-down box						

Do you think admissions not listed above occurred for this patient at other hospitals that are not associated with your center? Yes No Unknown

Possible responses below.

- | | |
|--|---|
| Acute Chest Syndrome or Pneumonia
Aplastic Episode
Asthma/Reactive Airway Disease
Avascular Necrosis, Hip(s)
Avascular Necrosis, Shoulder(s)
Avascular Necrosis, Spine
Bacteremia/Sepsis
Cardiac Failure
Central Nervous System Disease, Abnormal TCD
Central Nervous System Disease, Seizure
Central Nervous System Disease, Silent Infarct
Central Nervous System Disease, Stroke, Ischemic
Central Nervous System Disease, Stroke, Hemorrhagic
Central Nervous System Disease, TIA
Dactylitis (Hand Foot Syndrome)
Diabetes
Fever
Gall Bladder Disease
Hypertension, chronic, requiring treatment
Leg Ulcer
Liver Disease, Hepatic Fibrosis/Cirrhosis | Liver Disease, Hepatic Sequestration/
Sickle-Hepatopathy/Intrahepatic Sickling
Liver Disease, Hepatitis, Viral
Liver Disease, Iron Overload
Lung Disease, Pulmonary Fibrosis
Lung Disease, Pulmonary Hypertension
Meningitis
Osteomyelitis
Pain Crisis
Priapism
Renal Disease, Acute Renal Failure
Renal Disease, Chronic Renal Failure-Supportive
Renal Disease, Dialysis
Renal Disease, Microalbuminuria/Proteinuria
Renal Disease, Nephrotic Syndrome
Renal Disease, Transplant
Retinopathy
Splenic Sequestration
Transfusion/Chelation
Other |
|--|---|

Item	Instructions
Patient Exclusion	<ul style="list-style-type: none">• Check the appropriate response regarding whether or not this patient should be excluded from participation in a clinical trial.• The response to this question should be based on the patient's willingness to participate in medical studies, compliance with keeping clinic appointments, and taking medications.• If necessary, the patient's physician should be consulted if the nurse or study coordinator is not comfortable making a response.
Medical Information	<ul style="list-style-type: none">• Check the appropriate response regarding the source of this subject's medical information. As much medical information as possible should come from medical record.• Select "Some information was provided by the patient (or parent/guardian of the patient)" if the subject or the subject's guardian provided some of the information.• If some information was provided by the patient, please check all the pages that include any information by the patient to account for missing source documentation.• If Page 1 is checked, please specify which components of that form came from the patient <i>for page 1 only</i>.

Medical History Form IIA

CRF & Guidelines

All items on pages 1-4 of the interview should be determined by the patient's responses only. The interview forms will serve as source documentation.

Item	Instructions
<p>1. Race</p>	<ul style="list-style-type: none"> • The interviewer should either read all choices at once <u>or</u> read each choice separately and wait for a response. • Check all racial groups the patient considers themselves to be a part of, <i>as reported by the patient</i>. • If Other is marked, be sure to specify.
<p>2. Ethnicity</p>	<p>Check the appropriate ethnicity, <i>as reported by the patient</i>.</p>
<p>3. Siblings (parts a-c)</p>	<ul style="list-style-type: none"> • Record the total number of siblings. This number should include siblings of all types, including half-siblings and step-siblings as well as biological siblings. • If a number is recorded, be sure to fill in 3b) the number who have SCD and 3c) the number who do not have SCD. 3b and 3c should include only the siblings who share the same biological mother and father. Parts b and c may not be equal to the number recorded in part a (the total of all the subject's brothers and sisters).
<p>4. Employment Status</p>	<ul style="list-style-type: none"> • Check the appropriate current employment status of the patient. • If patient is NOT employed and NOT a student (Question 5), please skip Question 15.
<p>5. Student Status</p>	<ul style="list-style-type: none"> • Check the appropriate current student status of the patient. • If patient is NOT employed (Question 4) and NOT a student, please skip Question 15.
<p>6. Highest Grade</p>	<ul style="list-style-type: none"> • Record the highest grade of school completed or the number of years of college completed. • Enter 0 for pre-school or for children who have not yet begun school, K for Kindergarten, 1-12, 13= 1 year college, 14= 2 years college, etc.
<p>7. Number of Individuals (≥19)</p>	<p>Record the number of individuals in the household who are 19 years of age and above. This number should include the patient, if applicable.</p>
<p>8. Number of Individuals (<19)</p>	<p>Record the number of individuals in the household who are 19 years of age and below. This number should include the patient, if applicable.</p>

Patient Interview

Protocol # 2

**Collaborative
Data Project**

Date Form Completed: / /
Day Month Year

Form Completed by:

CSCC ID:

Center code:

Hospital code:

1. **Which of the following racial groups do you consider yourself a part of?** *(check all that apply)*

- American Indian/Alaska Native
- Asian
- Black or African-American
- Native Hawaiian or other Pacific Islander
- White
- Other, specify _____

2. **What is your ethnicity?** Are you: Hispanic or Latino, or
 Not Hispanic or Latino

3a. **How many siblings do you have?** _____

Of the siblings who share both your biological mother and father:

3b. How many have SCD? _____

3c. How many do not have SCD? _____

4. **What is your current employment status?** Are you: Full Time,
 Part Time, or
 Not Employed

5. **What is your current student status?** Are you: Full Time, *(If Questions 4 and 5 indicate that patient is NOT employed and NOT a student, please skip Question 15.)*
 Part Time, or
 Not a Student

6. **What is the highest grade of school you have completed, or how many years of college have you completed?** _____
(Enter 0 for pre-school or less, K for Kindergarten, 1-12, 13 = 1 year college, 14 = 2 years college, etc.)

7. **What is the number of individuals (19 years of age and up) in your household?** _____

8. **What is the number of individuals (under 19 years of age) in your household?** _____

Item	Instructions
<p>9. Insurance</p>	<ul style="list-style-type: none"> • Check all that apply. • If Other is marked, be sure to specify.
<p>10. Sickle cell related healthcare</p>	<ul style="list-style-type: none"> • Check “Yes” or “No” to indicate if the patient has ever received sickle cell related health care from any other center or institution in the last 5 years. Check “Unknown” if patient is unsure or refuses to answer. • If Yes is marked, be sure to record where and how many times the patient was seen for each location to the best of the patient’s knowledge.
<p>11. Transfusion</p>	<ul style="list-style-type: none"> • Check “Yes” or “No” to indicate if the patient has ever received a transfusion. Check “Unknown” if patient is unsure or refuses to answer. • If Yes is marked, be sure to check the category that includes the approximate number of transfusions received, as estimated by the patient.
<p>12. Unscheduled Visits</p>	<ul style="list-style-type: none"> • Check “Yes” or “No” to indicate if the patient has ever had an unscheduled visit because of pain due to Sickle Cell Disease. Check “Unknown” if patient is unsure or refuses to answer. • If Yes is marked for pain due to Sickle Cell Disease, be sure to check the category that includes the number of unscheduled visits, as estimated by the patient.
<p>13. Headache</p>	<ul style="list-style-type: none"> • Check “Yes” or “No” to indicate if the patient has ever had a headache in the past year. Check “Unknown” if patient is unsure or refuses to answer. • If Yes is marked, be sure to record how many headaches the patient had, how many occurred while having sickle cell pain, and how many headaches were not associated with sickle cell pain, fever/illness, or alcohol. • If no headaches occurred for question parts c and/or d, be sure to record a 0. • All numbers should be approximate. <p>Interviewers should feel free to help the patient determine the number of headaches for each part. For example, if the patient had 50 headaches in the past year, but is having trouble determining exactly how many of those headaches occurred while he/she had sickle cell pain, the interviewer may ask if the patient thinks that half, a third, etc. of those headaches occurred while he/she had sickle cell pain. If he/she agrees, record the number that corresponds with the fraction agreed upon by the patient.</p>

Patient Interview

Protocol # 2

**Collaborative
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Date Form Completed: / /
Day Month Year

Form Completed by:

CSCC ID:

Center code:

Hospital code:

9. **What type of health insurance do you have?** (check all that apply)

Private Medicare Medicaid None Other _____

10a. **In the last 5 years, have you received sickle cell-related healthcare from any other center or institution?**

Yes No Unknown

10b. [If yes] **Where?**

How many times?

11a. **Have you ever received a transfusion?** Yes No Unknown

11b. [If yes] **How many transfusions?** 1-5 6-20 21-99 100+

12a. **Have you ever gone to a doctor's office, a day hospital, an emergency department, acute day clinic, or other clinic for unscheduled visits because of pain due to Sickle Cell Disease?**

Yes No Unknown

12b. [If yes] **How many times?** 1-5 6-20 21-99 100+

13a. **In the past year, have you ever had a headache?** Yes No Unknown

13b. [If yes] **How many headaches have you had?** _____

13c. **How many of these headaches occurred while you had sickle pain?** _____ *Put 0 for none*

13d. **How many of these headaches were not associated with sickle pain, fever/illness, or alcohol?** _____ *Put 0 for none*

Item	Instructions
<p>14. Unscheduled Visits (past year)</p>	<ul style="list-style-type: none"> Record the approximate number of unscheduled visits in the past 12 months because of pain due to Sickle Cell Disease. If no unscheduled visits occurred because of pain due to Sickle Cell Disease, be sure to record a 0.
<p>15. Missed work/school</p>	<ul style="list-style-type: none"> Record the approximate number of days the patient had to miss work or school due to his/her Sickle Cell Disease in the past 12 months. If no days were missed due to Sickle Cell Disease, be sure to record a 0. If patient is not employed and is not a student, please skip Question 15 and leave this question blank.
<p>16. Painful Episodes treated at home</p>	<ul style="list-style-type: none"> Record the approximate number of painful episodes that were treated solely at home during the past year due to Sickle Cell Disease. If no episodes were treated solely at home, be sure to record a 0.
<p>Female Patients</p>	<ul style="list-style-type: none"> Check "NA" if the patient is male or is a female not of child-bearing potential. If checked, leave the pregnancy section blank.
<p>17. Currently pregnant</p>	<p>Check "Yes" or "No" to indicate if the patient is currently pregnant, as reported by the patient. Check "Unknown" if patient is unsure or refuses to answer.</p>
<p>18. Pregnancy History (parts a-f)</p>	<ul style="list-style-type: none"> Check "Yes" or "No" to indicate if the patient has ever been pregnant, as reported by the patient. Exclude current pregnancy, if applicable. Check "Unknown" if patient is unsure or refuses to answer. If Yes is marked, be sure to record the number of previous pregnancies for each category. If no pregnancies for that category, record a 0 in the space provided. <p>Full term births = # of full-term infants born 36 or more weeks of completed gestation, alive or dead</p> <p>Premature births = # of preterm infants born 22 weeks to under 36 weeks, alive or dead</p> <p>Miscarriages = # of spontaneous abortions under 22 weeks</p> <p>Abortions = # of elective (induced) abortions under 22 weeks</p> <p>Live births = # of infants, full term or preterm, born alive</p>

Patient Interview

Protocol # 2

**Collaborative
Data Project**

Date Form Completed: / /
Day Month Year

Form Completed by:

CSCC ID:

Center code:

Hospital code:

14. In the past year, how many times have you come to the doctor's office, the day hospital, Emergency Department, acute day clinic, or other clinic for unscheduled visits because of pain due to Sickle Cell Disease? _____ Put 0 for none
15. In the past year, how many days of work or school have you missed due to your Sickle Cell Disease? (If patient is not employed and is not a student, please skip this question.) _____ Put 0 for none
16. In the past year, what was the total number of painful episodes due to Sickle Cell Disease for which you were treated solely at home? _____ Put 0 for none

For Female Patients: NA (for males and females not of child-bearing potential)

17. Are you currently pregnant? Yes No Unknown

18a. Have you ever been pregnant (exclude current pregnancy if applicable)? Yes No Unknown

[If yes] How many previous pregnancies have resulted in: (number)

18b. ____ Full term births 18d. ____ Miscarriages (spontaneous abortions) 18f. ____ Live Births

18c. ____ Premature births 18e. ____ Abortions (elective)

Item	Instructions
<p>19. Tobacco (past year)</p>	<p>Check "Yes" or "No" to indicate if the patient used any type of tobacco <i>in the past 12 months</i>. Check "Unknown" if patient unsure or refuses to answer.</p>
<p>20. Tobacco (current use)</p>	<ul style="list-style-type: none"> • Check "Yes" or "No" to indicate if the patient is using any type of tobacco <i>currently</i>. Check "Unknown" if patient is unsure or refuses to answer. • If Yes is marked, be sure to have the patient provide a number for each of the tobacco categories listed. <i>If no products from a category were used, record a 0.</i> • In addition to the approximate number of each product, select the appropriate time period over which use occurred, day or week. <p>For the occasional tobacco user (less than 1 of any product per week), mark No to the question "Do you currently use tobacco?" and leave 20b – 20e blank.</p>
<p>21. Alcohol (past year)</p>	<p>Check "Yes" or "No" to indicate if the patient used any type of alcohol <i>in the past 12 months</i>. Check "Unknown" if patient unsure or refuses to answer.</p>
<p>22. Alcohol (current use)</p>	<ul style="list-style-type: none"> • Check "Yes" or "No" to indicate if the patient is using any type of alcohol <i>currently</i>. Check "Unknown" if patient is unsure or refuses to answer. • If Yes is marked, be sure to have the patient provide a number for each of the alcohol categories listed. <i>If no products from a category were used, record a 0.</i> • In addition to the approximate number of each product, select the appropriate time period over which use occurred, week or month. <p>For the occasional drinker (less than 1 of any product per month), mark No to the question "Do you currently drink alcohol?" and leave 22b – 22d blank.</p>
<p>23. Income</p>	<p>Please use the income card provided. After reading the question to the patient, have them respond with the letter that best describes their yearly income.</p> <ul style="list-style-type: none"> • Total income includes the total income of each member of the patient's household from all sources including jobs, disability payments, or money from the government. • If the patient seems to be uncomfortable answering the question, mark "H. Prefer not to answer".

Patient Interview

Protocol # 2

**Collaborative
Data Project**

Date Form Completed: / /
Day Month Year

Form Completed by:

CSCC ID:

Center code:

Hospital code:

Tobacco Use in the past year

19. Did you use any type of tobacco in the past year? Yes No Unknown

20a. Do you currently use tobacco? Yes No Unknown

[If yes] 20b. What is your usual number of **cigarettes**? _____ per

day
week

20c. What is your usual number of **cigars**? _____ per

day
week

20d. How often do you use **snuff/chew**? _____ per

day
week

20e. How often do you smoke a **pipe**? _____ per

day
week

Alcohol Use in the past year

21. Did you drink any type of alcohol during the past year? Yes No Unknown

22a. Do you currently drink alcohol? Yes No Unknown

[If yes] 22b. What is your usual number of **beers**? _____ per

week
month

22c. What is your usual number of **glasses of wine**? _____ per

week
month

22d. What is your usual number of **other alcoholic drinks**? _____ per

week
month

23. Which of these letters best describes your household's yearly income? This includes the total amount of money for all members of your household combined, from all sources including jobs, disability payments or money from the government?

A. Under \$4,999

D. \$15,000-24,999

G. \$45,000 and over

B. \$5,000-9,999

E. \$25,000-34,999

H. Prefer not to answer

C. \$10,000-14,999

F. \$35,000-44,999

I. Don't know

Medical History Form IIB

CRF & Guidelines

All items on pages 1-3 of the interview should be determined by the patient's (or accompanying adult's) responses only. The interview forms will serve as source documentation.

Item	Instructions
Who is accompanying this child today?	Check the one choice that best describes the relationship between the child (patient) and the adult who is accompanying them today.
1. Race	<ul style="list-style-type: none"> • The interviewer should either read all choices at once <u>or</u> read each choice separately and wait for a response. • Check all racial groups the patient considers themselves to be a part of, <i>as reported by the patient (or accompanying adult)</i>. • If Other is marked, be sure to specify.
2. Ethnicity	Check the appropriate ethnicity of this child, <i>as reported by the patient (or accompanying adult)</i> .
3. Siblings (parts a-c)	<ul style="list-style-type: none"> • Record the total number of siblings. This number should include siblings of all types, including half-siblings and step-siblings as well as biological siblings. • If a number is recorded, be sure to fill in 3b) the number who have SCD and 3c) the number who do not have SCD. 3b and 3c should include only the siblings who share the same biological mother and father. Parts b and c may not be equal to the number recorded in part a (the total of all the subject's brothers and sisters).
4. Highest Grade	<ul style="list-style-type: none"> • Record the highest grade of school completed or the number of years of college this child has completed. • Enter 0 for pre-school or for children who have not yet begun school, K for Kindergarten, 1-12, 13= 1 year college, 14= 2 years college, etc.
5. Number of Individuals (≥ 19)	Record the number of individuals in this child's household who are 19 years of age and above .
6. Number of Individuals (<19)	Record the number of individuals in this child's household who are 19 years of age and below . This number should include the patient.
7. Insurance	<ul style="list-style-type: none"> • Check all that apply. • If Other is marked, be sure to specify.

Protocol # 2

**Collaborative
Data Project**

Date Form Completed: / /
Day Month Year

Form Completed by:

CSCC ID:

Center code:

Hospital code:

Who is accompanying this child today? Parent Guardian Other adult relative

1. **Which of the following racial groups do you consider this child a part of?** *(check all that apply)*
 - American Indian/Alaska Native
 - Asian
 - Black or African-American
 - Native Hawaiian or other Pacific Islander
 - White
 - Other, specify _____

2. **What is this child's ethnicity?**
 - Hispanic or Latino, or
 - Not Hispanic or Latino

- 3a. **How many siblings does this child have?** _____
Of the siblings who share both this child's biological mother and father:
 - 3b. How many have SCD? _____
 - 3c. How many do not have SCD? _____

4. **What is the highest grade of school this child has completed?** _____ *(Enter 0 for pre-school or less, K for Kindergarten, 1-12, 13 = 1 year college, 14 = 2 years college, etc.)*

5. **What is the number of individuals (19 years of age and up) in this child's household?** _____

6. **What is the number of individuals (under 19 years of age) in this child's household?** _____

7. **What type of health insurance does this child have?** *(check all that apply)*
 - Private
 - Medicare
 - Medicaid
 - None
 - Other _____

Item	Instructions
<p>8. Sickle cell related healthcare</p>	<ul style="list-style-type: none"> • Check “Yes” or “No” to indicate if this child has ever received sickle cell related health care from any other center or institution in the last 5 years. Check “Unknown” if patient/accompanying adult is unsure or refuses to answer. • If Yes is marked, be sure to record where and how many times the patient was seen for each location to the best of the patient’s (or accompanying adult’s) knowledge.
<p>9. Transfusion</p>	<ul style="list-style-type: none"> • Check “Yes” or “No” to indicate if the patient has ever received a transfusion. Check “Unknown” if patient is unsure or refuses to answer. • If Yes is marked, be sure to check the category that includes the approximate number of transfusions received, as estimated by the patient (or accompanying adult).
<p>10. Unscheduled Visits</p>	<ul style="list-style-type: none"> • Check “Yes” or “No” to indicate if the patient has ever had an unscheduled visit because of pain due to Sickle Cell Disease. Check “Unknown” if patient is unsure or refuses to answer. • If Yes is marked for pain due to Sickle Cell Disease, be sure to check the category that includes the number of unscheduled visits, as estimated by the patient (or accompanying adult).
<p>11. Headache</p>	<ul style="list-style-type: none"> • Check “Yes” or “No” to indicate if the patient has ever had a headache in the past year. Check “Unknown” if patient (or accompanying adult) is unsure or refuses to answer. • If Yes is marked, be sure to record how many headaches the patient had, how many occurred while having sickle cell pain, and how many headaches were not associated with sickle cell pain, fever/illness, or alcohol. • If no headaches occurred for question parts c and/or d, be sure to record a 0. • All numbers should be approximate. <p>Interviewers should feel free to help the patient determine the number of headaches for each part. For example, if the patient had 50 headaches in the past year, but is having trouble determining exactly how many of those headaches occurred while he/she had sickle cell pain, the interviewer may ask if the patient thinks that half, a third, etc. of those headaches occurred while he/she had sickle cell pain. If he/she agrees, record the number that corresponds with the fraction agreed upon by the patient.</p>
<p>12. Unscheduled Visits (past year)</p>	<ul style="list-style-type: none"> • Check “Yes” or “No” to indicate if the patient has ever had an unscheduled visit because of pain due to Sickle Cell Disease. Check “Unknown” if patient (or accompanying adult) is unsure or refuses to answer. • If Yes is marked for pain due to Sickle Cell Disease, be sure to check the category that includes the number of unscheduled visits, as estimated by the patient (or accompanying adult).
<p>13. Missed school (child)</p>	<ul style="list-style-type: none"> • Record the appropriate number of school days this child has missed due to Sickle Cell Disease in the past year. • If no days were missed, be sure to record a 0.

Protocol # 2

**Collaborative
Data Project**

Date Form Completed: / /
Day Month Year

Form Completed by:

CSCC ID:

Center code:

Hospital code:

8a. In the last 5 years, has this child received sickle cell-related healthcare from any other center or institution?

Yes No Unknown

8b. [If yes] Where?

How many times?

9a. Has this child ever received a transfusion? Yes No Unknown

9b. [If yes] How many transfusions? 1-5 6-20 21-99 100+

10a. Has this child ever gone to a doctor's office, a day hospital, an emergency department, acute day clinic, or other clinic for unscheduled visits because of pain due to Sickle Cell Disease? Yes No Unknown

10b. [If yes] How many times? 1-5 6-20 21-99 100+

11a. In the past year, has this child ever had a headache? Yes No Unknown

11b. [If yes] How many headaches has he/she had? _____

11c. How many of these headaches occurred while he/she had sickle pain? _____ Put 0 for none

11d. How many of these headaches were not associated with sickle pain, fever/illness, or alcohol? _____ Put 0 for none

12. In the past year, how many times has this child come to the doctor's office, the day hospital, Emergency Department, acute day clinic, or other clinic for unscheduled visits because of pain due to Sickle Cell Disease? _____ Put 0 for none

13. In the past year, how many days of school has this child missed due to his/her Sickle Cell Disease? _____ Put 0 for none

Item	Instructions
<p>14. Missed work/school (parent)</p>	<ul style="list-style-type: none"> • Record the approximate number of days the primary caregiver(s) of this child had to miss work or school due to this child's Sickle Cell Disease <i>in the past 12 months.</i> • If no days were missed due to Sickle Cell Disease, be sure to record a 0.
<p>15. Painful Episodes treated at home</p>	<ul style="list-style-type: none"> • Record the approximate number of painful episodes that were treated <i>solely</i> at home <i>during the past year</i> due to Sickle Cell Disease. • If no episodes were treated <i>solely</i> at home, be sure to record a 0.
<p>16. Income</p>	<p>Please use the income card provided. After reading the question to the patient (or accompanying adult), have them respond with the letter that best describes their yearly income.</p> <ul style="list-style-type: none"> • Total income includes the total income of each member of the patient's household from all sources including jobs, disability payments, or money from the government. • If the patient (or accompanying adult) seems to be uncomfortable answering the question, mark "H. Prefer not to answer".
<p>17. For the Interviewer</p>	<p>Please check the appropriate response.</p>

Protocol # 2

**Collaborative
Data Project**

Date Form Completed: / /
Day Month Year

Form Completed by:

CSCC ID:

Center code:

Hospital code:

14. In the past year, how many days of school or work have the primary caregiver(s) of this child missed due to this child's Sickle Cell Disease? _____ *Put 0 for none*

15. In the past year, what was the total number of painful episodes due to Sickle Cell Disease for which this child was treated solely at home? _____ *Put 0 for none*

16. Which of these letters best describes this child's household's yearly income? This includes the total amount of money for all members of your household combined, from all sources including jobs, disability payments or money from the government?

- | | | |
|---|---|--|
| <input type="checkbox"/> A. Under \$4,999 | <input type="checkbox"/> D. \$15,000-24,999 | <input type="checkbox"/> G. \$45,000 and over |
| <input type="checkbox"/> B. \$5,000-9,999 | <input type="checkbox"/> E. \$25,000-34,999 | <input type="checkbox"/> H. Prefer not to answer |
| <input type="checkbox"/> C. \$10,000-14,999 | <input type="checkbox"/> F. \$35,000-44,999 | <input type="checkbox"/> I. Don't know |

For the interviewer:

17. Who answered the questions on pages 1 - 3?

- Primarily the patient
- Primarily the parent/accompanying adult
- Patient and parent/accompanying adult together

Encounter Form

CRF & Guidelines

Item	Instructions
Date of Clinical Encounter	Record the date of clinical encounter in dd/mmm/yy format.
Type of Clinical Encounter	<ul style="list-style-type: none"> • Select the type of clinical encounter from the drop-down box that best describes this encounter. • With the exception of a visit to the clinic for hydroxyurea, clinical encounters do not include visits which solely involve picking up prescriptions or medications.
Most Important Symptoms	<ul style="list-style-type: none"> • Select the most important symptoms/presenting problems/diagnoses from the drop-down box. • Up to three (3) symptoms/problems/diagnoses may be chosen. • Due to the lack of standard definitions, please select each symptom within one diagnosis separately. For example, if a patient is exhibiting symptoms of ACS, fever will not be assumed to also be present. ACS and Fever should be selected separately. • If type of encounter is Research Study (i.e., annual visit) or Routine follow-up, select W1 = Well visit/study visit for this field.
Date of Admission/Discharge	<i>If admitted to the hospital</i> , record the date of admission <u>and</u> the date of discharge in dd/mmm/yy format.
Most important Discharge Diagnosis	<ul style="list-style-type: none"> • Select <i>at least one</i> appropriate discharge diagnosis from the drop-down box. Up to three (3) of the <i>most important</i> diagnoses may be selected. • Due to the lack of standard definitions, please select each symptom within one diagnosis separately. For example, if a patient is diagnosed with ACS, fever will not be assumed to also be present. ACS and Fever should be selected.

Use the Encounter Worksheet provided to record multiple symptoms, presenting problems, or diagnoses. Print double-sided to display the complete list of symptoms/diagnoses on the back of the worksheet

******Encounter Forms may be filled out for clinical encounters that have occurred outside of your center only if adequate documentation of the encounter is present in the patient's medical record.***

Comprehensive Sickle Cell Centers	Encounter Form	Encounter
<p style="text-align: center;">Protocol # 2</p> <p style="text-align: center;">Collaborative Data Project</p>	<p>Date Form Completed: <input type="text"/> / <input type="text"/> / <input type="text"/> <div style="text-align: center; margin-left: 40px;">Day Month Year</div></p> <p>Form Completed by: <input type="text"/></p>	<p>CSCC ID: <input type="text"/></p> <p>Center code: <input type="text"/></p> <p>Hospital code: <input type="text"/></p>

<p>Date of clinical encounter:</p> <p><input type="text"/> / <input type="text"/> / <input type="text"/> <div style="text-align: center; margin-left: 40px;">Day Month Year</div></p>	<p>Type of clinical encounter: drop-down box:</p> <table border="1" style="width:100%; border-collapse: collapse;"> <tr><td>Routine follow-up</td></tr> <tr><td>Scheduled transfusion</td></tr> <tr><td>Research Study</td></tr> <tr><td>Hydroxyurea</td></tr> <tr><td>Acute clinic visit</td></tr> <tr><td>ED visit</td></tr> <tr><td>Hospital admission</td></tr> <tr><td>Day hospital</td></tr> <tr><td>Other</td></tr> </table>	Routine follow-up	Scheduled transfusion	Research Study	Hydroxyurea	Acute clinic visit	ED visit	Hospital admission	Day hospital	Other	<p>Most Important Symptoms/Presenting Problems/Diagnoses: (up to 3)</p> <p style="text-align: center;">drop-down box:</p> <table border="1" style="width:100%; border-collapse: collapse;"> <tr><td>Acute Chest Syndrome or Pneumonia</td></tr> <tr><td>Aplastic Episode</td></tr> <tr><td>Asthma/Reactive airway disease</td></tr> <tr><td>Avascular Necrosis</td></tr> <tr><td>Bacteremia/Sepsis</td></tr> <tr><td>Other</td></tr> </table>	Acute Chest Syndrome or Pneumonia	Aplastic Episode	Asthma/Reactive airway disease	Avascular Necrosis	Bacteremia/Sepsis	Other
Routine follow-up																	
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Asthma/Reactive airway disease																	
Avascular Necrosis																	
Bacteremia/Sepsis																	
Other																	
If admitted to hospital:																	
<p>Date of admission:</p> <p><input type="text"/> / <input type="text"/> / <input type="text"/> <div style="text-align: center; margin-left: 40px;">Day Month Year</div></p> <p>Date of discharge:</p> <p><input type="text"/> / <input type="text"/> / <input type="text"/> <div style="text-align: center; margin-left: 40px;">Day Month Year</div></p>	<p>Most Important Discharge Diagnoses: (up to 3)</p> <p style="text-align: center;">drop-down box:</p> <table border="1" style="width:100%; border-collapse: collapse;"> <tr><td>Acute Chest Syndrome or Pneumonia</td></tr> <tr><td>Aplastic Episode</td></tr> <tr><td>Asthma/Reactive airway disease</td></tr> <tr><td>Avascular Necrosis</td></tr> <tr><td>Bacteremia/Sepsis</td></tr> <tr><td>Other</td></tr> </table>		Acute Chest Syndrome or Pneumonia	Aplastic Episode	Asthma/Reactive airway disease	Avascular Necrosis	Bacteremia/Sepsis	Other									
Acute Chest Syndrome or Pneumonia																	
Aplastic Episode																	
Asthma/Reactive airway disease																	
Avascular Necrosis																	
Bacteremia/Sepsis																	
Other																	

Possible responses below.

- | | |
|---|---|
| <p>Acute Chest Syndrome or Pneumonia</p> <p>Aplastic Episode</p> <p>Asthma/Reactive Airway Disease</p> <p>Avascular Necrosis, Hip(s)</p> <p>Avascular Necrosis, Shoulder(s)</p> <p>Avascular Necrosis, Spine</p> <p>Bacteremia/Sepsis</p> <p>Cardiac Failure</p> <p>Central Nervous System Disease, Abnormal TCD</p> <p>Central Nervous System Disease, Seizure</p> <p>Central Nervous System Disease, Silent Infarct</p> <p>Central Nervous System Disease, Stroke, Ischemic</p> <p>Central Nervous System Disease, Stroke, Hemorrhagic</p> <p>Central Nervous System Disease, TIA</p> <p>Dactylitis (Hand Foot Syndrome)</p> <p>Diabetes</p> <p>Fever</p> <p>Gall Bladder Disease</p> <p>Hypertension, chronic, requiring treatment</p> <p>Leg Ulcer</p> <p>Liver Disease, Hepatic Fibrosis/Cirrhosis</p> | <p>Liver Disease, Hepatic Sequestration/
Sickle-Hepatopathy/Intrahepatic Sickling</p> <p>Liver Disease, Hepatitis, Viral</p> <p>Liver Disease, Iron Overload</p> <p>Lung Disease, Pulmonary Fibrosis</p> <p>Lung Disease, Pulmonary Hypertension</p> <p>Meningitis</p> <p>Osteomyelitis</p> <p>Pain Crisis</p> <p>Priapism</p> <p>Renal Disease, Acute Renal Failure</p> <p>Renal Disease, Chronic Renal Failure-Supportive</p> <p>Renal Disease, Dialysis</p> <p>Renal Disease, Microalbuminuria/Proteinuria</p> <p>Renal Disease, Nephrotic Syndrome</p> <p>Renal Disease, Transplant</p> <p>Retinopathy</p> <p>Splenic Sequestration</p> <p>Transfusion/Chelation</p> <p>Well visit/study visit</p> <p>Other</p> |
|---|---|

Annual Form Part IIA

CRF & Guidelines

All items on pages 1-4 of the interview should be determined by the patient's responses only. The interview forms will serve as source documentation.

Item	Instructions
<p>1. Siblings</p>	<ul style="list-style-type: none"> Record the total number of siblings. This number should include siblings of all types, including half-siblings and step-siblings as well as biological siblings If a number is recorded, be sure to fill in 3b) the number who have SCD and 3c) the number who do not have SCD. 3b and 3c should include only the siblings who share the same biological mother and father. Parts b and c may not be equal to the number recorded in part a (the total of all the subject's brothers and sisters).
<p>2. Employment Status</p>	<ul style="list-style-type: none"> Check the appropriate current employment status of the patient. If patient is NOT employed and NOT a student (Question 3), please skip Question 11.
<p>3. Student Status</p>	<ul style="list-style-type: none"> Check the appropriate current student status of the patient. If patient is NOT employed (Question 2) and NOT a student, please skip Question 11.
<p>4. Highest Grade</p>	<ul style="list-style-type: none"> Record the highest grade of school completed or the number of years of college completed. Enter 0 for pre-school or for children who have not yet begun school, K for Kindergarten, 1-12, 13= 1 year college, 14= 2 years college, etc.
<p>5. Number of Individuals (≥19)</p>	<p>Record the number of individuals in the household who are 19 years of age and above. This number should include the patient, if applicable.</p>
<p>6. Number of Individuals (<19)</p>	<p>Record the number of individuals in the household who are 19 years of age and below. This number should include the patient, if applicable.</p>
<p>7. Insurance</p>	<ul style="list-style-type: none"> Check all that apply. If Other is marked, be sure to specify.
<p>8. Sickle cell related healthcare</p>	<ul style="list-style-type: none"> Check "Yes" or "No" to indicate if the patient has received sickle cell related health care from any other center or institution in the past 12 months. Check "Unknown" if patient is unsure or refuses to answer. If Yes is marked, be sure to record where and how many times the patient was seen for each location to the best of the patient's knowledge.

Patient Interview

Protocol # 2

**Collaborative
Data Project**

Date Form Completed: / /
Day Month Year

Form Completed by:

CSCC ID:

Center code:

Hospital code:

1a. How many siblings do you have? _____

Of the siblings who share both your biological mother and father:

1b. How many have SCD? _____

1c. How many do not have SCD? _____

2. **What is your current employment status?** Are you: Full Time,
 Part Time, or
 Not Employed

3. **What is your current student status?** Are you: Full Time,
 Part Time, or
 Not a Student

(If Questions 2 and 3 indicate that patient is NOT employed and NOT a student, please skip Question 11.)

4. **What is the highest grade of school you have completed, or how many years of college have you completed?** _____

(Enter 0 for pre-school or less, K for Kindergarten, 1-12, 13 = 1 year college, 14 = 2 years college, etc.)

5. **What is the number of individuals (19 years of age and up) in your household?** _____

6. **What is the number of individuals (under 19 years of age) in your household?** _____

7. **What type of health insurance do you have?** *(check all that apply)*

Private Medicare Medicaid None Other _____

8a. **In the past year, have you received sickle cell-related healthcare from any other center or institution?**

Yes No Unknown

8b. *[If yes]* **Where?**

How many times?

Item	Instructions
<p>9. Headache</p>	<ul style="list-style-type: none"> • Check “Yes” or “No” to indicate if the patient has ever had a headache in the past year. Check “Unknown” if patient is unsure or refuses to answer. • If Yes is marked, be sure to record how many headaches the patient had, how many occurred while having sickle cell pain, and how many headaches were not associated with sickle cell pain, fever/illness, or alcohol. • If no headaches occurred for question parts c and/or d, be sure to record a 0. • All numbers should be approximate. <p>Interviewers should feel free to help the patient determine the number of headaches for each part. For example, if the patient had 50 headaches in the past year, but is having trouble determining exactly how many of those headaches occurred while he/she had sickle cell pain, the interviewer may ask if the patient thinks that half, a third, etc. of those headaches occurred while he/she had sickle cell pain. If he/she agrees, record the number that corresponds with the fraction agreed upon by the patient.</p>
<p>10. Transfusions</p>	<ul style="list-style-type: none"> • Check “Yes” or “No” to indicate if the patient has received a transfusion in the past year. Check “Unknown” if patient is unsure or refuses to answer. • If Yes is marked, be sure to check the category that includes the approximate number of transfusions received, as estimated by the patient.
<p>11. Missed work/school</p>	<ul style="list-style-type: none"> • Record the approximate number of days the patient had to miss work or school due to his/her Sickle Cell Disease in the past year. • If no days were missed due to Sickle Cell Disease, be sure to record a 0. • If patient is not employed and is not a student, please skip Question 11 and leave this question blank.
<p>12. Unscheduled Visits</p>	<ul style="list-style-type: none"> • Record the approximate number of unscheduled visits in the past year because of pain due to Sickle Cell Disease. • If no unscheduled visits for pain due to Sickle Cell Disease occurred, be sure to record a 0.
<p>13. Painful Episodes treated at home</p>	<ul style="list-style-type: none"> • Record the approximate number of painful episodes that were treated solely at home during the past year due to Sickle Cell Disease. • If no episodes were treated solely at home, be sure to record a 0.

Patient Interview

Protocol # 2

**Collaborative
Data Project**

Date Form Completed: / /
Day Month Year

Form Completed by:

CSCC ID:

Center code:

Hospital code:

9a. In the past year, have you ever had a headache? Yes No Unknown

9b. [If yes] How many headaches have you had? _____

9c. How many of these headaches occurred while you had sickle pain? _____ Put 0 for none

9d. How many of these headaches were not associated with sickle pain, fever/illness, or alcohol? _____ Put 0 for none

10a. Have you received a transfusion in the past year? Yes No Unknown

10b. [If yes] How many transfusions? 1-5 6-20 21-99 100+

11. In the past year, how many days of work or school have you missed due to your Sickle Cell Disease? (If patient is not employed and is not a student, please skip this question.) _____ Put 0 for none

12. In the past year, how many times have you come to the doctor's office, the day hospital, Emergency Department, acute day clinic, or other clinic for unscheduled visits because of pain due to Sickle Cell Disease? _____ Put 0 for none

13. In the past year, what was the total number of painful episodes due to Sickle Cell Disease for which you were treated solely at home? _____ Put 0 for none

Item	Instructions
<p>Female Patients</p>	<ul style="list-style-type: none"> • Check “NA” if the patient is male or is a female not of child-bearing potential. • If checked, leave the pregnancy section blank.
<p>14. Currently pregnant</p>	<p>Check “Yes” or “No” to indicate if the patient is currently pregnant, as reported by the patient. Check “Unknown” if patient is unsure or refuses to answer.</p>
<p>15. Pregnancy (parts a-f)</p>	<ul style="list-style-type: none"> • Check “Yes” or “No” to indicate if the patient has been pregnant <i>in the past year</i>, as reported by the patient. Exclude current pregnancy, if applicable. Check “Unknown” if patient is unsure or refuses to answer. • If Yes is marked, be sure to record the number of pregnancies <i>in the past year</i> for each category. If no pregnancies for that category, record a 0 in the space provided. <p>Full term births = # of full-term infants born 36 or more weeks of completed gestation, alive or dead</p> <p>Premature births = # or preterm infants born 22 weeks to under 36 weeks, alive or dead</p> <p>Miscarriages = # of spontaneous abortions under 22 weeks</p> <p>Abortions = # of elective (induced) abortions under 22 weeks</p> <p>Live births = # of infants, full term or preterm, born alive</p>
<p>16. Tobacco (past year)</p>	<p>Check “Yes” or “No” to indicate if the patient used any type of tobacco <i>in the past year</i>. Check “Unknown” if patient unsure or refuses to answer.</p>
<p>17. Tobacco (current use)</p>	<ul style="list-style-type: none"> • Check “Yes” or “No” to indicate if the patient is using any type of tobacco <i>currently</i>. Check “Unknown” if patient is unsure or refuses to answer. • If Yes is marked, be sure to have the patient provide a number for each of the tobacco categories listed. <i>If no products from a category were used, record a 0.</i> • In addition to the approximate number of each product, select appropriate time period over which use occurred, day or week. <p>For the occasional tobacco user (less than 1 of any product per week), mark No to the question “Do you currently use tobacco?” and leave 17b – 17e blank.</p>

Patient Interview

Protocol # 2

**Collaborative
Data Project**

Date Form Completed: / /
Day Month Year

Form Completed by:

CSCC ID:

Center code:

Hospital code:

For Female Patients: NA (for males and females not of child-bearing potential)

14. **Are you currently pregnant?** Yes No Unknown

15a. **Have you been pregnant within the past year (exclude current pregnancy if applicable)?**

Yes No Unknown

15b. *[If yes]* How many of these pregnancies resulted in: _____ Full term births
(number)

15c. _____ Premature births

15d. _____ Miscarriages (spontaneous abortions)

15e. _____ Abortions (elective)

15f. _____ Live Births

Tobacco Use in the past year

16. **Did you use any type of tobacco in the past year?** Yes No Unknown

17a. **Do you currently use tobacco?** Yes No Unknown

[If yes] 17b. What is your usual number of **cigarettes**? _____ per

day
week

17c. What is your usual number of **cigars**? _____ per

day
week

17d. How often do you use **snuff/chew**? _____ per

day
week

17e. How often do you **smoke a pipe**? _____ per

day
week

Item	Instructions
<p>18. Alcohol (past year)</p>	<p>Check “Yes” or “No” to indicate if the patient used any type of alcohol <i>in the past year</i>. Check “Unknown” if patient unsure or refuses to answer.</p>
<p>19. Alcohol (current use)</p>	<ul style="list-style-type: none"> • Check “Yes” or “No” to indicate if the patient is using any type of alcohol <i>currently</i>. Check “Unknown” if patient is unsure or refuses to answer. • If Yes is marked, be sure to have the patient provide a number for each of the alcohol categories listed. <i>If no products from a category were used, record a 0.</i> • In addition to the approximate number of each product, select appropriate time period over which use occurred, week or month. <p>For the occasional drinker (less than 1 of any product per month), mark No to the question “Do you currently drink alcohol?” and leave 19b – 19d blank.</p>
<p>20. Income</p>	<p>Please use the income card provided. After reading the question to the patient, have them respond with the letter that best describes their yearly income.</p> <ul style="list-style-type: none"> • Total income includes the total income of each member of the patient’s household from all sources including jobs, disability payments, or money from the government. • If the patient seems to be uncomfortable answering the question, mark “H. Prefer not to answer”.

Patient Interview

Protocol # 2

**Collaborative
Data Project**

Date Form Completed: / /
Day Month Year

Form Completed by:

CSCC ID:

Center code:

Hospital code:

Alcohol Use in the past year

18. Did you drink any type of alcohol during the past year? Yes No Unknown

19a. Do you currently drink alcohol? Yes No Unknown

[If yes] 19b. What is your usual number of **beers**? _____ per

week
month

19c. What is your usual number of **glasses of wine**? _____ per

week
month

19d. What is your usual number of **other alcoholic drinks**? _____ per

week
month

20. Which of these letters best describes your household's yearly income *during the past year*?
This includes the total amount of money for all members of your household combined, from all sources including jobs, disability payments or money from the government?

A. Under \$4,999

D. \$15,000-24,999

G. \$45,000 and over

B. \$5,000-9,999

E. \$25,000-34,999

H. Prefer not to answer

C. \$10,000-14,999

F. \$35,000-44,999

I. Don't know

Annual Form Part IIB

CRF & Guidelines

All items on pages 1-3 of the interview should be determined by the patient's (or accompanying adult's) responses only. The interview forms will serve as source documentation.

Item	Instructions
<p>Who is accompanying this child today?</p>	<p>Check the one choice that best describes the relationship between the child (patient) and the adult who is accompanying them today.</p>
<p>1. Siblings</p>	<ul style="list-style-type: none"> Record the total number of siblings. This number should include siblings of all types, including half-siblings and step-siblings as well as biological siblings. If a number is recorded, be sure to fill in 3b) the number who have SCD and 3c) the number who do not have SCD. 3b and 3c should include only the siblings who share the same biological mother and father. Parts b and c may not be equal to the number recorded in part a (the total of all the subject's brothers and sisters).
<p>2. Highest Grade</p>	<ul style="list-style-type: none"> Record the highest grade of school completed or the number of years of college this child has completed. Enter 0 for pre-school or for children who have not yet begun school, K for Kindergarten, 1-12, 13= 1 year college, 14= 2 years college, etc.
<p>3. Number of Individuals (≥ 19)</p>	<p>Record the number of individuals in this child's household who are 19 years of age and above.</p>
<p>4. Number of Individuals (≥ 19)</p>	<p>Record the number of individuals in this child's household who are 19 years of age and below. This number should include the patient.</p>
<p>5. Insurance</p>	<ul style="list-style-type: none"> Check all that apply. If Other is marked, be sure to specify.
<p>6. Sickle cell related healthcare</p>	<ul style="list-style-type: none"> Check "Yes" or "No" to indicate if this child has received sickle cell related health care from any other center or institution in the past year. Check "Unknown" if patient/accompanying adult is unsure or refuses to answer. If Yes is marked, be sure to record where and how many times the patient was seen for each location to the best of the patient's (or accompanying adult's) knowledge.
<p>7. Transfusions</p>	<ul style="list-style-type: none"> Check "Yes" or "No" to indicate if the patient has received a transfusion in the past year. Check "Unknown" if patient is unsure or refuses to answer. If Yes is marked, be sure to check the category that includes the approximate number of transfusions received, as estimated by the patient (or accompanying adult).

Protocol # 2

**Collaborative
Data Project**

Date Form Completed: / /
Day Month Year

Form Completed by:

CSCC ID:

Center code:

Hospital code:

Who is accompanying this child today? Parent Guardian Other adult relative

1a. How many siblings does this child have? _____

Of the siblings who share both this child's biological mother and father:

1b. How many have SCD? _____

1c. How many do not have SCD? _____

2. What is the highest grade of school this child has completed? _____ *(Enter 0 for pre-school or less, K for Kindergarten, 1-12, 13 = 1 year college, 14 = 2 years college, etc.)*

3. What is the number of individuals (19 years of age and up) in this child's household? _____

4. What is the number of individuals (under 19 years of age) in this child's household? _____

5. What type of health insurance does this child have? *(check all that apply)*
 Private Medicare Medicaid None Other _____

6a. In the past year, has this child received sickle cell-related healthcare from any other center or institution?
 Yes No Unknown

6b. *[If yes]* Where? _____ How many times? _____

7a. Has this child been transfused in the past year? Yes No Unknown

7b. *[If yes]* How many transfusions? 1-5 6-20 21-99 100+

Item	Instructions
<p>8. Headache</p>	<ul style="list-style-type: none"> • Check “Yes” or “No” to indicate if the patient has ever had a headache in the past year. Check “Unknown” if patient is unsure or refuses to answer. • If Yes is marked, be sure to record how many headaches the patient had, how many occurred while having sickle cell pain, and how many headaches were not associated with sickle cell pain, fever/illness, or alcohol. • If no headaches occurred for question parts c and/or d, be sure to record a 0. • All numbers should be approximate. <p>Interviewers should feel free to help the patients determine the number of headaches for each part. For example, if the patient had 50 headaches in the past year, but is having trouble determining exactly how many of those headaches occurred while they had sickle cell pain, the interviewer may ask if the patient thinks that half, a third, etc. of those headaches occurred while they had sickle cell pain. If they agree, record the number that corresponds with the fraction agreed upon by the patient.</p>
<p>9. Missed school (child)</p>	<ul style="list-style-type: none"> • Record the appropriate number of school days this child has missed due to Sickle Cell Disease in the past year. • If no days were missed, be sure to record a 0.
<p>10. Missed school/work (parent)</p>	<ul style="list-style-type: none"> • Record the approximate number of days the primary caregiver(s) of this child had to miss work or school due to this child’s Sickle Cell Disease in the past year. • If no days were missed due to Sickle Cell Disease, be sure to record a 0.
<p>11. Unscheduled Visits</p>	<ul style="list-style-type: none"> • Check “Yes” or “No” to indicate if the patient has had an unscheduled visit because of pain due to Sickle Cell Disease in the past year. Check “Unknown” if patient is unsure or refuses to answer. • If Yes is marked for pain due to Sickle Cell Disease, be sure to check the category that includes the number of unscheduled visits, as estimated by the patient (or accompanying adult).
<p>12. Painful Episodes treated at home</p>	<ul style="list-style-type: none"> • Record the approximate number of painful episodes that were treated solely at home during the past year due to Sickle Cell Disease. • If no episodes were treated solely at home, be sure to record a 0.
<p>13. Income</p>	<p>Please use the income card provided. After reading the question to the patient (or accompanying adult), have them respond with the letter that best describes their yearly income.</p> <ul style="list-style-type: none"> • Total income includes the total income of each member of the patient’s household from all sources including jobs, disability payments, or money from the government. • If the patient (or accompanying adult) seems to be uncomfortable answering the question, mark “H. Prefer not to answer”.

Protocol # 2

**Collaborative
Data Project**

Date Form Completed: / /
Day Month Year

Form Completed by:

CSCC ID:

Center code:

Hospital code:

8a. In the past year, has this child ever had a headache? Yes No Unknown

8b. [If yes] How many headaches has he/she had? _____

8c. How many of these headaches occurred while he/she had sickle pain? _____ *Put 0 for none*

8d. How many of these headaches were not associated with sickle pain, fever/illness, or alcohol? _____ *Put 0 for none*

9. In the past year, how many days of school has this child missed due to his/her Sickle Cell Disease? _____ *Put 0 for none*

10. In the past year, how many days of school or work have the primary caregiver(s) of this child missed due to this child's Sickle Cell Disease? _____ *Put 0 for none*

11. In the past year, how many times has this child come to the doctor's office, the day hospital, Emergency Department, acute day clinic, or other clinic for unscheduled visits because of pain due to Sickle Cell Disease? _____ *Put 0 for none*

12. In the past year, what was the total number of painful episodes due to Sickle Cell Disease for which this child was treated solely at home? _____ *Put 0 for none*

13. Which of these letters best describes this child's household's yearly income *during the past year*? This includes the total amount of money for all members of your household combined, from all sources including jobs, disability payments or money from the government?

- | | | |
|---|---|--|
| <input type="checkbox"/> A. Under \$4,999 | <input type="checkbox"/> D. \$15,000-24,999 | <input type="checkbox"/> G. \$45,000 and over |
| <input type="checkbox"/> B. \$5,000-9,999 | <input type="checkbox"/> E. \$25,000-34,999 | <input type="checkbox"/> H. Prefer not to answer |
| <input type="checkbox"/> C. \$10,000-14,999 | <input type="checkbox"/> F. \$35,000-44,999 | <input type="checkbox"/> I. Don't know |

Item	Instructions
14. For the Interviewer	Please check the appropriate response.

Protocol # 2

**Collaborative
Data Project**

Date Form Completed: / /
Day Month Year

Form Completed by:

CSCC ID:

Center code:

Hospital code:

For the interviewer:

14. Who answered the questions on pages 1 and 2?

- Primarily the patient
- Primarily the parent/accompanying adult
- Patient and parent/accompanying adult together

Termination/Transfer Form

CRF & Guidelines

Item	Instructions
<p>Patient Status</p>	<p>Check one box to indicate the reason this form was completed.</p> <ul style="list-style-type: none"> • Check “Deceased” if patient has died. • Check “Transferred” if patient transfers to another hospital or moves out of the area but knows that they will be seen at another sickle cell facility. • Check “Lost to follow-up” if the patient has not been heard from in quite some time and is unable to be contacted. • Check “Withdrawn” if the patient simply decides to no longer participate.
<p>Date of Death, Transfer, or Termination</p>	<ul style="list-style-type: none"> • Record the date of death, transfer, withdrawal <u>or</u> date patient determined to be lost to follow-up in dd/mmm/yy format. • If transferred, be sure to specify the institution/site transferred to. Record “Unknown” if necessary. • If patient died, complete the rest of the form. Otherwise, omit the rest of the form.
<p>Autopsy</p>	<ul style="list-style-type: none"> • Check “Yes” or “No” to indicate if an autopsy was performed. If this information is not known, check “Unknown”. • If Yes, be sure to record the institution where the autopsy was performed. • If Yes, be sure to file a copy of the report with the patient’s medical and research records.
<p>Hospital Death</p>	<ul style="list-style-type: none"> • Check “Yes” or “No” to indicate if the patient died in the hospital. If this information is not known, check “Unknown”. • If Yes, be sure to file a copy of the discharge summary with the patient’s medical and research records.
<p>Primary Cause of Death</p>	<ul style="list-style-type: none"> • Choose only one primary cause of death. • If Other is chosen, be sure to specify.
<p>Secondary Cause(s) of Death</p>	<ul style="list-style-type: none"> • Check “Yes” or “No” to indicate whether or not there were secondary cause(s) of death. • If Yes, check all that apply. • If Other is chosen, be sure to specify the secondary cause of death.

