

CSCC
Collaborative Data Project
C-Data

Baseline Medical History Form

Version 5.2 06Sep2007

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 |
|------------------------------------|---|
| General | All data recorded on Medical History Form Part I should have occurred either on or prior to the date of informed consent. |
| Date patient first seen | <ul style="list-style-type: none"> Record the date the patient was first seen <i>in your center</i> (not just hospital) in dd/mm/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> |
| Weight | <ul style="list-style-type: none"> Record the <i>most recent</i> 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> |
| Height | <ul style="list-style-type: none"> Record the <i>most recent</i> 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> |
| Date of measurement | Record the <i>most recent</i> dates of measurement in dd/mm/yy format for both height and weight. Dates may be the same or different. |
| Currently in research study | <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 <i>currently</i> 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, Priapism, Dexamethasone, Decitabine and Methadone 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><i>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.</i></p> |

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

| Item | Instructions |
|-------------------------|---|
| General | All data recorded on Medical History Form Part I should have occurred either on or prior to the date of informed consent. |
| Surgical History | <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 Tonsillectomy/Adenoidectomy, Hip Replacement, Insertion of a Permanent Indwelling Line and Removal of a 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 |
|---------------------------|--|
| General | All data recorded on Medical History Form Part I should have occurred either on or prior to the date of informed consent. |
| 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”. |

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

| Item | Instructions |
|---------------------------|--|
| General | All data recorded on Medical History Form Part I should have occurred either on or prior to the date of informed consent. |
| 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. |

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

| Item | Instructions |
|--|---|
| General | All data recorded on Medical History Form Part I should have occurred either on or prior to the date of informed consent. |
| 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, 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 |
|---|---|
| General | All data recorded on Medical History Form Part I should have occurred either on or prior to the date of informed consent. |
| Transfusion in the past year | <ul style="list-style-type: none"> • Check “Yes” or “No” to indicate if the patient has or has not received a transfusion in the past 12 months. Check “Unknown” if this information is not known. • If Yes, check the category that includes the number of <u>transfusions</u> received in the past 12 months. |
| Transfusion prior to the past year | <ul style="list-style-type: none"> • Check “Yes” or “No” to indicate if the patient has or has not received a transfusion prior to the past 12 months. Check “Unknown” if this information is not known. • If Yes, check the category that includes the number of <u>transfusions</u> received prior to the past 12 months. |
| Iron overload assessment | <ul style="list-style-type: none"> • Check “Yes” or “No” to indicate if the patient has or has not ever had iron overload assessed. Check “Unknown” if this information is not known. • If Yes, record results for the most recent 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> |
| Iron chelation therapy | <ul style="list-style-type: none"> • Check “Yes” or “No” to indicate if the patient has or has not ever 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. |

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| Comprehensive Sickle Cell Centers | Medical History Form Part I Transfusion History | Clinical Data Page: 6a 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: 40px;">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"/> Center code: <input type="text"/> <input type="text"/> <input type="text"/> Hospital code: <input type="text"/> <input type="text"/> <input type="text"/> |

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 (i.e., Exjade, Deferasirox) Unknown

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

| Item | Instructions |
|---|---|
| General | All data recorded on Medical History Form Part I should have occurred either on or prior to the date of informed consent. |
| Transplants in the past year | <ul style="list-style-type: none"> • Check “Yes” or “No” to indicate if the patient has or has not received a transplant <i>in the past 12 months</i>. Check “Unknown” if this information is not known. |
| Transplants prior to the past year | <ul style="list-style-type: none"> • Check “Yes” or “No” to indicate if the patient has or has not received a transplant <i>prior to the past 12 months</i>. Check “Unknown” if this information is not known. |
| Date of transplant, Site(s), Type of donor, Type of transplant | <ul style="list-style-type: none"> • If either of the two previous questions is marked “Yes”, press the “Add” button to record the Date of Transplant in the dd/mmm/yy format. • Record the site(s) of transplant. • Check the type of donor. • Check the type of transplant. |

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

| Item | Instructions |
|----------------------------------|---|
| General | All data recorded on Medical History Form Part I should have occurred either on or prior to the date of informed consent. |
| RBC antibodies | <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> |
| Selected Diagnostic Tests | <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. |

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

| Item | Instructions |
|---|---|
| General | All data recorded on Medical History Form Part I should have occurred either on or prior to the date of informed consent. |
| | <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> |
| Does this patient have labs recorded during the last 2 years that meet the criteria described above? | <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. |
| Lab tests | <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 |
|---|--|
| General | All data recorded on Medical History Form Part I should have occurred either on or prior to the date of informed consent. |
| Hospital Admissions | <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> |
| Admissions at other institutions | <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.

| 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>. |

