

Attachment D - The Minimum Database Project Sickle Cell Disease and Trait Instruction Manual

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**National Coordinating and Evaluation Center
Minimum Database Project Instruction Manual**

Welcome! This instruction manual has been developed to assist individuals in grantee and partner sites who will serve as data collectors or recorders for the **Minimum Database Project (MDP) for Sickle Cell Disease (SCD) and Sickle Cell Trait (SCT)**.

This Manual of Operations (MOO) is designed to accompany the MDP SCD and SCT questionnaires provided to each participating site.

Users are encouraged to make as many notes as necessary in this manual to help remember key pieces of information that will simplify the collection of accurate information. If you have questions about the information in this manual, do not hesitate to contact:

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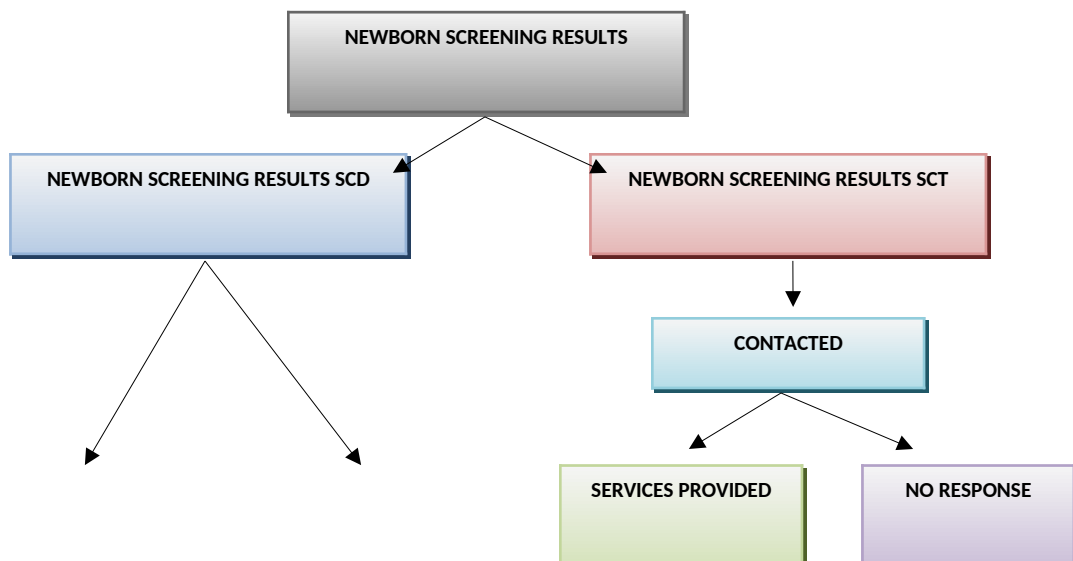
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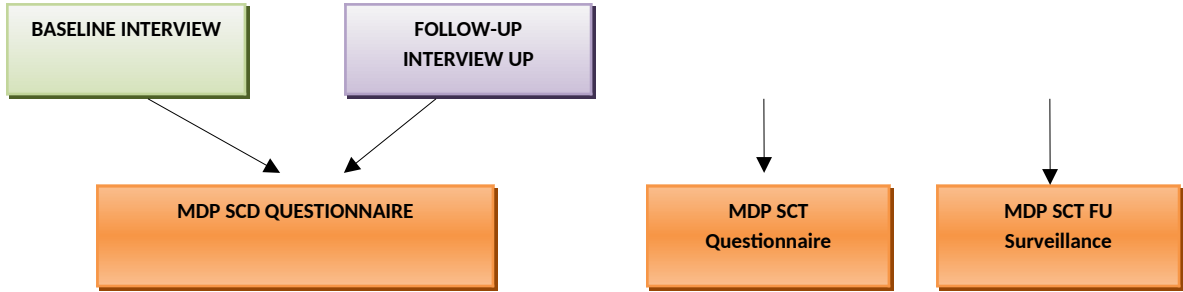
General Instructions

The Minimum Database Project (MDP) questionnaire will have three components as follows: (1) MDP for Sickle Cell Disease (SCD) only; (2) MDP for Sickle Cell Trait (SCT) only and; (3) MDP for Emerging Populations (included on both components 1 and 2).

The design of the MDP will be two-tiered wherein the first tier will be a demarcation option between SCD and SCT based on confirmatory diagnosis of the client. The second tier will be a demarcation option between baseline interviews and follow up interviews based on the type of visit/interview (see flow chart). All follow-up information will link back to the baseline initial interview with auto-populated fields. The set of questions for the follow-up interviews will be decidedly shorter than the initial interview since certain variables do not change over time, such as, DOB and race of the client. The follow-up form will be a different color for easier distinction and filing. **Trait questions will only be asked if the client is related to a child aged 0-5 years that has tested positive for trait through the NBS program.**

Flow Chart of Proposed MDP Data Collection Protocol





Pre-Interview Debriefing

- **Leave no question unanswered, otherwise the form will be considered incomplete.** Each section of the MDP SCT questionnaire is designed to capture key information that describes characteristics of the client or his/her family. It is therefore critical that every applicable question be answered or verified.
- **Every identified client or caregiver (e.g., parent) must have a face-to-face or phone interview.** Only under very rare exceptions should the client or family member be allowed to complete a paper version of the form on their own, even if the information will be entered at a later time by the participating site staff person.
- **When filling out the paper version of the data form, staff must follow NIH guidelines,** so please be sure to do the following:
 - ✓ Use black pen for all forms - **No Pencil**
 - ✓ Do not use white out to correct mistakes
 - ✓ Correct mistakes by putting a single line through it, then date and initial the change
 - ✓ Do not write in the margins of the form, use a separate sheet of paper to make notes
- **If completing paper forms, enter all information in to the web portal developed by the NCEC.** Paper forms will not be accepted.
- **Data submission will occur every three (3) months (quarterly)** (see page 19 for data submission schedule)
- Begin by explaining that all of the information in the interview is **confidential**. The MDP grantee sites will keep the completed questionnaire for its records, and the people analyzing the interviews (NCEC) **will never be able to identify who completed each interview**

Sickle Cell Disease Newborn Screening Program (SCDNBSP)
Minimum Dataset Project (MDP)
Sickle Cell Disease (SCD) Questionnaire Form

Section A: SITE IDENTIFYING INFORMATION

- **Today's Date:** This field will be auto-populated
- **Date of Visit/Interview:** Enter the date that you completed the interview.
- **Data Entry Personnel:** Enter the name of the person who entered the interview information into the database.
- **Site ID number:** Record site's unique ID number (two digit IDs) assigned by the NCEC.
- **State ID number:** Record the state in which the site is located. Use 2-digit code to designate state (e.g., 'AL' for Alabama)

Section B: CLIENT IDENTIFYING INFORMATION

Client ID number: Record client's unique ID number. The client ID (4-5 numbers) will be a unique and site specific ID which will be designated to each site by NCEC.

NOTE: The NCEC will create a unique identifier for each client that will include an algorithm of alpha-numeric characters as follows: state ID (two letters) where the site is located, client ID (four to five numbers) and site ID (two to three numbers) designated to each site by NCEC.

Additionally, there will be search field whereby clients could be searched by this unique ID number and their diagnosis.

Client being a newborn: Please check "yes" or "no" if the client is less than 2 months old

Section C: CLIENT INFORMATION

1. **Type of referral agency:** If this is a **first visit** to the clinic/agency, ask and check which type of agency referred the client. If the interviewee received more than one referral, use the one that, in the judgment of the interviewee, was most significant.
2. **Sex of the client:** Ask the interviewee and record as indicated.
3. **Client's confirmed diagnosis:** Please read down the whole list (so the interviewee hears all possible answers) and then record as answered.

4. **Age at confirmatory diagnosis:** Ask and record the date that the diagnosis was confirmed.
5. **Source of Confirmatory Diagnosis:** Enter the source of confirmatory diagnosis.

Section D: FAMILY INFORMATION

6. **Primary caregiver:** Verify, or ask and record the primary caregiver of the client. This assists in tracking and decision-making about current, ongoing, and anticipated service needs unique to the caregiver.
7. **Hemoglobin status of primary caregiver – Mother:** Verify, or ask and record if the mother knows about her hemoglobin status.
8. **If yes to Q.11,** indicate when mother knew about her hemoglobin status
9. **If no to Q. 11,** indicate if the mother has been asked to be tested for SCD/SCT
10. **Hemoglobin status of primary caregiver – Father:** Verify, or ask and record if the father knows about his hemoglobin status.
11. **If yes to Q.14,** indicate when father knew about his hemoglobin status
12. **If no to Q. 14,** indicate if the father has been asked to be tested for SCD/SCT
13. **Age of caregiver(s):** Record the age of primary caregiver. If more than one primary caregiver, then record the age in the other box.
14. **Relation of the child to the caregiver/family:** Ask and record whether the client is genetically related to the parents or not.
15. **Other children in the family with SCD:** Ask and record the number of other children in the home with SCD and/or SCT.
16. **Other child/children diagnosis:** Verify, or ask and record the confirmed diagnosis of the other child/children in the family with SCD and SCT.
17. **Number of persons (adult and children) in household:** Verify, or ask and record the number of persons living in household, including the person being interviewed.
18. **Zip code of the client or primary caregiver(s):** Verify, or ask and record in which zip code the client or caregiver resides. This is a proxy variable that identifies the geographic location of the respondent, allowing for matching of Census or other population level variables.

19. **Annual household income of the client's family:** This income should include everyone that resides in the home. Please total all incomes and choose one range.
20. **Type of health insurance for the client:** Be sure to read down the list and check off all options that apply to respondent. Do this even when the respondent offers an answer - they may have forgotten that they use different sources to pay for different medical services. Make sure the health insurance applies to the client. SCHIP is the State Children's Health Insurance Program. The name of this program can vary from state to state.

Section E: SERVICES CLIENT RECEIVED

21. **Where does the client go for primary care?** Verify, or ask and record the type of the health facility the client visits for primary care.
22. **Whom does the client see for primary care?** Verify, or ask and check the type of the primary or regular provider the client sees for regular health care.
23. **Has the client been seen by a hematologist in the past year:** Ask and record if the client has been seen by a hematologist in the past 3 months or year.
24. **During the past 3 months, how many times has the client received services at an ED:** Ask and record number of times client visited the ER/ED in the last year. **If respondent says "None," put a zero (0) in the space provided.**
25. **Reasons(s) for the ER/ED visit:** Ask and record all the reasons for ER visit.
26. **During the past 3 months, how many times the client has been admitted to the hospital:** Ask and record number of times client has been hospitalized during the previous three months. **If respondent says "None," put a zero (0) in the space provided.**
27. **The reasons(s) for the hospitalization:** Ask and record all the reasons for hospitalization.
28. **Is the client taking prophylactic antibiotic (i.e., penicillin):** Ask and record if the client is taking an?
If no, then why? Ask and record why the client is not taking an antibiotic like penicillin
29. **Age at what was the prophylactic antibiotic started:** Ask and record the age at which the client received the antibiotic like penicillin.
30. **How often the child is taking prophylactic antibiotics:** Ask and record client's frequency of penicillin use.

31. **Whether the client received the pneumococcal vaccine:** Please ask and record the answer given.
32. **Type of pneumococcal vaccine:** If yes to Q. 35, Ask and record the type of pneumococcal vaccine the client has received.
33. **Whether the client received any of the following treatments and procedures during the last 3 months (prior to the current visit):** Ask and record all the treatment/procedures that the client has received.

Section F: SERVICES CLIENT'S FAMILY RECEIVED

34. **During the past 3 months (prior to current visit), the number of genetic counseling sessions the client or caregiver(s) has received:** Ask and record how many times the client or caregiver(s) attended genetic counseling sessions. **If respondent says "None," put a zero (0) in the space provided.**
35. **In the last 3 months (prior to current visit), (the number of) referrals the caregiver(s) have received from a partner agency/site for case management services:** Ask and check the box next to the type of referrals for additional services given to the client's caregiver(s). **If respondent says "None," then check "None of these services."**
36. **During previous 3 months (prior to current visit), how many other services the family used:** Ask and record the number of other services the client's family received that is available through the organization and was not included in the previous questions. **If the respondent says "None," put a zero (0) in the space provided.**

Section G: CLIENT FAMILY COMMUNICATION

37. **For Caregivers of clients under age 18.** For those Clients under 18 the Caregiver must answer the questions in the left column.
- For Clients 18 years or older.** For those clients 18 years or older answer the question in the right column.
- a. **The primary spoken language.** Verify and record the primary spoken language of the client. There is a list provided but the responses are not limited this list.
 - b. **Translator required for medical services/medical information.** Verify and record whether a translator is needed for medical services/ medical information. Verify and record whether the client/caregiver speaks a second language.
 - c. **The language the client/caregiver is most comfortable reading.** Provide the language which the individual (client and/or caregiver) is most comfortable reading.

- d. The higher level of education attained.** Verify and record the education level attained by the individual (client/caregiver) in the space provided.

38. Are you (your child) of Hispanic or Latino origin?

- a. Ask the client the following question: Are you (your child) Hispanic or Latino?**
- b.** Read to the client the following response options:
 - i.** No, not Hispanic or Latino
 - ii.** Yes, Hispanic or Latino
- c.** Mark (X) on the appropriate box on the form that corresponds to the client's response.

39. The client's race.

- a. Ask the client the following question: What is your (your child's) race?**
- b.** Read to the client the following response options:
 - i.** White
 - ii.** Black or African American
 - iii.** American Indian or Alaska Native
 - iv.** Asian
 - v.** Native Hawaiian or Pacific Islander
- c.** Mark (X) on one or more boxes on the form that corresponds to the client's response.

Post-Interview Debriefing

Ending the Interview Debriefing

Please **thank the client** for their time and ask them the following:

- **Do they have questions about the confidentiality of their interview?** If they answer **yes**, address each question they have individually and be sure to reiterate what is in the Consent Form and offer to review the form with them. If they answer **no**, move to the next question.
- **Do they have questions about the use of the information?** If they answer **yes**, address each question they have individually and be sure to explain to them the multiple uses of the data as you understand them starting with service related use. If they answer **no**, move to the next question.
- **Do they want a copy of the most recent data summary when it is ready?** If they answer **yes**, be sure to record this and request a monthly report for your site from the NCEC. If they answer **no**, move to the next question.

Storing/Filing Interview Forms

- If paper forms are being used, be sure to have a **specific storage space** for all completed interview forms.
- Be sure to use the Data Tracking Form **record the name and unique identification number of the client** and the date each form was entered.
- Be sure to address all questions about data submission to the NCEC office.

Data Submission Schedule

Data will be submitted every 3 months (quarterly) to the NCEC as follows:

Data Submission	For Data Collected Between	Data Due to NCEC
1 st Quarter	Sept 1 – Nov 30	By Dec 15 th
2 nd Quarter	Dec 1 – Feb 28	By Mar 15 th
3 rd Quarter	Mar 1 – May 31	By Jun 15 th
4 th Quarter	Jun 1 – Aug 31	By Sept 15 th

MDP SCT Questionnaire Instruction Manual

Section A: SITE IDENTIFYING INFORMATION

- **Today's Date:** This field will be auto-populated
- **Date of Visit/Interview:** Enter the date that you completed the interview.
- **Data Entry Personnel:** Enter the full name of the person who entered the interview information into the database.
- **Site ID number:** Record site's unique ID number (2-3 digit IDs) assigned by the NCEC.
- **State ID number:** Record the state in which the site is located. Use 2-letter code to designate state (e.g., 'AL' for Alabama.)

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Additionally, there will be search field whereby clients could be searched by this unique ID number and their diagnosis.

Section C: CLIENT INFORMATION

1. **Type of referral agency:** Ask and check which type of agency referred the client. If the interviewee received more than one referral, use the one that, in the judgment of the interviewee, was most significant.
2. **Sex of the client:** Ask the interviewee and record as indicated.
3. **Zip code of the client:** Verify, or ask and record in which zip code the client or caregiver resides. This is a proxy variable that identifies the geographic location of the respondent, allowing for matching of Census or other population level variables.

Section D: FAMILY INFORMATION

4. **Relation of the client to child identified with SCT by newborn screening:** Select among choices on form.
5. **Child's confirmed SCT status:** Please read down the whole list (so the interviewee hears all possible answers) and then record as answered
6. **Source of Confirmatory Diagnosis:** Enter the source of confirmatory diagnosis.

Section E: SERVICES CLIENT RECEIVED

7. **Educational/counseling services received by client:** Check type of service client received
8. **Educational materials provided to client:** Check all that apply
9. **Client testing decision:** Record client's testing decision
10. **Results of testing:** Record results of testing
11. **Have any of the client's family members been tested for SCD/SCT?:** Ask and record answer
12. **Reason for not testing for SCD/SCT:** Record the reason for not being tested for SCD/SCT. Please add NA if no reason provided or don't know is checked.

Additionally, it is recommended that the grantees keep a master list and submit the following information as part of 'NBS SCT Follow-up Surveillance' (It is expected that this information will come from the client's electronic record)

- # of referrals from NBS program/lab
- # of contacts attempted i.e. letters, phone calls, mailings of educational materials etc.
- # of non-responders
- # of clients that accept offer to follow-up services

Section F: CLIENT FAMILY COMMUNICATION

13. **For Caregivers of clients under age 18.** For those Clients under 18 the Caregiver must answer the questions in the left column.

For Clients 18 years or older. For those clients 18 years or older answer the question in the right column.

- a. **The primary spoken language.** Verify and record the primary spoken language of the client. There is a list provided but the responses are not limited this list.
- b. **Translator required for medical services/medical information.** Verify and record whether a translator is needed for medical services/ medical information. Verify and record whether the client/caregiver speaks a second language.
- c. **The language the client/caregiver is most comfortable reading.** Provide the language which the individual (client and/or caregiver) is most comfortable reading.
- d. **The higher level of education attained.** Verify and record the education level attained by the individual (client/caregiver) in the space provided.

13. **Is the client Hispanic or Latino?**

Ask the client the following question: Are you (your child) Hispanic or Latino?

- a. Read to the client the following response options:
 - i. No, not Hispanic or Latino
 - ii. Yes, Hispanic or Latino
- b. Mark (X) on the appropriate box on the form that corresponds to the client's response

14. **The client's race. Ask the client the following question: What is your (your child's) race?**

- a. Read to the client the following response options:
 - i. White
 - ii. Black or African American
 - iii. American Indian or Alaska Native
 - iv. Asian
 - v. Native Hawaiian or Pacific Islander
- b. Mark (X) on one or more boxes on the form that corresponds to the client's response.

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