

MULTICENTER STUDY OF HYDROXYUREA  
IN SICKLE CELL ANEMIA

STUDY CLOSE-OUT FOR PARTICIPANT

FORM  
REV

MSH Form 75  
Rev 0 01/11/95  
Page 1 of 2

Instructions: Submit Form 75 for each living patient ever enrolled in the MSH. If the patient completes the Close-out Visit, administer Page 2 of this Form to him/her as the FIRST activity of the Close-out Visit. The Clinic Coordinator must complete Page 1 of this Form. The Clinic Coordinator must assure that the participant understands the questions and marks responses appropriately, but should not help answer the questions. The Coordinator must check the form for completeness and to assure that answers are clearly marked. Then the Clinic Coordinator and Clinic Director should conduct the remainder of the Close-out Visit and complete Questions 4.-7.

ID  
VISIT

CLINIC NO.					
I.D. NO.					
VISIT					

VIS

- 1. Namecode: NAMECODE
- 2. Date: VIS- DT

Day - Month - Year

- 3. Did the patient complete the MSH Close-Out Visit? **CLOSED** (1) (2)  
Yes No

If NO, please explain:

A. COMMENT1

If NO, skip to Question 7.

If YES, give the participant Page 2 of this Form 75 now.  
Complete the rest of this Page after completing the entire Close-Out Visit.

- 4. Have you completed:
 

	Yes	No	Not Required
Form 20 (Follow-Up Visit) <b>F75-F20</b> .....	(1)	(2)	(3)
Form 03 (Demographics) <b>F75-F03</b> .....	(1)	(2)	(3)
Form 11 (Health Status) <b>F75-F11</b> .....	(1)	(2)	(3)
Form 12 (Mood Profile) <b>F75-F12</b> .....	(1)	(2)	(3)
Form 23 (Medical Review) <b>F75-F23</b> .....	(1)	(2)	(3)
Collection of all Patient Diaries (Form 05) <b>F75-F05</b> .....	(1)	(2)	(3)
Signed authorization for the release of medical records <b>F75-RELS</b> .....	(1)	(2)	(3)
Consent for long-term follow-up of MSH patients <b>F75-CONS</b> .....	(1)	(2)	(3)
- 5. Has the Clinic Physician discussed the study results with the participant, reviewed the participant's options for management of his/her sickle cell anemia, and explained the long-term MSH follow-up to the participant? **F75-REVI** .....

If NO, please explain briefly:

A. COMMENT2

- 6. Please briefly describe any special requests or questions the patient may have had.

COMMENT3

- 7. Checked for completeness:

A. Certification number:

CERT-NO

B. Signature:

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STUDY CLOSE-OUT FOR PARTICIPANT  
QUESTIONS FOR THE PARTICIPANT TO ANSWER

8. At the time the study started, did you think hydroxyurea would work in reducing crises?
- I definitely thought it WOULD work. . . . . (1)
  - I thought it MIGHT work. . . . . (2)
  - I really did not know what to expect. . . . . (3)
  - I thought it might NOT work. . . . . (4)
  - I definitely thought it would NOT work. . . . . (5)

PT-EFFI

9. At the time the study started, did you think hydroxyurea would be generally safe to take?
- I definitely thought it WOULD be safe. . . . . (1)
  - I thought it MIGHT be safe. . . . . (2)
  - I really did not know what to expect. . . . . (3)
  - I thought it might NOT be safe. . . . . (4)
  - I definitely thought it would NOT be safe. . . . . (5)

PT-SAFE

10. What treatment did you really think you were taking for most of the study. (If you were "unblinded" during the study, try to remember what you thought before unblinding):
- Definitely hydroxyurea . . . . . (1)
  - Probably hydroxyurea . . . . . (2)
  - Absolutely no idea . . . . . (3)
  - Probably placebo . . . . . (4)
  - Definitely placebo . . . . . (5)

PT-DRUG

11. Did you notice any special "clues" that may have given you an idea of what treatment YOU were taking? (Fill in)

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COMENTA

12. Do you think YOU personally benefitted from being in the study? (1) (2)  
Please describe briefly: Yes No

PT-BENFT

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COMENTS

\*\*\*\*\* THANK YOU! PLEASE RETURN THIS PAGE TO THE CLINIC COORDINATOR. \*\*\*\*\*

Patient ID \_\_\_\_\_