

MULTICENTER STUDY OF HYDROXYUREA (MSH)

TREATMENT INITIATION

**Form 09
Instruction Sheet**

The final exclusion criterion at the Treatment Initiation Visit (TI01) is pregnancy. If the patient is pregnant, the form is to be completed according to instructions, the patient's first 12-week course is to be destroyed and documented on the respective Form 31, Study Treatments Inventory. The patient schedule and study card are to be destroyed.

If the patient has been transfused since qualifying for the MSH, the patient may be enrolled. All specified blood specimens except the 3 DNA tubes should be collected.

If the patient passes final qualification, the patient is given the assigned study treatment labeled for FV01, a two-week course of generic folic acid, a patient diary booklet with the two-week sheet labeled for FV01, and the patient study card. Appropriate reimbursements are also made. The answer YES to Item 6 "Has this patient's MSH treatment been started?" means that the patient was given study treatment and is irrevocably enrolled in the MSH.

**MULTICENTER STUDY OF HYDROXYUREA
 IN SICKLE CELL ANEMIA (MSH) CLINIC**

TREATMENT INITIATION

CLINIC NO.						
I.D. NO.						
VISIT	T	I	O	I		

PART I: IDENTIFYING INFORMATION

1. Patient Name Code: NAMECODE

2. Date of Treatment Initiation Visit: VIS-DT
 Day Month Year

PART II: FINAL ELIGIBILITY CHECK

3. Pregnant? PREG-STP YES NO
 (STOP) (2)
 IF YES
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Patient cannot be enrolled.

Dispose of study medications and document disposal.

Discard patient's labels, schedule of visits and study ID card.

Skip to Item 6.

4. Transfusion since qualification? TRAN-STP YES NO
 (1) (2)

If YES, complete Form 25 (Medical Contact).

PART III: ENROLLMENT

5. Were blood specimens drawn? **BLOODS** YES NO
 (1) (STOP)

If **YES**, skip to Item 5B.

A. Reason(s) specimen not drawn (check all that apply.)

1. No venous access	NOVENA	YES (1)	NO (2)
2. Patient refused	PATREF	(1)	(2)

Skip to Item 6.

B. All the following blood specimens are to be collected. Record which specimens were obtained: [Complete both labels for each tube or slide. Place one on the tube or slide and the duplicate label on Form 21-Blood Specimens Packing List.]

1. 5-ml EDTA (lavender top) tube for routine hematology	R-HEM	YES (1)	NO (STOP) (2)
2. 5-ml EDTA (lavender top) tube for 24-hour hold	B-HEM	(1)	(2)
3. 5-ml EDTA (lavender top) tube for special hematology	S-HEM	(1)	(2)
4. 5-ml routine (red top) serum separator tube	SERUM	(1)	(STOP) (2)
a. Was the tube centrifuged at 3000 rpm for 5 min.?	CENTR	(1)	(STOP) (2)
5. Two slides of smeared blood (miniprep)	SLIDE	(1)	(STOP) (2)

If patient has been transfused since qualification (Item 4 is YES) DO NOT COLLECT DNA specimens; answer (3) in Item B.6.

6. 3 5-ml EDTA (lavender top) tubes for DNA analysis --- (1) **DNA** (STOP) (3)
 [Place duplicate labels on Form 06 - Blood Specimens Packing List (T101 Supplement).] Tr.

C. Problems:

1. Difficult venipuncture	DIFVEN	YES (1)	NO (2)
2. Hematoma	HEMATO	(1)	(2)
3. Fainting	FAINT	(1)	(2)
4. Other	D-PROB	(1)	(2)
Specify: _____	S-PROB		

If the answer to Item 5 or any of 5.B.1 - 5.B.6. is **STOP**, the patient cannot be enrolled at this time. Dispose of study medications and document disposal. Discard patient's labels, schedule of visits and study ID card. If you wish to enroll this patient at a later time, submit a new Form 08, Request for Enrollment.

I.D. No.

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6. Has this patient's MSH treatment been started? TRT-STRT (1) (2)
YES NO

If YES, answer Item 6A.

A. Reimbursements:

- 1. Record amount of cash reimbursement given DIARY \$
for patient diary
- 2. Record amount of cash reimbursement given TRAVEL \$
for travel

PART IV: COORDINATION

7. Checked for completeness and accuracy:

A. Certification Number CERT-NO

B. Signature: _____

Retain a copy of this form for your files. Telecopy the original to the MSH Data Coordinating Center (410-435-4232).

I.D. No.

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