MULTICENTER STUDY OF HYDROXYUREA IN SICKLE CELL ANEMIA (MSH)

FORM REV

MSH Form 20
Rev 4 7/26/93

FOLLOW-UP VISIT

CURCLIN	CLINIC NO.					
ID	I.D. NO.					-
VISIT	VISIT	F	V			1

PART I: IDENTIFYING INFORMATION

1. Patient Name Code: NAMECODE ___ ___ ___ ___ ___
2. Date: ___ ___ - VIS_DT ___ ___ ___ - ___ ___
   Day Month Year

PART II: PHLEBOTOMY AND DIARIES

3. Is patient scheduled for blood specimens at this visit? ----- SCH_BL Yes (1) No (2)

   If NO, skip to Item 4.

   A. Were blood specimens drawn? ---------------- BLOODS (1) (2)

   If YES, skip to Item 3C.

   B. Reason blood not drawn

		Yes	No	
1.	No venous access -----	(1)	(2)	NOVENA
2.	Phlebotomy difficult -	(1)	(2)	PHLDIF
3.	Patient illness ------	(1)	(2)	PATILL
4.	Patient refused ------	(1)	(2)	PATREF
5.	Other ---------------	(1)	(2)	

   Specify: ______________________

   Skip to Item 4.

   C. Follow instructions for obtaining blood specimens for this visit, and record which specimens were obtained:

   1. 5 ml EDTA tube for routine hematology --- (1) (2) RHEM
   2. 5 ml EDTA for special hematology --- (1) (2) SHEM
   3. 5 ml serum separator tube ------- (1) (2) SERUM

      If NO, skip to Item 3C4.

      a. Was the tube centrifuged for 5 min at 300 rpm? ------ (1) (2) CENTR

   4. Two slides of smeared blood (Miniprep) ----- (1) (2) SLIDE

Collect and review the patient diary. Inquire about any medical contacts since the last visit.

4. According to the diary or the patient's report, has the patient been to a doctor or hospital since the last completed follow-up visit? ----- DR_VIS Yes (1)* No (2) Unknown (3)

PART III: MEDICAL REVIEW

5. Has the patient received a transfusion since the last completed visit? -------- FVTRAN Yes (1)* No (2) Unknown (3)

6. Has the patient been placed on a chronic transfusion program since the last completed follow-up visit? --------------- CHTRAN Yes (1)* No (2) Unknown (3)

7. Patient's weight: ---- WEIGHT ___ ___ ___ . ___ kg

   OR check here if not available --- (1)

8. Has the patient experienced any of the follow symptoms since the last visit?

		Yes	No	
a.	Hair loss -----------	(1)	(2)	HAIR_L
b.	Skin rash or abnormality -	(1)	(2)	SKIN_R
c.	Fever ---------------	(1)	(2)	FEVER
d.	Nausea/vomiting/diarrhea -	(1)	(2)	
e.	Other ---------------	(1)	(2)	O_SX

Specify: S_SX ______________________

____

*If YES, complete Form 25, Medical Contact.
**See definition in the Instructions.

9. Has this patient taken any prescribed oral or transcutaneous narcotics since the last visit? O_NARC ---------------- Yes (1) No (2) Unknown (3)

If NO or UNKNOWN, skip to Item 10.

A. Agents		B. Total dose (mg)	C. Check if dose N/A
1. Meperidine (Demerol) -----	(1) DEM	DEM_DO	(1)
2. Oxycodone (Percodan) -----	(1) OXY	OXY_DO	(1)
3. Morphine ----------------	(1) MOR	MOR_DO	(1)
4. Hydromorphone (Dilaudid) -	(1) HYD	HYD_DO	(1)
5. Codeine -----------------	(1) COD	COD_DO	(1)
6. Fentanyl patch -----------	(1) FEN	FEN_DO	(1)
Other (Specify):			
7. OR1	(1)	OR1_DO	(1)
8. OR2	(1)	OR2_DO	(1)

10. Is the patient or partner pregnant? ------------- PREG ---- Yes (1) No (2) Suspect (3) Unknown (4)

If YES or SUSPECT, see Form 20 Instructions.

11. Is the patient adhering to study requirements to avoid pregnancy? ------------------------------ PROTEC ----- Yes (1) No (2) N/A* (3)

12. Has patient had a therapeutic phlebotomy since the last completed follow-up visit ------------------------ TH_PHL Yes (1) No (2) Unknown (3)

PART IV: TREATMENT REVIEW

13. Has patient returned bottles and capsules of study treatment from any previous follow-up visit (do not list folic acid)? ------------------ RET-RX Yes (1) No (2)

If NO, skip to Item 13D.

i=1,6

A. Bottle Prescription Number	B. "For-FV" Number	C. Number of Capsules Returned
1. RX_NO{i}	FV RX_FV{i}	RX_CT{i}
2. ___ ___ ___ ___ ___ ___	FV ___ ___	___ ___
3. ___ ___ ___ ___ ___ ___	FV ___ ___	___ ___
4. ___ ___ ___ ___ ___ ___	FV ___ ___	___ ___
5. ___ ___ ___ ___ ___ ___	FV ___ ___	___ ___
6. ___ ___ ___ ___ ___ ___	FV ___ ___	___ ___

I.D. No.					-	
Visit	F	V			-	1

*Answer N/A if patient is on permanent stop.

13. (Continued)

D. Has patient taken <u>study treatment</u> in the last 14 days? - Yes (1) No (2) Unknown (3)

If <u>NO</u> or <u>UNKNOWN</u>, Skip to Item 14.

TK_TIM

1. How long ago? __ __ (1) hours (2) days

TK-UNIT

14. Since the last completed follow-up visit, has this patient had a medically indicated interruption to prescribed study medication, other than an an MSH STOP ORDER (Form 33)? TXINTC Yes (1) No (2) N/A Unknown (3)*

If <u>NO</u> or <u>UNKNOWN</u>, skip to Item 15.

A. Number of days of treatment interruption: ----- TXINTD __ __

<u>OR</u> check here if unknown ---- (1)

B. Reason for treatment interruption:

TXINTR

15. **Is patient cleared for receiving study treatment for next two weeks? --------- RX_OK Yes (1) No (2)

If NO, skip to Item 16.

A. Dispense study treatment and folic acid labeled for the next two weeks. Were study treatments dispensed? -------------- RXDISP Yes (1) No (2)

*Answer N/A for patients on permanent stop. See Form 20 Instructions.

16. Have telephone number(s) or best times to contact the patient by telephone changed? ------------------- TELEPH Yes (1) No (2)

If YES, submit a revised Form 10, Telephone Contact Schedule Form.

1. Make sure to schedule a follow-up visit in two weeks.
2. Give patient the diary sheets for the next two weeks and a spare.
3. Provide patient with appropriate reimbursements.
4. Remind patient that he/she may get a telephone call from the Central Office concerning either stopping taking the study medication, or about visits to doctors or hospital.
5. Remind patient about avoiding pregnancy.

<u>PART V: REIMBURSEMENTS</u>

17. A. Record amount of cash reimbursement for diary --- $ __ __ CASHDI

B. Record amount of cash reimbursement for travel -- $ __ __ CASHTR

C. Record amount of cash reimbursement for telephone ---------------- $ __ __ CASHTE

<u>PART V: COORDINATION</u>

18. Check for completeness and accuracy

A. Certification No.: __ __ - __ __ CERT_NO

B. Signature: ____________

Retain a copy of this form for your files. Send the original to the MSH Data Coordinating Center. Use MSH mailing labels:

MSH Data Coordinating Center
Maryland Medical Research Institute
600 Wyndhurst Avenue
Baltimore, Maryland 21210

I.D. No.					-	
Visit	F	V			-	1