## MULTICENTER STUDY OF HYDROXYUREA (MSH)

## TREATMENT INITIATION

## Form 09 Instruction Sheet

The final exclusion criterion at the Treatment Initiation Visit (T101) 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 <u>since qualifying</u> for the MSH, the patient may be enrolled. All specified blood specimens <u>except</u> 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.

		•					MSH For Rev 2 Page 1	09/30/92
	CENTER STU (LE CELL AN	DY OF HY EMIA (MS	DROXYUREA H)	CLINIC	CLINIC NO.			
·	MENT INITIA		/	ID.	I.D. NO.			
				VISIT	VISIT	TI	0 1 -	
PAI	<u> TI: IDENTI</u>	FYING INFO	RMATION				·	
1.	Patient Nar	ne Code: -			•••••		VAMECOD	E
2.	Date of Tre	atment In:	itiation Visi	ít:	Day	-	115-DT	Year
PAR	T II: FINAL E	LIGIBILITY	<u>CHECK</u>					
3.	Pregnant? -		• • • • • • • • • • • •		PREG	i-STP	IF YES	
			Patient ca	nnot be e	enrolled.		+	
- ·			Dispose of	study me	dications an	d docum	ent disposa	al.
				tient's 1	abels, sched			
			Skip to Ite	em 6.				
4.	Transfusion	since qual	ification? -		TRAN-S	57P	YES (1)	NO ( 2)
	•		If YES,	complete	Form 25 (Med	lical Co	ontact).	
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<u>PART I</u>	II: ENROLLMENT		
5. W	ere blood specimens drawn?	YES ( 1)	NO (STO)
	If <u>YES</u> , skip to	Item	58
Α.	Reason(s) specimen not drawn (check all that apply.) 1. No venous access	AYES	NO
	2. Patient refused PATREP	=	(2)
	Skip to Item 6.	(1)	(2)
В.	All the following blood specimens are to be collected. Rec specimens were obtained: [Complete both labels for each tub Place one on the tube or slide and the duplicate label on F Specimens Packing List.]	ord w e or form 2	hich slide. 1-Blood
	1. 5-ml EDTA (lavender top) tube for routine hematology	YES	NO
	2. 5-ml EDTA (lavender top) tube for 24-hour hold B-HEM	(1)	(STOP)
	for special hematology	(1)	(2)
	4. J-mi routine (red top) serum senarates aut SCRUM	(1) (1)	(2)
	a. Was the tube centrifuged at 3000 rpm CENTR for 5 min.?	( 1)	(STOP)
	5. Two slides of smeared blood (minimum) SLIDE	(1) (1)	(STOP) (STOP)
	If patient has been transfused since qualification (Item 4 is YES) DO NOT COLLECT DNA specimens; answer (3) in Item B.6.		
	6. <u>3</u> 5-ml EDTA (lavender top) tubes for DNA analysis ( [Place duplicate labels on Form 06 - Blood Specimens Packing List (TI01 Supplement).]	1)	DNA (STOP)
С.	Problems:	80	
	1. Difficult venipuncture		NO
	2. nematoma HEMATO		(2)
	3. Fainting		(2)
			( )
	4. Other $D_{PROB}$		(2) (2)

this time. Dispose of study medications and document disposal. Discard patient's labels, submit a new Form 08, Request for Enrollment.

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i	I.D.	No.	

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IF NO ITEM ON PAGE 2 IS ANSWERED STOP, THE PATIENT MAY BE ENROLLED:

- A. 1. Dispense patient's assigned study treatment labeled for FV01.
  - 2. Review the prescription instructions with the patient.
  - 3. Remind the patient to return the bottles and any unused capsules to the next visit.
- B. Dispense the folic acid bottle to the patient. Remind him/her to take one folic acid tablet every day for the rest of the study.
- C. Give the patient his/her study card. Remind him/her to carry the card at all times. If he/she goes to the hospital, he/she should bring the card and the study medication in case he/she is treated or admitted. He/she should present the study card to the treating physician.
- D. 1. Ask the patient for his/her last two-week diary. If he/she doesn't have it, remind him/her to find it and bring it with him/her for the next visit.
  - 2. Give the patient his/her two-week diary labeled for FV01. Remind him/her to fill it out every day and return it for the next visit.
- E. Schedule the patient for FV01 on the expected day according to the Visit Schedule sent to you for this patient.
- F. Make the following reimbursements in cash to the patient:

Diary: \$10 if 11 or more days are marked. \$ 5 if 6 - 10 days are marked. \$ 0 if 0-5 days are marked.

Travel: \$10

I.D. No.	-	
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MSH Form 09 Rev 2 9/30/92 Page 4 of 4 (2) YES NO If YES, answer Item 6A. Reimbursements: Α. 1. Record amount of cash reimbursement given DIARYfor patient diary -----2. Record amount of cash reimbursement given TRAVEL PART IV: COORDINATION 7. Checked for completeness and accuracy: CERT\_NO A. Certification Number 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.			_	