TE

NIDDK

VIRAL HEPATITIS C

TREATMENT EVALUATION

2/21/2003
Version 1.4

FORM KEYS

Patient ID __ __-__ __ __-__ __ __

Time point:

TMT Day _____ (7, 14, or 28)

TMT Week _____ (8, 12, 16, 20, 24, 28, 32, 36, 40, 44, or 48)

☐ Premature discontinuation of treatment

COMPLETION LOG

Data Collector ID _____
Initials

Data Collection __ __ - __ __ - __ __

Date Entered __ __ - __ __ - __ __

Date Verified __ __ - __ __ - __ __
MM DD YY

Patient ID __ __ -__ __ __- __ __ __

TREATMENT EVALUATION

Date of Evaluation ___/___/____
mm dd yy

1. Since the previous treatment evaluation has the patient had an adverse event?

☐ Yes *(Complete an AE form)* ⟶

☐ No

1.1 Was the event a serious adverse event?

☐ Yes *(Complete a MEDWATCH form)*

☐ No

SECTION I: PHYSICAL EXAM

Weight: __ __ __ lbs.

Heart rate: _____ beats/min

Temperature: __ __ __.__ °F

Blood pressure: _____/_____ mmHg

SECTION II: SYMPTOMS

Has the patient had the following symptoms since the last evaluation:

	Yes	No		Yes	No
1. Fatigue	☐	☐	9. Injection site reaction	☐	☐
2. Trouble sleeping	☐	☐	10. Rash	☐	☐
3. Irritability	☐	☐	11. Joint aches	☐	☐
4. Hair loss	☐	☐	12. Respiratory symptoms	☐	☐
5. Depression	☐	☐	13. Muscle aches	☐	☐
6. Weight loss	☐	☐	14. Headache	☐	☐
7. Flu-like symptoms	☐	☐	15. Itching	☐	☐
8. GI symptoms	☐	☐	16. Other	☐	☐

IF YES Specify: _____

SECTION III: CONCOMITANT MEDICATIONS

Is the patient currently taking any of the following:

1. Antidepressant medications ☐ Yes ☐ No
2. Respiratory agents ☐ Yes ☐ No
3. Thyroid medications ☐ Yes ☐ No
4. Growth Factor ☐ Yes ☐ No *If yes, complete GF form*
5. Herbal supplements ☐ Yes ☐ No

If yes, specify code(s):

5.1 ____ 5.2 ____ 5.3 ____ 5.4 ____ 5.5 ____ 5.6____

SECTION IV: DEPRESSION MANAGEMENT

1. Since your last visit, have you felt depressed, sad, or blue most of the time? ☐ Yes ☐ No
2. Since your last visit, have you often felt helpless about the future? ☐ Yes ☐ No
3. Since your last visit, have you had thoughts about harming or killing yourself or others? ☐ Yes ☐No

SECTION V: STUDY MEDICATION AND ADHERENCE

1. Was there a prescribed change in study medication dose or timing since the previous evaluation?

☐ Yes ☐ No *If yes, complete a Dose Change (DC) form*

2. Record the date and time of the most recent dose taken prior to this evaluation.

Ribavirin		**Interferon**	
Date	Military time	Date	Military time
___/___/_____	_____:_____	___/___/_____	_____:_____
mm dd yy	hr min	mm dd yy	hr min

SECTION VI: COMMENTS: ☐ Yes ☐ No (If yes, record comments on back)

IF YES

_____

_____

_____

_____