

**ADHERENCE TO HCV THERAPY**  
NIAID ADULT AIDS CLINICAL TRIALS GROUP

Patient Number	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	Date of Patient Visit	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
						mmm	dd	yy	yy		
Protocol Number	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	Institution Code	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Form Week	<input type="text"/>	<input type="text"/>	<input type="text"/>		* Seq. No.	<input type="text"/>	** Step No.	<input type="text"/>	<input type="text"/>	Key Operator Code	<input type="text"/>

\* Enter a "1" if this is the first of this form for this date. Designate subsequent forms on the same date with a 2, 3, etc.  
\*\*Enter the subject's current study step number. Enter '1' if the study does not have multiple steps.

**FOR OFFICE USE ONLY - TEAR OFF SHEET**

**INSTRUCTIONS TO THE STUDY NURSE:**

The ADHERENCE TO HCV THERAPY questionnaire should be given to the study participant prior to the clinical exam and preferably in a quiet secluded area (e.g., exam room or other office). The study participant must be able to read at the sixth-grade level at a minimum to complete the questionnaire without additional assistance.

It is important to be familiar with the content and format of the questionnaire before giving it to study participants. At the first visit, please begin by telling the study participant:

“We would like you to answer some questions about HCV medication.  
Your answers will help us understand the effects of the medication you are taking.  
We appreciate your filling out this questionnaire.”

You should then briefly go over the format of the questions and how to complete them.  
Have the study participant complete the questionnaire before vital signs, history, and physical are completed.

The questionnaire is very brief and should take no more than 10 minutes to complete.  
Before giving the study participant the questionnaire, please fill out the header(s) and DETACH THIS PAGE.

For data keying, if the study participant did not answer a question, enter “-1.”  
Do not leave any fields blank.

**PLEASE COMPLETE THE FOLLOWING ITEMS AFTER STUDY PARTICIPANT COMPLETES THE QUESTIONNAIRE OR AFTER YOU ASCERTAIN THAT THIS IS NOT POSSIBLE:**

1. How was the questionnaire completed? .....
- 1-Self administered by the study participant
  - 2-Face-to-face interview that you conducted
  - 3-Both self-administered and interview
  - 4-Not completed
  - 9-Other, specify

**If Other, specify [30]:** \_\_\_\_\_

- a. If you answered “4-Not completed,” please indicate the reason why:
- 1-Study participant refused
  - 2-Study participant missed clinic visit
  - 3-There was not enough time
  - 9-Other reason, specify

**If Other, specify [30]:** \_\_\_\_\_

**ADHERENCE TO HCV THERAPY**  
NIAID ADULT AIDS CLINICAL TRIALS GROUP

Patient Number	<input type="text"/>	<input type="text"/>	<input type="text"/>	Date of Patient Visit	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
					mmm	dd	yyyy	
Protocol Number	<input type="text"/>	<input type="text"/>	<input type="text"/>	Institution Code	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Form Week	<input type="text"/>	* Seq. No.	<input type="text"/>	** Step No.	<input type="text"/>	<input type="text"/>	Key Operator Code	<input type="text"/>

\* Enter a "1" if this is the first of this form for this date. Designate subsequent forms on the same date with a 2, 3, etc.  
 \*\*Enter the subject's current study step number. Enter '1' if the study does not have multiple steps.

**INSTRUCTIONS:**

This questionnaire asks about the HCV study medicines that you may have *missed* taking.

Most people with HIV and HCV have many medicines to take at different times during the day. Many people find it hard to always remember their medicines. Some people get busy and forget to carry their medicines with them. Some people decide to skip medicines to avoid side effects or just may not be taking medicines everyday.

We need to understand how people with HIV and HCV are really doing with their medicines. Please tell us what you are *actually* doing with the HCV medicines. Don't worry about telling us that you don't take all your medicines. We need to know what is really happening, not what you think we "want to hear".

Please answer the following questions by placing a "✓" in the appropriate box.  
Please check one box for each question.

**(Check one)**

1. Is pegylated-interferon (PEG-IFN) currently one of your study medications?
 

<input type="checkbox"/>	Yes	<input type="checkbox"/>	No
1		2	

**If No, go to question 2.**

  - a. Did you miss your PEG-IFN injection in the last week?
 

<input type="checkbox"/>	Yes	<input type="checkbox"/>	No
1		2	
  - b. Did you miss your PEG-IFN injection the week before that?
 

<input type="checkbox"/>	Yes	<input type="checkbox"/>	No
1		2	
  - c. When was the last time you missed your PEG-IFN injection?
 

Within the past week	<input type="checkbox"/>	5
1-2 weeks ago	<input type="checkbox"/>	4
3-4 weeks ago	<input type="checkbox"/>	3
1-3 months ago	<input type="checkbox"/>	2
4-6 months ago	<input type="checkbox"/>	1
Never skip PEG-IFN	<input type="checkbox"/>	0

**ADHERENCE TO HCV THERAPY**

Pt. No.  \* Seq. No.  \*\* Step No.  Date     
mmm dd yyyy

**(Check one)**

2. Is Ribavirin currently one of your study medications?

Yes  No  
1 2

**If No, STOP.**

a. Have you missed any doses of your Ribavirin in the last four days?

Yes  No  
1 2

**If Yes, how many doses did you miss?**

	<b>None</b>	<b>1 Dose</b>	<b>2 doses</b>
a1. Yesterday .....	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2
a2. Day before yesterday (2 days ago) .....	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2
a3. 3 days ago .....	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2
a4. 4 days ago .....	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2

b. Some people find that they forgot to take pills on the weekend days. Did you miss any of your Ribavirin last weekend - last Saturday or Sunday?

Yes  No  
1 2

c. When was the last time you missed any of your Ribavirin dose?

Within the past week  5  
 1-2 weeks ago  4  
 3-4 weeks ago  3  
 1-3 months ago  2  
 4-6 months ago  1  
 Never skip Ribavirin  0

Language:   
 English