

ELECTRONIC MONITORING SYSTEM QUESTIONNAIRE

NIAID 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	yyyy				
Protocol Number	<input type="text"/>				Institution Code	<input type="text"/>					
Form Week	<input type="text"/>			* Seq No.	<input type="text"/>	** Step No.	<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.

ELECTRONIC MONITORING SYSTEM QUESTIONNAIRE For Office Use Only - Tear Off Sheet

INSTRUCTIONS TO THE STUDY NURSE

The Electronic Monitoring System Questionnaire **SHOULD BE GIVEN TO THE SUBJECT PRIOR TO THE CLINICAL EXAM.** The subject 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. Have the patient complete a form for each drug that is being monitored.

At the first visit, please begin by telling the participant:

- The purpose of this form is to help us better understand how you are using your electronic monitoring device.
- Please answer all questions honestly; you will not be "judged" based on your responses.
- If you do not wish to answer a question, please draw a line through it.
- When completed, the form will be quickly reviewed to make sure you didn't mistakenly skip questions (without crossing them out); your specific responses to questions will not be reviewed.
- Please feel free to ask if you need any of the questions explained to you.
- Complete a separate questionnaire for each medication that comes in a bottle with a special top.

You should then briefly go over the format of the questions and how to complete them. The questionnaire is very brief and should take no more than 10 minutes to complete. Before giving the subject the questionnaire, please fill out the header(s) and **DETACH THIS PAGE.**

Each question is in the same general format and contains several items. Note that the subject is always asked to make a "✓" next to the appropriate category.

Collect the completed questionnaire before the clinical exam. Before going on, review the questionnaire for omissions. If the participant missed any of the questions, point this out and encourage him/her to complete the omissions.

For data keying, if the subject did not answer a question, enter "-1."

PLEASE COMPLETE THE FOLLOWING ITEMS AFTER SUBJECT 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 and stop:.....
- 1-Subject refused
 - 2-Subject missed clinic visit
 - 3-There was not enough time
 - 9-Other reason, specify

If Other, specify [30]: _____



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Patient Number Date of Patient Visit
mmm dd yyyy

Protocol Number Institution Code

Form Week * Seq. No. ** Step No. Key Operator Code

The purpose of this questionnaire is to help us better understand how you are using your electronic monitoring device. You were given some of your medications for this study in a bottle with a special top. You were told that when it was time for you to take the pills from this bottle, you should open the special top, remove the pills, put the top back on, and then take your pills right away. We know that people don't always follow these instructions exactly. For example, some people open the bottle and take out pills but wait to take that dose or take out pills that they plan to take for a later dose.

A. Write in the name of medication from the label [30]: _____

B. Think about how you used the special bottle since your last clinic visit. For the dose you intended to take at that time, how long did you usually wait, from the time you opened the bottle until the time you took the pills for that dose?

(Check one box.)

- 1 Right away
- 2 Within 5 minutes
- 3 Between 5 minutes and half an hour
- 4 Between 30 minutes and an hour
- 5 More than an hour

1. If you waited 5 minutes or more, please tell us why you waited. [140]:

C. Since your last clinic visit, how often did you open the special bottle and take out pills that you PLANNED to take for a later dose?

For example, you took out pills in the morning for your evening dose.

(Check one box.)

- 1 Never
- 2 A few times each month
- 3 A few times each week
- 4 Almost every day
- 5 Every day

1. If you took out extra pills almost everyday or everyday, please tell us when and why: [140]:

D. Since your last clinic visit, how often did you open the bottle but NOT remove a dose?

(Check one box.)

- 1 Never
- 2 A few times each month
- 3 A few times each week
- 4 Almost every day
- 5 Every day

1. If you opened the bottle almost everyday or everyday but did not remove a dose, please tell us when and why: [140]:

Language: English

