

PERSONAL SAFETY QUESTIONNAIRE

NIAID AIDS CLINICAL TRIALS GROUP

Patient Number	<input type="text"/>	<input type="text"/>	<input type="text"/>	Date of Patient Visit/Contact	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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"/>	Key Operator Code	<input type="text"/>	<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 PAGES 1 AND 2

INSTRUCTIONS TO THE STUDY NURSE:

The PERSONAL SAFETY QUESTIONNAIRE is confidential and 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). This questionnaire is designed for study participants who can read at the sixth-grade level; participants who have difficulty reading may need 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 participant:

"Estamos tratando de comprender mejor qué factores hacen que sea más fácil o más difícil para usted tomar su medicamento anti-VIH. Por favor conteste todas las preguntas con sinceridad. No se le "juzgará" con base en sus respuestas. Si usted no desea responder una pregunta, por favor, trace una línea sobre dicha pregunta. Por favor, siéntase libre de preguntar si necesita explicación sobre alguna de las preguntas."

You should then briefly go over the format of the questions and how to complete them. The questionnaire should take about 1-2 minutes to complete, but the study participant should feel free to take all the time they need. Before giving the study participant the questionnaire, please fill out the header(s) and DETACH PAGES 1 AND 2 from the rest of the form.

Each question is in the same general format and contains several items. Note that the study participant is always asked to make a check (✓) in the box for each question where there are check boxes.

Instruct the study participant to place the completed questionnaire in the envelope, seal it, and return it to you. The completed form can either be faxed or mailed to the Data Management Center.

- When faxing, address the fax to the DMC study data manager. The fax number is 716-834-8432. Include the country code when faxing from an international site. The person faxing should be someone other than the study nurse.
- If sending by postal mail, send to:

ACTG DATA FSTRF
 Attn.: ACTG [enter study number] Data Manager
 4033 Maple Road
 Amherst, New York 14226

Questions 1 through 3 on page 2 are completed and keyed by the clinic personnel.



PERSONAL SAFETY QUESTIONNAIRE

Pt. No. [][][][] *Seq. No. [][] **Step No. [][] Date [][][] [][] [][][][]
mmm dd yyyy

1. Was the questionnaire given to the participant?

1-Yes →
 2-No

a. How was the questionnaire completed?

- 1-Self administered by the participant
- 2-Face-to-face interview
- 3-Both self-administered and interview
- 9-Other, specify [70]:

Go to question 2.

b. Indicate reason:

- 1-Participant declined
- 2-Not enough time to complete form in clinic
- 9-Other, specify [70]:

STOP.

2. Was the sealed envelope returned to you to send to the Data Management Center? (1-Yes, 2-No)

3. Enter the country code for the location of the clinic and the language used to complete the form. Refer to Appendix 80 for Country and Language Codes.

Country: [][]

Language: [][]



