PERSONAL SAFETY QUESTIONNAIRE
NIAID AIDS CLINICAL TRIALS GROUP

Patient Number ☐☐☐☐☐☐☐   Date of Patient Visit/Contact ☐☐☐ ☐☐ ☐☐☐☐
                                            mmm   dd   yyyy

Protocol Number **A 0 0 0**   Institution Code ☐☐☐☐☐

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

  * 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:

> "We are trying to understand better what factors make it easier or harder for you to take your anti-HIV medications. 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. Please feel free to ask if you need any of the questions explained to you."

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.

11-21-08

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:** ☐☐

11-21-08

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Protocol Number | A | 0 | 0 | 0 | Institution Code ☐☐☐☐☐

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Please check one box for each question where there are check boxes. If you do not wish to answer a question, please draw a line through it.

1. Have you ever felt unsafe in your home? ………………………… ☐ Yes   ☐ No
   1   2

2. Have you ever been in a relationship in which you or your family members have been physically hurt or felt threatened?…… ☐ Yes   ☐ No
   1   2

   If Yes, do you feel you might be physically hurt or threatened in your present relationship? …………………………… ☐ Yes   ☐ No
   1   2

Thank you very much for completing this questionnaire.

11-21-08

Date Form Keyed (DO NOT KEY): _____ / _____ / _____