FOLLOW-UP BODY IMAGE QUESTIONNAIRE

NIAID ADULT AIDS CLINICAL TRIALS GROUP

Patient Number ☐☐ ☐☐☐☐ ☐ Date of Patient Visit ☐☐☐ ☐☐ ☐☐☐☐ (mmm dd yyyy)

Protocol Number ☐☐☐☐☐☐ 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.

INSTRUCTIONS TO THE STUDY NURSE:

The following questionnaire asks the subject about his/her assessment of their appearance and any change in appearance since the start of current study treatment. **It should be given to the subject prior to the clinical exam and preferably in a quiet secluded area (e.g., exam room or other office).** The subject must be able, at a minimum, to read at the sixth grade 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 participant:

> "We would like you to answer some questions about how you would describe your appearance and any recent change in your appearance. We appreciate you filling out this questionnaire."

You should then briefly go over the format of the questionnaire. Have the participant fill out the questionnaire before vital signs, history and physical are completed.

The questionnaire is very brief and should take no more than 5 minutes to complete. Before giving the subject the questionnaire, please fill out the header.

The questionnaire includes questions asking the subject to check the best answer.

Collect the completed questionnaire and review for omissions before the clinical exam. If the participant did not answer the questions, point this out and have him/her complete the omissions before continuing with the exam.

PLEASE COMPLETE THE FOLLOWING ITEMS AFTER THE SUBJECT COMPLETES THE QUESTIONNAIRE OR AFTER YOU ASCERTAIN THAT THIS IS NOT POSSIBLE.

1. How was the questionnaire completed? …… ☐
   If "4" go to question 1a.

   1-Self administered by the study participant
   2-Face to face interview that you conducted
   3-Phone interview
   4-Not completed
   9-Other, specify

   If Other, specify [30]:_____

   a. If you answered **"4-Not completed,"** please indicate the reason(s) why: …… ☐

      1-Subject refused
      2-Subject missed clinic visit
      3-There was not enough time
      9-Other reason, specify

      If Other reason, specify [30]: _____

09-18-98

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INSTRUCTIONS FOR SUBJECT: These questions are designed to learn more about how you feel your medications are affecting the way you look or feel. There are no right or wrong answers to these questions, so just answer them as they apply to you.

1. Thinking about your weight today, do you consider yourself to be: ***(Check one box.)***

Very Underweight	Somewhat Underweight	My Weight Is Just Right	Somewhat Overweight	Very Overweight
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

2. Thinking about your weight now and your weight before you started the study drugs you are currently taking, are you more worried or less worried about your weight?

(Check one box.)

Much More Worried	Somewhat More Worried	No Difference	Somewhat Less Worried	Much Less Worried
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

3. The following statements are about your appearance. Think about how you looked before you started taking the study drugs you are currently taking and how you look now. Do you think that your appearance has changed since you began study treatment?

(Check one)

Please check one box for each question.	Lost A Lot/ Much Smaller	Lost Some/ Some-what Smaller	No Change	Gained Some/ Some-what Larger	Gained A Lot/ Much Larger
a. I have noticed a change in the amount of flesh in my face.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b. I have noticed a change in the amount of flesh on the back of my neck or between my shoulder blades.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c. I have noticed a change in the size of my legs.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
d. I have noticed a change in the size of my belly.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
e. I have noticed a change in the size of my breasts.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
f. I have noticed a change in the size of my buttocks.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Language: English [E]

09-18-98

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