

ASSESSMENT OF BODY CHANGE AND DISTRESS

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 their assessment of their body change and distress since they started taking HIV medications. **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 level 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:

"These questions are designed to learn more about how you've felt since starting your HIV medicines. There are no right or wrong answers to these questions."

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? 1-Self administered by the study participant
 If "4" go to question 1a. 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]: _____



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INSTRUCTIONS FOR SUBJECT: These questions are designed to learn more about how you've felt since starting your HIV medicines. There are no right or wrong answers to these questions.

Many people with HIV have noticed changes in their bodies.

At Entry: Have you noticed any of the following since you started taking HIV medicines?

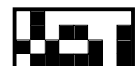
On Study: Have you noticed any of the following during the past 4 weeks?

(Check one)

- | | | | |
|---|--------------------------|--------------------------|--------------------------|
| | Yes | No | |
| 1. Your belt or waist size increased: | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| | 1 | 2 | |
| 2. You had to buy larger shirts, blouses or bras because your chest/breasts got bigger: . | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| | 1 | 2 | |
| 3. Your cheeks have sunken in (lost fat in face): | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| | 1 | 2 | |
| 4. You lost fat in your "butt": | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| | 1 | 2 | |
| 5. You lost fat from your arms and/or legs: | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| | 1 | 2 | |
| 6. You have more fat at the back of your neck: | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| | 1 | 2 | |

(Check one)

- | | | | | | | |
|---|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| | Very Satisfied | Satisfied | Not Sure | Dissatisfied | Very Dissatisfied | |
| 7. Overall, how satisfied are you with how your body looks right now? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| | 5 | 4 | 3 | 2 | 1 | |



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8. In the **past 4 weeks**, the changes in my body made me ...

(Please check one box for each statement.)

| | All of the time | Most of the time | Some of the time | A little of the time | None of the time | |
|--|-------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|--------------------------|
| a. ...feel frustrated because clothes don't fit right. | <input type="checkbox"/> 5 | <input type="checkbox"/> 4 | <input type="checkbox"/> 3 | <input type="checkbox"/> 2 | <input type="checkbox"/> 1 | <input type="checkbox"/> |
| b. ...spend more money than I wanted to on clothes. | <input type="checkbox"/> 5 | <input type="checkbox"/> 4 | <input type="checkbox"/> 3 | <input type="checkbox"/> 2 | <input type="checkbox"/> 1 | <input type="checkbox"/> |
| c. ...upset that I can't control my body. | <input type="checkbox"/> 5 | <input type="checkbox"/> 4 | <input type="checkbox"/> 3 | <input type="checkbox"/> 2 | <input type="checkbox"/> 1 | <input type="checkbox"/> |
| d. ...feel less self confident. | <input type="checkbox"/> 5 | <input type="checkbox"/> 4 | <input type="checkbox"/> 3 | <input type="checkbox"/> 2 | <input type="checkbox"/> 1 | <input type="checkbox"/> |
| e. ...confused about how to eat right. | <input type="checkbox"/> 5 | <input type="checkbox"/> 4 | <input type="checkbox"/> 3 | <input type="checkbox"/> 2 | <input type="checkbox"/> 1 | <input type="checkbox"/> |
| f. ...confused about how much to exercise. | <input type="checkbox"/> 5 | <input type="checkbox"/> 4 | <input type="checkbox"/> 3 | <input type="checkbox"/> 2 | <input type="checkbox"/> 1 | <input type="checkbox"/> |
| g. ...feel discomfort or pain. | <input type="checkbox"/> 5 | <input type="checkbox"/> 4 | <input type="checkbox"/> 3 | <input type="checkbox"/> 2 | <input type="checkbox"/> 1 | <input type="checkbox"/> |
| h. ...embarrassed about how I look. | <input type="checkbox"/> 5 | <input type="checkbox"/> 4 | <input type="checkbox"/> 3 | <input type="checkbox"/> 2 | <input type="checkbox"/> 1 | <input type="checkbox"/> |
| i. ...worry that my HIV is getting worse. | <input type="checkbox"/> 5 | <input type="checkbox"/> 4 | <input type="checkbox"/> 3 | <input type="checkbox"/> 2 | <input type="checkbox"/> 1 | <input type="checkbox"/> |
| j. ...upset that people may think I am sick. | <input type="checkbox"/> 5 | <input type="checkbox"/> 4 | <input type="checkbox"/> 3 | <input type="checkbox"/> 2 | <input type="checkbox"/> 1 | <input type="checkbox"/> |
| k. ...worry about dying. | <input type="checkbox"/> 5 | <input type="checkbox"/> 4 | <input type="checkbox"/> 3 | <input type="checkbox"/> 2 | <input type="checkbox"/> 1 | <input type="checkbox"/> |



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(Please check one box for each statement.)

| | All of the time | Most of the time | Some of the time | A little of the time | None of the time | |
|---|-------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|--------------------------|
| l. ...afraid that people will know I have HIV. | <input type="checkbox"/> 5 | <input type="checkbox"/> 4 | <input type="checkbox"/> 3 | <input type="checkbox"/> 2 | <input type="checkbox"/> 1 | <input type="checkbox"/> |
| m. ...avoid being around other people. | <input type="checkbox"/> 5 | <input type="checkbox"/> 4 | <input type="checkbox"/> 3 | <input type="checkbox"/> 2 | <input type="checkbox"/> 1 | <input type="checkbox"/> |
| n. ...feel less attractive to others. | <input type="checkbox"/> 5 | <input type="checkbox"/> 4 | <input type="checkbox"/> 3 | <input type="checkbox"/> 2 | <input type="checkbox"/> 1 | <input type="checkbox"/> |
| o. ...feel lonely and cut-off from others. | <input type="checkbox"/> 5 | <input type="checkbox"/> 4 | <input type="checkbox"/> 3 | <input type="checkbox"/> 2 | <input type="checkbox"/> 1 | <input type="checkbox"/> |
| p. ...feel depressed. | <input type="checkbox"/> 5 | <input type="checkbox"/> 4 | <input type="checkbox"/> 3 | <input type="checkbox"/> 2 | <input type="checkbox"/> 1 | <input type="checkbox"/> |
| q. ...dislike the way I look. | <input type="checkbox"/> 5 | <input type="checkbox"/> 4 | <input type="checkbox"/> 3 | <input type="checkbox"/> 2 | <input type="checkbox"/> 1 | <input type="checkbox"/> |
| r. ...want to avoid having sex or being intimate. | <input type="checkbox"/> 5 | <input type="checkbox"/> 4 | <input type="checkbox"/> 3 | <input type="checkbox"/> 2 | <input type="checkbox"/> 1 | <input type="checkbox"/> |
| s. ...think about changing my HIV medications. | <input type="checkbox"/> 5 | <input type="checkbox"/> 4 | <input type="checkbox"/> 3 | <input type="checkbox"/> 2 | <input type="checkbox"/> 1 | <input type="checkbox"/> |
| t. ...think about not taking my HIV medications. | <input type="checkbox"/> 5 | <input type="checkbox"/> 4 | <input type="checkbox"/> 3 | <input type="checkbox"/> 2 | <input type="checkbox"/> 1 | <input type="checkbox"/> |

Language:
English

