

REPRODUCTIVE CHOICES
 NIAID AIDS CLINICAL TRIALS GROUP

| | | | | | | | |
|-----------------|---|-------------------------------|---|---|---|-------------------|--|
| Patient Number | <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> | Date of Patient Visit/Contact | <input type="text"/> <input type="text"/> <input type="text"/> mmm | <input type="text"/> <input type="text"/> dd | <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> yyyy | | |
| Protocol Number | <input type="text" value="A"/> <input type="text" value="0"/> <input type="text" value="0"/> <input type="text" value="0"/> <input type="text" value="0"/> <input type="text" value="0"/> | Institution Code | <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> | | | | |
| Form Week | <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> | * Seq. No. | <input type="text"/> <input type="text"/> | ** Step No. | <input type="text"/> <input type="text"/> | Key Operator Code | <input type="text"/> <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 SHEET

INSTRUCTIONS TO THE STUDY NURSE:

The REPRODUCTIVE CHOICES questionnaire should be given to the study participant prior to the clinical exam and preferably in a quiet secluded area (for example, 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 would like you to answer some questions about children and contraception. 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. Have the study participant complete the questionnaire before vital signs, history, and physical are completed. The questionnaire is very brief and should take no more than 2-3 minutes to complete. Before giving the study participant the questionnaire, please fill out the header(s) and DETACH THIS PAGE 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.

For data keying, if the subject did not answer a question, enter “-1.” Do not leave any fields blank.

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

- | | |
|--|---|
| 1. How was the questionnaire completed? | 1-Self administered by the participant <input type="checkbox"/> |
| If “4- Not completed”, complete ‘a’ and Stop. | 2-Face-to-face interview |
| | 3-Both self-administered and interview |
| | 4-Not completed |
| | 9-Other, specify |

If Other, specify [70]: _____

- | | |
|---|--|
| a. If “4-Not completed”, indicate the reason and stop: | 1-Participant refused <input type="checkbox"/> |
| | 2-There was not enough time |
| | 9-Other reason, specify |

If Other, specify [70]: _____

2. 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:**

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| Form Week | <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> | * Seq. No. | <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> |
| | | ** Step No. | <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> |
| | | Key Operator Code | <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> |

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. How many children have you had (for example, babies born alive)? **(Check one)**

| | | | | | |
|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| None | One | Two | Three | Four | More than four |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 0 | 1 | 2 | 3 | 4 | 5 |

If more than four, also indicate the number of children: _____

2. How many children under 18 years of age currently live with you (your own and/or others')? **(Check one)**

| | | | | | |
|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| None | One | Two | Three | Four | More than four |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 0 | 1 | 2 | 3 | 4 | 5 |

If more than four, also indicate the number of children: _____

3. Do you want to have more children (for example, make a baby or adopt/foster a baby/child) in the future? **(Check one)**

| | | |
|--------------------------|--------------------------|--------------------------|
| Yes | No | Not sure |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 1 | 2 | 3 |

If Yes or Not sure, when? **(Check one)**

| | | | | |
|--------------------------|--------------------------|--------------------------|----------------------------|--------------------------|
| Within the next year | 1 to 2 years from now | 3 to 4 years from now | More than 4 years from now | I don't know |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 1 | 2 | 3 | 4 | 5 |

REPRODUCTIVE CHOICES

Pt. No. *Seq. No. **Step No. Date
mm dd yy

Birth Control Methods

4. Some forms of birth control could have occurred years ago, such as an intrauterine device (IUD) that is currently in place or a surgery that prevents pregnancy. Indicate if you or your partner(s) have had any of the following procedures that prevent pregnancy done:

(Check ALL that apply)

- a. Tied tubes, tubal ligation, hysterectomy (surgery of women to prevent pregnancy)..... 1
- b. Vasectomy (surgery of men to prevent pregnancy)..... 1
- c. An intrauterine device (IUD)..... 1

5. In the last 3 months, indicate if you and your partner(s) used any of the following birth control methods:

(Check ALL that apply)

- a. Male condoms..... 1
- b. Female condoms..... 1
- c. Birth control pills..... 1
- d. Withdrawal, pulling out..... 1
- e. 3-month shot, Depo-Provera..... 1
- f. A diaphragm..... 1
- g. Emergency contraception (Morning-after pill, Plan B)..... 1
- h. Monthly injection (Lunelle)..... 1
- i. Weekly hormonal patch (Ortho-Evra)..... 1
- j. Spermicide..... 1
- k. Abstinence (not having sex with someone of the other sex)..... 1
- l. None..... 1
- m. Other, please list [70]: _____ 1

Thank you very much for completing this questionnaire.