|  |  |  |
| --- | --- | --- |
|  | Was the participant enrolled in MTN-041? | 1 **Yes** 🡪 **GO TO 3**  0 **No** |
|  | Reason for non-enrollment of MTN-041 *[mark all that apply]*: | 1 Participant not interested  2 Eligibility criteria not met, specify \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  3 Other, specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ 🡪**END FORM** |
|  | Date of enrollment in MTN-041: | dd MMM yy |
|  | Gender of the participant *[mark one]*: | 1 Female  2 Male 🡪 **GO TO 6** |
|  | [*For pregnant/breastfeeding females*] How was participant’s HIV status confirmed? | 1 Self-report  2 Health record  3 Both of the above  4 Other, specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  | Date MTN-041 FGD or IDI conducted: | dd MMM yy |
|  | FGD participant pseudonym [*or N/A*]: | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  N/A |
|  | Type of interview conducted *[mark one]*: | 1 Female P & BF FGD 🡪 **GO TO 10**  2 Grandmother FGD 🡪 **GO TO 10**  3 Male Partner FGD 🡪 **GO TO 10**  4 KI IDI  5 Other (specify)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ 🡪 **GO TO 10** |
|  | [*For Key Informants*] Role in community *[mark one]*: | 1 Clinical doctor 4Nurse  2 Social service provider 5Traditional care provider  3 Community health worker 6 Religious leader  7Other (specify)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  | Date of termination from MTN-041: | dd MMM yy |
|  | Reason for termination from MTN-041 *[mark one]*: | 1 Participant completed study  2 Voluntary withdrawal  3 Inappropriate enrolment  4 Other, specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Comments**: | | |

**Participant Status Form (PSF)**

**Purpose:** This form is used to record participants’ MTN-041 enrollment status.

**General Information/Instructions:** This form will be completed for every potential participant who provides written informed consent.

**Overall Instructions:** Enter the PTID in the top left corner of this form and the date the form is completed in the top right corner, and initial and date in the bottom right corner. Any information recorded or modified on this form after the original date of completion should be initialed and dated, per GCP.

**Item-specific Instructions:**

|  |  |
| --- | --- |
| **Item** | **Instruction** |
| 2 | Record the reason for non-enrollment in MTN-041. If there was more than one reason, mark all responses that apply. If the reason is not specified, mark “other” and describe the reason on the line provided. |
| 3 | The date of enrollment is the date that all eligibility criteria were confirmed and certified following written informed consent. |
| 5 | ‘Health record’ may include a health passport, antenatal book, HIV test card, or similar document. |
| 6 | Enter the date that the IDI or FGD was conducted. If it was conducted on more than one day, enter the date that the interview was started and record a note in the comment box regarding the split visit, which includes the reason for splitting the visit. |
| 10 | Enter the termination date. This should be the day that the IDI/FGD is completed or, if the participant enrolled and never completed an interview, the date the participant was terminated by study staff. |
| 11 | Enter the reason for termination from MTN-041. If there was more than one reason, mark the main reason. If the reason is not specified, mark “other” and describe the reason on the line provided. If you have reached this question, you are now finished with the form. |