|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | [*If female*] Complete HOPE PTID -- **🡪 Go** **to 2** | | | |
| 1a | *[If male]*: Complete partner’s HOPE PTID -- **🡪 Go** **to 3** | | | |
|  | | | **Yes** | **No** |
|  | [*If female*] Was the participant enrolled in MTN-032 Phase 1? | | 1 **🡪 Go** **to 2a** | 0 **🡪 Go** **to 3** |
| 2a | [*If participated in Phase 1*] Complete MTN-032 Phase 1 PTID | | | |
|  |  | | **Yes** | **No** |
|  | Was the participant enrolled in MTN-032 Phase 2? | | 1 | 0 🡪**IF NO, GO TO 12** |
|  | Date of enrolment in MTN-032 Phase 2 | dd MMM yy | | |
|  | Date MTN-032 Phase 2 IDI or FGD conducted *[record date or check N/A]*: | or 🡪**IF N/A, GO TO 10**  dd MMM yy N/A | | |
|  | FGD participant pseudonym: | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  N/A | | |
|  | Type of interview conducted: [*mark one*] | 1 Female IDI 3 Male IDI **🡪 Go** **to 10**  2 Female FGD 4 Male FGD **🡪 Go** **to 10** | | |
|  | [*If female*] Whether participant thinks her drug results match with how she used ring in HOPE: | 1 Matches  0 Does not match | | |
|  | [*If female*] Whether participant trusts the method used to test the rings: | 1 Trusts  0 Does not trust | | |
|  | Date of termination from MTN-032 Phase 2 | dd MMM yy | | |
|  | Reason for termination from MTN-032 Phase 2 *[mark one]*: | 1 Participant completed study  2 Inappropriate enrolment  3 Other, specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_🡪**END FORM** | | |
|  | Reason for non-enrolment in MTN-032 Phase 2 *[mark one]*: | 1 Participant did not give permission to be contacted  2 Participant was contacted, but refused participation, specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  3 Participant scheduled three times, did not show  4 Eligibility criteria not met, specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  5 Participant did not provide written informed consent  6 Other, specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| **Comments (if applicable)**: | | | | |

**Participant Status Form (PSF)**

**Purpose:** This form is used to record participants’ MTN-032 Phase 2 enrollment and termination status.

**General Information/Instructions:** This form records essential administrative information about MTN 032 participants that are randomly selected, screened and enrolled. This form will be completed for every HOPE participant/ HOPE participant partner who is randomly selected for participation in MTN-032 Phase 2 until the point on the randomization list that the target number of enrollees for that subgroup is saturated.

**Overall Instructions:** Enter the PTID in the top left corner of this form, the date the form is completed in the top right corner, and initial and date in the bottom right corner. This form should be completed either on the date(s) that the IDI is completed for those enrolled into MTN-032 Phase 2, or on the date that the potential participant is determined to be ineligible for participation for all other participants. 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** |
| 1 | For all female participants considered for participation in MTN-032 Phase 2, record her HOPE PTID. For male participants, record the HOPE PTID of the participant’s partner. |
| 3 | Record whether or not the participant was enrolled in MTN-032 Phase 2. If they were not enrolled for any reason, go to item 12 and check the option that best matches the reason for non-enrolment. For those participants not enrolled, assign a MTN-032 PTID as per instructions in the SSP. |
| 4 | The date of enrolment is the date that the participant provided informed consent. |
| 5 | Enter the date that the IDI/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. If the participant never completed an interview, mark “N/A” and go to Q10. |
| 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, enter the date participant was terminated by study staff. |
| 11 | Enter the reason for termination from MTN-032 Phase 2. 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 specify line. If you have reached this question, you are now finished with the form and should not complete Q12. |
| 12 | Record the reason for non-enrolment in MTN-032 Phase 2. 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 specify line. |