

VOICE-C PTID

--	--	--	--	--

Screening 1 Date

dd		MMM			yy		

**VOICE-C Enrollment Status Form: Group 1 VOICE Participants (ESF\_G1)**

**Section 1. Screening 1**

*Instructions: This section is to be completed for all potential GROUP 1 VOICE-C participants on the day of Screening 1.*

1.	Woman willing (per verbal consent) to be screened for participation in VOICE-C substudy?									
	<input type="checkbox"/> <sub>1</sub> Yes → Assign VOICE-C PTID Complete VOICE PTID <table border="1" style="display: inline-table; margin-left: 20px;"> <tr> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> </tr> </table>									<input type="checkbox"/> <sub>2</sub> No → <b>INELIGIBLE. Write “0000” in VOICE-C PTID field. Go to item 10, then END FORM.</b>

**Inclusion Criteria:** The following must be marked **YES** in order for the woman to meet initial eligibility for the VOICE-C substudy.

	Yes	No
--	-----	----

2.	Enrolled in VOICE, and randomized to receive products approximately 12 weeks ago (minimum of 10 weeks) <b>(ENR-1, item 3)</b>	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>
----	---	---------------------------------------	---------------------------------------

**Exclusion Criteria:** All of the following must be marked **NO** in order for the woman to be eligible for the VOICE-C substudy.

	Yes	No
--	-----	----

3.	Permanently discontinued from study product use by the site IoR/designee, per specifications of the VOICE protocol, prior to recruitment into VOICE-C <b>(PH-1, item 4)</b>	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>
----	---	---------------------------------------	---------------------------------------

4.	Has any condition that, in the opinion of the site IoR/designee, would preclude informed consent, make study participation unsafe, complicate interpretation of study outcome data, or otherwise interfere with achieving the study objectives	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>
----	--	---------------------------------------	---------------------------------------

5.	More than 2 months on temporary study product hold by the site IoR/designee, per the specifications of the VOICE protocol <b>(PH-1, item 4)</b>	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>
----	---	---------------------------------------	---------------------------------------

6.	Confirm initial eligibility (#2 must be marked <b>YES</b> and exclusion criteria #3-5 must be marked <b>NO</b> in order for the woman to be eligible for enrollment)	Inclusion & exclusion criteria met above <input type="checkbox"/> <sub>1</sub> All met <input type="checkbox"/> <sub>2</sub> Not all met: <b>INELIGIBLE. Go to end of Section 1.</b>	
----	--	--	--

7.	Woman’s local language	<input type="checkbox"/> <sub>1</sub> Isizulu <input type="checkbox"/> <sub>3</sub> English <input type="checkbox"/> <sub>2</sub> Sesotho <input type="checkbox"/> <sub>4</sub> Other, specify: _____	
----	------------------------	--	--

8.	Woman’s study group in VOICE <b>(ENR-1 item 3d)</b>	<input type="checkbox"/> <sub>1</sub> Oral <input type="checkbox"/> <sub>2</sub> Vaginal	
----	---	--	--

9.	Woman willing to be considered for enrollment in VOICE-C substudy?	<input type="checkbox"/> <sub>1</sub> Yes, <b>go to item 11</b> <input type="checkbox"/> <sub>2</sub> No → <b>INELIGIBLE. Go to item 10.</b>	
----	--	---	--

10.	Reason(s) woman was unwilling to consider participation	_____ _____ <b>Go to end of Section 1 and END FORM.</b>	
-----	---	---	--

11.	Randomization assignment	<input type="checkbox"/> <sub>1</sub> In-Depth Interview (IDI) <input type="checkbox"/> <sub>2</sub> Focus Group Discussion (FGD) <b>Go to end of Section 1.</b> <input type="checkbox"/> <sub>3</sub> Ethnographic Interview (EI)	
-----	--------------------------	--	--

## Enrollment Status Form\_Group 1 (ESF\_G1-1)

**Purpose:** This form is used to collect Group 1 participants' screening and enrollment information.

**General Information/Instructions:** This form is completed in stages.

Section 1 (Screening 1) is to be completed on the day of Screening 1 for all potential VOICE-C group 1 participants.

Section 2 (Screening 2) is only to be completed if Screening 1 occurred more than 14 days ago.

Section 3 is to be completed at the Enrollment visit for all enrolled participants.

**Overall instructions:** Enter the PTID in the top left corner of every page of this form. Initial and date at the end of every section. In the majority of cases, the data at the end of Section 1 should match the date in the upper right-hand corner of Page 1 of the form. Responses to items on this form are obtained from asking the participant direct questions and looking at her VOICE participant folder. It is important that the participant is not waiting for long periods of time while information is obtained from the VOICE file. Therefore, it is important that the interviewer is well-prepared in advance to pull updated and specific information from the participant file.

### Item-specific Instructions:

Item	Instruction
1	Record the participant's response to the request for verbal consent for screening. This should be completed before recording the PTID or any other information in the Screening 1 section of the form. If the response is yes, assign the next sequential group 1 VOICE-C PTID from the Screening and Enrollment Log, record on the top left corner of Page 1, and document the VOICE PTID.
2	Obtain from item 3 of the Enrollment (ENR-1) Form from the participant's VOICE file. The date on item 3 of the ENR-1 should be <i>at least 10 weeks</i> prior to the Screening 1 date. That is, Screening 1 date must be not any earlier than the start of the window period for her VOICE Month 3 visit.
3	Obtain from item 4 of the Product Hold/Discontinuation Log (PH-1) from the participant's VOICE file. If PH-1 item 4 is marked 'no' due to permanent discontinuation, mark "Yes" here, and this woman cannot participate in VOICE-C. Otherwise, mark no.
4	If this item is marked "Yes," an explanation should be provided in the comments section at the end of the form. Only the IoR or designee can decide if this item should be marked "yes."
5	Temporary product hold can be determined from item 4 of the Product Hold / Discontinuation Log (PH-1) from the participant's VOICE file. If date of last product use (PH-1 item 3) is more than 2 months AND participant was not instructed to resume product use (PH-1 item 4 "no"), then mark "Yes" for this item. Note that 2 months is determined by calendar date, not number of days. E.g. Two months from July 15 is September 15.
7	Select one language only that matches the language the participant selected in VOICE. Please refer to a VOICE interviewer-administered form, i.e. Monthly Symptoms or Screening 2/ Enrollment Eligibility forms.
8	Obtain this information from item 3d of the Enrollment (ENR-1) Form from the participant's VOICE file.
10	Record in as much detail as possible why the participant was unwilling to consider participation. If she refuses to provide a reason, write "REF" on the line.
11	For participants randomized to the Focus Group Discussion (refer to MTN-003C Participant Tracking and Randomization List), mark NA, contact at PUEV. These male partners are randomized to an exit Focus Group Discussion. Primary partner information may change throughout the VOICE trial and therefore it is most accurate to contact the primary partner at the VOICE participants' PUEV.

VOICE-C PTID

--	--	--	--

12.	Does woman consent to have male partner contacted for VOICE-C screening?	<input type="checkbox"/> <sub>1</sub> Yes, <b>go to end of Section 1</b> <input type="checkbox"/> <sub>2</sub> No
13.	Reason(s) why female participant did not consent to allow male partner to be contacted for VOICE-C screening	_____ _____ <input type="checkbox"/> <sub>1</sub> Declined to answer

**End of Section 1.** Staff Initials and Date \_\_\_\_\_  
 Staff Initials/Date

**Section 2. Screening 2**

*Instructions: Complete this section if Screening 1 occurred more than 14 days ago. Otherwise go to Section 3.*

Today's Date  
    
 dd                      MMM                      yy

14.	Woman willing to be considered for enrollment in VOICE-C substudy?	<input type="checkbox"/> <sub>1</sub> Yes, <b>go to item 16</b> <input type="checkbox"/> <sub>2</sub> <b>No → INELIGIBLE.</b>
15.	Reason(s) woman was unwilling to consider participation	_____ _____ <b>Go to end of Section 2 and END FORM.</b>

Exclusion Criteria: All of the following must be marked <b>NO</b> in order for the woman to be eligible for VOICE-C		Yes	No
16.	Permanently discontinued from study product use by the site IoR/designee, per the specifications of the VOICE protocol ( <b>PH-1, item 4</b> )	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>
17.	More than 2 months on temporary study product hold by the site IoR/designee, per the specifications of the VOICE protocol ( <b>PH-1, item 4</b> )	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>
18.	Has any condition that, in the opinion of the site IoR/designee, would preclude informed consent, make study participation unsafe, complicate interpretation of study outcome data, or otherwise interfere with achieving the study objectives	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>

19.	Confirm exclusion criteria (#16 to #18 must be marked <b>NO</b> in order for the woman to be eligible for VOICE-C)	Exclusion criteria met <input type="checkbox"/> <sub>1</sub> All met <input type="checkbox"/> <sub>2</sub> Not all met → <b>INELIGIBLE. Go to end of Section 3.</b>
-----	--	---

20.	Does woman consent to have male partner contacted for VOICE-C screening?	<input type="checkbox"/> <sub>1</sub> Yes, <b>go to End of Section 2</b>	<input type="checkbox"/> <sub>2</sub> No
-----	--	--	--

21.	Reason(s) why female participant did not consent to allow male partner to be contacted for VOICE-C screening	_____ _____ <input type="checkbox"/> <sub>1</sub> Declined to answer
-----	--	--

**End of Section 2.** Staff Initials and Date \_\_\_\_\_  
 Staff Initials/Date

## Enrollment Status Form\_Group 1 (ESF\_G1-2)

### Item-Specific Instructions:

Item	Instruction
13	Obtain the VOICE-C Randomization assignment from the MTN-003C Participant Tracking and Randomization List
14	Confirm participant still willing to participate in VOICE-C.
Header	Record the date of Screening 2 at the Section 2 row header. If more than 14 days have passed since Screening 1, complete Screening 2. If 14 days or fewer have elapsed, proceed directly to <u>Section 3</u> : Enrollment.
16	Obtain this criterion from item 4 on the <b>Product Hold / Discontinuation Log</b> for of the participant's <b>VOICE file</b> , as described above in item 3.
17	Obtain this criterion from item 4 of the <b>Product Hold / Discontinuation Log (PH-1)</b> form from the participant's <b>VOICE file</b> , as described above in item 5
18	See instructions for Item 4.

VOICE-C PTID

--	--	--	--

<b>Section 3: Enrollment</b>		Today's Date <table style="width: 100%; text-align: center;"> <tr> <td style="width: 20px; height: 20px;">□</td> <td style="width: 20px; height: 20px;">□</td> <td style="width: 20px; height: 20px;">□</td> <td style="width: 20px; height: 20px;">□</td> <td style="width: 20px; height: 20px;">□</td> <td style="width: 20px; height: 20px;">□</td> </tr> <tr> <td colspan="2">dd</td> <td colspan="2">MMM</td> <td colspan="2">yy</td> </tr> </table>		□	□	□	□	□	□	dd		MMM		yy	
□	□	□	□	□	□										
dd		MMM		yy											
22.	Has it been more than 14 days since Screening 1?	<input type="checkbox"/> <sub>1</sub> Yes, ensure <b>Section 2</b> is completed before proceeding	<input type="checkbox"/> <sub>2</sub> No												
23.	Participant provided written informed consent for participation in VOICE-C	<input type="checkbox"/> <sub>1</sub> Yes, <b>go to End of Section 3</b>	<input type="checkbox"/> <sub>2</sub> No												
24.	Reason(s) woman did not provide informed consent for participation in VOICE-C	_____ _____ _____													
<b>End of Section 3.</b> Staff Initials and Date _____ <div style="text-align: center;">Staff Initials/Date</div>															
<b>Comments:</b> <i>Initial and date all comments.</i> _____ _____ _____ _____ _____ _____ _____															

## Enrollment Status Form\_Group 1 (ESF\_G1-3)

### Item-Specific Instructions:

Item	Instruction
Header	This section is intended to be completed on the date of enrollment, and the date of enrollment recorded in the header row under “today’s date.” If “today’s date” is not the date of enrollment, explain why in the Comments section.
22	Ensure section 2 has been completed if it has been more than 14 days since Screening 1.
24	Record reasons woman did not provide informed consent in as much detail as possible. If she refuses to answer, write “REF” on the line provided.
Comments	Multiple comments may be added to this section for any items that require further detail or explanation, or any relevant information pertinent to the screening and enrollment status of the participant. All comments entries should be followed by staff initials and dates.