

VOICE-C PTID

--	--	--	--

Screening 1 Date

dd		MMM		yy	

VOICE-C Enrollment Status Form: Group 2 Male Partners (ESF_G2)

Section 1. Screening 1

Instructions: This section is to be completed for all potential GROUP 2 VOICE-C participants on the day of Screening 1.

1.	Male partner willing (per verbal consent) to be screened for participation in VOICE-C substudy?					
	<input type="checkbox"/> ₁ Yes → Assign VOICE-C PTID Female partner's VOICE-C PTID <table border="1" style="display: inline-table; vertical-align: middle;"> <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> </tr> </table>					<input type="checkbox"/> ₂ No → INELIGIBLE. Write "0000" in VOICE-C PTID field. Go to item 11, then end Form.

Inclusion Criteria: The following must be marked YES in order for the man to meet initial eligibility for the VOICE-C substudy.	Yes	No
---	------------	-----------

2.	18 years of age or older	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂
3.	Identified as a male partner of a female VOICE or VOICE-C participant who meets eligibility criteria for VOICE-C (i.e., no permanent or temporary (>2 months product hold) (PH-1, item 4)	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂
4.	Identified by a VOICE or VOICE-C participant as a current male sex partner (current is defined as a sex partner by the VOICE or VOICE-C participant at the time she is asked permission to contact him) (Permission to Contact Form)	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂
5.	Identified by a VOICE or VOICE-C participant as someone she consents to have the study team contact for VOICE-C screening (Permission to Contact Form)	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂

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

6.	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"/> ₁	<input type="checkbox"/> ₂
7.	Has already participated in a VOICE-C male partner IDI	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂

8.	Confirm initial eligibility (#2-5 must be marked YES and #6-7 must be marked NO in order for the man to be eligible for enrollment)	Inclusion & exclusion criteria met above <input type="checkbox"/> ₁ All met <input type="checkbox"/> ₂ Not all met: INELIGIBLE. Go to end of Section 1 and Form.	
9.	Female partner's study group in VOICE (ENR-1, item 3d)	<input type="checkbox"/> ₁ Oral <input type="checkbox"/> ₂ Vaginal	
10.	Man willing to participate in VOICE-C substudy?	<input type="checkbox"/> ₁ Yes, go to item 13 <input type="checkbox"/> ₂ No → INELIGIBLE. Go to item 12	

Enrollment Status Form_Group 2 (ESF_G2-1)

Purpose: This form is used to collect Group 2 participants' screening and enrollment information.

General Information/Instructions: This form is completed in 2 stages.

Section 1 (Screening 1) is to be completed on the day of Screening 1 for all potential Group 2 VOICE-C participants.

Section 2 (Screening 2): Items 15, 22 and 23 should be completed for all potential Group 2 VOICE-C participants. Items 16-21 are to be completed only if it has been 14 or more days since Screening 1.

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 on this form.** In the majority of cases, the date at the end of Section 1 should match the date in the upper right-hand corner of Page 1 of the form. It is important that the participant is not waiting for long periods of time while eligibility information is obtained and verified. Therefore, the interviewer should have the female partner's VOICE and VOICE-C files, and the Permission to Contact form with him/her during Screening 1.

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 2 VOICE-C PTID from the Screening and Enrollment Log, record on the top left corner of Page 1, and document the female partner's VOICE-C PTID.
2	Obtain this information by asking the participant his age. Age will be verified in-person at the enrollment visit, prior to data collection.
3	Obtain from item 4 of the Product Hold/Discontinuation Log (PH-1) from the female participant's VOICE file. If PH-1 item 4 is marked 'no' due to permanent discontinuation, mark "Yes" here, and this man cannot participate in VOICE-C. 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 the female participant is on temporary product hold: mark "Yes" for this item, and this man cannot participate in VOICE-C.
4	Refer to Permission to Contact form, item 2.
5	Refer to Permission to Contact form, item 1. Make sure Yes is marked and participant initials and date are filled out before marking yes on the male partner's ESF form.
6	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."
7	Verify this participant has not already participated in a VOICE-C IDI by referring to the Group 2 Screening and Enrollment Log.
9	Obtain this information from item 3d of the Enrollment (ENR-1) Form from the participant's VOICE file.

VOICE-C PTID

--	--	--	--

11.	Reason(s) man was unwilling to consider participation.	<p>_____</p> <p>_____</p> <p>_____</p> <p>Go to end of Section 1 and Form.</p>		
12.	Female partner’s study group in VOICE_C (ESF_g1, item 11)	<input type="checkbox"/> ₁ In-Depth Interview (IDI) <input type="checkbox"/> ₂ Exit Focus Group Discussion (FGD) <input type="checkbox"/> ₃ Ethnographic Interview (EI) <input type="checkbox"/> ₄ NA, not in VOICE-C		
13.	VOICE-C group assignment	<input type="checkbox"/> ₁ In-Depth Interview (IDI) <input type="checkbox"/> ₂ Focus Group Discussion (FGD)		
14.	Language(s) he is comfortable using for data collection (<i>mark all that apply</i>)	<input type="checkbox"/> ₁ Isizulu <input type="checkbox"/> ₁ Sesotho <input type="checkbox"/> ₁ English <input type="checkbox"/> ₁ Other, specify: _____		
<p>End of Section 1. Staff Initials and Date _____</p> <p style="text-align: center;">Staff Initials/Date</p>				
Section 2. Screening 2 & Enrollment		<input type="checkbox"/> <input type="checkbox"/> dd	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> MMM	<input type="checkbox"/> <input type="checkbox"/> yy
15.	Has it been more than 14 days since Screening 1?	<input type="checkbox"/> ₁ Yes	<input type="checkbox"/> ₂ No, go to item 22	
Inclusion Criteria: The following inclusion criteria must be marked YES in order for the man to be eligible for enrollment.		Yes	No	
16.	Identified as a male partner of a female VOICE or VOICE-C participant who meets eligibility criteria for VOICE-C (i.e., no permanent or on temporary [>2 months] product hold) (PH-1, item 4)	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	
17.	Identified by a VOICE or VOICE-C participant as a current male sex partner (current is defined as a sex partner by the VOICE or VOICE-C participant at the time she is asked permission to contact him) (Permission to Contact Form)	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	
18.	Identified by a VOICE or VOICE-C participant as someone she consents to have the study team contact for VOICE-C screening (Permission to Contact Form)	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	
Exclusion Criteria: The following exclusion criteria must be marked NO in order for the man to be eligible for VOICE-C		Yes	No	
19.	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"/> ₁	<input type="checkbox"/> ₂	
20.	Has already participated in a VOICE-C male partner IDI	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	

Enrollment Status Form_Group 2 (ESF_G2-2)

Item-Specific Instructions:

Item	Instruction
12	Obtain this information from item 11 of the Enrollment Status Form (ESF_G1) from the participant's VOICE-C file. Do not tick NA unless instructed by the VOICE Management Team.
13	The man's VOICE-C group assignment should match his female partner's assignment (per ESF_G1).
14	Explain to the participant that we need to know which language or languages he is most comfortable having an in-depth discussion in. The purpose of this question is not to know just what languages the participant understands, but to ensure that we place the participant in an FGD that he will be able to fully understand and participate in. Mark all languages that apply. If the participant is comfortable in additional languages, tick "other" and specify the language(s) (i.e. Xhosa)
Header	Section 2: Enter the date of Screening 2 in the dd/MMM/yy field at the beginning of Section 2.
15	If more than 14 days have passed since Screening 1, complete items 16-21. Record the date of Screening 2 at the Section 2 row header. If 14 days or fewer have elapsed, mark no and proceed directly to item 22 as indicated.
16	Obtain from verifying female partner's eligibility criteria on her Product Hold form.
17	Refer to Permission to Contact form, item 2.
18	Refer to Permission to Contact form, item 1. Make sure Yes is marked and participant initials and date are filled out before marking yes on the male partner's ESF form.
19	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."
20	Verify this participant has not already participated in a VOICE-C IDI by referring to the Group 2 Screening and Enrollment Log.

VOICE-C

VOICE-C PTID

--	--	--	--

21.	Confirm eligibility (#16-18 must be marked YES and #19-20 must be marked NO in order for the man to be eligible for enrollment)	Inclusion & exclusion criteria met above <input type="checkbox"/> ₁ All met <input type="checkbox"/> ₂ Not all met INELIGIBLE. Go to end of Section 2 and Form.
22.	Provided written informed consent for participation in VOICE-C	<input type="checkbox"/> ₁ Yes, go to end of Section 2 <input type="checkbox"/> ₂ No
23.	Reason(s) man did not provide informed consent for participation in VOICE-C	_____ _____ _____ Go to end of Section 2 and Form.

End of Section 2. Staff Initials and Date _____
Staff Initials/Date

Comments: *Initial and date all comments.*

Enrollment Status Form_Group 2 (ESF_G2-3)

Item-Specific Instructions:

Item	Instruction
23	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.