

VOICE-C PTID

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Screening Date

dd		MMM		yy	

VOICE-C Enrollment Status Form: Group 3 CAB Members (ESF_G3)

Section 1: Screening

Instructions: This section is to be completed for all potential GROUP 3 VOICE-C participants.

1.	Individual willing (per verbal consent) to be screened for participation in VOICE-C substudy?	
	<input type="checkbox"/> ₁ Yes → Assign VOICE-C PTID	<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 individual to meet eligibility for the VOICE-C substudy.		Yes	No
2.	18 years of age or older	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂
3.	Has been a member of a CAB affiliated with the site for at least 3 months, as reported by the site CAB liaison	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂
4.	Is considered an active CAB member, as reported by the site CAB liaison	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂

Exclusion Criteria: All of the following must be marked NO in order for the individual to be eligible for the VOICE-C substudy.		Yes	No
5.	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
6.	CAB member who has been involved in the VOICE-C protocol development process	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂

7.	Confirm initial eligibility (#2-4 must be marked YES and #5-6 must be marked NO in order for the individual 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.
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8.	Language(s) s/he is comfortable using for data collection (<i>mark all that apply</i>)	<input type="checkbox"/> ₁ Isizulu <input type="checkbox"/> ₁ English <input type="checkbox"/> ₁ Sesotho <input type="checkbox"/> ₁ Other, specify: _____
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End of Section 1. Staff Initials and Date _____
Staff Initials/Date

Section 2: Enrollment

9.	Participant provided written informed consent for participation in VOICE-C	<input type="checkbox"/> ₁ Yes <input type="checkbox"/> ₂ No → INELIGIBLE. Go to item 11.
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Enrollment Status Form_Group 3 (ESF_G3-1)

Purpose: This form is used to collect Group 3 participants' screening and enrollment information.

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

Section 1 (Screening) is to be completed on the day of Screening for all potential VOICE-C group 3 participants.

Section 2 (Enrollment) is only to be completed on the day of Enrollment for Group 3 VOICE-C participants. There is no Screening 2 process for Group 3.

Overall instructions: Enter the PTID in the top left corner of both pages 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.

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 section of the form. If the response is yes, assign the next sequential Group 3 VOICE-C PTID from the Screening and Enrollment Log and record on the top left corner of Page 1.
2	Obtain this information from asking the participant his/her age. Age will be verified in-person at the enrollment visit, prior to data collection.
3	Obtain from CAB Roster
4	Verify the potential participant is on the current CAB Roster
5	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."
6	Obtain this information from the CAB roster
8	Explain to the participant that we need to know which language or languages he or she 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/ she 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)
Section 2: Enrollment	Complete this section on the day of Enrollment for all Group 3 participants.

VOICE-C

VOICE-C PTID

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10.	Date of enrollment	<table border="1"><tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr><tr><td colspan="2">dd</td><td colspan="3">MMM</td><td colspan="2">yy</td><td></td></tr><tr><td colspan="8" style="text-align: center;">→ Go to end of Section 2.</td></tr></table>									dd		MMM			yy			→ Go to end of Section 2.							
dd		MMM			yy																					
→ Go to end of Section 2.																										
11.	Reason(s) individual was unwilling to consider participation.	<hr/> <hr/>																								
End of Section 2. Staff Initials and Date _____ Staff Initials/Date																										
Comments: <i>Initial and date all comments.</i> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/>																										

Enrollment Status Form_Group 3 (ESF_G3-2)

Item-Specific Instructions:

Item	Instruction
10	Record the date of enrollment into VOICE-C (day consent form was signed). Then proceed to the end of Section 2.
11	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.