

VOICE-C PTID

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Screening Date

dd		MMM		yy	

**VOICE-C Enrollment Status Form: Group 4 Key Community Stakeholders (ESF\_G4)**

**Section 1. Screening**

*Instructions: This section is to be completed for all potential GROUP 4 VOICE-C participants.*

1.	Individual willing (per verbal consent) to be screened for participation in VOICE-C substudy?		
	<input type="checkbox"/> <sub>1</sub> Yes → Assign VOICE-C PTID	<input type="checkbox"/> <sub>2</sub> No → <b>INELIGIBLE. Write “0000” in VOICE-C PTID field. Go to item 10, then end Form.</b>	
<b>Inclusion Criteria:</b> The following must be marked <b>YES</b> in order for the individual to meet eligibility for the VOICE-C substudy.		<b>Yes</b>	<b>No</b>
2.	18 years of age or older	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>
3.	Lives or works within the community in which the parent study is being conducted	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>
<b>Exclusion Criteria:</b> All of the following must be marked <b>NO</b> in order for the individual to be eligible for the VOICE-C study.		<b>Yes</b>	<b>No</b>
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.	Current CAB member at that site	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>
6.	Confirm initial eligibility (#2-3 must be marked <b>YES</b> and #4-5 must be marked <b>NO</b> in order for the individual 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.</b> <b>Go to end of Section 1 and Form.</b>	
7.	Language(s) s/he is comfortable using for data collection ( <i>mark all that apply</i> )	<input type="checkbox"/> <sub>1</sub> Isizulu <input type="checkbox"/> <sub>1</sub> Sesotho	<input type="checkbox"/> <sub>1</sub> English <input type="checkbox"/> <sub>1</sub> Other, specify: _____

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

## Enrollment Status Form\_Group 4 (ESF\_G4-1)

**Purpose:** This form is used to collect Group 4 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 4 participants.

Section 2 (Enrollment) is only to be completed on the day of Enrollment for Group 4 VOICE-C participants. Screening 2 procedures are not applicable for Group 4.

**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 4 VOICE-C PTID from the Screening and Enrollment Log and record on the top left corner of Page 1.
2	Obtain this information by asking the participant his/her age. Age will be verified in-person at the enrollment visit, prior to data collection.
3	Obtain by asking participant what community he or she lives and/or works in. The participant may live or work in the community where the VOICE clinic is located, or where the VOICE study is recruiting.
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	Refer to the current CAB roster and confirm that the participant's name is not on the list. If he or she is not listed as a CAB member, mark 'no'. If he or she is listed as a current CAB member, mark 'yes'.
7	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)

VOICE-C PTID

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**Section 2: Enrollment**

8.	Participant provided written informed consent for participation in VOICE-C	<input type="checkbox"/> <sub>1</sub> Yes <input type="checkbox"/> <sub>2</sub> No → <b>INELIGIBLE.</b> <b>Go to item 10.</b>														
9.	Date of enrollment	<table style="width: 100%; text-align: center;"> <tr> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> </tr> <tr> <td>dd</td> <td>MMM</td> <td>yy</td> <td colspan="4"></td> </tr> </table> <p>→ <b>Go to end of Section 2.</b></p>								dd	MMM	yy				
dd	MMM	yy														
10.	Reason(s) individual was unwilling to consider participation.	<hr/> <hr/> <hr/>														

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

**Comments:** *Initial and date all comments.*

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## Enrollment Status Form\_Group 4 (ESF\_G4-2)

### Item-specific Instructions:

Item	Instruction
Section 2: Enrollment	Complete this section on the day of Enrollment for Group 4 VOICE-C participants.
9	Record the date of enrollment into VOICE-C (day consent form was signed). Then proceed to the end of Section 2.
10	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.