

Date

PTID

VOICE-C: CHECKLIST FOR VERBAL CONSENT AT SCREENING

Instructions: When conducting the verbal consent either in-person or over the phone, use this checklist to ensure that each item is discussed with the potential participant. This is not a script, but a prompt to ensure that no points are missed. The verbal consent can be carried out in the staff members own words.

- Interviewer introduces self and role at the site:

Hello, my name is [insert name] and I am the [role] at [name of study clinic].

- Groups 2 and 4:** let the person know who referred him/her to the study (so they know how RHRU got their name/number)
- Provide name of study: The ancillary study is referred to as VOICE-C
- Introduce where VOICE-C is currently taking place: VOICE-C is taking place at the R and T Centre, Esselen Street, Hillbrow.
- State the study's overarching purpose: VOICE-C is a sub-study which looks at gel and tablet use in VOICE.
- Further detail the study's purpose: The purpose of this research is to help researchers do 4 things:
 - a. Explore the cultural and social aspects that influence gel and tablet use in VOICE
 - b. To see if there is a difference between use of the gel and use of the tablet
 - c. To get individuals' views on the importance of gel and tablet adherence
 - d. Get the views on the trial and gel and tablet use from male partners, men, community stakeholders, and CAB members.
- Commitment (If eligible and interested): We would only like to ask you a couple of questions [over the phone] today. If you are eligible and interested you will be asked to:
 - a. **Group 1:** participate in either a larger group discussion at the end of your participation in VOICE, a once off individual interview, or a series of four home interviews throughout the next year.
 - b. **Group 2:** participate in either a larger group discussion at the end of your participation in VOICE, or a once off individual interview.
 - c. **Group 3:** participate in a series of four focus group discussions with other CAB members.
 - d. **Group 4:** participate in a single focus group discussion with other community stakeholders.

We will ask you to provide written informed consent before any research activities begin.

- Risk/Benefits: You may experience no direct benefit from participating in VOICE C. But you as well as others may benefit in the future from what is learned in this study about conducting HIV prevention trials and familiarizing communities about HIV prevention trials.
- Are you willing to be screened for participation in the VOICE-C Study?
 - a. Your participation in the study is voluntarily and you can quit at any time
 - b. If you are eligible, we can explain the research study further and answer any questions you have
 - c. If you want to join you will be scheduled for an interview, and you will go through a written informed consent process, answer some basic questions about yourself, have the interview, and be reimbursed for your transport.
 - d. All the information will be treated confidentially
- Ask the potential participant if he/she has any questions about the study or what happens if they volunteer.
- If the individual is willing, mark the Enrollment Status Form (ESF) appropriately and move on with the questions on the respective ESF. In the individual is not willing, mark "0000" on the ESF form and as prompted on the form, describe why the individual is not willing to be screened (if s/he offers a reason).
- For Group 1 if screened and eligible:** inform the participant of her randomization arm and explain this study group in more detail as needed.
- After screening, provide the contact name and number in case the individual wants further information. Thank the participant for his/her time.

Staff Initials

Date