

MTN-009 Study-Specific Training
Role Play

Day 1

Accrual

Role Play 1: Participant reports she is at the site for VOICE

A potential participant, who has already pre-screened and referred to the site by Recruitment staff, presents at the study site to screen for VOICE. She is presented with MTN-009 and offered to join the study. The participant has questions about the study, such as:

- what is the study about
- why is she being asked to participate
- why wasn't she told about this study before?

Discussion Points

1. The counselor should address the participant's questions.
2. How does the counselor communicate to the participant that this study is not being advertised broadly within the community, without raising suspicions within the community that MRC is doing "secret research"?

Outcome

- After participant's questions were answered, the participant agrees to join and the informed consent is administered.

Role Play 2: Participant reports she is at the site for the HIV positive study

A potential participant presents at the study site and informs study staff that she heard from a friend there was a study for HIV positive women and she would like to join. She states that she thinks she is HIV negative but she is not sure. If she is HIV positive, she does not want anyone to know her status, so she would like staff to pretend she is enrolling in VOICE.

Discussion Points

1. The counselor should explain to this participant that she is not eligible for MTN-009 since she did not present to the study site to participate in a HIV prevention trial.
2. Also, include all the counseling messages that will be provided to this woman.

Role Play 3: Participant that reports after explanation of the study that she knows about the study and that's why she is here.

A potential participant presents at the study site to screen for VOICE. Per the pre-screening information she appears to be eligible. When MTN-009 is presented to the participant she agrees to join. During the informed consent process, the participant confides to the counselor that she heard about the study from a friend, who is enrolled. She further explains that the main reason for her visit to the clinic today was to enroll in 009, not VOICE, because she thinks she is HIV positive.

Discussion Points

1. The counselor should explain to this participant that she is not eligible for MTN-009 based on the information she presented during the IC process (i.e. her main reason for coming to the site was to enroll in MTN-009)
2. Since she is already going through the IC process, how will you handle this situation?
3. Also, include all the counseling messages that will be provided to this woman.