THE SCIENCE OF IMPROVING LIVES

MTN-003
Ongoing Informed Consent Comprehension Assessment

MTN Regional Meeting
October 2010

MTN microbicide trials network

Rationale for Ongoing Assessment

- Per protocol, section 13.5, ongoing assessments of participant comprehension of informed consent topics will be undertaken among a sub-sample of participants during follow-up.
- Collect data to identify:
  - Topics that are understood well
  - Topics that are not understood well
  - Rumors or misperceptions
- Take action as needed:
  - Update/improve IC process/materials
  - Develop IC refreshers for participants
  - Develop/update community education efforts

VOICE ONGOING Informed Consent Comprehension Checklist (11 August 2010)

PTID:			Date:		
	Open-Ended Question/Statement	Required Points of Comprehension	Yes	No	Comments
1	Please describe your understanding of the purpose of the study.	a. Testing to learn if gel and each tablet are safe to use			
		b. Testing to learn if gel and each tablet may prevent HIV			
2	Please tell me about the different groups of women in the study.	a. There are different gels and tablets - some have medicine and some do not			
		b. Some of the study tablets are ARV medicines and are currently used to treat HIV; we do not know yet if they work to prevent HIV			
		c. No one knows who receives which gel and which tablet			
3	How often should you use your study gel or tablets?	Study product should be used every day			
4	If a woman always uses study gel or study tablets, but does not use condoms, can she get HIV?	Yes, such a woman can get HIV			
5	Why should women stay on a reliable family planning method while they are in the study?	a. The gel and tablets have not been thoroughly tested in pregnant women			
		b. If they get pregnant, they must stop using their gel or tablets until after the pregnancy			
6	What do you understand about the possible risks of participating in this study?	a. Gel or tablets may cause bad effects *(must mention at least one)*			
		b. Others may treat participants badly for being in the study (social harms)			
		c. Possibility of resistance to ARV medicines used in this study			
7	What are the benefits of participating in this study?	Counseling, condoms, contraception, medical exams, tests, clinical care, helping to find ways to prevent getting HIV (must mention at least one)			
8	Why is it important to not join another research study at the same time that you are in this study?	a. This is important for your safety			
		b. If you join other studies, researchers will not be able to understand if the gel and tablets in this study are safe and work to prevent HIV			
9	What should women do if they have a question about the study or a problem related to being in the study?	Contact the study staff			
10	Are women who join the study allowed to leave the study?	Although clinic staff will ask women to consider options for staying in the study, and try to help women overcome any problems they may be having, yes, women can choose to leave without penalty			

INSTRUCTIONS: This checklist is not completed in the same manner as the enrollment checklist. Ask each main question and then tick "yes" for each sub-item that the participant demonstrates comprehension of during discussion with you, without further explanation of the correct answer. Additional clarification of the questions and probing of responses may be done during administration of the checklist, but additional explanation of the correct answers should not be provided until after the entire checklist is administered. For sub-items that the participant is not able to demonstrate comprehension of, tick the "no" box and provide education/counseling after the checklist has been administered. Use the comments column to document follow-up discussions and outcomes. For items that are ticked "yes", comment category a or b should appear. For items that are ticked "no", comment category c should typically appear, although category d also may appear. Complete the Ongoing Informed Consent Comprehension DataFax form (ICC-1), based on responses recorded on this checklist.

Comment Categories:

a. Answered correctly on first try

b. Could not answer at first, but answered correctly after some probing

c. Could not answer correctly with probing, but demonstrated comprehension after additional explanation/counseling

d. Other (describe)

Staff Signature:

Procedural Overview

- Administer Ongoing Informed Consent Comprehension Checklist to 20 participants completing scheduled monthly visits on day randomly selected by SCHARP
- May continue on consecutive days if needed
- Best if only 1 or 2 people from each site do the assessment, for consistency
- Administer at the beginning of the participant's visit. No review or discussion of informed consent topics should take place prior to assessment

Procedural Overview

- Discussion style format similar to the enrollment assessment
- However, the ongoing comprehension checklist is not completed in the same manner as the enrollment comprehension checklist.
- Tick items on the checklist only if the participant is able to demonstrate comprehension of the items without additional explanation of correct responses to the item.

Procedural Overview

- It is acceptable to clarify or explain the questions to the participant, and to probe for more information in her response, but it is not acceptable to explain required points of comprehension while administering the checklist.
- Provide information/education/counseling after administering checklist to ensure understanding of all items before continuing with rest of the visit

Documenting the Ongoing Assessment

- The Ongoing Informed Consent Comprehension Checklist serves as the primary source document for the ongoing assessment.
- After the checklist is completed, transcribed from the checklist onto the DataFax CRF the assessment outcomes and comment codes
- Once the CRF is completed, fax to SCHARP

Documenting the Ongoing Assessment

- In addition to the Ongoing Informed Consent Comprehension Checklist and CRF, document the assessment in chart notes.
- Sites may choose to use a worksheet to document the details of the assessment. When such a worksheet is used, the chart note documenting the assessment may be brief

Statistical Center for HIV/AIDS Research & Prevention (SCHARP) **Ongoing Informed Consent Comprehension (ICC-1)**

SAMPLE: DO NOT FAX TO DATAFAX

Visit Code ☐☐.☐ 1

MTN003 VOICE (160) ICC-1 (157)

Participant ID

☐☐☐-☐☐☐☐☐-☐

Site Number | Participant Number | Chk

Ongoing Informed Consent Comprehension

Visit Date

☐☐ dd ☐☐☐ MMM ☐☐ yy

Instructions: *For each VOICE Ongoing Informed Consent Comprehension Checklist item listed below, mark the "yes" box if a tick mark is present in the "yes" box on the completed checklist. Mark the "no" box if a tick mark is present in the "no" box on the completed checklist.*

	yes	*no*	***Comments:***
Item 1a	☐	☐	Item 1a _____
Item 1b	☐	☐	Item 1b _____
Item 2a	☐	☐	Item 2a _____
Item 2b	☐	☐	Item 2b _____
Item 2c	☐	☐	Item 2c _____
Item 3	☐	☐	Item 3 _____
Item 4	☐	☐	Item 4 _____
Item 5a	☐	☐	Item 5a _____
Item 5b	☐	☐	Item 5b _____
Item 6a	☐	☐	Item 6a _____
Item 6b	☐	☐	Item 6b _____
Item 6c	☐	☐	Item 6c _____
Item 7	☐	☐	Item 7 _____
Item 8a	☐	☐	Item 8a _____
Item 8b	☐	☐	Item 8b _____
Item 9	☐	☐	Item 9 _____
Item 10	☐	☐	Item 10 _____

For sub-items for which the participant is not able to demonstrate comprehension, provide education/counseling after the checklist has been administered.

Review of Data

- SCHARP will issue a data report for Protocol Team and study site for review
- Based on results, Protocol Team action may be needed for certain items
- Additional site-specific action may be needed for other items

Next Steps

- Translate questions on IC comprehension assessment checklist; send to FHI for review
- Protocol team will notify sites of the randomly chosen date that assessments will occur
- Further instruction will be provided throughout process

What are your questions?