Section 5. Informed Consent

This section provides information on informed consent procedures for MTN-003. MTN-003 involves three types of informed consent:

- Informed consent for screening
- Informed consent for enrollment
- Informed consent for long term specimen storage and possible future research testing

Potential study participants must provide written informed consent for screening in order to undergo protocol-specified procedures for determining eligibility. Potential participants who are found to be eligible must then provide written informed consent to enroll in the study. For enrolled participants, informed consent for long term specimen storage and possible future research is optional. Participants may choose not to consent to long term specimen storage and possible future research testing and still be enrolled in the study.

This section contains general information and instructions applicable to all three types of informed consent required for MTN-003. In addition, detailed guidance is provided for the standardized approach to the enrollment informed consent process that must be followed at all sites.

5.1 Overview of Informed Consent Requirements and Procedures

Informed consent is a process by which an individual voluntarily expresses her willingness to participate in research, after having been informed of all aspects of the research that are relevant to her decision. Informed consent is rooted in the ethical principle of respect for persons. It is not merely a form or a signature, but a process, involving information exchange, comprehension, voluntariness, and documentation. Each of these aspects of the process is described in greater detail below. Please also refer to Section 4.8 of the *International Conference on Harmonization (ICH) Consolidated Guidance for Good Clinical Practice* (GCP) and the informed consent section of the DAIDS policy on *Requirements for Source Documentation in DAIDS Funded and/or Sponsored Clinical Trials* for further guidance on the informed consent process and documentation requirements.

For MTN-003, informed consent is first obtained for screening procedures only. Then, for participants found to be eligible, informed consent is obtained for enrollment. For both screening and enrollment, informed consent must be obtained prior to undertaking screening and enrollment procedures, respectively. For enrolled participants, informed consent also must be understood as an ongoing process that continues throughout the study follow-up period.

Enrolled study participants are asked to provide informed consent for long term storage of blood and vaginal fluid specimens for possible future research testing. Under protocol Version 1.0, the specimen storage informed consent process must take place at the enrollment visit. At each site, after protocol Letter of Amendment #01 has been approved by all responsible institutional review boards and/or ethics committees (IRBs/ECs), the specimen storage informed consent process may be deferred to the Month 1, Month 2, or Month 3 visit. Participants may choose to not have their specimens stored for possible future research testing and still remain in the study.

US regulations (45 CFR 46) specify the elements of informed consent that must be conveyed to research participants through the informed consent process. It is the responsibility of the Investigator of Record (IoR), and by delegation all study staff involved in the informed consent process, to deliver all required information to potential study participants.

Based on the technical and regulatory reviews that are completed as part of the MTN protocol development and study activation processes, there is adequate assurance that once the MTN CORE has "activated" a site for study implementation, the site-specific informed consent form specifies all information required by the regulations. However, responsibility for informed consent does not end with preparation of an adequate informed consent form. It also is the responsibility of the IoR and designated study staff to:

- Deliver all required information in a manner that is understandable to potential study participants
- Assure that informed consent is obtained in a setting free of coercion and undue influence
- Confirm that the participant comprehends the information
- Document the process

If the participant is not literate (not able to read), an impartial literate witness must be present during the entire informed consent process/discussion with the participant. As part of the documentation steps detailed below, the witness will be asked to sign and date the informed consent form to attest that the information in the consent form was accurately explained to and apparently understood by the participant and that informed consent was freely given by the participant. ICH GCP guidance identifies an "impartial" witness as a person who is independent of the study, who cannot be unfairly influenced by people involved with the study. The MTN CORE has received guidance from the US Food and Drug Administration's GCP office stating that the witness need not be "totally unaffiliated with the study. It may be possible, for example, to designate a "subject advocate" who would be available at each site …" Refer to Section Appendix 5-1 for a summary of considerations for obtaining informed consent from illiterate participants.

When a witness is present during the informed consent process, care should be taken to minimize the perception of coercion due to the presence of the witness. For example, the purpose of having the witness present should be clearly explained to the participant, with emphasis on the fact that the witness is there as a protection for the participant, not as an agent of the study per se.

As a condition for study activation, each study site must establish an SOP for obtaining informed consent from potential study participants that ensures that all of the above-listed requirements are met. The SOP must be consistent with the DAIDS policy on *Requirements for Source Documentation in DAIDS Funded and/or Sponsored Clinical Trials*. It is recommended that the SOP contain the following elements (listed below) and that each site seek IRB/EC review and approval of the SOP:

- The minimum legal age to provide independent informed consent for research at the study site
- Procedures for determining participant identity and age
- Procedures for determining participant literacy
- Procedures for providing all information required for informed consent to the participant
- Procedures for determining participant comprehension of the required information
- Procedures to ensure that informed consent is obtained in a setting free of coercion and undue influence
- Procedures for documenting the informed consent process
- Considerations and requirements for illiterate participants, including specification of who may serve as a witness to the informed consent process
- Storage locations for blank informed consent forms
- Storage locations for completed informed consent forms
- Procedures (e.g., color-coding) to ensure that the many different study informed consent forms are easily distinguished and used appropriately
- Procedures for implementing a change in the version of the informed consent form used
- Staff responsibilities for all of the above (direct and supervisory)
- QC/QA procedures related to the above (if not specified elsewhere)

5.2 Informed Consent for Screening

At each site, the informed consent process for screening will be conducted according to site SOPs. Informed consent for screening must be obtained before performing any study screening procedures. For participants who do not consent to screening, no screening procedures should be performed and no data that can be linked to the participant's name or other personal identifier(s) should be recorded.

5.3 Informed Consent for Enrollment

At each site, the informed consent process for enrollment will be conducted according to site SOPs. However, site SOPs must reflect the standardized approach to the enrollment informed consent process that is described in this section. Informed consent for enrollment must be obtained before performing any "on-study" procedures. An overview of the standardized approach to the enrollment informed consent process is provided in Figure 5-1. Additional details related to key steps in the process are provided in the remainder of this section.

5.3.1 Informed Consent Process for Participants who Resume Study Participation After Voluntary Withdrawal

In the event a participant voluntarily withdraws from MTN-003 and wishes to re-join the study, she must undergo a re-consenting process to restart participation in the study regardless of any previously documented written informed consent. The two types of written informed consent for MTN-003 participants who are re-joining the study are:

- Informed consent for enrollment
- Informed consent for long term specimen storage and possible future research testing

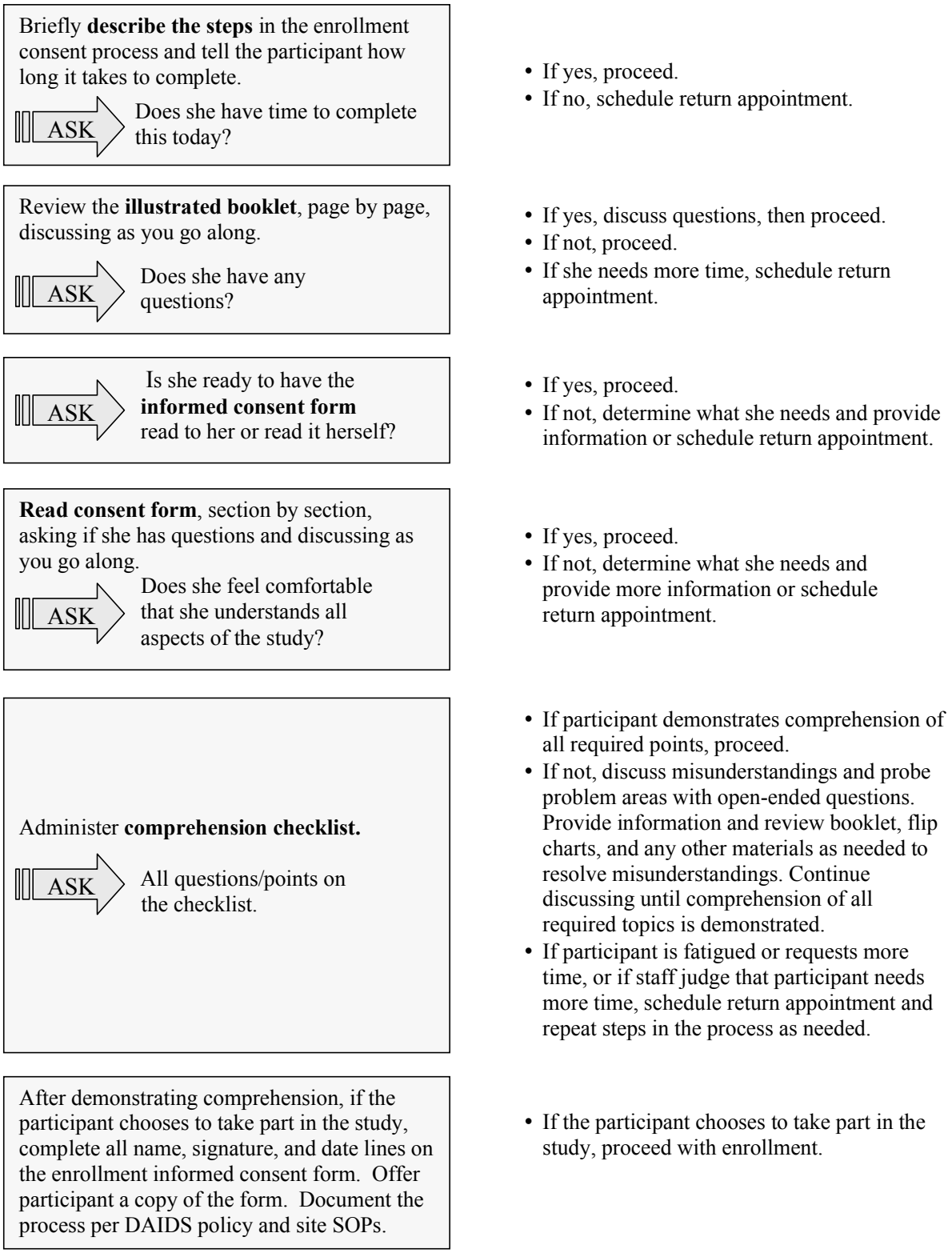
Written informed consent for enrollment must be obtained prior to any on-study procedures, including clinical procedures, and prior to any procedures to determine product use eligibility (see section 6.12). Written informed consent for long term specimen storage and possible future research testing is optional for participants re-joining the study. Participants may choose not to re-consent to long term specimen storage and possible future research testing and still re-join the study.

The documentation requirements for the new written informed consent documents are the same as the requirements for participants joining the study for the first time (See Section 5.5).

5.3.2 Informed Consent Support Materials

Site-specific informed consent forms: The informed consent forms used at all sites must be reviewed and approved by MTN CORE (FHI), study site IRBs/ECs and the DAIDS Protocol Registration Office prior to their use. After the forms are approved, each site is responsible for preparing bulk supplies of their approved forms and for only using the currently approved versions of the forms at all times during the study. It is recommended that all sites consider the use of color-coding or other techniques to ensure that the various study informed consent forms are easily distinguished and used appropriately.

Figure 5-1
Overview of MTN-003 Enrollment Informed Consent Process



MTN-003 Study Information Booklet: The illustrated informational booklet was developed to aid in introducing MTN-003 to potential study participants and in explaining the information contained in the enrollment informed consent form. The booklet contains information corresponding to the eight elements of informed consent that US regulations require to be conveyed in any informed consent discussion. The booklet does not substitute for the enrollment informed consent form, since additional site-specific details are provided in the informed consent form. Also, participants who decide to take part in the study must sign or mark the enrollment informed consent form (as described in Section 5.5).

Each site should determine how best to use the booklet with its study population, and specify the preferred approach in its SOP for obtaining informed consent for MTN-003. The booklet was designed to be given to women who have screened as eligible for the study, at least through Screening Part 1. The recommended approach for use of the booklet and an alternate approach are described below.

- **Recommended Approach:** When the time comes (per site SOPs) to begin the enrollment informed consent process, a study staff member will sit with the potential participant and first explain the purpose of the consent session. According to site SOPs, the participant will likely have received the booklet at a prior screening visit. If so, staff should begin the conversation by asking if she has reviewed the booklet and/or has any questions about it. Even if the potential participant previously reviewed the booklet, staff should read through it in its entirety to ensure all information was understood. Staff will decide if it is best to sit side-by-side, at a desk, and/or use the table top flip chart and other visual aids (described below) in addition to the booklet. The potential participant will be encouraged to ask questions throughout the reading. If the participant seems shy, embarrassed, or nervous, staff may ask her questions and/or engage in conversation about the illustrations, to set the tone for free discussion. For example, the illustration on page 2 of the booklet shows a group of people hearing about a study. Staff might ask the potential participant where she first heard about the study to help create rapport and make the participant feel more at ease.

  Staff should determine the potential participant's literacy level (per site SOP) and make adjustments accordingly. If a participant is deemed literate, she might be given time to read through the entire booklet on her own, and then she and the staff member would review the booklet page by page. If a participant is not literate, staff may choose to read each page word for word, and then discuss before going to the next page. For semi-literate participants, a page by page review may be appropriate, with staff paraphrasing the content. After the booklet has been reviewed and discussed, staff should ask if the participant has any additional questions or concerns before proceeding to reading the enrollment informed consent form.

- **Alternate Approach:** Sites may choose to read the enrollment informed consent form first, and then use the booklet to provide additional information or explanation. If reading the informed consent form first, staff may read section by section, with discussion as needed before moving to the next section. The booklet could then be used as a review or reinforcement of the information provided in the consent form. As in the recommended approach, adjustments should be made based on participant literacy levels.

MTN-003 Table Top Flip Chart: Table-top flip charts have been prepared based on the content of the informational booklet. The flip charts include the illustrations from the booklet as well as one additional illustration that is not in the booklet: an illustration of a woman having a pelvic exam. This illustration was not included in the booklet because of its more sensitive nature. However, since some participants may not fully anticipate what is required in a pelvic exam, it was felt that this illustration could be useful during the informed consent process.

The flip chart is intended to be used as a reference and review tool during informed consent discussions, to provide a brief overview or reminder when needed. The flip charts also may be used in group educational sessions as well as during ongoing informed consent discussions with enrolled study participants.

Additional pages can be added to the flip chart at the discretion of each site. Consideration should be given to adding the illustrated instructions for product use. Illustrations that demonstrate proper condom use, or a map to the site, also may be useful additions.

Visual Aids: Use of visual aids — in addition to the booklet and flip chart — is encouraged throughout the informed consent process to facilitate participant comprehension. Each site should determine the most appropriate visual aids for its study population and ensure that a "kit" containing each of these aids is available in each room where informed consent discussions take place. Sample study products and photographs of study products have been prepared as visual aids for each site. In addition to the visual aids decided upon at each site, it may be helpful to point out such things as a locked file cabinet, a referral clinic across the way, or a calendar on the wall. It is not necessary to use each visual aid with each participant. Study staff should use their best judgment of each participant's information needs and how best to address those needs.

Suggested visual aids for each site to consider using are as follows:

- Calendar
- Male and female condoms
- Sample gel applicators and cartons
- Sample tablet bottles
- Photographs of study products
- Urine specimen cup
- Blood collection tubes
- 5 L jug (to demonstrate the total blood volume in the human body)
- Vaginal and/or pelvic model
- Speculum
- Sample randomization envelopes
- Other randomization explanation visual aids (e.g., sack or box containing five items of different colors)
- Placebo explanation visual aids (e.g., sugar with and without vitamin A, hair gels with and without straightener, food flavoring sauces in sweet and non-sweet versions)

When using vaginal and pelvic models, remember that participants may not be familiar with such models. Introduce the models in a sensitive manner and use information, rapport, and humor to help make the participant feel comfortable with the models.

When using a vaginal model to demonstrate gel use, be sure to lubricate the sample applicator before insertion. If this is done while the participant is present, point out that women normally have some lubrication, and you are just adding some to the model to make it more realistic (you might also joke that it seems pretty realistic already). Hold the applicator at the end of the barrel and insert it as far as it will go or until your fingers touch the pelvic model. After inserting the applicator, point out that there is plenty of room for the applicator inside.

When using a pelvic model to demonstrate gel use, it may be necessary to first orient the participant to the model and the anatomical parts shown. Be sure that all staff who may use the model are able to explain what each part is. Point out that the vaginal opening starts at the outside edge of the plastic model.

Regardless of use of the vaginal and pelvic models, study staff who take part in informed consent discussions should be prepared to demonstrate the various insertion positions and "mime" the application of gel with two hands between their legs.

5.3.3 Comprehension Assessment

Study staff are responsible for determining whether potential participants comprehend all information required to make an informed decision about study participation before proceeding to make a final enrollment decision. The MTN-003 Enrollment Informed Consent Comprehension Checklist (see Section Appendix 5-2) will assist staff in assessing participant comprehension and targeting follow-up educational efforts to ensure that participants understand all information required to make an informed decision. The checklist is available as a separate electronic file in the Study Implementation Materials section of the MTN-003 web page.

The checklist will be administered to each potential participant after she has completed the informed consent discussions described above and before she is asked to sign or mark the enrollment informed consent form. The checklist should not be presented to participants as a "test," but rather as a way of double-checking that study staff have fulfilled their responsibility to provide all information needed for the participant to make an informed decision about enrolling in the study.

It is generally expected that the checklist will be administered by the same staff member who conducted the enrollment informed consent discussion with the participant; however, this is not required.

The checklist is structured around eight open-ended questions that correspond with the required elements of informed consent for research. Each question should be read to the potential participant, giving her time to respond to each one.

Each question should be satisfactorily answered by the participant before moving to the next question. For each question, the checklist specifies particular points that must eventually be included in the participant's response. These are identified on the checklist as "Required Points of Comprehension." When the potential participant mentions one of the required points, study staff should check off that point. If the participant does not mention one or more of the required points, study staff should follow-up with another open-ended question to elicit a response about that point. For example, one of the required points in item 1 is "study is testing a vaginal gel and two different tablets." If the potential participant does not mention this in her initial response to Question 1, the study staff member may then ask "Can you tell me about the products being tested in this study?" If the participant responds correctly, the point may then be checked off. All required points must be satisfactorily addressed by the participant, and checked off, before proceeding to the final informed consent decision and signing or marking of the enrollment informed consent form.

When responding to the various questions, potential participants may report back more information than is included on the checklist. This is acceptable, as long as the required information is reported back. However, if any misinformation is reported back, study staff should explain the correct information before proceeding to another question.

Once administration of the comprehension checklist discussion begins, it is possible that the participant may spontaneously mention many of the required points, without each separate question being asked. In these cases, study staff should check off the relevant points on the checklist and then ask the remaining questions, or probe about the remaining points. It doesn't hurt to ask a question that a participant may have already answered in her response to a previous question. However, if staff are confident that a previous response was adequate, the specific question and/or point does not need to be repeated.

It is expected that study staff administering the informed consent process and checklist will be sufficiently knowledgeable about MTN-003 to make good judgments about potential participants' comprehension of the required information. It is possible that a participant might repeat the correct information, yet the staff member may not be convinced that she really understands it. In these cases the staff should decide if further explanation or discussion is needed before proceeding to the final informed consent discussion and signing or marking of the informed consent form. The further explanation or discussion could take place at the same visit or at another visit.

Whenever additional information or explanation is needed, all of the informed consent support materials may be used. Study staff should decide which materials may be most helpful to each participant. Some potential participants may be more comfortable interacting with the same study staff person throughout the informed consent process. However, another staff member may be consulted, if necessary or desired, to help explain problematic concepts and/or respond to participant questions or concerns.

The comprehension checklist is considered a study source document that should be completed, handled, and retained in the participant's study chart like any other source document. After administering the checklist, study staff should carefully review the checklist to verify that all required points have been satisfactorily addressed by the participant and that this is adequately documented on the checklist (i.e., with a check mark beside each point). Consideration should be given to having two study staff members complete this verification because failure to document comprehension of all required points on the checklist will be considered an informed consent and enrollment violation.
Comments may be recorded in the designated column on the checklist (and on the back of the checklist if additional space is needed); however, this is not required. Lastly, after the enrollment consent process is completed, the final outcome of the process should be recorded in the bottom left corner of the checklist and the staff member who completed the checklist should ensure his/her signature is recorded in the space provided.

5.4 Informed Consent for Specimen Storage and Possible Future Research Testing

At each study site, the informed consent process for specimen storage and possible future research testing will be conducted according to site SOPs among enrolled study participants. Under protocol Version 1.0, the specimen storage informed consent process must take place at the enrollment visit. At each site, after protocol Letter of Amendment #01 has been approved by all responsible IRBs/ECs, the specimen storage informed consent process may be deferred to the Month 1, Month 2, or Month 3 visit. For participants who do not consent to specimen storage and possible future research testing, specimens collected and stored on-site per protocol will be retained until the study is completed and all protocol-specified testing has been done. Thereafter, any remaining specimens collected from these participants will be destroyed.

5.5 Documenting the Informed Consent Process

US regulations require that informed consent be documented by "the use of a written informed consent form approved by the IRB/EC and signed and dated by the subject or the subject's legally authorized representative at the time of consent."

To fulfill this requirement, complete all signature and date lines on the informed consent form in ink. Legal names should be used. Fabricated/falsified names should not be used. Initials may not be used in place of a participant's full surname, and it is strongly recommended that initials not be used in place of a participant's full first name. However, if a participant commonly signs her name using an initial for her first name, the initial may be used, provided this practice is acceptable per the policies of the study site institution(s).

On the informed consent form for specimen storage and future research testing, in addition to completing signature requirements as described above, the participant must indicate on the form whether she agrees to storage and future testing of blood specimens and to storage and future testing of vaginal fluid specimens.

If the participant is not literate, the witness who was present during the informed consent discussion must sign and date the informed consent form to attest that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the participant, and that informed consent was freely given by the participant. The participant's printed name, signature, and signature date lines on the informed consent form should be completed as described in Section Appendix 5-1.

The DAIDS policy on *Requirements for Source Documentation in DAIDS Funded and/or Sponsored Clinical Trials* lists detailed requirements and suggestions for documenting the informed consent process. All requirements listed in the DAIDS policy must be met. In order to also meet some of the suggestions listed in the DAIDS policy, site staff may use an informed consent "coversheet" similar to the sample included in Section Appendix 5-3. Sites choosing to use a coversheet should list the coversheet as a source document in their SOPs for source documentation for MTN-003 and should use the coversheet consistently to document all informed consent processes with all participants. The sample coversheet is available as a separate electronic file in the Study Implementation Materials section of the MTN-003 web page.

In addition to completing the documentation requirements on the informed consent form itself, each informed consent process must be documented in a signed and dated chart note. It is essential that the note and all other documentation (e.g., the informed consent form, the coversheet) document that informed consent was obtained before any study procedures were conducted. In particular, the documented date and end time of the informed consent process must precede the documented date and time of randomization. The chart note recorded to document the informed consent process should also document adherence to the requirements of the informed consent section of the DAIDS policy on *Requirements for Source Documentation in DAIDS Funded and/or Sponsored Clinical Trials*. If an informed consent coversheet is used, a chart note is still required, but it is not necessary to transcribe all information recorded on the coversheet into the chart note.

Regulations require that participants be given a signed copy of the informed consent forms. If a participant opts not to receive a copy, document this in a chart note and offer the participant an alternate form of study contact information (e.g., a contact card or appointment card) in lieu of the full informed consent form.

Section Appendix 5-1
Summary of Considerations for Obtaining Informed Consent from Illiterate Persons

- Each site must specify procedures for obtaining and documenting informed consent from illiterate persons in its SOP for obtaining informed consent. These procedures must be consistent with the DAIDS policy on *Requirements for Source Documentation in DAIDS Funded and/or Sponsored Clinical Trials* and must be followed each time informed consent is obtained. It is recommended that each site seek IRB/EC review and approval of these procedures.

- An impartial witness must be present during the entire informed consent discussion with an illiterate participant. The witness must sign and date the informed consent form to attest that the information in the consent form was accurately explained to, and apparently understood by, the participant, and that informed consent was freely given by the participant.

- The site SOP for obtaining informed consent should define who may serve as the witness to the informed consent process.

- Take care to minimize the perception of coercion due to the presence of the witness.

- Unless other conventions that have been endorsed by DAIDS are specified in site SOPs, the study staff member who completes the informed consent process/discussion with the participant should print the participant's name below the "participant's printed name" line, together with a signed and dated note documenting the name of the person who made the entry and the date of the entry (see Figure 5-2 below).

- The participant should make her mark on the "participant's signature" line.

- Unless other conventions that have been endorsed by DAIDS are specified in site SOPs, the study staff member who completes the informed consent process/discussion with the participant should enter the date upon which the participant made her mark on the informed consent form below the "participant signature date" line, together with a signed and dated note documenting the name of the person who made the entry and the date of the entry (see Figure 5-2).

- Refer to Section 4.8 of the ICH GCP guidance and the informed consent section of the DAIDS policy on *Requirements for Source Documentation in DAIDS Funded and/or Sponsored Clinical Trials*.

Figure 5-2
Example of Completion of Informed Consent Form Signature Lines for Illiterate Participants

SIGNATURES

Participant Name	Participant Signature	Date
Mary Phiri		**25 NOV 2009**

Participant name and date written by Martha Moore. MM 25 NOV 09

Martha Moore		**25 NOV 2009**
Name of Staff Person Conducting Consent Discussion	Study Staff Signature	Date

Debra Ross		**25 NOV 2009**
Witness Name	Witness Signature	Date

Section Appendix 5-2
Enrollment Informed Consent Comprehension Checklist

Name or PTID: **Date:**

	Open-Ended Question/Statement	Required Points of Comprehension	✓	Comments
1	**Please tell me your understanding of the purpose of the study.**	Testing a vaginal gel and two different tablets		
		Testing if gel and each tablet is safe to use (does not cause bad effects)		
		Testing if gel and each tablet may prevent getting HIV		
		Study may not show that gel or either tablet prevent getting HIV		
2	**Please tell me about the different groups of women in the study.**	There are different gels and tablets -- some have medicine and some do not		
		Some participants get gel and some get tablets		
		Some who get gel get gel containing Tenofovir, others get placebo gel (no medicine); some who get tablets get tablets containing Tenofovir or Truvada, others get placebo tablets (no medicine)		
		No one knows who gets which gel or which tablets		
3	**What are participants being asked to do in this study?**	Come for monthly clinic visits for up to three years		
		Depending on group -- insert gel in vagina or take two tablets by mouth every day		
		Have examinations and blood and urine tests, including monthly HIV and pregnancy tests		
		Use reliable family planning and not get pregnant while in the study		
		Not share gel or tablets with anyone else		
		Not take part in other studies		
4	**What are the possible risks for participants in the study?**	Gel or tablets may cause bad effects *(must mention at least one)*		
		Others may treat participants badly for being in the study (social harms)		
		Possibility of resistance to ARV medicines used in this study		
5	**What will happen if women decide not to join the study?**	Free to make her own decision about joining the study		
		No change to her access to health care whether she joins the study or not		
6	**How will information about participants in the study be protected?**	Information about participants is confidential, private, and locked away		
		Only people working on the study have access to her information		
7	**What are the possible benefits for participants in the study?**	Counseling, condoms, contraception, medical exams, tests, clinical care, helping to find ways to prevent getting HIV *(must mention at least one)*		
8	**What should participants do if they have questions or concerns about their health or about what is happening in the study?**	*Must state how to contact study staff*		

Outcome

☐ Demonstrated comprehension of all required points, decided to enroll in study.
☐ Demonstrated comprehension of all required points, decided NOT to enroll in study.
☐ Demonstrated comprehension of all required points, deferred enrollment decision.
☐ Did not demonstrate comprehension of all required points (yet), needs more time/discussion.
☐ Unable to demonstrate comprehension of all required points, consent process discontinued.
☐ Other (specify):_____

Staff Signature:

Optional Comment Codes

a. Answered correctly on first try
b. Could not answer at first but answered correctly with probing
c. Answered incorrectly at first but answered correctly after discussion
d. Not able to answer correctly at this time
e. Other (describe)

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Section Appendix 5-3
Sample Informed Consent Coversheet for MTN-003

Participant Name or PTID:	
Name of study staff person completing informed consent process/discussion (and this coversheet):	
Is the participant of legal age to provide independent informed consent for research?	☐ Yes ☐ No ⇒ STOP. Participant is not eligible for MTN-003.
Date of informed consent process/discussion:	
Start time of informed consent process/discussion:	
Language of informed consent process/discussion:	
Was the informed consent process/discussion conducted according to site SOPs for MTN-003?	☐ Yes ☐ No ⇒ Record and explain departures from site SOPs below.
Can the participant read?	☐ Yes ☐ No ⇒ A literate impartial witness should be present during the entire informed consent process/discussion. Refer to DAIDS policies and site SOPs for specific instructions. Record name of witness here: Record relationship of witness to participant here:
Version number/date of informed consent form used during informed consent process/discussion:	
Was all information required to make an informed decision provided in a language that was understandable to the participant?	☐ Yes ☐ No ⇒ Explain below.
Were all participant questions answered?	☐ Yes ☐ No ⇒ Explain below.
Did the participant comprehend all information required to make an informed decision?	☐ Yes ☐ No ⇒ Explain below.
Was the participant given adequate time and opportunity to consider all options, in a setting free of coercion and undue influence, before making her informed decision?	☐ Yes ☐ No ⇒ Explain below.
Did the participant choose to provide written informed consent?	☐ Yes ☐ No
Did the participant accept a copy of the informed consent form?	☐ NA (participant chose not to provide informed consent) ☐ Yes ☐ No ⇒ Offer alternative form of study contact information
End time of informed consent process/discussion:	
Notes/Comments (continue on back if needed):	
Signature of study staff person completing informed consent process/discussion (and this coversheet):	

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