Section 5. Informed Consent

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This section provides information on informed consent procedures for MTN-020. MTN-020 involves two types of informed consent:

1) Informed consent for screening
2) Informed consent for enrollment, which includes:

- Informed consent for off-site visits
- Informed consent for long term specimen storage and possible future research testing
- Informed consent for in-depth interviews (IDIs) and focus groups discussions (FGDs) (at sites participating in qualitative component of ASPIRE, per LoA #2)

Some sites may choose to use a separate informed consent form specifically for the consent of long term specimen storage and possible future research testing, off-site visits, or for IDIs/FGDs (if applicable). This section contains general information and instructions applicable to any informed consent required for MTN-020.

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.

US regulations (45 CFR 46.116) 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 (FHI 360) has activated a site for study implementation, site-specific informed consent forms specify all information required by the regulations. However, responsibility for informed consent does not end with preparation of an adequate informed consent form. It is the responsibility of the IoR and designated study staff to perform the following:

- 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

5.2 Site-Specific Informed Consent Forms

Sample informed consent forms (ICFs) are provided in the MTN-020 study protocol and, for the qualitative component of ASPIRE, sample language to add to the enrollment ICF is available in LoA #2. Sites are responsible for adapting the samples as needed for local use. Local adaptation may include reformatting the consent forms in accordance with local IRB/EC requirements, as well as translating the forms into applicable participant languages. Sites are responsible for following the procedures in the MTN Manual of Operations (MOP) Section 11.2 and the DAIDS protocol registration requirements when adapting and translating site-specific ICFs (see also SSP Section 3.6 of this manual regarding translations). Unless waived by the IRB, all adapted ICFs must still contain the eight required elements of informed consent as defined in 45 CFR 46.116. All ICFs (English, translated, and back-translations) must be reviewed and approved by MTN CORE (FHI 360) prior to IRB/EC submission. After ethics approval, ICFs must be submitted to the DAIDS Protocol Registration Office (DAIDS PRO) prior to their initial use.

Each site is responsible for preparing bulk supplies of their approved ICFs and for only using the currently approved versions of the ICFs 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. A strong system for tracking version control and approvals of ICFs is also recommended. Upon receiving final IRB/EC and any other applicable regulatory approval(s) for an amendment to the informed consent forms, sites should implement the consent forms immediately and submit updated versions to DAIDs PRO per the timelines outlined in the protocol registration manual.

5.3 SOP for Obtaining Informed Consent

As a condition for study activation, each site must establish an SOP for obtaining informed consent from potential study participants. This SOP should minimally contain the elements listed below. A template for this SOP is available from MTN CORE (FHI 360) by request.

- 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)

At each site, the informed consent process for screening, enrollment, off site visits, specimen storage, and IDIs and FGDs will be conducted according to site SOPs.

5.4 Informed Consent for Screening

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.

5.5 Informed Consent for Enrollment

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.

5.5.1 Informed Consent for Off-site Visits

Included in the informed consent for enrollment is a consent for off-site visits in which enrolled study participants are asked to provide informed consent for visits that may take place outside of the research clinic. Participants may choose not to be visited off-site or withdraw their consent for off-site visits at any time and still remain in the study. See SSP Section 6.4.3 for more information on conducting off-site visits.

Some sites may choose to separate the off-site visit ICF from the enrollment ICF, per IRB/EC requirements or site preference. A sample stand-alone ICF for off-site visits is available upon request

from MTN CORE (FHI 360). Regardless of whether the Off-site Visit ICF is a stand-alone form or included as part of the Enrollment ICF, informed consent for off-site visits should be conducted at the enrollment visit.

5.5.2 Informed Consent for Specimen Storage and Possible Future Research Testing

Enrolled study participants are asked to provide informed consent for long term storage of blood and vaginal fluid specimens for possible future research testing. Participants may choose to not have their specimens stored for possible future research testing or withdraw their consent for specimen storage at any time and still remain in the study.

For participants who do not consent to specimen storage and possible future research testing, all specimens are still collected and stored on-site per protocol requirements. These specimens will be retained until the study is completed and all protocol-specified testing has been done. Thereafter, any remaining specimens already collected from these participants will be destroyed. Participants who provide consent to specimen storage and possible future research testing are allowing for the remaining (leftover) samples to be kept and not destroyed at the end of the study.

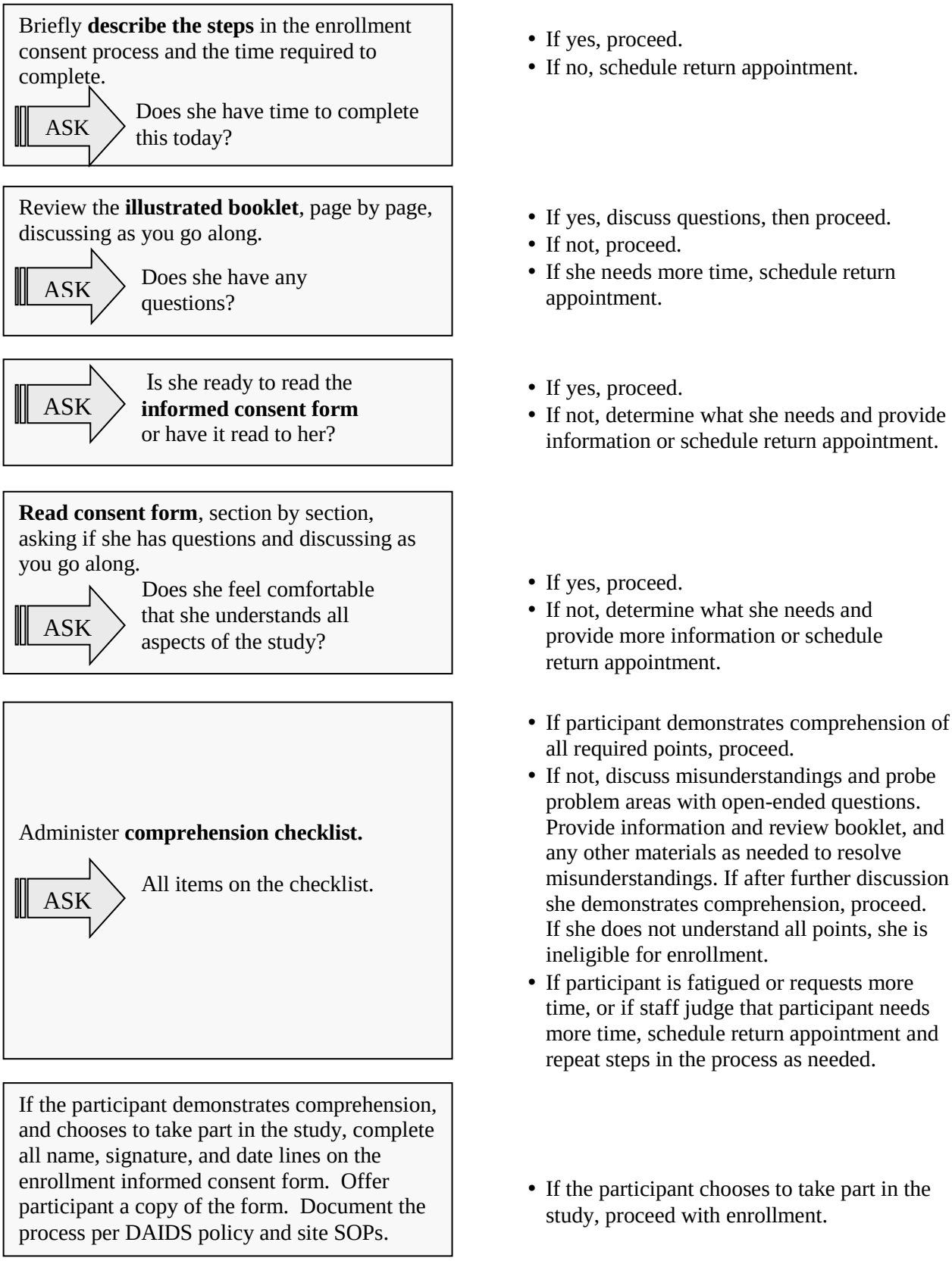
Some sites may choose to separate the specimen storage ICF from the Enrollment ICF, per IRB/EC requirements or site preference. A sample stand-alone ICF for specimen storage and possible future research testing is available upon request from MTN CORE (FHI 360). If the Specimen Storage and Possible Future Research Testing ICF is included as part of the Enrollment ICF, it should be conducted at the time of enrollment; if the site has chosen to use a stand-alone form, informed consent should be conducted either at the time of enrollment or at the Month 1 visit.

5.5.3 Informed Consent for IDIs and FGDs

Sites who participate in the qualitative component of the ASPIRE study (per LoA#2) will need to obtain informed consent for IDIs and FGDs from participants prior to conducting these procedures. LoA #2 includes sample language to include in the enrollment informed consent for the qualitative component. Key elements of the qualitative informed consent should be reviewed with participants prior to the first interview, and willingness to continue should be confirmed. This review/confirmation can be documented on visit checklists (and chart notes as needed).

Some sites may choose to separate the qualitative ICF from the enrollment ICF, per IRB/EC requirements or site preference. A sample stand-alone ICF for off-site visits is available upon request from MTN CORE (FHI 360). At these sites, only participants selected for an interview (serial IDI, single IDI, or FGD) will be approached for informed consent for the qualitative component. This consent should be done prior to the start of the interview for single IDIs and FGD, and prior to the start of the first interview for serial IDIs. Further details on the qualitative component can be found in SSP Section 18.

Figure 5-1
Overview of MTN-020 Enrollment Informed Consent Process



5.6 Considerations for Obtaining Informed Consent from Illiterate Persons

Illiterate participants can be consented and enrolled in ASPIRE, providing they are otherwise willing and eligible and if independent consent is ensured. Site SOPs must outline the process for assessing participants for literacy and how independent consent is ensured for participants who are not literate. If the participant is illiterate (not able to read), an impartial literate witness who speaks the language of the participant must be present during the entire informed consent process/discussion with 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." The site SOP for obtaining informed consent should define who may serve as the witness to the informed consent process.

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.

Section 5.9 describes documentation guidelines for illiterate participants.

5.7 Informed Consent Support Materials

5.7.1 MTN-020 Informed Consent Booklet

The illustrated informational booklet was developed to aid in introducing MTN-020 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.

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-020. The booklet was designed to be given to women at their Screening visit for review prior to their Enrollment visit. The participant should be encouraged to take the booklet home for review before her enrollment visit and to share with people who are important to her.

5.7.2 MTN-020 Table Top Flip Chart

Table-top flip charts are available for site use if requested from the MTN CORE (FHI 360) and are based on the content of the informed consent booklet mentioned above. 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.

5.7.3 Fact Sheets

Fact sheets have been developed for MTN-020 and are available in the *Study Implementation Materials* section of the MTN-020 web page for use with participants, partners, and community members, as study staff deem appropriate. These fact sheets include information on condoms, male circumcision, HIV resistance, the ASPIRE study, and the dapivirine and placebo vaginal rings. Factsheets should be translated into local languages as appropriate and IRB/EC approved before use. These fact sheets can be used during the informed consent process, or any other time throughout the

study once they are approved for use. Information contained in the factsheets should be reviewed with all participants prior to enrollment (randomization) in the ASPIRE study.

5.7.4 Other Informed Consent Visual Aids

Use of visual aids — in addition to the booklet and fact sheets — 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 supplemental study illustrations have been provided to each site to use as visual aids. 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 may not be 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 vaginal ring and packaging
- Urine specimen cup
- Blood collection tubes
- 5 L jug (to demonstrate the total blood volume in the human body)
- Vaginal and/or pelvic model or illustrations
- Speculum
- Other randomization explanation visual aids (e.g., sack or box containing two 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). Visual aids to explain placebos should look identical to each other.

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. If using a pelvic model to demonstrate ring placement, it may be necessary to first orient the participant to the model and the anatomical parts shown. Point out that the vaginal opening starts at the outside edge of the plastic model. Be sure that all staff members that may use the model are able to explain what each part is and, if demonstrating ring use, are able to insert and remove the ring with ease using the 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 insertion of the ring.

5.8 Comprehension Assessment

The participant must not be asked to agree to take part in the screening/study, or to sign the informed consent form, until she fully understands the screening process and the study. Site SOPs should explain the procedures that study staff members are responsible for implementing to ensure that each participant understands the screening process and the study prior to signing the screening and enrollment informed consent forms, respectively, and undertaking any screening or study procedures.

The MTN-020 Enrollment Informed Consent Comprehension Checklist (see Section Appendix 5-1)

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 ASPIRE web page. Note that use of this comprehension checklist for enrollment is required. 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. It is expected that study staff administering the informed consent process and checklist will be sufficiently knowledgeable about MTN-020 to make good judgments about potential participants' comprehension of the required information. 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. If any misinformation is reported back, study staff should explain the correct information before proceeding to another question.

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 process deviation.

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. 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.

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.

While an informed consent comprehension checklist is not required at Screening, or during other consent processes (for off-site, specimen storage or the qualitative component if these are stand-alone ICFs), assessment of comprehension must still be performed prior to the participant signing the informed consent form. Sites may develop similar comprehension tools to be used for these other informed consents, but this is optional. All comprehension checklists should be translated into local language(s) (bolded left hand column questions only) and submitted to local IRB/ECs for approval prior to use. Detailed information for how comprehension will be assessed must be specified in the site SOP for obtaining informed consent.

If any of the assessment results indicate misunderstanding of certain aspects of the study, review those aspects again until the participant fully understands them. If after all possible efforts are exhausted, the participant is not able to demonstrate adequate understanding of the study, do not ask her to sign the informed consent form or screen /enroll in the study. Similarly, if the participant has concerns about possible adverse impacts on her if she were to take part in the study, or indicates that she may have difficulty adhering to the study requirements, do not ask her to sign the informed consent form to screen/enroll in the study. Staff should document any questions or discussions that take place during the consent process according to Section 5.9 and their site's SOP guidelines.

5.9 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, sites should comply with the guidance provided in the DAIDS SOP on Source Documentation. Complete all signature and date lines on the informed consent form in dark 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).

If a participant signs her name in a form that deviates from the specifications listed above (e.g. she uses initials for both her first and last names, or signs only using her first name), document in the research record that the name/initials/mark as written deviates from the DAIDS policy, but represents her signature as she wrote it. Sites may choose to use a standard memo to document these deviations, provided the memo has been approved for use by the site's OCSO representative.

On the enrollment informed consent form, in addition to completing signature requirements as described above, the participant must indicate on the form whether she agrees to off-site visits, storage and future testing of biological specimens, as well as the qualitative components of ASPIRE, if applicable (unless the site has chosen to create stand-alone ICFs for these topics, in which case these forms should be completed separately). The participant may decline any of these options and still enroll in MTN-020.

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, in the participant's language of fluency, 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 and illustrated in Figure 5-2. Following these procedures fulfills the protocol requirement for obtaining written informed consent from all study participants.

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

- 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 and date of informed consent below the "participant's printed name" and "date" line, respectively, together with a signed and dated note documenting the name of the person who made the entry and the date of the entry.
- The participant should add her fingerprint or make her mark above the "participant's signature" line.
- The witness will print, sign, and date in the section designated for "Witness"

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

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 each time an ICF is signed. In order to also meet some of the suggestions listed in the DAIDS policy, site staff are strongly encouraged to use an Informed Consent Coversheet similar to the sample included in Section Appendix 5-2. Sites choosing to use a coversheet should list the coversheet as a source document in their SOPs for source documentation for MTN-020 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 ASPIRE web page. The first half of the coversheet (items up to and including "Version number/date of informed consent form used during informed consent process/discussion:") should be completed at the start of the IC session. The remainder should be completed at the end of the informed consent session. If a site chooses not to utilize the Informed Consent Coversheet, all elements of each informed consent process must be documented in a signed and dated chart note.

It is essential that all informed consent documentation (e.g., the informed consent form, the coversheet) document that informed consent was obtained before any study procedures were conducted.

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 on the cover sheet or 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.

5.10 Reconsenting Requirements and Procedures

If updates to the ASPIRE ICFs are required at any time throughout the study, revisions should be submitted to MTN CORE (FHI 360) for review and approval prior to IRB/EC submission. If ICF changes are made, the study management team and IRB/EC will help determine whether reconsenting is required. Regulatory files should be updated to reflect any determinations made regarding reconsenting requirements.

5.10.1 Reconsenting Requirements for Minor Modifications, LoAs, and Per Participant Request

When reconsenting of participants is required due to minor modifications or new information contained in an LoA, the consenting procedures may be abbreviated. The staff member conducting the informed consent session should review the changes made to the ICF with the participant, but does not need to read or review the entire consent form again.

Similar procedures should be conducted for participants who change their mind about participating in the optional components of the ASPIRE study, namely off site visits, long term specimen storage, and the qualitative component. Using the most current version of the appropriate ICF, review the information pertinent to the participant's decision (e.g. If a participant who previously declined off site visits later indicates that she would like to take advantage of this option, review the information on off site visits contained in the relevant ICF). If the current ICF differs in any way from the version the participant originally signed, these changes should be reviewed with her as well. Note that any time reconsenting procedures are being conducted using an enrollment informed consent that contains signature blocks for off site visits, specimen storage, and/or IDIs and FGDs, all items should be reviewed and re-signed based on the participant's current preferences. The signature lines at the end of the consent for participant, staff, and witness (if applicable) must also be completed in full.

Although a comprehension checklist does not need to be completed in the circumstances described above, participant understanding should be assessed and all participant questions should be answered prior to signing the new consent form. Once comprehension has been evaluated and ensured, documentation of informed consent should be conducted per SSP section 5.9. The participant should be offered an updated, signed copy of the ICF to take home.

5.10.2 Reconsenting Requirements for Protocol Version Changes

If reconsenting of participants is required due to a protocol version change, a complete review of the ICF must be conducted. When changes to the enrollment ICF have been made as a result of protocol version changes, a new comprehension checklist must be completed. Documentation of informed consent should be conducted per SSP section 5.9 and participants should be offered an updated, signed copy of the ICF to take home.

5.10. 3 Informed Consent Process for Participants who Resume Study Participation After Terminating Early

In the event a participant is terminated early from MTN-020 and then is able to re-join the study, she must undergo a re-consenting process which includes a complete review of the enrollment ICF to restart participation in the study regardless of any previously documented written informed consent.

For participants resuming study participation, written informed consent for enrollment must be obtained prior to any study procedures, including clinical procedures, and prior to any procedures to determine product use eligibility (see Section 6.9). Participants rejoining the study should also undergo informed consent procedures for off-site visits, long term specimen storage and possible

future research testing, and IDIs and FGDs, however, they may decline participation in these elements 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 5.9).

5.11 Ongoing Assessment of Participant Comprehension

For enrolled participants, informed consent also must be understood as an ongoing process that continues throughout the study follow-up period. Periodically, at study visits, staff should assess participants' comprehension using a discussion style similar to the enrollment assessment. The key elements of informed consent also should be reviewed at study follow-up visits. Sites may choose to review key elements of informed consent with individual participants, or in group sessions. Elements of informed consent can be reviewed at every visit, or periodically, as per site SOPs. Reviewing key elements of informed consent during follow-up visits may focus on the remainder of study participation. Some routine study assessments (e.g. the prevention study experiences CRF) may also identify gaps in participant understanding about the study. In these situations, staff should provide counseling or additional education as needed to clarify potential misunderstandings, especially those that impact participant safety.

For example, for participants being followed for 12 months, at study month 1, the discussion might focus on the fact that the participant has completed the first month, and therefore has about 11 remaining months. Study staff might review that this visit will include a check on the ring placement, that each study visit will include an HIV test, and that the participant should feel free to express questions or concerns about the study at any time. These informal assessments will help to identify aspects of the enrollment informed consent process that are, and are not, optimally effective for study participants. The assessments also may identify rumors or misperceptions about the study that require a response by the Protocol Team, either across sites or on a site-by-site basis. This discussion should be noted in the participant's chart note for that visit date.

Section Appendix 5-1
MTN-020 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 if vaginal ring is safe to use		
		Testing if vaginal ring may prevent getting HIV		
2	**Please tell me about the different groups of women in the study.**	Women will receive one of two different vaginal rings -- some have study medication and some do not		
		Women can not choose their group		
		No one knows who receives which vaginal ring		
3	**What are participants being asked to do in this study?**	Wear a vaginal ring for about 1-2 years		
		Come for monthly clinic visits for about 1-2 years		
		Have examinations and blood and urine tests, including monthly HIV and pregnancy tests		
4	**What are the possible risks for participants in the study?**	Pain or discomfort in genital area or other side effects, discomfort from exams or blood draws, potential HIV drug resistance *(must mention at least one)*		
		Others may treat you badly for being in the study (social harms)		
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)

Section Appendix 5-2
Sample Informed Consent Coversheet for MTN-020

Type of Informed Consent: _____

PTID:	
Name of study staff person completing informed consent process/discussion (and this coversheet):	
Date of informed consent process/discussion:	
Start time of informed consent process/discussion:	
Participant choice of language for the IC process and written ICF:	
Is the participant comfortable/fluent in other language(s) that are used at this CRS for ASPIRE?	☐ Yes: (List) _____ ☐ No
Is the participant of legal age to provide independent informed consent for research?	☐ Yes ☐ No ⇒ STOP. Participant is not eligible for MTN-020.
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:	
Were all participant questions answered?	☐ Yes ☐ No ⇒ Explain below. ☐ NA (participant had no questions)
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:	
Was informed consent signed prior to conducting study procedures listed in the ICF?	☐ Yes ☐ No ⇒ Explain below.
Notes/Comments (include any deviation from SOP; continue on back if needed):	
Signature of study staff person completing informed consent process/discussion (and this coversheet):	