Section 6. Participant Follow-up

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This section provides information on requirements and study visit procedures for participants in follow-up. Additional procedure-specific details can be found in the visit checklists in Section 7 of this manual. Also see Section 9 for all product-related guidance, Section 10 for clinical procedures, Section 12 for counseling procedures, Section 13 for laboratory-related procedures and Section 14 for data management.

6.1 Study Follow-up Plan and Participant Retention Targets

After enrollment, each enrolled participant will be followed until approximately 120 events (HIV-1 seroconversions) are observed; it is anticipated that the first enrollees will have 24 months or more of follow-up and the last enrollees at least 12 months. To minimize bias and ensure accuracy of study results, each study site will target a 95% per-visit retention rate. Further information on MTN-020 retention definitions and procedures is provided in Section 8 of this manual.

6.2 Types of Follow-up Visits

Throughout study follow-up, the following types of visits will be conducted:

- **Scheduled visits** are those study visits required per protocol. The protocol specifies that follow-up visits are targeted to occur approximately every 28 days for the duration of the study. Types of scheduled follow-up visits for MTN-020 include:

    - Monthly
    - Quarterly
    - Semi-Annual
    - Product Use End Visit (PUEV)
    - Study Exit/Termination

- **Interim visits** are those visits that take place between scheduled visits. There are a number of reasons why interim visits may take place including, but not limited to:

    - For product-related reasons, e.g., a participant may need a replacement vaginal ring or want to discuss problems with adherence to product use.
    - In response to AEs, SAEs or social harms.
    - For interim STI counseling and testing in response to STI symptoms, or interim HIV counseling and testing in response to presumed exposure to HIV.

All scheduled and interim visits will be documented in participants' study records and on applicable CRFs. Site staff should also refer to Section 14 for details about visit scheduling, visit windows, and visit codes for scheduled and interim visits.

6.3 Follow-up Visit Locations

MTN-020 study visits will typically be completed at the study clinic. When necessary, follow-up visits may be conducted off-site at the participant's home or location suitable to the participant with documented participant consent and allowable per site-specific SOPs. See Section 6.4.3 for more information on the conduct of off-site study visits.

6.4 Follow-up Visit Procedures

Required follow-up visit procedures are listed in protocol Sections 7.4 and 7.5 and Appendix I. Several additional clarifications of the procedural specifications are provided in the

remainder of this section. Further operational guidance on completing protocol-specific procedures at follow-up visits is incorporated into the visit checklists which are included in Section 7 of this manual. Sites participating in the qualitative component of ASPIRE (per LoA#2) should reference SSP Section 18 for details regarding In-depth Interviews (IDIs) and Focus Group Discussions (FGDs).

As a general guide:

- **Monthly** visit procedures include:

  - Review/updating locator information, visit scheduling, and reimbursement
  - Ring adherence assessment
  - HIV pre- and post-test and HIV/STI risk reduction counseling, including provision of condoms (See SSP Section 12)
  - Contraception counseling and, if needed, provision of contraception (Section 12)
  - Interval medical/menstrual/medication history including recording/updating any adverse events (AEs) (Section 10)
  - If needed, a physical and/or pelvic exam (Section 10)
  - HIV serology, urine pregnancy testing, and collection of a self-administered vaginal swab (Section 13; Section 10 for guidance on how to collect the vaginal swab)
  - Provision of all available test results and treatment or referrals for UTI/RTI/STIs.
  - Collection of used ring and provision of new ring for insertion, ring insertion instructions (as needed), and adherence counseling (Sections 9 and 12)
  - If needed, a digital exam to check ring placement (required at month 1)
  - Collection of used vaginal rings for storage and future testing (Sections 9 and 13)
  - If per site practice, provision of bottled water

- **Quarterly** visit procedures include <u>all monthly visit procedures</u>, plus:

  - ACASI (Month 3 visit only; Section 16)
  - Behavioral and acceptability assessments (Section 14)
  - Social harms assessment (Sections 11 and 14)
  - Physical exam (Section 10)
  - Blood for serum chemistries, CBC with platelets and plasma storage (Section 13)
  - Administration of Prevention Study Experiences (PSE) CRF at Month 3

- **Semi-Annual** visit procedures include <u>all quarterly visit procedures,</u> plus:

  - Pelvic exams, including pelvic sample collection and rapid test for Trichomonas (Section 10)
  - Urine NAAT for GC/CT (Section 13)
  - Administration of Prevention Study Experiences (PSE) CRF at Month 12

While conducting all visit procedures for each scheduled visit is ideal, it is acknowledged that this might not always be possible. At a minimum, all of the following procedures must be conducted in order to dispense study product:

- AE assessment and reporting (verbal report of symptoms is acceptable; if symptoms indicate that further evaluation is necessary, this must be conducted prior to dispensing study product)
- HIV testing and counseling (including risk reduction counseling) and pregnancy testing are required for product dispensation if this has not been done at the research clinic within the past 60 days
- Collection of Used Ring (and unused, if applicable), if available
- Adherence Counseling/Product Use Instructions, as needed

See Section 9 for more information about study product dispensation.

6.4.1 Split Visit Procedures

All procedures specified by the protocol to be performed at a particular follow-up visit ideally will be completed on a single day. In the event that all required procedures cannot be completed on a single day (e.g. a participant must leave the study site before all required procedures are performed), the remaining procedures may be completed on subsequent day(s) within the visit window. When this happens, it is referred to as a "split visit" (required visit procedures are split across more than one day within the visit window). Split visits are permitted for any type of follow-up visit in MTN-020. For more information on visit codes for split visits see SSP Section 14; for study product considerations during split visits see Section 9.8.

Note that while a visit may be split, individual procedures should not be split. For example, HIV pre and post-test counseling and HIV testing should all occur on one day. ACASI questionnaire completion should also occur all on one day and not split across days. Guidelines in Section 7.2 regarding sequence of procedures should also be followed for split visits.

6.4.2 Missed Visits

If no procedures of a scheduled visit are conducted within the visit window a Missed Visit CRF is completed and faxed to SCHARP. Section 14 gives detailed information regarding the completion of the Missed Visit form. Section 9.9 provides guidance on study product considerations around missed visits.

If a quarterly or semi-annual visit is missed, the following procedures should be completed at the participant's next clinic visit (scheduled or interim):

<u>When a Quarterly visit is missed:</u>

- Physical exam
- Complete blood count with platelets
- Blood chemistries
- Plasma storage

<u>When a Semi-annual visit is missed (in addition to the list above):</u>

- Pelvic exam and pelvic sample specimens
- NAAT for GC/CT

Only the procedures listed above are required to be made-up at subsequent visits. Data from questionnaires (e.g. behavioral assessment CRFs, and ACASI questionnaires) will not be made-up.

6.4.3 Off-site Visit Procedures

MTN-020 protocol Section 7 specifies that visit procedures may be conducted off-site with participant consent. Note that it is generally expected that regularly scheduled study visits will be conducted at the study clinic, and off-site visit procedures should occur infrequently. While there is no formal restriction, sites should aim to do no more than 3 consecutive off-site visits for a participant due to the inability to complete full safety evaluations (e.g. physical and pelvic exams) during these visits. Off-site visit procedures are distinct from participant contacts made for the purposes of retention/tracing or to collect product in response to a product hold/discontinuation; these procedures are described separately in SSP Section 8 and Section 10, respectively.

This section describes requirements which must be met prior to implementation of off-site visits, as well as situations which may warrant an off-site visit and what visit procedures will be permitted. It is strongly suggested that sites include the option of off-site visits for a defined set of reasons and procedures based on site capacity thus ensuring advance preparation to respond to adherence and/or retention issues. Site-specific procedures for off-site visits should be described in site SOPs.

6.4.3.1 Informed Consent

Off-site visit procedures (excluding site procedures for retention efforts and product collection due to product hold) may only be conducted if the participant has provided written consent to be visited by study staff outside of the clinic. Sample text for off-site visit consent is included within the sample enrollment informed consent form. Should local IRB/ECs require a separate informed consent to conduct off-site visits; a template will be provided on request from MTN CORE.

During the administration of the informed consent for off-site visits, sites should discuss with participants any issues that may jeopardize participant confidentiality and/or safety, such as living situation (e.g. persons living with participant, availability of private space at participant's home or place of work). Also, in an effort to minimize the potential risk of social harm to participants and to study staff who will conduct off-site visits, discuss with participants whether they have disclosed participation in the study to family, neighbors, or others who may learn of these off-site visits. Where participation has not been disclosed, maximal effort should be made to ensure inadvertent unwanted disclosure does not occur as a consequence of the off-site visit.

Each time an off-site visit is warranted, clinic staff must verify consent for off-site visits. When communicating with participants ahead of off-site visits, when possible, the rationale and the procedures to be conducted for the visit should be clearly explained to her as well as the approximate time that will be needed to complete the required procedures. Every effort should be made to ensure that the time and location is convenient for the participant.

6.4.3.2 Reasons for Conducting Off-Site Visits

Site leadership should use good clinical judgment and discretion when determining that an off-site visit is needed for a particular participant. Examples of situations which may warrant an off-site visit for MTN-020 include, but are not limited to:

- Participant does not have time or is unable to come to the clinic for the visit
- Follow-up on an adverse event/ serious adverse event
- Collect samples that were inadequately collected or inadvertently missed at scheduled visits or compromised in transit to or at laboratory
- Collect confirmatory HIV samples
- Provide study product (for example, if the ring fell out somewhere dirty and cannot be reinserted; or the participant had to leave the clinic without receiving study product)
- Follow-up on a participant who:
  - is unable to come to the clinic and may potentially fall outside of the visit window for the current visit
  - has voluntarily withdrawn from the study, but is willing to have a final HIV test/ pregnancy test/ safety bloods drawn off-site

6.4.3.3 Permitted Locations, Visit Types, and Procedures

Off-site visits may occur at a participant's home or at other appropriate venues, provided that both participant and staff are comfortable with the venue and provided that safety and confidentiality can be maintained.

Any type of follow-up visit (i.e. interim, monthly, quarterly, semi-annual, PUEV, study exit/termination) may be conducted off-site. Generally, the required visit procedures should remain largely the same as they would for an in-clinic visit. However, it is recognized that some procedures may need to be modified or omitted due to limited capacity to conduct them off-site. For example, ACASI and physical exams (or some elements of the exam) may be omitted for quarterly visits, and pelvic exams may be omitted for semi-annual visits. Site staff should document within participants records which visits were conducted off-site and what procedures were omitted or modified as a consequence (if any). As with any visit (in-clinic or off-site), participants have the right to decline/refuse completing any study procedures; site staff should clearly document refusals in the participant chart. Required visit procedures that are not conducted during an off-site visit are required to be made up and will be handled the same way as procedures missed for an in-clinic visit of the same type (see Section 6.4.2). If possible, it is best if the participant could come to the clinic later in the visit window to finish these procedures (and a split visit conducted).

The minimum procedures required to dispense study product from site pharmacy and deliver during at an off-site visit are the same as listed in Section 6.4 above for in-clinic visits.

NOTE: Per protocol, the IoR may use his/her discretion to provide up to one additional ring. This provision may occur in the clinic, or be delivered to the participant as an interim off-site visit. In this situation, provided that safety tests (e.g. HIV testing, pregnancy testing) were conducted within the last 60 days, the only procedures that need to take place are AE assessment and recording (this can be based on participant-report), and adherence

counseling/product use instructions, as needed. However, as with in-clinic visits, it is best to conduct as many of the scheduled visit procedures as feasible when off-site.

6.4.3.4 Off-Site Visit SOP Requirements

Sites interested in conducting off-site visits must complete certain requirements such as IRB approval and SOP development, prior to implementation of such visits. Sites are encouraged but not required to prepare for off-site visits as a part of the study activation process. If sites do not include this as a part of their activation procedures for MTN-020 and decide to implement off-site visits at a later stage, sites should contact the MTN-020 management team (mtn020mgmt@mtnstopshiv.org) and begin completing the requirements outlined below. Completion of these requirements will be overseen by the management team. No sites should implement off-site visits without completing all requirements and receiving a notification from the MTN-020 management team to initiate implementation.

Considerations that should be addressed in the SOP for off-site visits are as follows:

- Feedback and operational suggestions received from the MTN 020 Community Working group and Sites Community Advisory Board or Group as relevant with regard to conducting off-site visits.
- Procedures for contacting and scheduling participants for off-site visits.
- Procedures for verifying participants' consent prior to conducting off-site visits.
- Procedures to protect the safety of study staff, participants and any family members present during off-site visits, as well as confidentiality of participants.
- Identification of staff member roles and responsibilities for off-site visits:
    - In general, most off-site visits will require two staff members, including one who is able to provide clinical assistance in case of symptoms or AEs, perform phlebotomy, conduct and verify rapid tests results and assist with specimen processing
    - Ensure that at a minimum one of these staff members are conversant in the language of choice of the participant
    - Ensure that these staff members are thoroughly versed in confidentiality and pharmacy and lab chain of custody issues
    - Procedures for management of symptoms/illness requiring medical attention. Specifically, procedures for management of positive pregnancy tests, positive or discordant HIV rapids, STI symptoms, contraceptive use and potential SAE/EAE, as well as provision of any necessary referrals should be described.
        - NOTE: If genital symptoms are reported during an off-site visit, the participant should be asked to report to the clinic as soon as possible for a pelvic exam.
    - Generally, if any issues requiring further follow-up arise at an off-site visit, the participant should be referred (or brought) to the clinic as soon as possible for further evaluation. Depending on the severity of the issue, site staff may need to transport participant immediately from the off-site visit to the clinic or nearest healthcare facility.
- Description of how routine participant identification procedures will be modified for off-site visits.
- List of materials and supplies that will be needed for an off-site visit.

Lab considerations:

Sites may perform off-site visits to collect specimens for transport to an outsourced or site laboratory or to perform rapid HIV testing and urine pregnancy testing at the off-site location. Prior to off-site specimen collection or testing, sites must submit SOPs to the MTN LC and DCLOT to obtain authorization. It is recommended that the primary site SOP for off-site visits reference existing laboratory SOPs when possible, and these SOPs include components on off-site procedures (for example, performing HIV rapid tests and pregnancy tests off-site).

Considerations for collection of specimens for transport to an outsourced and on-site laboratory:

- Chain of custody, for specimens to be transported from off-site visits
- Safety considerations, including details on how biological specimens and bio-waste will be handled and procedures to prevent and respond to specimen accidents
- Adhering to allowable time intervals to get specimens to testing laboratories
- Specimen handling and transport methods
- All HIV rapid tests must have face-to-face post-test counseling conducted on the same day the test was conducted
- Equipment and supplies

Considerations for testing performed in an off-site location:

- Source documentation for test results
- Staffing: 2 staff members qualified in HIV rapid testing will be required to perform and review HIV testing results
- Safety considerations, including details on how biological specimens and bio-waste will be handled and procedures to prevent and respond to specimen accidents
- Equipment and supplies
- Appropriate area in off-site location to perform testing

NOTE: Staff should follow the same procedures specified in section 6.5 below in the event of a possible seroconversion (i.e. a positive rapid HIV test) identified during an off-site visit. If possible and agreed upon by the participant, sites should offer immediate transport to clinic for directed post-test counseling, blood sample collection for seroconversion, and used study product collection for storage and future testing.

Source Document considerations:

- No *completed* CRFs or other source documents should leave the study clinic. Blank CRFs and blank chart note pages should be taken off-site to allow visit documentation to occur in real time.
- Staff notes (summarizing source documents in the binder) may be necessary to follow up on AEs/symptoms/contraceptive use documented at the last visit. These may be *transcribed* from source documents in the participant binder and brought off-site. The system for this should be outlined in the site off-site SOP.
- Updates to log CRFs (e.g. AE logs, Con Meds) or other site-specific trackers can be made upon return to the clinic based upon chart notes taken during the visit, but documentation of the off-site visit should never rely on memory. CRFs that are considered source documents (e.g., interviewer-administered forms such as VP-1,

BA-1~2, PSE-1) must be completed during the visit. They should not be updated or completed after the visit based upon visit notes or memory.
- All documentation from the off-site visit should be filed in the participant binder and no documentation from the off-site visit should ever be destroyed (for instance, no notes should be jotted on scrap paper that is later thrown away at the clinic).
- Source Documentation and Data Management SOPs apply to off-site visit documentation and data collection/management just as they do for on-site visits.

Pharmacy considerations:

- Specifications on product supply procedures for off-site visits. *NOTE: All pharmacy procedures outlined in the MTN-020 off-site visit SOP should be reviewed and approved by the MTN Director of Pharmacy prior to implementation.*
  - Requesting participant-specific study product from the pharmacy prior to the off-site visit (should include how this will be documented as an off-site visit on the MTN-020 Vaginal Ring Request Slip and the time line for notifying pharmacy prior to the off-site visit).
  - Ensuring proper chain of custody of participant-specific study product from time of receipt from the pharmacy to time of delivery to the participant, including ensuring that participant-specific study product is delivered to the correct participant
  - Transporting participant-specific study product at appropriate temperatures from time of receipt to time of delivery to the participant
  - Handling/returning participant-specific study product when the participant cannot be located or refuses to receive the product dispensed for her
  - Handling of used and unused study product, including procedures for collection and transportation back to clinic for disposal
  - Documenting all of the above, and appropriately storing all documentation in either the study clinic and/or pharmacy (as per site SOP)

6.5 Procedures for Participants Who Have a Positive Rapid HIV Test Result

The following procedures must be **done the same day of a positive rapid HIV test result(s**) during follow-up:

- **Collect blood and send for Western Blot, HIV RNA, and CD4+ testing**. Record all results on a HIV Confirmatory Results CRF. The blood used for the Western Blot must be collected and labeled separately from the sample used for the HIV rapid tests. RNA and CD4 tests should be run together with the Western Blot and not postponed until Western Blot results are received.
- **Collect blood for plasma storage** for future HIV seroconversion confirmation testing. Document collection on Monthly Laboratory Results CRF.
- Complete a **Vaginal Ring Request Slip** and **Product Hold/Discontinuation Log CRF** to document the product hold.
- Counsel the participant regarding her HIV status per SSP Section 12 and site SOPs; provide referrals per site SOPs.

Refer to protocol Sections 7.5.1 and 9.6 and the guidance below for additional information.

- Perform all of the procedures listed above even if a participant's rapid test results are discordant.
- The samples for Western Blot, HIV RNA, CD4+, and plasma storage are collected separately from the sample used for HIV rapid testing.

See Section 13.7 of this manual for guidance regarding plasma storage at visits where there is both routine plasma storage and HIV algorithm required plasma storage. This situation occurs if there are positive or discordant HIV rapids at a visit in which plasma storage is already required per protocol: quarterly, semi-annual, PUEV, Study Exit Visit.

6.5.1 Modified Procedures for Participants Who Become HIV-infected (Have a Positive Western Blot Result)

The following procedures must be done for participants whose HIV infection <u>is confirmed</u> per the algorithm in protocol Appendix III:

- **Step 1: Permanently discontinue participant from study product.** Once the participant is identified as HIV-infected, complete a new Vaginal Ring Request Slip to notify the Pharmacy, update item 4 the Product Hold/Discontinuation Log CRF (the one originally completed for the positive HIV rapid test result) with the date of permanent discontinuation being the date the HIV results were confirmed, and make sure item 5 of the HIV Confirmatory Results CRF is updated to reflect the participant's HIV-infected status. Re-fax the Product Hold/Discontinuation Log and HIV Confirmatory Results CRFs. You should not wait to inform the participant of her HIV-infected status to complete these items.
- **Step 2: Inform participant of her confirmed HIV-infection status.** Counsel and refer per SSP Section 12 and site SOPs.
- **Step 3: Administer PUEV/Discontinuers ACASI and Ring Worries CRF, complete the Follow-up ACASI Tracking CRF (Per LoA#2).**
  - Once LoA#2 is approved, this ACASI interview and the Ring Worries CRF are administered, either at the interim visit when participant is provided results of her WB or at her next scheduled visit. The Follow-up ACASI Tracking CRF is also completed.
  - If the ACASI or Ring Worries assessments are not done at the required visit, they are not done ("made up") later – they are reflected as missed assessments.

Participants with confirmed HIV infection will be offered the option to continue MTN-020 follow-up visits per their original study schedule. These participants will also be encouraged to enroll in MTN-015. For those who choose to remain in MTN-020 follow up (regardless of enrollment in MTN-015), all protocol-specified procedures for MTN-020 will continue except for the following:

- HIV serology, HIV pre- and post-test counseling
  - Note: HIV/STI risk reduction counseling should be modified to address primary and secondary infection prevention
- Provision of vaginal ring, instructions, product adherence counseling
- Complete blood count with platelets
- Blood chemistries

- Quarterly plasma storage and self-collection of vaginal fluid swab (note that vaginal gram stain and endo-cervical swab samples collected during pelvic examination will continue)
- Once LoA #2 is approved, completion of PUEV/Discontinuers ACASI questionnaire at PUEV.
- Scheduled MTN-020 Study Exit Visit. HIV-infected participants will be terminated once they complete the PUEV.

In addition, the following procedures will be performed for HIV-infected participants as part of the regularly-scheduled MTN-020 study visits occurring 1, 3, 6, 12, 18, and 24 months following the visit with the positive rapid HIV test result. A seroconverter specimen collection calendar has been developed for ease in determining this collection schedule and is posted on the ASPIRE website under *Study Implementation Materials.*

- Seroconverter plasma storage
- CD4+ T cell count
- HIV-1 RNA PCR

Staff should complete the Seroconverter Laboratory Results CRF when results are available.

These procedures are discontinued once the participant enrolls in MTN-015, but the site should continue to complete the Seroconverter Laboratory Test Results CRF at the time points listed above (even if the participant enrolls in MTN-015).

For any participants who become HIV-infected and also become pregnant during follow-up, study staff will ensure access to current prevention of mother to child transmission regimens to reduce the probability of HIV transmission to the participant's infant (see also Section 6.6). Should a pregnant participant seroconvert or if a participant has a positive pregnancy test and positive rapid HIV results, the PSRT should be notified.

6.5.2 Procedures for Participants Who Have an Unclear HIV Status (Have a Negative or Indeterminate Western Blot Result)

If the Western Blot is negative or indeterminate, notify the MTN Laboratory Center. Use the results of the HIV RNA viral load to determine HIV infection status using the below:

- **If the participant has a RNA viral load result above the limit of detection, the participant should be counseled that she is probably HIV-infected (see SSP section 12 for further details regarding counseling messages).** Repeat Western Blot in about 1 month (at the next MTN-020 scheduled visit) for endpoint confirmation. When collecting repeat Western Blots, also collect post seroconversion samples (CD4, RNA and plasma storage). Testing for the RNA and CD4 should proceed immediately. Document all results on a new HIV Confirmatory Results CRF.

- **If the participant has a RNA viral load result below the limit of detection, the participant is considered HIV-uninfected.** Follow the participant per her normal MTN-020 visit schedule per the guidance provided in Section 6.5.3 below.

- **If the participant has a RNA viral load result of "target not detected" or technical problems with the assay, consult the Laboratory Center for further guidance.** Continue to follow the participant per her normal MTN-020 visit schedule, and continue to hold study product.

The LC may also request that HIV DNA testing be conducted in rare situations. The LC will provide any necessary guidance to sites regarding sample collection, testing, and result interpretation in the event that a HIV DNA test is performed.

6.5.3 Participants With a Positive Rapid HIV Test Who Are Confirmed as HIV-uninfected

For participants who have a positive rapid HIV test result and are later confirmed HIV-uninfected per the algorithm in protocol Appendix III, product may be resumed. Once product is resumed, clinic staff should inform pharmacy staff of the resumption in writing, using a Vaginal Ring Request Slip signed by an authorized prescriber. Clinic staff should also update the Product Hold/Discontinuation Log form to document resumption of product use.

Moving forward, sites must adhere to all guidance provided by the LC for follow-up HIV testing plans for these participants (e.g. using alternate approved HIV rapid tests). In cases where an alternate HIV rapid kit is used, sites must have a system to alert testing personnel of this in advance. The HIV algorithm must be initiated whenever there is an HIV positive rapid test.

6.6 Modified Procedures for Participants Who Become Pregnant

Pregnancy testing will be performed for all participants at monthly visits. Testing will also be conducted if indicated at interim visits. Participants will be encouraged to report all signs or symptoms of pregnancy to study staff. The IoR/designee will counsel any participant who becomes pregnant regarding possible risks to the fetus according to site SOPs. This counseling may include messages such as:

- Like for any new medication, Dapivirine has not been formally evaluated in women who are pregnant – medications are usually studied in women who are not pregnant first.
- For that reason, women who become pregnant in ASPIRE are withdrawn from the study medication.
- Studies in animals, and studies in women of medications similar to Dapivirine, do not suggest harm to women who become pregnant or their babies.
- It is important to gather additional information in women for Dapivirine, and that is the reason that the study sites will follow women who become pregnant and their infants.

The IoR/designee also will refer the participant to antenatal care available per site SOPs; however, sites will not be responsible for paying for pregnancy-related care.

Participants who become both pregnant and infected with HIV will also be referred to prevention of mother-to-child transmission (PMTCT) services and will be offered expedited resistance testing at the MTN LC to provide information that may be useful for identifying optimal PMTCT regimens. Site staff should notify the PSRT promptly. HIV testing of participants' infants will be offered through the study if such testing is not otherwise available. All referrals and offers of additional testing available through the study will be documented in participants' MTN-020 study records.

Participants who become pregnant during the course of the study will temporarily hold study VR and will not routinely be withdrawn from the study. While in scheduled follow-up, all protocol-specified study procedures including pregnancy testing will continue to be conducted for pregnant participants, with the following exceptions:

- Provision of vaginal ring, product use instructions, and adherence counseling
  - Note: The retention check-in (Step 6 per the ACE Program) should continue, despite this being embedded with the 'adherence' counseling procedure.
- Contraceptive counseling should continue during pregnancy, but can be abbreviated and should be tailored to changing participant needs over time. For example, early discussions may focus on what contraceptive method she was using prior to pregnancy and whether the pregnancy was due to contraceptive failure or not, while discussions later in pregnancy may focus on method selection and initiation post-delivery.
- Vaginal swab specimens may be collected during pelvic exams up to 24 weeks of pregnancy; however, specimens should be collected with care and participants should be counseled that they may experience vaginal spotting following the exam. They also should be counseled to return to the clinic to report any heavy or prolonged genital bleeding.
  - Under LoA#2, pelvic exams and self-administered swab for vaginal fluid may be conducted if the participant indicates comfort with continuing vaginal procedures. It should be documented in chart notes (or other source documentation) that the participant was agreeable to these procedures post 24-weeks.

For participants who become pregnant, a Pregnancy Report CRF must be completed to report the pregnancy. Participants who are pregnant at the Study Exit/Termination Visit will continue to be followed until the pregnancy outcome is ascertained (or, in consultation with the PSRT, it is determined that the pregnancy outcome cannot be ascertained). A Pregnancy Outcome CRF also must be completed to document the outcome of the pregnancy. Whenever possible, pregnancy outcomes should be collected from medical records or other written documentation from a licensed health care practitioner. When medical records cannot be obtained, however, outcomes may be based on participant report. All study sites are encouraged to use a pregnancy management worksheet similar to the one in Appendix 6-1 (also posted on the ASPIRE website under *Study Implementation Materials*) to ensure proper documentation of the pregnancy and timely discontinuation of VR use.

If the pregnancy occurs during the VR use period, site pharmacy staff must be informed of the product hold in writing using the Vaginal Ring Request Slip and a Product Hold/Discontinuation Log form (see Section 14) must be completed and transmitted to the MTN SDMC. Note that a separate Product Hold/Discontinuation Log form must be

completed if the participant delivers and begins breastfeeding (since the reason for hold has changed).

Product use may be resumed after birth (provided the participant is not breastfeeding) or termination of the pregnancy, as evidenced by a negative pregnancy test performed by study staff. In instances of a pregnancy loss, vaginal ring use should not be resumed earlier than 2 weeks after a 1st trimester loss, or earlier than 4 weeks after 2nd trimester or later loss (see Section 10). Product restart timelines should begin when the pregnancy is lost (i.e., bleeding, elective termination, etc). This restart timeline should only be based off a negative pregnancy test if the date of pregnancy loss is completely unknown. A pelvic exam must be performed prior to resumption to confirm the absence of any findings that would contraindicate resumption, in the opinion of the IoR/designee.

All pregnant participants also will be referred to MTN-016. They may be informed about MTN-016 upon first identification of their pregnancy, but should not be actively referred for screening and enrollment in MTN-016 until after the pregnancy confirmation requirements of MTN-016 are met. Written referrals to MTN-016 are not required; documentation of referral (verbal or otherwise) should be present in participant chart notes. All discussions related to potential participation in MTN-016 must be fully documented in participant study records.

6.7 Modified Procedures for Visits When Product Is Not Dispensed (Participant is on a Clinical Hold/Discontinuation or Refuses to Accept Study Product)

This section applies to situations where study product will not be dispensed to the participant, either because the participant has been placed on a clinical product hold/discontinuation by study staff, or she refuses to accept/use study product.

Note that clinical product holds/permanent discontinuations ("clinical" meaning the hold/discontinuation was initiated by study staff) require documentation on a Product Hold/Discontinuation Log CRF. Instances where a participant declines or refuses study product are not documented as product holds/discontinuations on a Product Hold/Discontinuation CRF, however, a vaginal ring request slip marked 'decline' is still completed to inform the pharmacy of the refusal (See SSP Section 9).

The following procedures will be discontinued starting at the visit/contact during which site staff initiate a clinical product hold/discontinuation or the participant refuses study product:

- Provision of vaginal ring
- Provision of product adherence counseling, product use instructions
  - Note: The retention check-in (Step 6 per the ACE Program) should continue, despite this being embedded with the 'adherence' counseling procedure.

Participants who continue to not receive or accept study product will have modified visit procedures since they will not have a VR available to them. All protocol-specified follow-up study procedures will continue except for the following:

- Removal/collection of used ring
- Provision of new study ring
- Provision of product adherence counseling, product use instructions

- Note: The retention check-in (Step 6 per the ACE Program) should continue, despite this being embedded with the 'adherence' counseling procedure.

If a participant permanently discontinues from study product use at her Month 3 visit, the PUEV/ Discontinuers ACASI is administered at this visit instead of the Month 3 ACASI. As usual, only one FAT-1 CRF is completed at the Month 3 visit, with the PUEV/ Discontinuers survey marked (there is no need to document that the Month 3 ACASI was not completed).

Per LoA#2, participants who permanently discontinue from study product use should have the PUEV/Discontinuers ACASI and Ring Worries CRF administered at the visit they are confirmed discontinued from study product use (or next regularly scheduled visit if this is done at an interim visit). No future ACASI or Ring Worries questionnaires will be administered to the participant.

Participants who have voluntarily chosen to not use study product but are willing to continue in follow-up should be approached at all subsequent visits about restarting VR use.

6.8 Participant Transfers

During the course of the study, participants may leave the area in which they enrolled in the study and re-locate to another area where the study is taking place. To maximize participant retention, participants who re-locate from one study location to another should be encouraged to continue their study participation at their new location. To accomplish this, study staff at both the original site (called the "transferring" site) and the new site (called the "receiving" site) will complete the process of a participant transfer. An optional Transfer Checklist and Transfer Inventory Log is available on the MTN website which summarizes the guidance below. Before initiating this process, the transferring site should ensure that the receiving site will be able to conduct study procedures in a language spoken by the transferred participant.

Upon identifying the need for a participant transfer to another site, the transferring site will notify the receiving site as well as the MTN-020 study management team and the MTN Pharmacist. After the logistical details of the transfer have been discussed and agreed upon by the two sites, the following steps will be completed:

- The MTN SDMC will notify the transferring site of all outstanding data QC notes for the transferring participant; the transferring site will resolve these QCs.

- The transferring site will explain the transfer arrangements to the participant and obtain her written permission to provide copies of her study records to the receiving site. If the participant has already moved and cannot return to sign the records release, this may be accomplished by the transferring site faxing the release to the receiving site for completion by the participant.

- The transferring site will deliver certified copies of all of the participant's study records to the receiving site via courier or overnight mail service. Copies of participant-specific records maintained in the transferring site pharmacy must be delivered directly to the receiving site pharmacy, separate from the participant's clinic records. Pharmacy records may not be delivered in the same shipping envelope or carton as the clinic records. The transferring site (clinic and pharmacy)

will document all materials sent to the receiving site and inform the receiving site of the shipment date and expected arrival date. The receiving site (clinic and pharmacy) will confirm receipt of the shipment.

- The transferring site will complete and fax a Participant Transfer case report form to the MTN SDMC (see Section 14 of this manual).

- The receiving site will establish contact with the participant, obtain her written informed consent to continue in the study at the receiving site (using the receiving site's informed consent form), and complete and fax the Participant Receipt case report form to the MTN SDMC (see Section 14 of this manual).

- Upon receipt of the Participant Transfer and Participant Receipt forms, the MTN SDMC will re-map the participant's PTID to reflect the change in site follow-up responsibility. The participant's original PTID and follow-up visit schedule will remain unchanged. Her random assignment also will remain unchanged.

- An authorized prescriber at the receiving site will be required to prepare an original signed and dated note to pharmacy staff at the receiving site stating that the participant has provided written informed consent to take part in the study at the receiving site and that the prescriber authorizes the participant to continue study product use per the MTN-020 protocol at the receiving site. Clinic staff will deliver the original signed and dated note to pharmacy staff and retain a photocopy of the note in the participant's study chart. Upon receipt of the original signed and dated note, and a completed MTN-020 Vaginal Ring Request Slip, pharmacy staff at the receiving site will dispense study product to the participant according to the random assignment documentation received from the transferring site pharmacy.

- The transferring site will retain responsibility for storage, and shipment to the MTN LC, if applicable, of all specimens collected from the participant prior to her transfer, unless otherwise instructed by the MTN LC.

6.9 Voluntary Withdrawal/Early Termination

As stated in protocol Section 9.8, participants may voluntarily withdraw from the study (withdraw consent) for any reason at any time.

If the participant decides to withdraw from the study, staff should complete the following:

- Ask participant if she is willing to complete one last visit, during which the Early Termination Visit procedures (consisting of PUEV and Termination Visit procedures) would be conducted. At the minimum, staff should try to perform a final HIV test (two rapid HIV tests).
- When completing the Termination form, mark item 2c "participant refused further participation, specify".
- Record the reason(s) for the withdrawal in participants' study records.
- Update participant locator form
- Complete the Study Exit Worksheet and Permission for Future Contact log (if applicable)

- Ensure all referrals are provided to participant as needed

If the participant chooses to withdraw consent after completion of her PUEV but before the study end date, complete a Missed Visit CRF for the missed study exit visit as well as a Termination CRF (marking item 2c) and an End of Study Inventory CRF.

As specified in protocol section 9.8, the IoR may withdraw participants from the study to protect their safety and/or if they are unwilling or unable to comply with required study procedures, in consultation with the PRST. It is recommended that site IoRs use their discretion with regards to terminating participants who relocate and cannot transfer to another study site, or can no longer come to the clinic, or consistently refuse to accept or use study product and are unlikely to resume study visits or product use after counseling efforts and discussions with appropriate study staff.

- If participants exhibit actions such as those listed above that indicate they may no longer be interested in study participation, it is recommended that they be offered a meeting with site leadership to discuss their desire to continue participation.
- When making termination decisions, study teams should weigh the advantages of keeping a participant in the trial against the negative impacts of a participant's poor retention or adherence on the study outcomes and clinic resources.
- Participant terminations should be viewed as a last resort and utilized only after other options have been thoroughly explored.
- Site teams are encouraged to discuss particularly challenging participants and potential terminations as a full group, on the available cross-site listservs, and with the study management team, as needed.
- All discussions, counseling, and decisions about early termination should be adequately documented in the participant's study records. Consultation with the PSRT regarding early terminations per IoR decision should be printed and filed in the participant chart. PSRT consultation is not required for voluntary withdrawals.
- 'IoR discretion' should only be marked as the reason for termination on the Termination CRF if no other reason for termination applies.
- Site teams are encouraged to review their Retention SOPs to make sure any site-specific procedures are in line with this guidance (e.g. that site teams may consider early termination as one option for participants who permanently relocate). Updates should be sent to FHI 360 for review before finalization

For all participants who are terminated early (regardless of reason) and have not been permanently discontinued from study product by the time of early termination, site staff should complete a Vaginal Ring Request Slip to inform the pharmacy that this has happened. The Vaginal Ring Request Slip should be marked "permanent discontinuation" and the specify reason is that the participant is being terminated early. A Product Hold/Discontinuation Log CRF is not needed to document that a participant is ending product use as a result of the early termination from the study.

6.9.1 Resumption of Study Participation After Voluntary Withdrawal

The protocol allows for participants who terminate early from the study to reverse their decision and re-join the study during their planned follow-up period, resume study procedures and follow-up at the investigator's discretion.

If such cases arise, study staff is advised to contact the mtn020mgmt@mtnstopshiv.org for additional guidance on how to manage various aspects of protocol implementation and data collection as the participant resumes participation in the study and to contact the PSRT to determine if product can be restarted with the participant. If a participant rejoins the study, her random study product assignment will remain the same, as will her PTID and follow-up visit schedule. A clinical examination must be conducted prior to restarting product; procedures required should be confirmed by the PSRT.

Prior to performing any study procedure, the participant must provide written informed consent to document that she voluntarily rejoined the study. For re-consenting procedures, refer to Section 5.10 of this study manual.

Site staff should thoroughly document, in the participant's chart notes, her resumption of study follow-up and study product use and all communication with the study management team and PSRT.

6.10 Product Use End Visit and Study Exit Visit

The final two required follow-up visits for MTN-020 are the Product Use End Visit (PUEV) and the Study Exit visit (SEV). The PUEV occurs at the study's planned end of product use period; the Study Exit visit occurs as the final follow-up visit for all participants with the exception of those who have seroconverted (in this case, the participant will be terminated at her PUEV). The Study Exit visit takes place approximately 4 weeks after the participant's PUEV.

Once it is determined that the required number of HIV-infections has been obtained, study end/study closure procedures will begin. Separate operational guidance describing study closeout plans will be circulated to the protocol team.

Visit codes/visit months for the PUEV and study exit visits will be assigned in continuation with a participant's specific visit schedule (described in the Data Collection section of this manual). For example, if a participant completes her scheduled PUEV within her Month 17 visit window, the visit is assigned a visit month of "17.0". If the same participant completes her Study Exit Visit within the Month 18 window (as targeted), her study exit visit is assigned a visit month of "18.0". Neither the PUEV nor the Study Exit visit has a special visit code assigned to it.

Note that the PUEV is conducted according to PUEV requirements (and is referred to as the PUEV) even if the participant had been permanently discontinued from study product prior to her PUEV. The same is true if a participant is on a clinical product hold at the time of her PUEV – the PUEV procedures are still performed as required.

If a participant has HIV seroconverted during follow-up, she is not required to complete a Study Exit visit (as the purpose of this visit is to identify delayed seroconversions in participants who are HIV-negative at the PUEV). The participant should be terminated once the PUEV is completed – complete a Termination and End of Study Inventory CRFs once the PUEV is completed.

Procedural requirements for conducting PUEV and Study Exit visits are specified in protocol Sections 7.4.2 and 7.4.3; further procedural guidance is incorporated in the PUEV/Early Termination/Termination Visit checklist in Section 7 of this manual, as well as in Operational Guidance #9. Provided in the remainder of this section is additional information related to key aspects of PUEV and Study Exit visits.

It is recommended that participant follow-up plans be documented on a study exit worksheet similar to the sample provided in Section Appendix 6-2, which is also available on the ASPIRE website under *Study Implementation Materials*.

6.10.1 Participant Locator Information

Accurate participant locator information will be needed for post-study contact with study participants. As such, locator information should be actively reviewed and updated at all study exit visits and all participants should be counseled to contact the study site should their locator information change after study exit. See Section 8 for more detail on locator information.

6.10.2 HIV Counseling and Testing

HIV testing is performed at the study exit visit per the algorithm Section 13. HIV pre- and post-test counseling provided at the study exit visit should emphasize that additional counseling and testing will be provided to the participant after her study exit visit if needed to clarify or confirm her HIV status. HIV counseling considerations are outlined further in Section 12.

For participants who test HIV positive at the study exit visit and have ambiguous HIV testing results (i.e. positive or discordant rapid tests and negative or indeterminate western blot), study termination should be postponed until the algorithm is completed and all necessary samples are collected.

6.10.3 AE Management and Documentation

More information about the clinical management of AE's is discussed in the Clinical Management and AE Reporting Sections 10 and 11. All AE Log forms completed for each participant should be reviewed at the study exit visit and updated as needed. For AEs that are ongoing at the Study Exit/Termination visit, the status/outcome of the AE should be updated to "continuing at end of study participation" and the AE Log form should be re-faxed to MTN SDMC DataFax. Information related to following up AEs after participant termination can be found in Section 11.

6.10.4 Final Study Contact

Although the Study Exit visit is the last scheduled study visit, a final contact may be needed after the exit visit to provide the participant with her final study test results, post-test counseling, and treatment, if needed. Additional contacts also are required for:

- Participants who are pregnant at study exit (note that if a participant is confirmed pregnant at the study exit visit she may be eligible for MTN-016), if eligibility criteria are confirmed during the visit

- Participants with certain types of AEs that are ongoing at study exit (see SSP Section 11)

As needed, a final contact should be scheduled based on the participant's overall clinical picture at study exit, as well as the time required to obtain all final study test results. Study staff may complete final contacts at the study site, by telephone, or at community-based locations, depending on site capacities and site and participant preferences. All final contacts must be documented in participant study records, but no case report forms are completed for these contacts.

6.10.5 Referral to Non-Study Service Providers

After completing their study exit visits and final study contacts, participants will no longer have routine access to services provided through the study, such as reproductive health care and HIV counseling and testing. Participants should be counseled about this —before and during their study exit visits — and provided information on where they can access such services after study exit. It is strongly recommended that all study sites develop a sample script which can be used when discussing this issue with exiting participants, as well as written referral sheets that can be given to participants at their study exit visits (after obtaining IRB/EC approval of the written information). A sample script which may be tailored for use at each site is provided in Appendix 6-3, also available on the ASPIRE website under *Study Implementation Materials*.

6.10.6 Post-Study Contact

It is expected that all participants will be re-contacted by study staff when study results are available for dissemination.

To facilitate post-study contact with participants, locator information should be updated at the study exit visit, and participants should be counseled to contact the study site should their locator information change after study exit. In addition, participant preferences for methods to be used for contacting them when study results are available should be documented in participant study records. It is recommended that participant preferences be recorded on a study exit worksheet referenced in Section 6.10.4.

Lastly, for participants whom study staff may wish to contact regarding participation in future studies, permission for such contact should be sought from the participant and documented. In addition, for ease of retrieving information on participant permissions, it is recommended that study staff maintain future study contact permission logs. It is recommended that participant permission (or lack thereof) for future studies be documented on a study exit worksheet similar to the sample referenced in Section 6.10.4. In addition, for ease of retrieving information on participant permissions, it is recommended that study staff maintain future study contact permission logs similar to the example provided in Appendix 6-4, also on the ASPIRE website under *Study Implementation Materials.*

Appendix 6-1
Sample MTN-020 Pregnancy Management Worksheet

PTID			
First day of last menstrual period			
Date of positive pregnancy test			
Estimated full term pregnancy date			
PREGNANCY MANAGEMENT INFORMATION		**Initial and Date When Done**	**Comments**
1	**Hold Product: Vaginal Ring Request Slip marked HOLD completed and delivered to pharmacy**		
2	**Product retrieved from participant** ***(NA if no product left to retrieve)***		
3	**Complete Pregnancy Report and History CRF**		
4	**Complete Product Hold/Discontinuation Log CRF**		
5	**Participant referred to antenatal care**		
6	**Participant referred to MTN-016 (once eligible)**		
7	**Pregnancy outcome determined, based on:** **❒ Medical records or other written documentation from licensed practitioner** ***(obtain whenever possible)*** **❒ Participant self-report** **❒ Negative pregnancy test performed by study staff** **❒ Other** ***(specify in comments)***		
8	**Complete Pregnancy Outcome CRF**		
9	**AE Log form completed and faxed** ***(NA if pregnancy outcome not a reportable AE)***		
10	**EAE Report completed and submitted** ***(NA if pregnancy outcome not an EAE)***		
11	**Contraception counseling provided**		
12	**Participant counseled to breastfeed per current WHO guidelines and Product Hold/Discontinuation Log CRF started for breastfeeding** ***(NA if ppt did not give birth)***		
13	**Confirmed complete cessation of breastfeeding** ***(NA if ppt did not give birth)***		
14	**Pelvic exam done confirming absence of contraindications to ring use**		
15	**Vaginal Ring Request Slip marked RESUME completed and delivered to pharmacy** ***(NA if product use not resumed)***		
16	**Study Product Provided/Inserted**		
17	**Update Product Hold/Discontinuation Log CRF(s)**		

Operational Guidance for Product Resumption: Refer to protocol Sections 7.5.2 and 9.3 and SSP Section 6.6. Participants may resume product use as of the date of their first negative pregnancy test performed by study staff, provided they are not breastfeeding. After a pregnancy hold, VR use should not be resumed earlier than 2 weeks after a 1st trimester loss, or earlier than 4 weeks after 2nd trimester (or later) pregnancy loss or delivery. Product restart timelines should begin when the pregnancy is lost (i.e., bleeding, elective termination, etc). This restart timeline should only be based off a negative pregnancy test if the date of pregnancy loss is completely unknown. A pelvic exam must be performed prior to resumption to confirm the absence of any findings that would contraindicate resumption in the opinion of the IoR/Designee. Participant should be counseled to breastfeed per current WHO guidelines.

Section Appendix 6-2
Study Exit Worksheet

Participant ID:	**Termination Visit Date:**

Plan for providing participant with final study results

Method by which participant wishes to be contacted when study results are available

Does participant have study product remaining in her possession?
❒ No, per participant report, all product has been collected/returned
❒ Yes ⇒ describe plan for product collection (continue on back if needed)

❒ Completed _____

Is participant currently pregnant?
❒ No
❒ Yes ⇒ describe plan for ascertaining pregnancy outcome (continue on back if needed). If enrolled in MTN-016, discuss plan for continued follow-up in MTN-016 (e.g. next scheduled visit). If not already enrolled, discuss potential enrollment in MTN-016.

IoR approval or designee: _____
❒ Completed: _____

For HIV positive participants ONLY: Are they enrolled in MTN-015?
□ No → Discuss potential enrollment into MTN-015 and plans for continued access to HIV-related care. Provide referrals and/or schedule MTN-015 enrollment as appropriate.
□ Yes → Discuss plan for continued follow-up in MTN-015 (e.g. next scheduled visit)

Does participant have any ongoing SAEs/EAEs or any AEs at this visit?
❒ No
❒ Yes ⇒ describe plan for AE follow-up (continue on back if needed)

IoR approval or designee: _____
❒ Completed: _____

Is participant willing to be contacted about future studies for which she may be eligible?
❒ No
❒ Yes

Staff Signature and Date:

Section Appendix 6-3
Sample Script for Study Exit Visits

Before we finish your visit today, I would like to take some time to sincerely thank you for taking part in this study. By taking part, you have made an important contribution to the fight against HIV/AIDS. In recognition of this contribution, I would like to present you with this certificate of completion which you can take with you today [sites to modify as needed].

I also would like to review a few more details with you:

- Your appointment to receive your final exam and test results is scheduled for [date]. This appointment will take place [here at the clinic / other specify]. If you need to change this appointment for any reason, please contact us to let us know.

- Although your scheduled study visits have now been completed, the study is planned to be ongoing until the end of June this year. After that, we expect it will take about another 6 months to determine the results of the study. At that time, we will also learn which participants received active or placebo study product. In order for us to share the results of the study with you and tell you which ring you received, we need to be able to keep in touch with you. [Tell the participant about any future results events you have planned- a group event etc.] Therefore we ask you to please inform us if you move to a new home, change your phone number, or have any other new details that would help us keep in touch with you. [Give contact card.]

- As you have heard, if the results of ASPIRE show that the ring is effective in preventing HIV, there will e a follow-on study called HOPE. All women who enrolled in ASPIRE will be invited to participate in HOPE. If you are eligible to participate, you would receive the active study product, there will be no placebo ring.

- We would like to be able to contact you in the future about other studies that you may be eligible for, such as HOPE. Are you willing to give us your permission to do that? [Record response on study exit worksheet; if permission is granted, explain that information recorded on the participant's locator form would be used for this purpose and enter participant on future contact permission log.]

- *If applicable, reinforce plans to determine pregnancy outcome.*

- *If applicable, reinforce plans for AE follow-up*.

- *If applicable, reinforce plans for follow-up HIV counseling and testing*.

- *If applicable, let the participant know about any services that will continue to be provided at the research clinic after ASPIRE (family planning, HIV testing etc).*

- Lastly, we would like to give you some information on places where you can go for different types of services now that you will not be coming here for regular study visits [give referral sheet]:

    - For HIV counseling and testing
    - For family planning and other reproductive health care
    - For other types of health care
    - Other

- *If applicable, replace above bullet with a discussion of plans for ongoing participation in MTN-015 and/or MTN-016.*

- Please feel free to contact us if you have any questions about the study that we have not answered today, or if you encounter any problems related to your participation in the study. Once again, we sincerely thank you for your contributions to the study and we look forward to sharing the results with you when they become available.

Section Appendix 6-4
Sample Future Study Contact Permission Log

Participants Willing to Be Contacted for Future Studies By Participant Name

No.	Name, address and phone	Date of Contact Approval	Method of Contact Preferred