Section 9. Study Gel Considerations for Non-Pharmacy Staff

This section provides information and instructions for non-pharmacy staff related to conducting the HPTN 059 Study. Associated instructions for pharmacy staff are provided in the *HPTN 059 Pharmacist Study Gel Management Procedures Manual*, which will be made available to each study Study Pharmacist of Record (PoR) by the DAIDS Protocol Pharmacist. Please also refer to related information in Sections 4 and 6 of this manual.

9.1 Responsibilities and Obligations with Regard to Blinding

Note: In the remainder of this document, reference of the term "study gel supplies" will refer to the study tube(s) of tenofovir or placebo gel and the study supplied applicators.

HPTN 059 Investigators of Record (IoRs), and by delegation, all HPTN 059 study staff, are responsible for maintaining the integrity of the study's blinded design. All Protocol Team members and study participants, with the exception of the DAIDS Protocol Pharmacist and Study Pharmacists, will not be provided information on the identity of the specific study gels to which participants in the study gel groups have been assigned.

The Pharmacist of Record (PoR) at all sites will be unblinded to all treatment assignments. Access to study pharmacy facilities, and all study gel supplies and documentation stored in these facilities, is limited to study pharmacy staff only. The IoR or designee must ensure the security of study pharmacy facilities by empowering the HPTN 059 PoR to control access to these facilities and all study gel supplies and documentation stored therein.

With the exception of the Study Pharmacists, blinding will be maintained throughout the study and until all study endpoint data have been verified and are ready for final analysis. There are no circumstances under which it is expected that unblinding will be necessary to protect the safety of study participants. In the event that study staff becomes concerned that a participant may be put at undue risk by continuing use of her assigned study gel, the IoR or designee may discontinue study gel use by the participant. Knowledge of the specific study gel to which the participant was assigned should not be necessary to guide further follow-up and/or treatment. If an IoR or designee feels that study gel-specific information is necessary to protect participant safety, he/she should notify the HPTN 059 Protocol Safety Review Team (PSRT).

9.2 Study gel Use Instructions

Participants in the daily use group will be instructed to insert one dose of study gel – the entire contents of one applicator – into the vagina once daily at bedtime or longest period of rest. Participants in the coitally dependent group will be instructed to insert one dose of study gel — the entire contents of one applicator — into the vagina up to 2 hours before each act of vaginal intercourse but not more than twice a day.

Detailed instructions for insertion of study gel are listed in Table 9-1 below. These instructions will be translated into local languages at each site and illustrated to optimize participants' understanding of them. A listing of frequently asked study gel use questions, and answers to these questions, is provided in Section Appendix 9-1.

Table 9-1
Study gel Use Instructions for HPTN 059

Removing the Applicator: • Tear open the clear, plastic wrapper • Remove applicator from wrapper
Filling the Applicator: • Remove the cap from the tube of study gel • Puncture the metal seal on the tube with the pointed tip of the cap • Screw the end of the applicator onto the tube • Slowly squeeze gel out of the tube and into the applicator. Plunger will stop when the applicator is full
Inserting the Applicator: • Choose a comfortable position to insert the applicator, for example lying on your back with your knees bent or standing up with one leg raised and resting on an object • Hold the filled applicator about half-way along the barrel • Gently insert the filled applicator into the vagina as far as it will comfortably go • Slowly press the plunger until it stops to deposit the gel into the vagina • Withdraw the applicator from the vagina ** Note: Study Staff should inform participants that they may experience some minor gel leakage from the vagina, when inserting the filled applicator into the vagina*
Follow up Information: • Dispose of the *used* applicator, plastic wrapper, used gel tube and cap. If you can not dispose of your study supplies at your home or off site, you can bring your used tubes and applicators to the study clinic for disposal in accordance with applicable biowaste requirements (See SSP Section 9.5.2) • Bring all of your *unused* study gel tubes to your next visit

9.3 Dispensing Study Gel During Visits

Upon receipt of a completed and signed HPTN 059 Prescription (at enrollment) or a completed and signed HPTN 059 Study Gel Request Slip (during follow-up), pharmacy staff will dispense study gel supplies for study participants per instructions in the HPTN 059 Pharmacist Study Gel Management Procedures manual and/or site specific SOPs. Study gel supplies will be dispensed in study gel cartons containing 10 identically-labeled tubes of study gel and 10 individually-wrapped plastic applicators. Study gel cartons will be sealed with tamper-evident tape and labeled by the PoR in accordance with US and local requirements. In all cases, labeling of the study gel carton will include the PTID of the participant for whom the supplies have been prepared and to whom they should be dispensed/delivered.

Participant-specific study gel cartons may be dispensed to participants in one of three ways:

- From the pharmacy directly to the participant
- From the pharmacy to clinic staff who will then deliver the study gel cartons to the participant

- From the pharmacy to authorized transport staff (or "runners") who will transfer the study gel cartons to authorized clinic staff who will then deliver the study gel cartons to the participant

- Participant reconsents (if participant discontinues and then re-enrolls in study) must be forwarded to the pharmacy. Additionally, any documentation that will have an effect on product administration must be forwarded to the pharmacy. This may include:

    - copies of signed, dated chart notes which may provide further detail in change of a participants study gel administration
    - signed and dated informed consent forms of participants who reconsent to the study

Refer to Sections 4.2.7 and 6.6 of this SSP manual for further information on procedures for participant randomization, initial ordering and dispensation of study gel for enrolled study participants, and study gel re-supply during follow up. Detailed instructions for completing HPTN 059 Prescriptions and HPTN 059 Study Gel Request Slips are provided in these sections.

9.3.1 Dispensing Study Gel Cartons from the Pharmacy Directly to Participants

If a site chooses to dispense study gel cartons directly from the pharmacy to participants, then and HPTN 059 prescription and study gel request slips are expected to be delivered to the pharmacy by the participant themselves, by fax, by clinic staff or by a runner. Upon receipt of a completed and signed HPTN 059 prescription or study gel request slip, the PoR will prepare the number of participant-specific study gel cartons entered on the HPTN 059 prescription or request slip. Study gel cartons may be prepared based on either original documents or faxed copies. Once the study gel cartons are prepared, study gel will be released to participants when the original HPTN 059 prescription or study gel request slip is received.

9.3.2 Dispensing of Study Gel from the Pharmacy to Clinic Staff or Runner

If a site chooses to dispense study gel cartons to clinic staff or a runner who will then deliver the study gel cartons to participants, an HPTN 059 prescriptions and Study Gel Request Slips are expected to be delivered to the pharmacy by fax, or hand delivered. Upon receipt of a completed and signed HPTN 059 prescription or study gel request slip, the PoR will prepare the number of participant-specific study gel cartons entered on the HPTN 059 prescription or request slip. Study gel cartons may be prepared based on either original documents or faxed copies, but study gel cartons will be released to clinic staff or runner when the original HPTN 059 prescription or request slip is received.

The HPTN 059 Record of Receipt of Participant-Specific Study Gel Cartons Forms (see Section Appendices 9-2a and 9-2b) must be used to document dispensing of participant-specific study gel cartons to clinic staff. There are two different forms for clinic staff and runners. The original forms must be returned to the pharmacy at the end of every business day. The clinic staff can keep a copy of these forms for their internal records. If after five days the original forms have not been received in the pharmacy, the pharmacist will contact the pharmacist of record (POR) at PAB for further action.

Clinic staff also must document delivery of study gel cartons to designated participants in the participants' study charts. Delivery may be documented in chart notes, on visit checklists, or on other source documents designated for this purpose by clinic staff. In the event that all study gel cartons dispensed for a participant are not delivered to the participant, clinic staff will document this in the participant's study chart and return the remaining study gel cartons to the pharmacy as soon as possible after the participant's visit is completed.

9.3.2.1 Dispensing Study Gel from the Pharmacy to Clinic Staff

Clinic Staff will complete the Record of Receipt Form in Appendix 9-2a when transferring the study gel supplies from the pharmacy to the clinic.

The Record of Receipt must be used when transferring the study gel supplies from the pharmacy to the clinic. The "Site Name", "Site Number", and "Clinic Name" must be completed by the clinic staff. The pharmacy staff will complete the first four columns on the Record of Receipt form.

When receiving study gel cartons from the pharmacy, clinic staff will verify the PTIDs, confirm the number of study gel cartons received for each PTID, and complete the remaining three columns on the Record of Receipt for each PTID. Comments may be recorded in the designated column and, if additional space is needed, on the back of the record. Records of Receipt forms will be retained in the study pharmacy.

9.3.2.2. Dispensing Study Gel Cartons from the Pharmacy to Runners for Further Transfer to Clinic Staff

Runners will complete the Record of Receipt Form in Appendix 9-2b when transferring the study gel supplies from the pharmacy to the clinic.

Clinic staff will complete the top section (site name, site number, clinic name) and the Pharmacy Staff will complete the first four columns on the Record of Receipt form. When receiving study gel cartons from the pharmacy, runners will verify the PTIDs, confirm the number of study gel cartons received for each PTID, and complete the two columns, PTID and Runner Initials, on the Record of Receipt form. Comments may be recorded in the designated column and, if additional space is needed, on the back of the record. Records of Receipt forms will be retained in the pharmacy.

Runners are expected to deliver participant-specific study gel cartons to authorized clinic staff directly after collecting the study gel cartons from the pharmacy. Runners must control access to the study gel cartons dispensed into their custody and deliver the study gel cartons only to authorized clinic staff. Runners also must retain and control access to their Record of Receipt forms until they are returned to the pharmacy staff at the end of the work day, at which time the pharmacist assumes responsibility for the forms. If completed Record of Receipt forms are not returned to the Pharmacy by the end of each work day, the Pharmacist will notify appropriate clinic supervisory staff to ensure timely recovery of the forms. If completed forms are not recovered within five calendar days, the PoR will notify the DAIDS Protocol Pharmacist.

Ultimately, clinic staff is responsible for controlling access to the study gel cartons transferred into their custody, ensuring that the study gel cartons are delivered to the participants for whom they were dispensed.

9.4 Dispensing More Than a One-Month Supply of Study Gel

The HPTN 059 protocol specifies that study gel will be dispensed in quantities expected to be sufficient until a participant's next follow-up visit. Dispensation of more than a one-month supply of study gel should occur rarely and must be fully considered, justified, and documented by the IoR or designee.

Note: *In the remainder of this section, reference is made to decisions made by IoRs or designees to dispense more than a one-month supply of study gel. At sites where the IoR or designee is not a physician, decisions to dispense more than a one-month supply of study gel must be made by the senior research physician delegated responsibility for medical oversight of study participants.*

In general, it is expected that dispensation of more than a one-month supply of study gel will be associated with participant's travel away from the study site. When determining whether to authorize dispensation of more than a one-month supply of study gel, IoR or designees must give careful consideration to all aspects of participant safety, including but not limited to the following:

- The circumstances of the participant's travel away from the study site:
  - Where will the participant be?
  - Will she be with a sexual partner(s)?
  - How far will she be from the study site?
  - How far will she be from other sources of medical care?
  - Will she be able to store and/or use study gel securely and confidentially?
  - Will it be possible for study staff to contact her either by phone or in person while she is away?
- The participant's prior history of study gel use:
  - How long has the participant been in the study?
  - How often has she used the study gel?
  - Has she demonstrated a good understanding of how to use the study gel per protocol?
  - Has she had adequate exposure to allow for an assessment of the likely safety of continued study gel use for more than one month's time?
  - Has she had any signs, symptoms, or other adverse events associated with study gel use? If so, what was the severity of the events and what is the likelihood they will recur?
  - If the participant were to experience an adverse event while away from the study site, what is the likelihood that she would be able to contact study staff and/or discontinue study gel use on her own?

- The participant's reproductive history:
  - Is the participant currently using a reliable contraceptive method? How long has she been using this method? Has her use been consistent?
  - Is the participant likely to be able to continue use of a reliable contraceptive method while away from the study site?
  - In your best judgment, how likely is the participant to become pregnant while away from the study site?

After considering all of the above, and any other relevant factors, should the IoR or designee wish to dispense up to a three-month supply of study gel to a participant, he/she may do so, without obtaining any additional approvals, if all of the following criteria are met:

- The participant has been in the study for at least three months AND
- The participant has not experienced any adverse events of severity grade 3 or higher

In this case, the IoR or designee will enter a signed and dated note in the participant's chart documenting the participant's circumstances and the factors leading to and supporting his/her decision to dispense more that a one-month supply of study gel. The IoR or designee also will complete an HPTN 059 Study Gel Request Slip to request the required amount of study gel for the participant from the pharmacy (up to a maximum three-month supply) with additional supportive documentation for pharmacy staff.

If any of the above-listed criteria are not met, the IoR or designee must obtain approval from the DAIDS PSB Medical Officer to dispense up to a three-month supply of study gel for the participant. Refer to the Protocol Team Roster for contact information for the Medical Officer.

After discussion with the IoR or designee, the Medical Officer will provide an immediate verbal approval or disapproval of the IoR or designee's request to dispense more than a one-month supply of study gel. Within two business days thereafter, the IoR or designee will prepare a written summary of the participant's circumstances, the key factors leading to and supporting the IoR or designee's decision, and the date and time of the conversation with the Medical Officer. The IoR or designee will email the written summary to the Medical Officer (copied to the HPTN 059 PSRT). Within one business day after receiving the IoR or designee's summary, the Medical Officer will reply by email to document her prior verbal approval or disapproval of the request (copied to the HPTN 059 PSRT). The IoR (or designee) will print and file the correspondence in the participant's chart. For approvals only, the IoR or designee also will enter a note on the HPTN 059 Study Gel Request Slip that he/she completes to request the required amount of study gel for the participant (up to a maximum three-month supply) documenting the date and time of the conversation during which the Medical Officer's verbal approval was received.

In all cases in which more than a one-month supply of study gel is dispensed, clinic staff will obtain any available locator information from the participant and arrange to maintain periodic contact with her while she is away, if contact would not jeopardize the participant's safety and confidentiality. All contacts, and contact attempts, will be documented per standard study site documentation practices. Prior to their departure from the study site, participants will be counseled to contact the clinic staff if at all possible to report suspected pregnancy and/or any adverse events that they may experience while away.

9.5 Return of Study Gel Supplies

Study participants will be instructed to return unused study gel supplies, tubes and applicators, to the study site at each visit. Further considerations are provided in Sections 9.6.1 and 9.6.2 below.

9.5.1 Unused Study gel Supplies

Participants who do not use all of the study gel provided to them at a previous visit will be instructed to return the unused study gel supplies to the study site at their next visit.

In the event that a participant becomes pregnant or experiences an adverse event that requires permanent discontinuation of study gel use (per protocol Section 4.9), any unused study gel supplies remaining should be returned to the pharmacy on the day of collection. Similarly, as study gel use is not permitted among HIV-infected participants, any unused study gel supplies remaining in an infected participant's possession should be collected as soon as possible after infection is confirmed per the algorithm in protocol Appendix III and returned to the pharmacy on the day of collection. It is not necessary to collect remaining study gel supplies from participants for whom study gel use is temporarily held. However, study gel supplies may be collected from such participants, to protect their safety, if it is suspected that the participant may not comply with clinic staff instructions to refrain from study gel use for the duration of the temporary hold.

In the event that an issue or problem is identified that would necessitate collection of unused study gel supplies from all participants, detailed instructions for collection and handling of the study gel supplies, and documentation thereof, will be provided by the DAIDS Protocol Pharmacist. Other associated operational and/or data collection instructions also may be provided by the HPTN CORE and/or HPTN SDMC. Clinic and pharmacy staff will follow all such instructions.

Unused study gel supplies collected from participants for any reason should be returned to the pharmacy on the day of collection. When unused study gel supplies are collected by clinic staff, the staff may return the collected unused study gel supplies to the pharmacy themselves or, if study gel runners are utilized at the site, clinic staff may transfer the collected unused study gel supplies to a runner for return to the pharmacy. In such cases, the HPTN 059 Daily Runner Log should be used to document transfer of the collected unused study gel supplies into the custody of the runners and subsequent return to the pharmacy, with notations in the "comments" column of the log indicating that the study gel supplies are being returned by, rather than received by, clinic staff.

Any unused study gel supplies remaining in a participant's possession at the time of study exit must be collected from the participant and returned to the pharmacy on the day of

collection. When planning and scheduling study exit visits, clinic staff should instruct participants to bring all remaining unused study gel supplies to their exit visits. For participants who do not bring their unused study gel supplies to their exit visits, clinic staff should make all reasonable efforts to collect the remaining unused study gel supplies in a timely a manner, and document all such efforts in participants' study charts. For participants for whom all reasonable efforts fail, guidance should be sought from the HPTN 059 PSRT.

9.5.2 Used Study gel Supplies

Participants will be instructed to dispose of used study gel tubes and applicators off-site (e.g., at their homes). When this is not possible or allowed, participants may return their used applicators to the study clinic for disposal in accordance with applicable biowaste requirements. Clinic staff should provide participants with plastic bags or other suitable containers in which to store their used applicators between visits. Clinic staff also may wish to consider installing easily accessible biowaste containers near the clinic doorway and/or in other common areas within the clinic. Clinic staff should not return used study gel tubes or applicators to the pharmacy.

9.6 Study Gel-Related Scenarios

For illustrative purposes, a number of study gel-related scenarios are provided in Sections 4 and 6 of this manual (see Section Appendix 4-2 and Section Appendix 6-5).

Table 9-2
Frequently Asked Study gel Use Questions

9-1.1 What is the best position to insert the study gel? Any position that is comfortable can be used to insert the study gel. The positions that are recommended include sitting, standing, and lying down.
9-1.2: What should I do if it hurts when I use the applicator to insert the study gel? Inserting the study gel should not be painful. If you have pain when inserting the study gel, try another position (sitting, standing, or lying down). If you still have pain in the new position, perhaps you need to change the angle of the applicator. The applicator should be angled slightly upward, towards your back, when you insert it. If you try to change the angle, and you still feel pain on insertion, please contact the study clinic.
9-1.3: Where does the study gel go to after I put it inside? The study gel stays in the vagina. If you are in the coitally dependent group, the study gel will stay in your vagina until you have sex. Some study gel will likely come out of the vagina during sex. The rest of the study gel will come out of the vagina (through the same opening where it was inserted) over the next day after having sex. Sometimes when the study gel comes out it looks clear. It is not normal to see a yellow or green discharge from the vagina, or a discharge with a bad odor, or with pain or itching. If this happens, it could mean you have an infection, in which case you should contact the study clinic.
9-1.4: Can the applicator get lost inside me? No, the applicator cannot get lost inside you. When you use the applicator, hold it with your fingers about half-way along the barrel, and insert it until your fingers touch your body. Half of the barrel of the applicator should go inside your body. The other half should stay outside the body. Once completed, remove the entire applicator and discard.
9-1.5: What should I do if I have trouble inserting the study gel with the applicator? The applicators should be easy to use. If you have difficulty using the applicators, please contact the study clinic, as the clinic staff may be able to show you different ways that you can insert the study gel, which might make it easier.
9-1.6: What should I do if I think there is something wrong with a tube or applicator? If there seems to be something wrong with a tube or applicator (for example, you find it difficult to push the study gel out of the applicator, or if study gel has leaked out, or you think there is some other problem), do not use the applicator. Use another applicator instead. Keep the applicator that had something wrong and bring it to the study pharmacy at your next study visit. If you think that something is wrong with all of your applicators, contact the study staff as soon as possible (i.e., do not wait until your next visit) so the staff can make sure you have enough working applicators for each time you have sex or until your next visit.

Table 9-2 continued
Frequently Asked Study gel Use Questions

9-1.7: What happens if I press the plunger too early and most of the study gel comes out on my outside? Can I put more in? Yes. If most of the study gel comes out on your outside, Dispose of that applicator and use a new applicator to insert another dose of study gel.
9-1.8: Should I use the study gel during my period? Yes. If you are in the coitally dependent group, you should use the study gel before every sex act, even during your period.
9-1.9: Can I use tampons at the same time as the study gel? You can use tampons while taking part in this study. If you use tampons, you should take out the tampon when you insert the study gel. If you are in the coitally dependent group, you should put another tampon in two hours after you have had sex.
9-1.10: What if I have bleeding between periods? Please contact the study clinic.
9-1.11: How do I store the study gel? Store the study gel in a cool, dry place at room temperature and not in the sun.
9-1.12: What happens if the applicators get wet before I use them? If only the wrapper gets wet, the applicator can still be used. Dry the wrapper off before taking out the applicator. If the applicator itself gets wet, it should not be used, but this might only happen if the wrapper is already open.
9-1.13: What should I do if the wrapper is already open when I want to use the study gel? You should only use applicators with sealed wrappers, so you should always open the wrapper right before inserting the study gel. If you notice an applicator with a wrapper that is not sealed, do not use that applicator. Use a different applicator with a sealed wrapper instead. Keep the applicator with the open wrapper and bring it to the study pharmacy at your next study visit.
9-1.14: What should I do if I am in the coitally dependent group and I forget to use the study gel before sex? If you remember the study gel during sex, and can interrupt the sex act, you can insert study gel at that time. If you remember the study gel after you have had sex, try to remember to use the study gel before sex the next time you have sex.

Table 9-2 continued
Frequently Asked Study gel Use Questions

9-1.15: What should I do if I am in the once daily group, and I forget to insert the study gel one day? Continue to use the study gel the next day and let the study staff know about missed doses at your next visit
9-1.16: If I am in the once daily group, and I forget to insert the study gel for more than one day, what should I do? Continue to use the study gel the next day and let the study staff know about missed doses at your next visit
9-1.17: If I am in the coitally dependent group, and for example I put the study gel in at 9:00 pm, because I expect my partner to arrive at 9:30 pm, but he only arrives at 10:30 pm, should I put more study gel in while I wait for him? No. You can insert a does up to two hours before sex, and your partner arrived an hour and a half after you inserted the study gel. If for some reason your partner would have arrived after 11:00 pm, and more than two hours elapsed, then you would insert another dose of gel, however, remember you can not insert more than two doses of gel per day.
9-1.18: If I am in the coitally dependent group, what should I do if I have sex a second time? You should use another applicator to insert another dose of study gel before the second sex act (even if the second sex act takes place within an hour of inserting study gel for the first sex act). However, YOU SHOULD NOT USE THE STUDY GEL MORE THAN TWICE A DAY
9-1.19: If I am in the once daily group, how long after inserting the study gel can I clean my vagina? It is not necessary to clean your vagina. Your vagina works on its own to clean itself, and this is healthier for you than using water, soap, or other substances to clean the vagina, since soap and other substances can damage the inside of the vagina. If you feel you must clean your vagina after sex, please wait at least two hours after using the study gel before cleaning, and try wiping or cleaning the outside of the vagina, rather than washing the inside.
9-1.20: If I am in the coitally dependent group, how long after sex can I clean my vagina? It is not necessary to clean your vagina. Your vagina works on its own to clean itself, and this is healthier for you than using water, soap, or other substances to clean the vagina, since soap and other substances can damage the inside of the vagina. If you feel you must clean your vagina after sex, please wait at least two hours after using the study gel before cleaning, and try wiping or cleaning the outside of the vagina, rather than washing the inside.

Table 9-2 continued
Frequently Asked Study gel Use Questions

9-1.21: Is the study gel contraceptive? We don't know if the study gels will prevent pregnancy during sex acts when the study gels are used. It is possible that the study gels could prevent pregnancy. It also is possible they could have no effect on pregnancy (especially the placebo gel). There is no reason to think the study gels will prevent pregnancy during sex acts when they are not used. If you wish to avoid pregnancy, you should use known reliable method of contraception while you are in this study.
9-1.22: Will the study gel affect my partner's ability to father children? No. The ingredients in the study gels are not known to have any effect on male fertility. The ingredients also are not known to have any effect on female fertility. However, as noted in Q21, it is possible that the study gels could prevent pregnancy when used during sex. Your partner should use a condom when having sex.
9-1.23: What should I do if my partner has a reaction to the study gel? Contact the study clinic and ask their advice. They might ask your partner to go to the clinic to be assessed and receive treatment if needed. However, previous studies have shown this is unlikely to happen.
9-1.24: What should I do if I have a reaction to the study gel (e.g., unusual itching, stinging)? Contact the study clinic.
9-1.25: What should I do if I think I am pregnant? Contact the study clinic immediately. The clinic staff will give you a pregnancy test to find out if you are pregnant or not.
9-1.26: Should I use the study gel before oral sex (i.e., no intercourse)? If you know you will only be having oral sex, there is no need to use the study gel.
9-1.27: If I am in the coitally dependent group, what should I do if my partner touches me in the vaginal area after the study gel has been inserted? Should I re-insert the study gel? It is not necessary to re-insert the study gel in this situation, unless you think that most of the study gel has been removed. In that case, you should use another applicator to insert another dose of study gel.
9-1.28: Can I have sex straight away after inserting study gel, or do I need to wait? You don't need to wait to have sex after inserting study gel.

Table 9-2 continued
Frequently Asked Study gel Use Questions

9-1.29: If I am in the coitally dependent group, can I have sex a second time straight away after having sex with the study gel inserted? You don't need to wait to have sex a second time, but you should use another applicator to insert another study gel dose before you having sex again. However, you should not use the study gel more than twice a day.
9-1.30: If I am in the coitally dependent group, what do I do if I forgot to use the study gel before having sex? This would be considered a missed dose. The next time you have sex, remember to use the study gel up to two hours before having sex. At your next study visit, report the missed dose to study staff.
9-1.31: Does it matter what brand condoms we use? Ideally, you should use the condoms given to you by the study clinic staff. However, if you do not have one of those condoms, and you have a different condom, use that condom. If a condom other than the condoms given to you by the study clinic staff is used, inform the study clinic staff of the change. Condoms are the only known way to protect against HIV and other sexually transmitted diseases (STIs), so it is always better to use any condom (even if it was not given to you by the study) than to use no condom.
9-1.32: Do we have to use condoms or can we rely on another form of birth control? You should try to use condoms each time you have sex because condoms also protect against HIV and other sexually transmitted diseases (STIs). We do not know if the microbicide study gels tested in this study protect against HIV and other STIs. Also, not all women in the study will get the microbicide study gel. Some will get the placebo study gel. If you do not use a condom, you increase your risk of getting pregnant as well as getting HIV and other STIs. You must use another method of birth control (as specified in the informed consents and protocol) while in the study to give more protection against pregnancy, but you should also use condoms to protect against HIV and other STIs.
9-1.33: What should I do if the study gel leaks out? It is likely that some study gel will leak out. This is normal and you don't need to do anything about it. You should always insert the full amount in the applicator. It may be helpful to wipe yourself on the outside with a dry cloth/tissue if you have been standing for a minute or two after you applied the study gel, if you find that a small amount leaks out.

Table 9-2 continued
Frequently Asked Study gel Use Questions

9-1.34: Can I use herbs or other substances for tight or dry sex while I am using the study gel? Herbs or other substances could damage the inside of the vagina. These substances also could interfere with the study gels. Therefore, we recommend that you do not use herbs or other substances in the vagina. If you feel you must use these substances, please do not use them from two hours before you insert the study gel to two hours after you have had sex or inserted the study gel. This will help make sure the substances do not interfere with the study gel.
9-1.35: If I am in the coitally dependent group, does it matter if I put the study gel in and don't have sex? No, this doesn't matter.
9-1.36: If I am in the once daily group, does it matter if I do not insert the study gel at the same time every day (at bedtime or longest period of rest)? Ideally, you should insert the study gel at bedtime or longest period of rest, to prevent the study gel from leaking out when you are standing or being active.
9-1.37: Can my partner insert the study gel for me? It is preferable that you insert the study gel yourself, but if you are happy that your partner knows how to do it in a way that won't cause you discomfort, then this is acceptable. It is better for your partner to insert the study gel for you than to not use the study gel at all.
9-1.38: Will I have access to the study gel if it is shown to be effective? If the study gel is shown to be safe and effective, it will take some time for the study gel to be allowed to be sold in the shops, but we will try to make sure this happens as quickly as possible.

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Section Appendix 9-2bb (for Runners)
*HPTN 059 Record of Receipt of Participant-Specific Study gel Cartons

Site Name:
Site Number:

Clinic Name:

PHARMACY STAFF				RUNNER			
Date Dispensed by Pharmacy dd-MMM-yy	*PTID	No. of Study gel cartons Dispensed by Pharmacy	Pharmacist Initials	PTID *(*Verify PTID transcribed from box matches PTID recorded by Pharmacist in Pharmacy Staff Section*)	Date and Time Received by Clinic Staff (dd mmm yy, 00:00 AM/PM)	Runner Initials	COMMENTS

Instructions: Complete one row each time participant-specific study gel cartons are dispensed to non-pharmacy staff for delivery to a study participant. All entries must be made in dark ink. Corrections may be made by drawing a single line through incorrect entries, entering correct information, and initialing and dating the correction.

*** Form must be returned to the pharmacy at the end of every business day**

Section Appendix 9-2aa (For Clinic Staff)
*HPTN 059 Record of Receipt of Participant-Specific Study gel Cartons

Site Name:	Clinic Name:
Site Number:	

PHARMACY STAFF				CLINIC STAFF			
Date Dispensed by Pharmacy dd-MMM-yy	*PTID	No. of Study gel cartons Dispensed by Pharmacy	Pharmacist Initials	PTID *(*Verify PTID transcribed from box matches PTID recorded by Pharmacist in Pharmacy Staff Section*)	Date and Time Received in Clinic (dd MMM yy, 00:00 AM/PM)	Clinic Staff Initials	COMMENTS

Instructions: Complete one row each time participant-specific study gel cartons are dispensed to non-pharmacy staff for delivery to a study participant. All entries must be made in dark ink. Corrections may be made by drawing a single line through incorrect entries, entering correct information, and initialing and dating the correction.

*** Form must be returned to the pharmacy at the end of every business day**