

## Microbicide Trials Network

### Clarification Memo #03 to:

#### MTN-004

#### Phase I Study of the Safety and Acceptability of 3% w/w SPL7013 (VivaGel™) Applied Vaginally in Sexually Active Young Women, Version 3.0, Dated 30 June 2008

#### DAIDS PROTOCOL #10492

#### IND #62,482

**Date of Clarification Memorandum: 03 September 2008**

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#### *Section 1: Summary of Clarifications and Rationale*

The procedures clarified in this memorandum have been approved by the NIAID and NICHD Medical Officers and are to be implemented immediately upon issuance. IRB approval of this Clarification Memorandum is not required by the sponsor; however, investigators may submit the clarification memo to the IRB overseeing the study at their site for information.

This clarification memo is official MTN-004 documentation. It is effective immediately. A copy of this memo must be retained in each study site's Essential Documents file for MTN-004.

No change in informed consent is necessitated or included in this clarification memo.

The primary goals for this clarification memo are to clarify the instructions for the destruction of study product cited in Section 6.2.6, Retrieval of Unused Study Products and to clarify the nature of Adverse Event reporting in Section 8.3.1, Adverse Events. Table 13, Enrollment Visit is also modified to omit the provision of resealable plastic bags in order to be consistent with the changes made in MTN-004, Version 3.0, dated June 30, 2008. A change in contact information in the Protocol Team Roster is also noted here.

Further detail can be found in the section below.

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#### *Section 2: Implementation*

Text to be deleted is noted by ~~strikethrough~~ and text to be added is noted below in **bold**.

1. The Protocol Team Roster is updated to reflect the new contact information for one team member:

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 MTN Safety Physician  
 Microbicide Trials Network  
**MWH of UPMC**  
**Department of OB/GYN/RS**  
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 (412)-641-6170 FAX  
[kbunge@mail.magee.edu](mailto:kbunge@mail.magee.edu)

2. Section 6.2.6, Retrieval of Unused Study Products, third and fourth sentences are updated to provide clear directions regarding the destruction of unused study product:

All unused study products must be returned **by the participant** to the site, **placed in a biohazard container** and then **destroyed at the site**. **Unused study product remaining in the pharmacy must be** forwarded to the MTN CORE pharmacist for **destruction** after the study is completed or terminated unless otherwise instructed by the MTN CORE.

3. Section 7.6.3 Enrollment Visit, Table 13 Enrollment Visit, Study Supplies row, is modified to omit the provision of resealable plastic bags in order to maintain consistency with direction provided in MTN-004, Version 3.0, dated June 30, 2008:

<b>Study Supplies</b>	<ul style="list-style-type: none"> <li>• Dispense two cartons (20 applicators) of study gel, male condoms and panty liners, and/or pads, <del>and resealable plastic bags</del></li> <li>• Participant to insert first dose in study clinic</li> </ul>
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4. Section 8.3.1, Adverse Events, fourth paragraph, second sentence is deleted and fourth sentence is modified to omit AE reporting for male partners since the results for the male tolerance study are now available:

Second sentence

~~Participants will be encouraged to report to the study clinician any problems experienced by their male partners that might be potentially related to study product.~~

Fourth sentence

Study site staff will document on study CRFs all AEs reported by or observed in enrolled study participants ~~or their partners~~ from the time of their first dose of study gel through the Three-Week Clinic Visit or early termination, regardless of severity and presumed relationship to study gel or applicators.