

**Microbicide Trials Network**

**Clarification Memo #02 to:**

**MTN-002**

**Phase I Study of the Maternal Single-Dose Pharmacokinetics and Placental Transfer of Tenofovir 1% Vaginal Gel among Healthy Term Gravidas**

**Version 1.0 / 29 August 2007**

**DAIDS PROTOCOL #10600**

**IND #55,690**

**Date of Clarification Memorandum: 14 April 2009**

---

*Section 1: Summary of Clarifications and Rationale*

The procedures clarified in this Clarification Memorandum (CM) have been approved by the NIAID Medical Officer and are to be implemented immediately upon issuance. Institutional Review Board (IRB) approval of this CM is not required by the sponsor; however, investigators may submit the CM to the IRB overseeing the study at their site for information. This CM is official MTN-002 documentation and is effective immediately. A copy of this CM must be retained in the study site's Essential Documents file for MTN-002. No change in informed consent is necessitated by or included in this CM. The primary goal for this CM is to modify references to *Trichomonas* culture to allow for consistency with alternate *Trichomonas* testing methods planned for utilization by the study site. Additionally, the Protocol Team Roster and Sections 1.2 and 1.4 are updated.

---

*Section 2: Implementation*

With the exception of modifications to the Protocol Team Roster, 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 modifications to the Protocol Team, as well as updates to contact information for various team members.

The following additions are made to the Protocol Team Roster:

**Katherine Bunge, MD**  
**MTN Protocol Safety Physician**  
Magee-Womens Hospital of UPMC  
300 Halket Street  
Pittsburgh, PA 15213 USA  
Phone: 412-917-9936  
Fax: 412-641-6170  
Email: [kbunge@mail.magee.edu](mailto:kbunge@mail.magee.edu)

**Ross D. Cranston MD, FRCP**  
**MTN Protocol Safety Physician**  
Division of Infectious Disease, University of Pittsburgh Medical Center  
Falk Medical Building, Suite 611, 3601 Fifth Avenue  
Pittsburgh, PA 15213 USA  
Phone: 412-647-4007  
Fax: 412-647-5519  
Email: [rdc27@pitt.edu](mailto:rdc27@pitt.edu)

**Mala Shah, MPH**  
**MTN Protocol Development Manager**  
Microbicide Trials Network  
204 Craft Avenue, #B506  
Pittsburgh, PA 15213 USA  
Phone: 412-641-3859  
Fax: 412-641-6170  
Email: [shahms@mail.magee.edu](mailto:shahms@mail.magee.edu)

**Molly Swenson, RN, MSN, MPH**  
**MTN SDMC - Clinical Affairs Safety Assoc.**  
FHCRC--SCHARP  
1100 Fairview Ave. North, LE-400, PO Box 19024  
Seattle, WA 98109-1024 USA  
Phone: 206-667-5410  
Fax: 206-667-4812  
Email: [mollys@fhcrc.org](mailto:mollys@fhcrc.org)

**Megan Valentine, PA-C, MS**  
**Research Specialist**  
Family Health International  
P.O. Box 13950  
Research Triangle Park, NC 27709 USA  
Phone: 919-542-7498  
Fax: 919-544-0207  
Email: [mvalentine@fhi.org](mailto:mvalentine@fhi.org)

The following listings are deleted from the Protocol Team Roster: Sheila Clapp, Mitch Creinin, Pat Farrell, and Bryna Harwood.

The following listings have updated contact information:

**Henry Gabelnick, PhD**  
**Co-Sponsor Representative**  
CONRAD  
1911 North Fort Myer Drive, Suite 900  
Arlington, VA 22209 USA  
Phone: 703-524-4744  
Fax: 703-524-4770  
E-mail: [hgabelnick@conrad.org](mailto:hgabelnick@conrad.org)

**Jill Schwartz, MD**  
**Co-Sponsor Representative**  
CONRAD  
1911 North Fort Myer Drive, Suite 900  
Arlington, VA 22209 USA  
Phone: 703-276-3913  
Fax: 703-524-4770  
E-mail: [jschwartz@conrad.org](mailto:jschwartz@conrad.org)

2. Sections 1.2 Sponsor and Monitor Identification and 1.4 Site Investigators are updated.

#### 1.2 Sponsor and Monitor Identification

Sponsor: CONRAD  
~~1611 North Kent Street, Suite 806~~**1911 North Fort Myer Drive, Suite 900**  
Arlington, VA 22209 USA

#### 1.4 Site Investigators

Site Investigator: ~~Mitchell Creinin, MD~~  
~~Magee Womens Hospital of UPMC~~  
~~300 Halket Street~~  
~~Pittsburgh, PA 15213 USA~~

3. Edits are made to Sections 7.1, 7.6, 7.9.2 and Appendix I to modify specifications for Trichomonas testing, and clarify study expectations for timing of the Screening and Enrollment Visit.

In Section 7.1 Screening and Enrollment, first paragraph, the first sentence is edited for clarity:

The Screening and Enrollment Visit will occur approximately one **day** to four weeks prior to the participant's scheduled C/S, but no more than four weeks before the expected date of cesarean section.

In Section 7.1 Screening and Enrollment, Table 2, the following modification is made:

<b>Laboratory</b>	<ul style="list-style-type: none"><li>• Collect pelvic specimens<ul style="list-style-type: none"><li>○ Trichomonas <del>culture</del><b>test</b></li><li>○ *Wet prep and vaginal pH</li><li>○ *Herpes Culture</li></ul></li></ul>
-------------------	--

In Section 7.6 Unscheduled Visit, Table 6, the following modification is made:

<b>Laboratory</b>	<ul style="list-style-type: none"><li>• *Serum creatinine</li><li>• *ALT</li><li>• *AST</li><li>• *RPR</li><li>• *Confirmatory testing for syphilis</li><li>• *Rapid HIV Test</li><li>• *Confirmatory testing for HIV with pre-and post-test counseling</li><li>• *HBsAg</li><li>• *Maternal plasma tenofovir level</li><li>• *Urine SDA for CT and GC</li><li>• *Urinalysis</li><li>• *Urine culture and sensitivity</li><li>• *Wet prep and vaginal pH</li><li>• *Trichomonas <del>culture</del><b>test</b></li><li>• *Herpes culture</li><li>• *Other laboratory tests deemed clinically appropriate, when possible after consultation with the PSRT</li></ul>
-------------------	---

In Section 7.9.2 Network Laboratory, the following modification is made:

The Network Laboratory will run the following:

- Urine SDA for chlamydia and gonorrhea
- Trichomonas ~~culture~~**test**
- Pharmacokinetic analyses (at NL Pharmacology Core)

In Appendix I SCHEDULE OF STUDY VISITS AND EVALUATIONS, the following modification is made:

Trichomonas <del>Culture</del> <b>Test</b>	x							▲
--	---	--	--	--	--	--	--	---