

## Microbicide Trials Network

### Clarification Memorandum #02 to:

#### MTN-015

### An Observational Cohort Study of Women following HIV-1 Seroconversion in Microbicide Trials, Version 1.0, 19 June 2007

#### DAIDS PROTOCOL #10529

Date of Clarification Memorandum: 21 August 2008

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

The procedures clarified in this Clarification Memorandum (CM) have been approved by the NIAID Medical Officers and are to be implemented immediately upon issuance. 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-015 documentation. It is effective immediately. A copy of this CM must be retained in each study site's Essential Documents file for MTN-015. No change in informed consent is necessitated or included in this CM.

The goal of this CM is to provide an updated Protocol Team Roster, and an up-to-date listing of Sites, Site Investigators, and Site Laboratories.

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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 modified to reflect current Protocol Team members and contact information.

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2. The list of Site Investigators (Appendix II) is removed from the protocol and replaced with content directing the reader to the MTN website for an up-to-date list.

## APPENDIX II: SITES AND SITE INVESTIGATORS

For a current list of Site Investigators please go to <http://www.mtnstopshiv.org/>.

- ~~Lisa Maslankowski, University of Pennsylvania, Philadelphia, Pennsylvania, USA~~
- ~~Bonus Makanani and Newton Kumwenda, Queen Elizabeth Central Hospital, Blantyre, Malawi~~
- ~~Francis Martinson, Lilongwe Central Hospital, Lilongwe, Malawi~~
- ~~Muzala Kapina, Kamwala Health Centre, Lusaka, Zambia~~
- ~~Mike Chirenje, and Tsitsi Magure, University of Zimbabwe Obstetrics and Gynaecology Research Clinic at Spilhaus Zimbabwe~~
- ~~Mike Chirenje and Tsitsi Magure, Seke South Clinic (Chitungwiza), Chitungwiza, Zimbabwe~~
- ~~Gita Ramjee, Medical Research Council-Hlabisa, Hlabisa, South Africa~~
- ~~Gita Ramjee, R.K. Khan Hospital, Chatsworth, South Africa~~
- ~~Smita N. Joshi, Jehangir Hospital – NARI Clinic, Pune, India~~
- ~~Craig Hoesley, University of Alabama at Birmingham, Birmingham, Alabama, USA~~
- ~~Jessica Justman, Bronx-Lebanon Hospital Center, New York, New York, USA~~
- ~~Sharon A. Riddler, University of Pittsburgh, Pittsburgh, Pennsylvania, USA~~
- ~~Michael Lederman, Case Western Reserve University, Cleveland, Ohio, USA~~
- ~~Laura Guay, Makerere University, Kampala, Uganda~~

- ~~David Coetzee, University of Cape Town, Cape Town, South Africa~~
3. The list of Site Laboratories (Appendix III) is removed from the protocol and replaced with content directing the reader to the MTN website for an up-to-date list.

### APPENDIX III: SITE LABORATORIES

**For a current list of Site Laboratories please go to <http://www.mtnstopshiv.org/>.**

~~Site Laboratory: National AIDS Research Institute  
Plot No. 73, G Block  
M.I.D.C. Bhosari  
Pune, Maharashtra 411 026  
India~~

~~Site Laboratory: University of Alabama Hospital Lab  
619 South 19th Street  
Birmingham, Alabama 35233-1924  
USA~~

~~Site Laboratory: UAB Div of Infectious Diseases Lab  
THT 220 1900 University Boulevard  
Birmingham, Alabama 35294  
USA~~

~~Site Laboratory: LabCorp  
Raritan Facility  
69 First Avenue  
Raritan, NJ 08869  
USA~~

~~Site Laboratory: CIDRZ Central Laboratory  
Kalingalinga District Clinic  
Off Alick Nkhata Road  
Kalingalinga  
Post Office Box 34681  
Lusaka  
Zambia~~

~~Site Laboratory: Children's Hospital of Philadelphia  
Abramson Research Center 1204K  
34th Street and Civic Center Boulevard  
Philadelphia, PA 19104  
USA~~

Site Laboratory: ————— Queen Elizabeth Central Hospital  
P.O. Box 1131  
Chipatala Avenue  
Blantyre, Malawi

Site Laboratory: ————— Tidziwe Centre  
Lilongwe Central Hospital  
100 Mzimba Road  
Lilongwe, Malawi

Site Laboratory: ————— UZ-UCSF Collaborative Research Programme in Women's  
Health  
15 Phillips Avenue  
Harare, Zimbabwe

Site Laboratory: ————— Lancet  
102 Lancet Medical Centre  
74 Lorne Street  
Durban, South Africa

Site Laboratory: ————— Lancet (BARC)  
First Floor, Napier House  
Napier Road, Richmond  
Johannesburg, South Africa

Site Laboratory: ————— Empangeni Garden Hospital  
Suite 8, 1st Floor  
Consulting Blocks  
Corner of Ukula and Biyela Street  
Empangeni, South Africa

Site Laboratory: ————— Department of Cytology  
Nkosi Albert Luthuli Central Hospital  
800 Bellair Road  
Mayville, 4091 South Africa

Site Laboratory: ————— MU-JHU Research Collaboration Lab  
IDIL at New Mulago Hospital Complex  
P.O. Box 22418,  
Kampala, Uganda