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

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.

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
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