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1 NETWORK OVERVIEW AND STRUCTURE

1.1 Background of the Microbicide Trials Network

Although significant strides have been made in the treatment of HIV, with gains seen in the uptake of antiretroviral therapy globally, advances in the area of prevention have for the most part lagged behind. Recent years have seen renewed optimism beginning with the U.S. Food and Drug Administration’s (FDA) approval in 2012 of the combination antiretroviral (ARV) oral tablet Truvada® (tenofovir/emtricitabine) as pre-exposure prophylaxis (PrEP) for HIV prevention. In 2016, the World Health Organization (WHO) recommended oral PrEP for all persons at substantial HIV risk, and a number of countries, including South Africa and Kenya, have approved Truvada as PrEP for adults 18 years of age and older.

There is also a new method for women – a vaginal ring containing the ARV dapivirine that women use for a month at a time. The dapivirine vaginal ring is the first HIV prevention product developed specifically for women that was found to be safe and to help protect against HIV in two independently conducted large-scale trials. [ASPIRE](#), also known as MTN-020, was conducted by the Microbicide Trials Network (MTN). The Ring Study was conducted by the International Partnership for Microbicides (IPM), which also developed the dapivirine ring. IPM is seeking regulatory approval of the dapivirine ring based on the results of ASPIRE and The Ring Study, as well as several supporting studies, including studies led by the MTN.

No one strategy will be appropriate for or acceptable to all high-risk populations. While hope of having an HIV vaccine still exists, it may be a decade or more until one is available. Moreover, no vaccine is likely to be 100 percent effective or be acceptable to all groups. Ending the HIV epidemic will require multiple approaches that incorporate a range of prevention strategies. Different methods are needed to meet the different needs and preferences of individuals, because people are more likely to use a product if it suits their circumstances and lifestyle.

The need has never been more critical. More than 2 million new infections occur annually (about 5,700 every day), a figure that has remained unchanged from 2010 to 2015. Approximately one-third of new infections are among people ages 15-24. Women in their child-bearing years, which includes pregnant and breastfeeding women, remain at high risk for HIV infection. In sub-Saharan Africa, where nearly 60 percent of people with HIV are women, adolescent girls and young women are particularly vulnerable. Most new infections are through heterosexual transmission. However, across the globe, men who have sex with men (MSM) and transgender persons also continue to be at very high risk, with unprotected anal sex the primary driver for the high prevalence in these populations. By some estimates, the risk of acquiring HIV through unprotected anal receptive intercourse, practiced by both men and women, is at least 20 times greater than through unprotected vaginal sex.

An important area of HIV prevention research is focused on microbicides, which are products applied inside the rectum or vagina to reduce the risk of acquiring HIV through sexual transmission. Microbicides were originally envisioned as vaginal products that women in resource-poor settings could use to protect themselves from acquiring HIV from their male partner. The need for similar products for individuals at risk of acquiring HIV through anal sex was soon recognized.

Most of the products being developed contain ARV drugs. Products being evaluated for rectal use include lubricant-like gels and quick-dissolving tablet inserts that would be used around the time of sex. Vaginal products under investigation include different formulations of intravaginal rings, including rings that could provide sustained protection for up to 90 days and/or that combine both HIV protection and contraception in one product for women wishing to avoid pregnancy.

Finding any one of these products to be safe and effective would be critically important to the global response against HIV/AIDS, provided they are simple and inexpensive to manufacture and can be made readily available to those populations in greatest need at little or no cost.

Yet, even the most effective product will not provide any benefit if it is not used properly and consistently. To be successful, HIV prevention research must focus on the interaction of multiple variables: an individual's social context; sexual behavior and perception of risk; facilitators and obstacles to product use; and other factors, such as pharmacology and biology.

There remains an urgent need for safe, effective and practical HIV prevention products that both women and men will use. Research, that includes different at-risk populations, must continue so that a variety of safe and effective vaginal and rectal products can be licensed and made widely available.

1.2 The Microbicide Trials Network's Mission

The Microbicide Trials Network (MTN) was first established in 2006 to identify safe and effective microbicides for preventing the sexual transmission of HIV in different high-risk populations, from the early phase clinical trials through final approval by regulatory authorities. From the outset, MTN has targeted key populations at risk of acquiring HIV, including women in sub-Saharan Africa, adolescent girls and young women, pregnant and breastfeeding women, MSM and transgender individuals. To accomplish its mission, MTN conducts scientifically rigorous, ethically sound and highly efficient clinical studies on the safety, effectiveness,

pharmacokinetics and behavioral aspects associated with microbicide use. The MTN's scientific portfolio is designed to support the potential licensure of a range of safe and effective products that will meet the needs and preferences of various at-risk populations. Toward this end, MTN's specific goals are to:

- Conduct rigorous clinical trials to establish safe and effective vaginal and rectal microbicide products as well as safe and effective multipurpose, extended release microbicide products
- Integrate innovative biomedical and behavioral science into the MTN clinical trials portfolio
- Perform novel and routine product, immunologic, virologic, pharmacologic and other testing in support of and as part of MTN studies
- Implement and oversee data collection and management as necessary for successful implementation of proposed clinical trials
- Provide statistical and epidemiologic leadership and support throughout protocol development and implementation, including study design, monitoring, analysis and reporting
- Collaborate, when appropriate, with other U.S. National Institutes of Health (NIH)-sponsored HIV clinical trials networks to harmonize clinical, laboratory and data-management methods and to maximize the efficiency of protocol development, implementation and analysis
- Encourage collaboration with external investigators, pharmaceutical companies and scientific research groups that will facilitate the evaluation of novel products and strategies within MTN
- Provide training and mentorship to clinical, behavioral and laboratory junior investigators to develop the next generation of HIV prevention scientists
- Provide ongoing internal and external assessment of MTN activities and strategic vision to ensure that MTN's scientific output is of the highest quality and is relevant to HIV prevention science

1.3 The Microbicide Trials Network's Organization

The MTN operates under a cooperative agreement with the Division of AIDS (DAIDS) of the National Institute of Allergy and Infectious Diseases (NIAID), which is the main institute of the NIH Consortium, as described in Section 1.5. Other members of the NIH Consortium include the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) and the National Institute of Mental Health (NIMH).

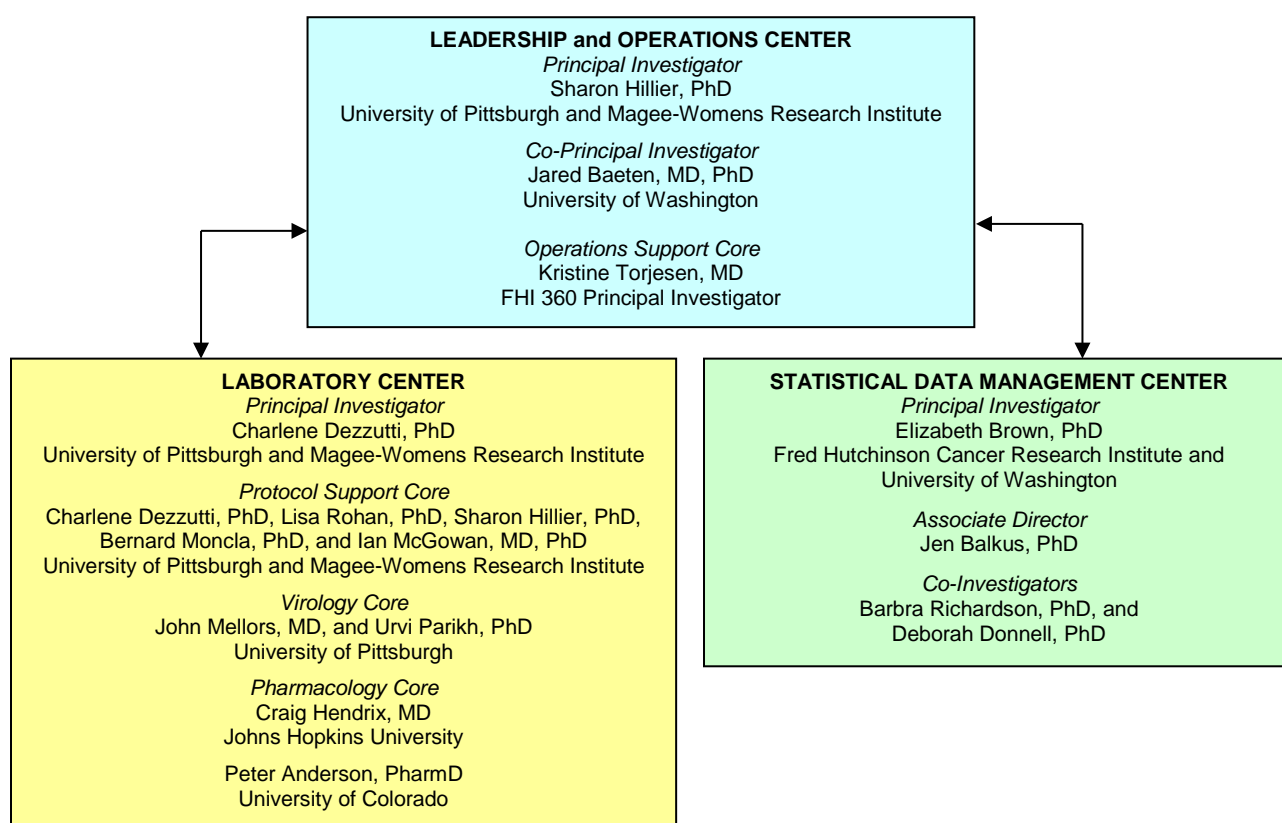
MTN's governance and network operations serve as a product-development model that functions within an NIH-funded grant structure. MTN has developed a streamlined structure to increase productivity while ensuring the scientific integrity of its research. The scientific leadership embodied in the Executive Committee (EC) and other key MTN organizational units has direct authority and responsibility for (i) facilitating the development of Phase I, II and III study protocols and implementation plans for microbicide trials; (ii) collaboratively setting priorities among scientific and protocol concepts; (iii) ensuring the engagement of key stakeholders across the field and within communities; and (iv) ensuring sound fiscal management of resources allocated to MTN by NIAID, NICHD and NIMH.

MTN's primary governance body is the EC, which is responsible for the overall scientific direction, development and implementation of policy, procedural decisions and resource allocation. The EC is supported by three resource committees: the Manuscript Review Committee (MRC), Study Monitoring Committee (SMC) and Network Evaluation Committee (NEC); and three working groups: the Biomedical Science Working Group (BSWG), Behavioral

Research Working Group (BRWG) and Community Working Group (CWG). These committees and working groups ensure that scientific quality and community engagement are the hallmarks of every MTN study. In addition, protocol teams are created for each MTN clinical protocol so that studies are designed and implemented with the highest scientific and ethical standards. (See Section 4 of this manual for more information about MTN committees, working groups and protocol teams.)

MTN's operational structure consists of three key organizational units: a Leadership and Operations Center (LOC), a Laboratory Center (LC) and a Statistical Data and Monitoring Center (SDMC) (Figure 1.1). The LOC includes functions across three institutions: the University of Pittsburgh, FHI 360 and the University of Washington. These organizational units are described in greater detail in Section 3 of this manual.

Figure 1.1 MTN Organizational Structure



Overall operational authority rests with the Leadership Group, which is comprised of MTN's Principal Investigator (PI), MTN co-PI, the PIs from the MTN LOC Support Core, the PI of the MTN LC and the PI of the MTN SDMC.

1.4 The Microbicide Trials Network's Operational Policies

The organizations that comprise MTN adhere to relevant U.S. federal regulations and U.S. NIH/NIAID/DAIDS policies as a condition of receiving NIH funding. Each Clinical Trials Unit (CTU) and Clinical Research Site (CRS) affiliated with the MTN must also adhere to relevant

local regulations and policies. MTN-specific policies and procedures guide MTN members in meeting relevant requirements and standardizing site operations for each MTN study. These policies and procedures are contained in the following:

- **The MTN Manual of Operational Procedures (MOP):** This manual includes all MTN policies and procedures and general guidelines relevant to all MTN sites, study teams and staff.
- **Site- and Study-Specific Standard Operating Procedures (SOPs):** SOPs for site and study operations ensure (i) the standardized and uniform performance of site-related and study-related tasks; and (ii) compliance with MTN's procedures, the International Conference on Harmonization/Good Clinical Practice (ICH/GCP) guidelines and FDA regulations, where applicable. (See Section 11.4 of this manual for further information on SOPs for site and study operations.)
- **Study-Specific Procedures (SSP) Manuals:** In addition to the study protocol, the conduct of an MTN study is also guided by its SSP manual. An SSP manual is developed for each study and provides detailed, standardized instructions for conducting protocol-specified procedures. (See Section 11.13 of this manual for further information on the development of an SSP manual.)

1.5 U.S. Governmental Organizations Involved in MTN Research

Because the MTN is funded through a Cooperative Agreement, the NIH has substantial scientific and programmatic involvement in MTN's activities. As such, MTN functions in close collaboration with NIAID/DAIDS, NICHD, NIMH and the other Institutes/Centers/Offices that comprise the NIH Consortium. In addition, MTN works cooperatively with governmental regulatory agencies and offices, including the FDA, the U.S. Office for Human Research Protections (OHRP) and regulatory agencies in other countries where MTN research is conducted.

More information is available at each organization's website:

- DAIDS: <https://www.niaid.nih.gov/about/daids>
- NIAID: <https://www.niaid.nih.gov/>
- NICHD: <https://www.nichd.nih.gov/Pages/index.aspx>
- NIMH: <http://www.nimh.nih.gov>
- FDA: <http://www.fda.gov/>
- OHRP: <http://www.hhs.gov/ohrp/>

1.5.1 National Institute of Allergy and Infectious Diseases

MTN was established in 2006 by NIAID with co-funding from NIMH and NICHD. The NIAID funding and coordination of MTN's research are provided through DAIDS, and within DAIDS, through the Prevention Sciences Program (PSP). At the institute level, the role of NIAID's staff is to assist and facilitate, but not direct, MTN's research activities. However, NIAID has direct involvement in and oversight of two key areas, as described below.

1.5.1.1 NIAID Data and Safety Monitoring Boards

An independent Data and Safety Monitoring Board (DSMB) chartered by NIAID/DAIDS provides oversight of ongoing Phase IIB and Phase III MTN studies. The DSMB's purpose is to ensure the safety and welfare of participants by reviewing safety, efficacy and overall study conduct.

The members of the DSMB are independent experts in a variety of fields that reflect the disciplines and medical specialties necessary to interpret trial data — for example, biostatistics, medicine, clinical trials design and medical ethics. The members have no conflicts of interest in the outcomes of the studies they review. *Ad hoc* members may be appointed for specific protocols as circumstances require and/or to ensure appropriate country representation for non-U.S. studies. Appointments to the DSMB are made by NIAID.

As a fundamental monitoring principle of blinded clinical studies, access to endpoint data is limited to as small a group as possible. Because the DSMB has access to unblinded interim data, the study's Protocol Chair(s) are relieved of the burden of deciding whether it is ethical to continue to randomize participants. This process helps to protect the study from bias in participant evaluation. For these reasons, DSMB meetings are closed to the public. Protocol Chair(s) are expected to participate in the open session of the DSMB review to discuss study progress and respond to questions from the DSMB. Other protocol team members may be requested by DAIDS or the DSMB to take part in the review. Protocol statisticians also take part in open sessions, but only the unblinded statistician takes part in both open and closed sessions.

In circumstances when there is a major recommendation, the DSMB first communicates this to NIAID leadership, that is, the NIAID Director. In all cases, the NIAID Director makes the final decision whether to accept the DSMB's recommendations.

More information on the NIAID DSMB can be found in Section 16.10 of this manual.

1.5.1.2 NIAID Office of Communications and Government Relations

The NIAID Office of Communications and Government Relations (OCGR) provides oversight to the MTN Communications and External Relations team and has primary responsibility for certain communications-related activities of the MTN, as described in Section 8 of this manual.

1.5.2 Division of AIDS

Various DAIDS programs and offices provide services and oversight and/or facilitate MTN's mission as described below and depicted in the organogram found at <https://www.niaid.nih.gov/about/division-aids-org-chart>

1.5.2.1 Clinical Microbicide Research Branch

The Clinical Microbicide Research Branch (CMRB) is one of four scientific branches within the DAIDS Prevention Sciences Program (PSP). The PSP plans, develops, implements and evaluates a comprehensive extramural program in support of research on HIV prevention. The function of the CMRB is to:

- Plan, develop, implement and evaluate an extramural program in support of HIV topical microbicide research
- Oversee clinical research programs to develop models and biomarkers to evaluate the safety, efficacy and acceptability of HIV topical microbicide candidates
- Provide guidance to the MTN, as needed
- Prepare analyses of gaps, needs and research efforts and determine scientific priorities to recommend funding levels within the program area
- Authorize site-specific study activation for MTN clinical studies

- Coordinate and communicate with DAIDS leadership and other DAIDS policy and program components to ensure timely and accurate interchange or transfer of scientific information relevant to achieving DAIDS's mission
- Communicate and partner with other NIAID components; other NIH institutes and centers; the Office of AIDS Research; and appropriate U.S. Department of Health and Human Services (DHHS) public health agencies and other governmental and nongovernmental organizations (NGO) and institutions, both domestically and internationally, regarding topical microbicide clinical research strategies

1.5.2.1.1 DAIDS Medical Officer

Each MTN protocol is assigned a CMRB staff member, who serves as the DAIDS Medical Officer (MO) for the study.

The DAIDS MO participates in the MTN protocol development process and guides the protocol through DAIDS' procedures for review and approval, including evaluation by the Prevention Science Review Committee (PSRC). The DAIDS MO monitors the safety of the intervention(s) in ongoing studies and reviews all relevant study reports. When a collaborating institution or research group (for example, NICHD or NIMH) sponsors or co-sponsors an MTN protocol, safety-monitoring activities may also be conducted by their respective medical representative(s).

1.5.2.2 Office for Policy and Clinical Research Operations

The Office for Policy and Clinical Research Operations (OPCRO) ensures the effective and efficient implementation of DAIDS's clinical research agenda, policies and procedures. OPCRO, which includes the Regulatory Affairs Branch, Clinical Research Resources Branch and the Protection of Participants, Evaluation and Policy Branch, provides division-wide oversight and support services for DAIDS-sponsored clinical research sites to ensure compliance with applicable regulations, standards and good clinical practice guidelines; the safety and welfare of study participants; and the quality and integrity of the study. This work includes the following:

- Developing and maintaining DAIDS-wide clinical research policies and standard procedures and coordination of related training and quality assurance activities (<https://www.niaid.nih.gov/research/daids-clinical-research-policies-standard-procedures>)
- Implementing the DAIDS safety monitoring and reporting system, related safety standards and the pharmacovigilance capacity
- Managing Investigational New Drug (IND) applications and serving as the point of contact for all FDA/IND communications from Sponsor organizations for trials for which DAIDS does not hold the IND
- Developing negotiated clinical trials agreements (CTAs) and other agreements for DAIDS clinical research and collaborative activities (in general, terms in the CTA covering data access and sharing conform to policies developed jointly by the MTN LOC and DAIDS)
- Protecting the rights and well-being of clinical research subjects

1.5.2.3 Office of Clinical Site Oversight

The DAIDS Office of Clinical Site Oversight (OCSO) facilitates clinical research and verifies that sites are employing optimal safeguards for participants' safety and engaging in high quality research practices. OCSO, which includes the Pharmaceutical Affairs Branch (PAB), Monitoring and Operations Branch, Africa and the Domestic Partners Branch, oversees the performance

and capabilities of DAIDS Network CTUs, CRSs and protocol-specific (PS) sites. This work includes the following:

- Assuming primary responsibility as the DAIDS point of contact for the distribution and oversight of core funds to the CTU and affiliated CRSs
- Assuming primary responsibility as the DAIDS point of contact with sites for matters related to the preparation and approval of the site (including PS); assessing the site's capacity for additional protocols and/or MTN affiliations; monitoring the site; evaluating site performance and suspending or closing sites
- Assuming lead responsibility within DAIDS for collaborating with the Networks to develop and implement harmonized site-evaluation systems and to use this information for analyzing the progress, effectiveness and outputs of clinical trials programs
- Monitoring Network-associated CTU and CRS progress toward the enrollment of underserved populations and the inclusion of community representation
- Overseeing monitoring activities and resolving findings
- Developing protocol-specific monitoring plans in conjunction with the assigned DAIDS MO
- Providing pharmaceutical expertise and support for protocol development and implementation, managing study products and pharmacist training regarding them, and overseeing and providing guidance to site pharmacies, when needed

The PAB is responsible for the review and approval of each CRS Pharmacy Establishment Plan, which must be in place at each CRS prior to protocol registration. The PAB assesses the pharmaceutical aspects of each protocol and communicates its assessment during PSRC reviews.

1.5.2.4 Prevention Sciences Review Committee

The PSRC was established within DAIDS as a mechanism to assess and evaluate proposed clinical studies.

As part of its formal review of MTN's clinical research proposals, the PSRC assesses the following:

- The relevance of the proposal to DAIDS's scientific priorities and its other planned or ongoing clinical studies
- The scientific merit of the study, especially its primary objectives and study design
- Plans to ensure participants' safety based on the eligibility requirements, study evaluations, toxicity management and for monitoring data and safety
- The operational feasibility of the study
- Compliance with OHRP and FDA regulations and guidelines for the protection of human subjects
- The statistical plan and the proposed analysis of this plan
- The pharmaceutical aspects of the study, as appropriate
- Whether the protocol merits implementation or whether it has major issues that warrant additional PSRC review

The PSRC membership consists of the following:

- Chair(s)
- The head or a designated representative from the following NIAID components:
 - Office of the Director, DAIDS PSP

- Office of the Director, DAIDS Vaccine Research Program (VRP)
- CMRB, DAIDS PSP
- Clinical Prevention Research Branch, DAIDS PSP
- Preclinical Microbicide and Prevention Research Branch, DAIDS PSP
- Vaccine Clinical Research Branch, DAIDS VRP
- Preclinical Research Development Branch, DAIDS VRP
- Vaccine Clinical Research Branch, DAIDS VRP
- Biostatistics Research Branch, Division of Clinical Research, NIAID
- PAB, DAIDS OCSO
- Regulatory Affairs Branch, DAIDS OPCRO

The PSRC reviewers include the following:

- DAIDS primary reviewer
- Biostatistics reviewer
- Pharmacy reviewer (if applicable)
- Regulatory reviewer
- Additional reviewer(s) if requested by the DAIDS primary reviewer or program director

Attendees include the following:

- DAIDS PSRC Coordinator
- Regulatory Support Center (RSC) PSRC Coordinator
- DAIDS staff
- National Institute on Drug Abuse staff (if applicable)
- NIMH staff (if applicable)
- NICHD staff (if applicable)
- Department of Clinical Bioethics staff (if applicable)
- Others invited by the PSRC

The full PSRC reviews protocols. The PSRC Chair or designee returns written comments and recommendations to the protocol team within 10 business days after review. If a protocol is not approved, DAIDS will not provide study products or permit expenditure of DAIDS funds for the proposed study. (See Appendix I for the DAIDS PSRC Policy.)

1.5.3 DAIDS Contractors

DAIDS oversees the research activities it sponsors through grants and contracts.

1.5.3.1 Regulatory Support Center

The OPCRO, within DAIDS, contracts with the RSC (<http://rsc.tech-res.com/>) to provide regulatory support to DAIDS-sponsored studies. This support consists of the following:

- For all protocols:
 - Reviewing protocol and informed consent for regulatory compliance
 - Registering protocols
 - Preparing CTAs
 - Tracking regulatory records
- For DAIDS-held INDs or New Drug Applications (NDAs):

- Preparing and maintaining the IND applications and amendments, annual reports and responding to FDA comments
- Preparing NDAs, including providing responses to FDA's comments
- Preparing and submitting the IND safety reports to FDA
- For non-DAIDS-held INDs or NDAs:
 - Receiving and managing expedited adverse event (EAE) reports
 - Distributing and managing investigators' brochures
 - Distributing and managing safety information

All MTN studies will follow the policies and procedures outlined in the most recent versions of the *DAIDS Protocol Registration Policy and Procedures Manual* and the *DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events*, which are located on the RSC's website: <http://rsc.tech-res.com/clinical-research-sites/protocol-registration> and <http://rsc.tech-res.com/clinical-research-sites/safety-reporting/daids-grading-tables>.

1.5.3.2 Clinical Site Monitoring Group

DAIDS contracts with a Clinical Site Monitoring Group (CSMG) to evaluate the quality and integrity of study data at MTN study sites. (See Section 17 of this manual for detailed information regarding monitoring.) Site product shipment reports are provided to the CSMG by the CRPMC for use during monitoring visits.

1.5.3.3 NIAID HIV and Other Infectious Diseases Clinical Research Support Services Contract

Clinical Research Support Services (CRSS) has specialized experience in providing support services to DAIDS for both U.S. and non-U.S. HIV clinical research. Services include, but are not limited to, site trainings, assessments, audits and other special assignments.

1.5.4 U.S. Food and Drug Administration

In its capacity as the U.S. drug regulatory authority, the FDA acts as a close advisor and important liaison to NIAID in developing and monitoring studies of investigational products. Because many of the clinical studies conducted by the MTN are performed under the auspices of IND applications, the FDA has direct responsibility for reviewing MTN study protocols and amendments, regardless of whether the studies are conducted at U.S. or non-U.S. sites. In some MTN studies, DAIDS holds the IND and is therefore responsible for communicating with the FDA.

The FDA also receives and reviews IND Safety Reports that meet reporting criteria under the *Code of Federal Regulations* 21 CFR 312.56. As part of its role in the review of new products, the FDA may conduct audits of MTN's studies.

1.5.5 U.S. Department of Health and Human Services

NIH is a component of the Department of Health and Human Services (DHHS). The DHHS OHRP fulfills responsibilities set forth in the Public Health Service Act. This includes monitoring for compliance with DHHS regulations for the protection of human subjects in research supported by any component of DHHS. The OHRP is also responsible for establishing criteria for and the negotiation of Assurances of Compliance with institutions engaged in research involving human subjects supported by DHHS. MTN and its protocols operate in full compliance with OHRP's regulations and guidelines.

1.5.5.1 DHHS Participating Granting Organizations

DHHS is the primary funder of outside network monies for microbicide research. The primary goal of many such awards is to provide support for the microbicide development pipeline. For example, the Integrated Preclinical/Clinical Program for HIV Microbicides and Biomedical Prevention supports multiproject, multidisciplinary, pre-clinical and exploratory clinical studies. The goal of these studies is to advance safe and novel topical microbicides and microbicide combination strategies for preventing the sexual transmission of HIV. The MTN EC will work with DHHS and other relevant organizations to review products that are the farthest along the development pipeline and will decide which to put into clinical trials. The work done by MTN will be through a Memorandum of Understanding (MOU) and/or a CTA with the grant awardee.

1.5.5.2 U.S. Office for Civil Rights

The U.S. Office for Civil Rights (OCR) is responsible for enforcing the Health Insurance Portability and Accountability Act (HIPAA) for all covered entities. Compliance with HIPAA is mandatory for studies conducted in U.S. institutions that are covered entities. Each non-U.S. institution is responsible for determining its status as a covered entity under HIPAA. All covered entities are responsible for ensuring compliance with this requirement, as set forth in 45 CFR 160 and 45 CFR 164: <http://www.hhs.gov/ocr/privacy/hipaa/administrative/privacyrule/index.html>.

1.6 Other Organizations

Several other organizations support the development of microbicides for the prevention of sexual transmission of HIV. These include, but are not limited to, The Bill & Melinda Gates Foundation, the Population Council, the International Partnership for Microbicides and CONRAD. Through contractual agreements or MOUs, these organizations provide MTN with additional financial support or study products for MTN's clinical trials. MTN works in cooperation with these groups to further microbicide research.