5 Microbicide Trials Network's (MTN) Funding Procedures

The Microbicide Trials Network (MTN) is funded by the U.S. National Institutes of Health (NIH) through a mechanism called a UM1 Cooperative Agreement, with three UM1 awards from the Division of AIDS (DAIDS) of the National Institute of Allergy and Infectious Diseases (NIAID) supporting the MTN Leadership Group infrastructure. The MTN also receives co-funding from the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) and the National Institute of Mental Health (NIMH). Currently, the MTN is in its second award cycle. The first award cycle was from June 29, 2006 through December 31, 2013. The second award cycle covers January 1, 2014 through November 30, 2020. For fiscal oversight in the current funding award cycle, the MTN operates on a fiscal year from December 1 to November 30.

The MTN consists of three main components: Leadership and Operations Center (LOC), Statistical and Data Management Center (SDMC) and Laboratory Center (LC). Each is funded through separate awards. The awardee institutions for each component are:

- Magee-Womens Research Institute and Foundation (MWRIF) for the LOC
- Fred Hutchinson Cancer Research Center (FHCRC) Statistical Center for HIV/AIDS Research & Prevention (SCHARP) for the SDMC
- MWRIF for the LC

The LOC (University of Pittsburgh [Pitt]) and the LC include groups receiving subawards that are involved in carrying out various responsibilities and are managed through MWRIF.

In a UM1 Cooperative Agreement, the NIH has substantial scientific and programmatic involvement. Under a UM1, the NIH supports and facilitates the recipients' activities by working jointly with the awardees in a partner role. However, it is not NIH's role to assume direction, prime responsibility or dominance of the recipients' activities or the Network's scientific direction. See the *NIH Grants Policy Statement* (http://grants.nih.gov/grants/policy/nihgps_2013/) for more information about the cooperative agreement funding mechanism, and Section 1.5 of this manual for a description of the U.S. health service agencies and offices involved in MTN research.

5.1 Funding Procedures

Funding consists of core funds and protocol funds (PF). Core funds are awarded directly by DAIDS to the MTN LOC (Pitt), LC and SDMC as well as to Clinical Trials Units (CTUs) and their associated Clinical Research Sites (CRSs) through separate UM1 cooperative agreements. All areas of the MTN must follow the *NIH Grants Policy Statement* on the use of funds (http://grants.nih.gov/grants/policy/nihgps_2013/).

Protocol funds for the LOC, LC, and CTUs/CRSs are awarded to the MTN LOC (Pitt) and distributed as subawards to the participating institutions and sites. For the SDMC, their PFs are awarded directly to their grants office. For the LOC, LC and SDMC, PF are funds that can be directly attributed to a specific protocol. PFs for the CTUs/CRSs are funds provided by the MTN for recruiting, enrolling and following study participants. MTN Leadership determines the CTU/CRS PFs on an annual basis, based on the number of participants currently on study and anticipated will be enrolled in the next budget year. The CTUs/CRSs are required to submit individual protocol budgets for the following fiscal year (December 1 – November 30) to the MTN LOC (Pitt) Director of Fiscal Operations. These budgets will be developed in close coordination with the MTN Leadership to estimate individual site needs accurately. A summary of PF expenditures for the previous funding year is submitted by the MTN LOC (Pitt) Director of Fiscal Operations to DAIDS annually on March 31.

5.1.1 Network Leadership Core and Protocol Funds

Budgets are reviewed by MTN Leadership yearly to ensure proper allocation of funds. The MTN LOC (Pitt) Director of Fiscal Operations works closely with the NIAID Prevention Sciences Program (PSP) Clinical Microbicide Research Branch, Branch Chief, Office of Clinical Site Oversight (OSCO) representatives and Grants Management Specialist (GMS). Guidance on when required information is needed is provided in the timeline below (Table 5.1).

Table 5.1. Budgetary Review Timeline

Time of review	Budgetary items reviewed and due dates
March/April	The MTN Executive Committee meets to discuss the upcoming noncompetitive renewal along with the MTN's programmatic goals and direction. This discussion helps MTN's Principal Investigator (PI) and co-PI develop next year's budgets. Financial guidance will also be given to the MTN PI and co-PI according to anticipated funds for the next funding year. Guidance to all MTN components on the annual progress reports will be given by the MTN PI and co-PI.
	The PF expenditure annual report is due to DAIDS March 31.
	The MTN LOC (Pitt) Director of Fiscal Operations issues a budget request and detailed budgetary guidance for PF to the LOC, LC, SDMC, CTUs and CRSs.
August	Formal budget requests for core and PF are sent by the MTN LOC (Pitt) Director of Fiscal Operations to the LOC, LC and participating groups who received subawards for the upcoming funding year. The budgets are reviewed by MTN Leadership and any necessary changes are made.
September	Final budget submissions are due to the MTN LOC (Pitt) Director of Fiscal Operations. Submissions are reviewed and consolidated. Progress reports from the LOC, LC and groups receiving subawards also will be due to the MTN PI and Co-PI.
October	The noncompetitive renewal (annual reports and core/PF budgets) and carryover requests (if needed) are due to NIAID on October 1
November	The funding year ends on November 30. All final invoices must be submitted to LOC (Pitt) in a timely manner and according to the subaward. No funds from the previous fiscal year can be used after this date. The funds may or may not be accessible through a carryover request submitted by the Network.
December	The funding year begins December 1.

MTN must submit its Federal Financial Report (FFR) to NIH within 120 days of the calendar quarter in which the current budget period ends, which is March. This is managed by the LOC (Pitt) Fiscal Operations Team.

After the FFR is accepted by NIH, MTN may submit a carryover request if unobligated funds are available. The LOC (Pitt) Fiscal Operations Team will query institutions receiving subawards about whether additional funds are necessary for the budget year, and if so, will require budgetary information by the middle of January. The LOC (Pitt) Fiscal Operations Team submits the carryover request to the PSP Program Officer (PO) and GMS by February 1. If an amended Notice of Award (NoA) is received, the LOC (Pitt) Fiscal Operations Team will issue an amended subaward. There will be two additional opportunities to request unobligated funds for a June 1 or August 1 review date.

5.2 CTU and CRS Core Funds

The MTN-affiliated CTUs/CRSs will receive their core funds directly from DAIDS through their own grant awards. The information below outlines the renewal process, and carryover and supplemental core funds.

5.2.1 Noncompeting Continuation Progress Reports (Annual Progress Reports)

Each CTU must submit a noncompetitive grant renewal application to DAIDS annually. The CTU PI will receive a letter in August from the OCSO PO that contains specific instructions for

completing the annual progress report and the amount of core funds available to be awarded should the request be approved. Each CTU has an annual award date or budget period of December 1.

Annual awards, which support the administrative components of the CTU and its affiliated CRSs, are contingent on DAIDS approval of the CTU/CRS annual progress report. Progress reports for multi-year funded awards must be submitted using the Research Performance Progress Report (RPPR). Instructions may be found at http://grants.nih.gov/grants/rppr/index.htm.

5.2.2 Carryover Funds

The carryover of unobligated core funds by a CTU/CRS is restricted — these funds cannot be used without prior approval by the CTU's DAIDS OCSO PO and GMS. A CTU wishing to use such funds must submit a carryover request with justification to its GMS and OCSO PO.

All documents must be submitted through the site's business official. The current form and instructions may be found at http://grants2.nih.gov/grants/funding/phs398/phs398.html. All requests should be in keeping with MTN's goals and priorities.

The request will be reviewed after NIH accepts the FFR. Carryover funds cannot be approved until after the FFR is submitted and approved. The FFR must be submitted to NIH through the electronic Research Administration (eRA) Commons within 120 days of the calendar quarter in which the budget period ended.

5.2.3 Supplement Requests

CTU PIs and/or CRS leaders may need additional PF to pay for expenses that are within the scope of an award, but were unforeseen when a grant application was submitted. Any requests related to additional PF should be negotiated with the MTN through the CRS subaward (see section 5.3). The approval of administrative supplement requests is not guaranteed and depends on the availability of funds.

A CTU/CRS that requires supplemental funding for core costs, that is, costs that are not related to any specific protocol, should contact its OCSO PO and GMS. The approval of administrative supplement requests is not guaranteed and depends on the availability of funds. All core fund requests must be submitted to the OCSO PO and GMS through the business official and include the following:

- PHS 398 Face Page
- Reason for request
- Detailed budget and composite budget page if more than one year is requested
- Justification for the funds
- Biographical sketch and human subjects documentation (if applicable) for any new key personnel
- Checklist from the PHS 398

See the following website for the current form and instructions: http://grants2.nih.gov/grants/funding/phs398/phs398.html.

5.3 CTU and CRS Protocol Funds

All PFs for CTUs and CRSs are issued via a subaward with MTN LOC (Pitt). MWRIF is the funding institution for the LOC (Pitt) and LC, and is the institute with which the sites will enter into a subaward agreement.

5.3.1 MTN Contacts for Protocol Funds

Questions regarding PFs should be directed to:

- Cheryl Richards, MTN LOC (Pitt) Director of Fiscal Operations, at 412-641-8983 or crichards@mwri.magee.edu.
- Kim Comer, MTN Fiscal Operations Team Coordinator, at 412-641-6159 or comekj@mwri.magee.edu.

5.3.2 CTU and CRS Contacts

CTUs and CRSs should inform the MTN Fiscal Operations Team of the names and contact information for the following:

- Who needs to be copied on all CTU and CRS communication
- From whom to request budgets
- To whom awards should be sent for review and signature
- Who to contact for audits

5.3.3 Communication with CTU and CRS

All PF communication between the CRS and MTN LOC (Pitt) Director of Fiscal Operations must copy the associated CTU and include the following information:

- Budget submissions
- Subawards
- Notice of Payment
- Other communication as needed

5.3.4 Site Budget Development for Protocol Funds

Template and budgetary guidance will be provided to the CTU/CRS as follows:

- The budget will be organized into two sections: the first section will be used to budget visit costs (screening, enrollment and follow-up) and the second will be used to budget fixed costs.
- Interim visits cannot be tied to an accrual table; an estimate must be included in the fixed cost section of the budget.
- Fixed costs include any expenses that cannot be allocated solely to a visit, such as salaries of PIs, administrative staff, drivers or security; expenses related to community outreach and recruiting; equipment; or travel.
- The CTU and CRS may each have a budget for PF depending on the fiscal relationship of the two.
- For CTUs and associated CRSs that do not rely on the U.S. dollar, the budget should include the local currency amount, the U.S. exchange rate used (with date obtained), and the resulting U.S. dollar value based on that exchange rate.
- Site questions will be directed to MTN LOC (Pitt) Director of Fiscal Operations.

- Submitted budgets will be reviewed by MTN LOC (Pitt and FHI 360), LC, and/or SDMC on an *ad hoc* basis to ensure appropriate expenditure.
- Revisions will be requested when necessary.

5.3.5 Subaward Agreements

Because budget development may occur months prior to the time of the subaward, performance, enrollment targets, regulatory compliance, and the budget of a CTU/CRS will be reviewed prior to issuing the subaward. Unobligated balances and carryovers will also be considered before issuing additional funds. Awards may be issued in one of two ways:

- One award to the CTU and one award to the CRS
- One award to the CTU, which disburses funds to the CRS

Note: There will be no third party subawards

MTN communications with CRSs regarding the subaward will differ depending on the CRS funding scenario:

- If the CTU and CRS are one institution, all communication will occur within one subaward. The communication will be clear and specific to the CTU or CRS.
- If the CTU is not the same institution as the CRS, and the CTU is also receiving funds, communication with regards to CRS funds will be provided in the CTU award.
- If the CTU is not the same institution as the CRS, and the CTU is not receiving funds, the CTU will receive written communication in reference to CRS's funding.

Subawards will be sent to the email contact provided by the CTU/CRS. They will be sent by and should be returned to:

- Cheryl Richards, MTN LOC (Pitt) Director of Fiscal Operations, 412-641-8983, crichards@mwri.magee.edu

Important subaward information:

- The U.S. dollar amount on the subaward will be the potential maximum based on negotiated budgets.
- The terms of the award are flexible based on CTU/CRS needs.
- Awards can be issued on a cost reimbursement or cash advance payment basis; however, advance payments will be made on a case-by-case basis.
- CTU/CRS payments will not be initiated without a signed consortium agreement in place.
- Renewal of consortium agreements at the beginning of a budget period will follow the same process, but will receive a new subaward.
- A copy of the NoA will be attached to each subaward.

5.3.6 CTU and CRS Payments

The payment process for non-U.S. and U.S. CTUs/CRSs is the same, except non-U.S. CTUs/CRSs typically will be paid by bank wire, and U.S. CTUs/CRSs typically by check.

The standard payment for PF is on a cost-reimbursement basis. Cash advance payments are only given at protocol start-up or if the site has a legitimate need. At protocol start-up, the

advance payment is based on an estimation of fixed start-up costs negotiated with the site and also a pre-determined number of screening and/or enrollment visits. Requests for a cash advance during the course of the protocol are reviewed on a case-by-case basis. If approved, a one-month advance is issued based on the prior month's expenditures.

Payments are made based on the approved budgets and are invoiced on a monthly basis. Invoices must include a report(s) of the expenses with the protocol-specific charges identified and the U.S. exchange rate used to determine the total cost. A sample/template invoice can be provided by the MTN LOC (Pitt) Fiscal Operations Team.

Timeline for Payments:

- Payments will be made on a monthly basis.
- The site must submit all monthly data forms to the SDMC by Day 5 of the following month.
- The SDMC will issue a report to MTN LOC (Pitt) Fiscal Operations Team monthly detailing the number of visits by visit type (screening, enrollment, follow-up, interim) and by protocol. This information will be used to define activity versus the expenses noted in the invoice.
- Invoice for monthly expenses should be received by MTN LOC (Pitt) Fiscal Operations Team by Day 15.
- MTN LOC (Pitt) Fiscal Operations Team will issue payment by the last day of the month. For example: February visit CRFs must be submitted to the SDMC by March 5. On March 15, the SDMC will issue a report to the MTN LOC (Pitt) Fiscal Operations Team. The site will send an invoice for February by March 15. MTN LOC (Pitt) Fiscal Operations Team will review the invoice request and issue payment by March 31.
- Advance payment requests must be made a month ahead of the anticipated need and must be received by the MTN LOC (Pitt) Fiscal Operations Team by Day 7 of that month to be approved by Day 15 and issued by Day 21.
- A template of the advance payment procedures can be obtained from the MTN LOC (Pitt) Fiscal Operations Team.

5.3.6.1 Protocol Changes

If protocol changes occur during the course of the study, the site is contacted by the MTN LOC (Pitt) Director of Fiscal Operations to ascertain whether additional expenses are expected. At this time, a budget for the additional expenses will be requested and reviewed. The subaward will be amended to include the additional funds.

5.3.7 Restricted Funds and Cost Items Requiring Prior Approval

Sites should request approval to use restricted funds or cost items that require additional approval by sending an email to the MTN LOC (Pitt) Director of Fiscal Operations. The MTN LOC (Pitt) Director of Fiscal Operations will review the request and submit a formal request to NIAID for approval. The approval will be issued to the MTN via email, and then the MTN will issue written approval via email to the CTU/CRS.

5.3.7.1 Clinical Trials Insurance

Clinical Trials Insurance (CTI) must be a country requirement, used for research-related injuries only and be protocol-specific. The CTU/CRS must submit the required documentation to the MTN LOC (Pitt) Director of Fiscal Operations to obtain approval to use PF for the purchase of CTI. Requests must be per CTU/CRS and on a per protocol basis even if the actual purchase of

the insurance is at the CTU level. All requests must be signed by the CTU's/CRS's business official and the following documentation must be submitted with each request:

- A copy of guidance or laws stating that CTI coverage is required
- A written explanation of:
  - Type of insurance coverage required
  - Reason that the institution does not carry this insurance
  - Insurance-carrier selection process
  - Length of coverage, specifying whether annual payments are to be made or one payment encompassing the entire protocol period
  - Adequate justification if a quote is not available
- Identification of person(s) responsible for selecting insurance company
- Three insurance quotes
- Completed CTI checklist to include premium amounts (provided on request), exclusive of value added tax (VAT)

If the use of PF to purchase CTI coverage is approved, the NIH GMS will notify the MTN LOC (Pitt) Director of Fiscal Operations via e-mail. Once the e-mail is received, the MTN LOC (Pitt) Director of Fiscal Operations will notify the CTU/CRS of the approval. The CTU/CRS must not use PF funds to purchase CTI until they receive this notification.

5.3.8 Resource Sharing

When CTUs and CRSs are developing budgets, they should take into consideration any resources that could be shared between the CTU and CRS, or between CRSs if the CTU has more than one CRS participating in an MTN protocol. This can include any cost item, such as equipment, staffing, community activities or recruiting costs.

Once budgets are established and approved, any re-allocation of funds must be requested by emailing the MTN LOC (Pitt) Director of Fiscal Operations. The request must include a justification for the re-allocation so the CTU/CRS spending can be monitored appropriately. A CTU/CRS can re-budget within protocols, but again must email the MTN LOC (Pitt) Director of Fiscal Operations with a justification for the request.

Re-allocation of funds between CTUs/CRSs will be managed at the MTN LOC (Pitt) and will be based on performance. If a site is underperforming and enrollment slots are re-allocated to another CTU/CRS, funds will also be redistributed. This will be done by amending subawards.

5.3.9 Start-Up and Close-Out Costs

Guidance for budgeting start-up and close-out costs will be provided when budgets are requested. Advance payments will be made at protocol start-up based on an estimation of start-up costs negotiated with the CTU/CRS and also for a pre-determined number of screening and/or enrollment costs. During the year in which a protocol will close out, the CTU/CRS will receive budgetary guidance at the time of budget development to consider the decreased level of funding and resources that are required during this time.

5.3.10 Monitoring Site Performance

The MTN LOC (Pitt) Director of Fiscal Operations monitors CRS performance in collaboration with other areas of MTN, such as the MTN Network Evaluation Committee (NEC). Invoices are also reviewed to ensure expenses are appropriate to the CTU's/CRS's budget and

performance. If questions arise, the MTN LOC (Pitt) Director of Fiscal Operations may ask for support from the MTN LC and/or MTN SDMC personnel involved in the studies at the CRS. The MTN NEC and MTN Regulatory Department provide routine updates regarding CRS performance and regulatory approval status of protocols.

If any CTU/CRS is unable to meet the requirements of the MTN LOC and DAIDS by its negotiated deadline, funding may be withdrawn and a plan to phase-out the CRS will be established. If the scope of work changes, the MTN LOC (Pitt), in conjunction with DAIDS, reserves the right to negotiate efforts and funds upward or downward as appropriate for that budget year.

5.4 MTN Financial Disclosure Requirements

Pursuant to the U.S. Food and Drug Administration (FDA), Code of Federal Regulations (CFR) Title 42, Part 50, *Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding Is Sought* (http://grants.nih.gov/grants/policy/coi/coi_faqs.htm) and the DAIDS Networks' Standard Operating Procedures (SOPs), network members in key leadership or decision-making positions must report any significant financial relationships that they or family members have with relevant entities that might be construed as engendering a conflict of interest when conducting clinical research.

Methods for disclosure will adhere to the procedures outlined in the cross-network policy, titled *NIH HIV/AIDS CLINICAL TRIALS NETWORKS Financial Disclosure and Conflict of Interest Guidelines Standard Operating Procedure* (http://www.mtnstopshiv.org/node/1639). These disclosures are submitted at least annually.

Additionally, for studies conducted in support of an Investigational New Drug (IND) Application or an Investigational Device Exemption (IDE), a separate disclosure must be obtained from all investigators listed on FDA Form 1572s, pursuant to Title 21 CFR 54, *Financial Disclosure by Clinical Investigators*. For these trials, disclosure must be obtained from the investigator when he or she is first added to the FDA Form 1572 (prior to beginning study-associated responsibilities, that is prior to or on the day of the investigator and/or sub-investigators being added to the FDA Form 1572), within 30 days of discovering or acquiring a new significant financial interest, at the completion of all study-specific activities and for one year following study completion. MTN also applies this requirement to all investigators listed on the DAIDS IoR Form for non-IND/IDE studies whose primary objective(s) are other than behavioral. The disclosure relating to Title 21 CFR 54 (http://www.ecfr.gov/cgi-bin/text-idx?SID=ff6ecdc2625b8d544dc8753c60ce46aa&node=pt21.1.54&rgn=div5) will be study-specific and separate from the DAIDS disclosure document described above. These paper disclosure forms must be signed and dated by hand in ink. No electronic signatures or dates will be accepted.

5.5 Financial Disclosure and Conflict of Interest Policy

To minimize the potential for bias in the design, conduct, reporting and analysis of research funded by any of the Awarding Components of the Public Health Service, U.S. Federal regulation, *Title 42 CFR 50,* states that each institution receiving or applying for such funding must obtain sufficient, accurate financial information that will allow the institution to identify and manage financial conflicts of interest (FCOI) and report them to NIH through the eRA Commons

FCOI Module. The requirements of *Title 42 CFR 50* (http://www.ecfr.gov/cgi-bin/text-idx?rgn=div5&node=42:1.0.1.4.23#se42.1.50_1604) apply to clinical and non-clinical research and focus broadly on senior/key personnel who are responsible for the design, conduct, analysis and reporting of the funded research. Failure to comply with these regulations, depending on the severity and duration of noncompliance, could result in suspension or termination of funding by the NIH.

Similarly, the FDA requires clinical investigators who are conducting research under an IND or IDE to disclose certain financial information to study sponsors. U.S. Federal regulations, *Titles 21 CFR 312.53* and *21 CFR 812.43*, state that before permitting an investigator to participate in a clinical study, the IND/IDE sponsor must obtain sufficient, accurate financial information, as required by *Title 21 CFR 54*, that will allow a marketing applicant to submit complete and accurate certification or financial disclosure statements to the FDA as part of the application (*Titles 21 CFR 314.50* and *21 CFR 814.20*). The requirements of *Title 21 CFR 54* (http://www.ecfr.gov/cgi-bin/text-idx?SID=ff6ecdc2625b8d544dc8753c60ce46aa&node=pt21.1.54&rgn=div5) apply only to clinical research conducted under an IND/IDE and focus on the financial interests of the clinical investigators participating in the investigation at the various CTUs/CRSs. When the FDA reviews the data from a clinical study that supports an application for marketing approval, it may consider a study inadequate if appropriate steps have not been taken to minimize the potential for bias and ensure the objectivity of the research. MTN also applies this requirement to all investigators listed on the DAIDS IoR Form for non-IND/IDE studies whose primary objective(s) are other than behavioral.

DAIDS, which is the financial sponsor and in some instances the regulatory sponsor for the research facilitated and managed by the MTN, has delegated to MTN the responsibility for collecting the financial disclosure information required by Federal regulations *Titles 21 CFR 54* and *42 CFR 50.* Two guidance documents are provided for the HIV/AIDS Networks to follow:

- *Title* 42 CFR 50 compliance: NIH HIV/AIDS Clinical Trials Networks Financial Disclosure and Conflict of Interest Guidelines Standard Operating Procedure (SOP) developed by the Office of HIV/AIDS Network Coordination (HANC), and which may be found on the MTN website (http://www.mtnstopshiv.org/node/1639).
- *Title* 21 CFR 54 compliance: DAIDS provided guidance (dated July 1, 2014), which can be found on the protocol registration web page: http://rsc.tech-res.com/protocolregistration/.

Some investigators may be required to disclose significant financial interests according to both procedures, depending on their study and Network responsibilities.

Financial disclosures in compliance with *Title 42 CFR 50* will be completed and maintained by the Office of HIV/AIDS Network Coordination (HANC) in the online HANC Financial Disclosure System (https://fd.hanc.info). To guide all investigators needing to complete their disclosures relative to *Title 42 CFR 50,* a list of the products and manufacturers that MTN has or is currently working with on microbicide research is located on the website (http://www.mtnstopshiv.org/node/1639) and updated, as needed.

Financial disclosures completed in compliance with *Title 21 CFR 54* will be documented on a study-specific paper form that must be kept on file with other Essential Documents for each study (see section 11.1 of this manual for further information on Essential Documents). The DAIDS Clinical Site Monitoring Group will routinely review site Essential Documents files to

ensure that required documentation is maintained. These paper disclosure forms must be signed and dated by hand in ink. No electronic signatures or dates will be accepted.

5.6 NIH Certificate of Confidentiality

MTN holds a U.S. Government Certificate of Confidentiality (COC) that covers U.S.-based sites conducting sensitive biomedical, behavioral, clinical or other health-related MTN research. The certificate permanently protects investigators and study-site staff at U.S. sites who have access to research records or biological samples for listed studies from being forced — even under court order or subpoena — to release any data or study samples from which a participant could be identified without the participant's written consent. The staff at LOC (Pitt) facilitate registration of each MTN U.S. study site, to which the certification applies, and are responsible for updating and maintaining records on an ongoing basis, as needed.

The COC does not cover voluntary disclosures (that is, voluntary disclosure by a research participant to his/her health provider or insurer), reporting of suspected harm to others or self or requests by authorized U.S. Department of Health and Human Services personnel. Site staff are responsible for informing participants of the COC's limitations of coverage. MTN protocols incorporate a standard informed consent form (ICF) that contains language describing the COC and its limitations to participants. The staff at LOC (FHI 360) work with U.S. sites to ensure that a description of the COC is included in the ICF, as needed. When COC coverage has been obtained for the site, LOC (Pitt) staff will notify the site.