

MTN Manual of Operational Procedures (MOP)

Section 5: Network Funding Procedures

5	NETWORK FUNDING PROCEDURES	5-1
5.1	Funding Procedures	5-2
5.1.1	Network Leadership Core and Protocol Funds	5-3
5.2	CTU and CRS Core Funds	5-4
5.2.1	Noncompeting Continuation Progress Reports (Annual Progress Reports)	5-4
5.2.2	Carryover Funds	5-4
5.2.3	Supplement Requests	5-4
5.3	CTU and CRS Protocol Funds	5-4
5.3.1	MTN Contacts for Protocol Funds	5-4
5.3.2	CTU and CRS Contacts	5-5
5.3.3	Communication with CTU and CRS	5-5
5.3.4	Site Budget Development for Protocol Funds	5-5
5.3.5	Subaward Agreements	5-5
5.3.6	CTU and CRS Payments	5-6
5.3.7	Restricted Funds and Cost Items Requiring Prior Approval	5-7
5.3.8	Resource Sharing	5-7
5.3.9	Start-Up and Close-Out Costs	5-7
5.3.10	Monitoring Site Performance	5-8
5.4	Regulatory Financial Disclosure Requirements	5-8
5.5	MTN Financial Disclosure and Conflict of Interest Policy	5-9
5.6	NIH Certificate of Confidentiality	5-10

5 Network 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 (FHCR) 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* <https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf> for more information about the cooperative agreement funding mechanism, and Section 2.1 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: <https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf>.

PF are funds that can be directly attributed to a specific protocol. PF for leadership responsibilities are awarded to the MTN LOC (Pitt) and distributed as subawards to the participating institutions. PF for CTU/CRS salary support are awarded directly to the CTUs/CRSs via their award. PF for CTU/CRS "all other costs" are awarded to the MTN LOC (Pitt) and distributed as subawards to the participating sites. PF for the LC are awarded to the LC for distribution to the participating institutions. PF for the SDMC are awarded to the SDMC. PF for the CTUs/CRSs are funds provided by the MTN for recruiting, enrolling and following study participants. MTN Leadership determines the CTU/CRS PF on an annual basis, based on the number of participants currently on study and anticipated to 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 initially developed collaboratively by the CTUs/CRSs and the MTN LOC (Pitt) Director of Fiscal Operations and reviewed by MTN Leadership yearly to ensure proper allocation of funds. The 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
February	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.
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 for the previous budget year is due to DAIDS March 31.
	Submit PF request for the next budget year by March 31.
August	A formal request for core budgets is sent by the MTN LOC (Pitt) Director of Fiscal Operations to the LOC, LC and participating groups who are expected to receive 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, core budgets and PF approved plan) 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) for the LOC and LC 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.

If needed, requests for supplemental funds can be submitted at the discretion of DAIDS. Guidance for these requests is provided by DAIDS.

5.2 CTU and CRS Core Funds

The MTN-affiliated CTUs/CRSs will receive their core funds and PF for salary support directly from DAIDS through their own UM1 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 <https://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. All requests should be in keeping with MTN's goals and priorities.

The Federal Financial Report (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 the annual PF plan was approved. Any requests related to additional PF should be negotiated with the MTN through the CRS subaward (see section 5.3). The approval of requests is not guaranteed and depends on the availability of funds.

5.3 CTU and CRS Protocol Funds

PF for "all other costs" for CTUs/ 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 PF 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 communications
- From whom to request budgets
- To whom subawards 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.
- 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, and the resulting U.S. dollar value based on that exchange rate.
- Site questions will be directed to the MTN LOC (Pitt) Director of Fiscal Operations.
- Submitted budgets will be reviewed by MTN LOC (Pitt) and LC 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. 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

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 to the CTU. If the CTU is not the same institution as the CRS, and the CTU is not receiving funds, the CTU will receive written communication about 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 subaward agreement in place.
- Renewal of subaward agreements at the beginning of a budget period will follow the same process but will receive a new subaward.
- A copy of the Notice of Award (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 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 and the anticipated, next month's expenditures.

Payments are made based on the approved budgets and are invoiced monthly. Invoices must include a report(s) of the expenses with the protocol-specific charges identified. 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.

- MTN LOC (Pitt) reviews monthly accrual, enrollment and follow-up to assure adequate progress. This information will be used to verify activity noted in the invoice.
- Invoices 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. Advance payment requests must be made a month ahead of the anticipated need.
- 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 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, if required, to NIAID for approval. The approval will be issued to the MTN via email, and then the MTN will issue approval via email to the CTU/CRS.

5.3.7.1 Clinical Trials Insurance

Clinical Trials Insurance (CTI) will be purchased, in compliance with DAIDS policies and procedures.

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. See Section 5.3.6 of this Manual regarding cash advance payments. 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 Regulatory Financial Disclosure Requirements

Pursuant to the U.S. Public Health Service (PHS), *Code of Federal Regulations (CFR), Title 42, Part 50, Promoting Objectivity in Research* (<https://www.ecfr.gov>) and the DAIDS Networks' financial disclosure guidelines/standard operating procedure (https://mtnstopshiv.org/sites/default/files/hanc_fdcoi_sop_v7.0_04.19.18_0.pdf), network members in key leadership or decision-making positions must report any significant financial relationships that they or their family members have with relevant entities that might be construed as engendering a conflict of interest when conducting clinical research.

Methods for disclosure must adhere to the procedures outlined in the cross-network guidance, *NIH HIV/AIDS CLINICAL TRIALS NETWORKS: Financial Disclosure and Conflict of Interest Guidelines Standard Operating Procedure* (https://mtnstopshiv.org/sites/default/files/hanc_fdcoi_sop_v7.0_04.19.18_0.pdf). These disclosures must be submitted when first joining the Network and at least annually, thereafter.

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 1572*, pursuant to *Title 21 CFR 54, Financial Disclosure by Clinical Investigators* and DAIDS requirements (<https://www.ecfr.gov>). As per DAIDS Guidance (<https://rsc.niaid.nih.gov/sites/default/files/FinancialDisclosureINDTrials.pdf>), financial disclosure for these studies must be obtained from the investigator prior to or on the day he or she is first added to the *FDA Form 1572* (i.e., prior to beginning study-associated responsibilities), within 30 days of discovering or acquiring a new significant financial interest, at the completion of all their 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 will be study-specific and separate from the DAIDS disclosure document relating to *Title 42 CFR 50*, described above.

In the absence of electronic systems approved for use by DAIDS and/or the Network (see Section 9.2.2 of this Manual), these paper disclosure forms must be signed and dated by hand

and in ink. No electronic signatures or dates will be accepted unless approved according to MTN Good Documentation Practices Policy (see Section 9.2.2 of this Manual).

5.5 MTN 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* (<https://www.ecfr.gov/>) 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/>) 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 42 CFR 50* and *21 CFR 54*. 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), which may be found on the MTN website (<http://www.mtnstopshiv.org/resources/financial-disclosure-policies-tables-and-forms>)
- *Title 21 CFR 54* compliance: DAIDS provided guidance (dated July 1, 2014), which can be found on the DAIDS Regulatory Support Center web page: <http://rsc.tech-res.com/clinical-research-sites/daids-financial-disclosure-forms>.

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 by investigators 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 previously or is currently working with is located on the MTN website (https://mtnstopshiv.org/sites/default/files/2018_table_product_corporate_developers_09.17.18_final.pdf) and is updated, as needed.

Financial disclosures completed in compliance with *Title 21 CFR 54* will be documented on a study-specific paper form (available from the Network website under “Study Implementation Materials” for the study). In the absence of electronic systems approved for use by DAIDS and/or the Network (see Section 9.2.2 of this Manual), these paper disclosure forms must be signed and dated by hand and in ink. No electronic signatures or dates will be accepted. These completed forms must be uploaded to DPRS and 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.

5.6 NIH Certificate of Confidentiality

MTN holds an NIH Certificate of Confidentiality (CoC), which was first issued on May 29, 2007. This certificate protects the privacy of all MTN study participants (U.S. and/or international) whose personal information has been or will be collected, either in the U.S. or abroad, and stored in the U.S.

Effective October 1, 2017, in compliance with *Section 2012 of the 21st Century Cures Act* (<https://www.congress.gov/bill/114th-congress/house-bill/34/text>) and updated NIH policy (<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-109.html>), all NIH-funded studies are automatically added to the certificate and all participating U.S. investigators are required to protect the privacy of all study participants and shall not:

- Disclose or provide, in any U.S. federal, state or local civil, criminal, administrative, legislative or other proceeding, the name of such individual or any such information, document or biospecimen that contains identifiable, sensitive information about the individual and that was created or compiled for purposes of the research, unless such disclosure or use is made with the consent of the individual to whom the information, document or biospecimen pertains; or
- Disclose or provide to any other person not connected with the research the name of such an individual or any information, document or biospecimen that contains identifiable, sensitive information about such an individual and that was created or compiled for purposes of the research, unless the disclosure is intended for the purposes of other scientific research that is in compliance with applicable U.S. federal regulations governing the protection of human subjects in research.

The CoC does not cover voluntary disclosures made by the research participant (including voluntary disclosures by a research participant to his or her healthcare provider or insurer), the reporting of suspected harm to self or others, or requests by authorized U.S. Department of Health and Human Services personnel. MTN protocols incorporate a standard informed consent form (ICF) that contains language describing the CoC and its limitations to participants,

and 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. U.S. site staff are responsible for informing participants of the CoC's limitations of coverage, as required.