12. TRAINING

The Microbicide Trials Network (MTN) is committed to developing qualified and trained staff, capable of reliably protecting the safety and confidentiality of study participants and producing high quality, clinical research. To achieve this goal, all key MTN personnel, whether at clinical research site or network operational levels, are required to comply with the training requirements described in this section. Section 12.1 lists training requirements for the Network operational level staff [including MTN LOC (Pitt), MTN LOC (FHI 360), LC and SCHARP]. Section 12.2 lists training requirements for Clinical Research Sites (CRSs).

12.1 Network Operational Level Training Requirements

All key MTN personnel (i.e., all Network level investigators having a key role in the design, conduct, oversight, reporting or analysis of MTN research) are required to complete *Good Clinical Practice* (GCP), *Human Subject Protection* (HSP), *Good Documentation Practice* (GDP) and *Financial Disclosure* (FD) training prior to assuming meaningful, unsupervised responsibility in the areas of study design, conduct, oversight, management, reporting or analysis of MTN research and, at minimum, every three years thereafter. These requirements are based on those of the U.S. Public Health Service (PHS), the National Institutes of Health (NIH) and the National Institute of Allergy and Infectious Diseases (NIAID), Division of AIDS (DAIDS).

12.1.1 42 CFR 50 Financial Disclosure

PHS requires that "any person who is responsible for the design, conduct or reporting of research funded by PHS (42 CFR 50.603)" or any of its components (42CFR 50.603) completes financial disclosure training [42 CFR 50.604(b)] prior to assuming their Network responsibilities and, at least, every four years thereafter. The MTN LOC (Pitt) provides this training annually, through email, in the weeks prior to the annual DAIDS Network Financial Disclosure period, in addition to the time preceding the first disclosure request. The MTN LOC (Pitt) identifies which Network investigators are required to receive training and disclose their financial interests and maintains training records. CRS staff whose responsibilities are limited to direct involvement in the treatment and/or evaluation of study participants are not included. (See Sections 11.5 and 12.2.3.2 of this Manual.)

12.1.2 Good Clinical Practice and Human Subjects Protection

NIH requires "all NIH-funded clinical investigators and clinical trial staff who are involved in the design, conduct, oversight or management of clinical trials" to be trained in *Good Clinical Practice* (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-148.html) and *Human Subjects Protection* (https://grants.nih.gov/grants/guide/notice-files/not-od-00-039.html) standards prior to assuming their Network responsibilities and, at least, every three years thereafter. Each Network organizational unit [MTN LOC (Pitt and FHI 360), LC and SCHARP] will identify which of their investigators (staff) must receive and maintain training and how training documentation will be collected and stored.

12.1.3 Responsible Conduct and Ethics

In accordance with the MTN RFA-AI-12-008 Grant Application (#12167005), MTN LOC (Pitt), MTN LOC (FHI 360) and SCHARP Clinical Data Managers (formerly titled "Project Managers") must complete Responsible Conduct and Ethics training at the time of their hire and every three years thereafter, according to the requirements of their institution.

12.1.4 Good Documentation Practice

While Good Documentation Practice (GDP) training is not specifically named by any federal U.S. regulatory bodies, GDP is an integral part of ICH E6 GCP and is essential to establishing the integrity and reliability of clinical research results. Because of its importance, the Network requires that GDP training be completed by Network investigators who are members of the MTN Groups listed in Table 9.1 (See Section 9.2.2 of this Manual). Each Network organizational unit will identify which of their investigators (staff) must receive and maintain training and how training documentation will be collected and stored.

12.1.5 DAIDS Policies and Procedures

In accordance with the MTN RFA-AI-12-008 Grant Application (#12167005), specific training regarding DAIDS policies, such as *Critical Event Reporting*, is required to be completed by all Protocol Chairs, FHI 360 staff, SCHARP Clinical Data Managers, the Director of Pharmacy Affairs, Laboratory Site Support staff and managers, Protocol Development staff, Network Evaluation staff, MTN Regulatory staff and the MTN Director of Operations. Each Network organizational unit [MTN LOC (Pitt), MTN LOC (FHI 360), LC and SCHARP) will identify which of their investigators (staff) must receive and maintain training and determine how training documentation will be collected and stored.

12.1.6 Other Required Training

Additionally, each of the Network organizational units will require their investigators (staff) to complete documented training on applicable portions of the following materials, as they pertain to their Network responsibilities:

- The *MTN Manual of Operational Procedures* (MOP)
- Organization-specific internal policies, procedures and work instructions
- The regulations and guidance documents of the Food and Drug Administration (FDA)

Training should be completed before the investigator (staff member) begins to assume unsupervised responsibility in the affected area and as soon as possible following the release of a new or revised MOP or agency policy, procedure, work instruction, regulation or guidance. Training to internal policies, procedures and work instructions should occur prior to their effective date.

12.2 Clinical Research Site (CRS) Training Requirements

This section describes MTN training requirements and procedures that must be completed by Clinical Trials Unit (CTU) and CRS staff involved in conducting MTN clinical (biomedical and/or behavioral) studies. These requirements are based, in part, on those of the NIH and DAIDS and are principally presented in DAIDS Training Policy, DWD-POL-CL-03, see Section 12.2.1. MTN has added some additional requirements (See Section 12.2.3).

The Investigator of Record (IoR) is responsible for ensuring that all relevant CRS personnel complete all required and necessary training prior to screening and enrollment of the first study participant and every three years thereafter while the study is ongoing. For new key personnel (staff hired after study activation), documentation of the required training must be completed within 90 days of assignment to the MTN study and prior to their functioning without direct supervision, unless it was received within the past three years and documentation is available. The IoR must ensure that training records, covering the duration of each investigator's study involvement, are maintained onsite and must make these records available to the representatives of MTN, the study sponsor(s), the U.S. federal government, including the U.S. FDA, the U.S. OHRP, NIH and/or contractors of the NIH, and other local, U.S., and international regulatory entities upon request.

12.2.1 DAIDS Training Policy (DWD-POL-CL-03)

DAIDS policy (https://www.niaid.nih.gov/sites/default/files/gcp_hsp_sitetrain_policy.pdf) defines key personnel (those requiring training) at CRSs as individuals who are involved in conducting of human subject clinical research funded and/or sponsored by NIAID/DAIDS. This includes any site personnel who are more than minimally involved with the conduct of the research (such as performing study evaluations, participating in procedures or providing intervention) or who have more than minimal contact with study participants or confidential study data, records or specimens related to study conduct. All other personnel who have minimal involvement in the conduct of the research or minimal study-related contact with participants should receive training that emphasizes the protection of participant privacy and confidentiality. Drivers, couriers, clerical staff and administrative staff are considered minimally involved personnel.

This policy defines the following training requirements for CRS staff:

- Human Subjects Protection (HSP): https://www.hhs.gov/ohrp/

- Good Clinical Practice (GCP): https://www.fda.gov/downloads/Drugs/Guidances/UCM464506.pdf
- U.S. Food and Drug Administration (FDA) Regulations: https://ecfr.io/Title-21/
    - Electronic Records and Signature (*21 CFR Part 11*)
    - Investigational New Drug Application (*21 CFR Part 312*)
    - Protection of Human Subjects (*21 CFR Part 50*)
    - Financial Disclosure by Clinical Investigators (*21 CFR Part 54*)
    - Institutional Review Boards (*21 CFR Part 56*)
- DAIDS Policies and Procedures:
    - https://www.niaid.nih.gov/research/daids-clinical-site-implementation-operations
    - https://daidslearningportal.niaid.nih.gov/getting-started-daids-training/required-training

12.2.2 DAIDS Training Resources

The Office of HIV/AIDS Network Coordination (HANC) serves as a resource for information about training programs available to site staff working with MTN and other clinical trials networks that are funded by NIAID/DAIDS.

The HANC website provides a calendar that lists DAIDS-sponsored training sessions and locations (http://www.hanc.info/training/Pages/default.aspx). Information can be searched by topic or date. The website also includes a link to the Collaborative Institutional Training Initiative (CITI) Program, which offers online training in HSP, GCP and Responsible Conduct of Research to DAIDS-sponsored CRSs. CITI training courses can also be accessed directly at the following website: https://www.citiprogram.org/. Interested individuals should follow the instructions on the HANC website to make sure they obtain access to appropriate training.

In addition to the HANC website, the DAIDS Learning Portal (https://daidslearningportal.niaid.nih.gov/) provides access to DAIDS training materials and resources, a social learning community to share training resources and new information, a training navigator to ask questions about DAIDS trainings and a direct link to the DAIDS Learning Management System (LMS). The LMS allows site staff and Network members to access online training on a variety of topics related to clinical research, including policies, laboratory and pharmacy. LMS offers sites the capability to assign required training, track and monitor its progress and run reports on its completion. Site staff and Network members accessing the DAIDS Learning Portal and LMS can use the same username and password.

The DAIDS policy describes a number of acceptable training resources and methods, including the CITI HSP training (mentioned above) and the NIH online training module, *Protecting Human Research Participants,* which is accessible at the following website: http://phrp.nihtraining.com/users/login.php.

12.2.3 Additional Training Requirements for Clinical Research Sites

Additionally, each CRS will require their investigators (staff) to complete documented training on the following materials, as they pertain to their study responsibilities:

12.2.3.1 Good Documentation Practices (GDP)

All applicable study site personnel must train on Good Documentation Practices (GDP) procedures. Satisfactory training may include (but need not be limited to) review of the MTN

GDP Training Slides and Section 9.2.2 of this Manual (see https://mtnstopshiv.org/resources/clinical-research-training).

12.2.3.2 Financial Disclosure

All site personnel listed on the *Form FDA 1572* or *DAIDS IoR Form* must complete training necessary to satisfy FDA (21 CFR 54) and Network requirements regarding Financial Disclosure. Satisfactory training will include review of the Financial Disclosure Training Slides appropriate for the study (see https://mtnstopshiv.org/resources/clinical-research-training) and written guidance included as page 2 of the study-specific Financial Disclosure (FD) form.

12.2.3.3 Investigator of Record (IoR)

Each IoR must complete training specifically designed for them by the MTN (see IoR Training Slides found at https://mtnstopshiv.org/resources/clinical-research-training). This training must be completed prior to study initiation or prior to assuming responsibility for an on-going study. It remains current for a period of three years.

12.2.3.4 MTN Manual of Operational Procedures

The *MTN Manual of Operational Procedures* outlines the administrative and operational requirements of each of the operational units of the Network and its associated CRSs. As a document produced by Network management and DAIDS, site staff should complete training to sections relevant to their study responsibilities prior to their functioning without direct supervision.

12.2.3.5 Emergency Unblinding

The IoR, or individual staff member delegated responsibility for emergency unblinding, is required to undergo specific training by the SDMC on emergency unblinding procedures within the Electronic Data Capture (EDC) system, which may include an eLearning module (e.g. for Medidata Rave), prior to being granted user permission to unblind within the EDC.

12.2.3.6 Laboratory-Related Training

The HSP and GCP training requirements described in Section 12.2.1 apply to MTN CRS laboratory staff who are considered key personnel. In addition, key laboratory personnel should complete *Good Clinical Laboratory Practice* (GCLP) training prior to involvement in an MTN study (see https://www.niaid.nih.gov/sites/default/files/gclp.pdf); certain studies may require at least one key staff member to have completed GCLP training before study activation. At a minimum, key personnel include the site Laboratory Director, Laboratory Manager/Supervisor and/or Laboratory Quality Assurance/Quality Control (QA/QC) Technologist(s). GCLP training of all key MTN laboratory staff is facilitated through online HANC training, accessible via the DAIDS LMS, which can be accessed at this site: https://daidslearningportal.niaid.nih.gov/. See also Section 14 of this Manual.

Site laboratory staff involved in MTN studies must have the appropriate education and experience for their positions. Before performing any laboratory tests or other laboratory-related activities for MTN studies, staff must also receive proper training. A staff member's training and competency in performing laboratory tests and other laboratory-related activities must be demonstrated and documented before he or she begins performing any test or activity (and again after six months, after 12 months and annually thereafter). If there is any question of competency, re-training should occur and competency should be re-assessed, confirmed and

documented. Other laboratory-related training requirements, such as training in laboratory safety, specimen transportation and the use of the Laboratory Data Management System (LDMS), are cross-referenced in Section 14 of this Manual.

12.2.3.7 Standard Operating Procedures

The DAIDS policy on *Requirements for Manual of Operational Procedures* specifies a core set of Standard Operating Procedures (SOPs) that must be in place at each site prior to the initiation of any DAIDS-funded or DAIDS-sponsored studies, and can be accessed at this site: https://www.niaid.nih.gov/sites/default/files/mop_policy.pdf.

Prior to the initiation of any MTN study, all study site personnel assigned to the study must complete training on the core SOPs that are relevant to their study roles and responsibilities, as determined by the IoR or designee. Study staff who have previously been trained on the required SOPs must repeat the training if it was not completed within the past 12 months or when a new version is released. For more information about site-specific study activation requirements see Section 11 of this Manual.

In addition to the core set of DAIDS SOPs, the MTN Director of Pharmacy Affairs and staff from the SDMC, MTN LOC (FHI 360) and/or LC may require site- or study-specific SOPs to be in place prior to the initiation of an MTN study. Prior to the initiation of any MTN study, all personnel assigned to the study must complete training on the study-specific SOPs that are relevant to their study roles and responsibilities, as determined by the IoR or designee. Study personnel must be re-trained when SOPs are updated during the study.

All SOP training must be documented. Documentation must be maintained on site and must be made available upon request to DAIDS study monitors; the MTN Director of Pharmacy Affairs; and staff from the MTN LOC (FHI 360), SDMC, LC and other designated MTN site visitors.

12.2.3.8 Study-Specific Training

Each site's IoR is responsible for ensuring that all study staff are adequately trained to serve their designated site- and study-specific functions for a protocol. The MTN Director of Pharmacy Affairs, MTN LOC (FHI 360), SDMC, LC, the BRWG representative or designee, and other MTN LOC (Pitt) and DAIDS personnel collaborate with the IoR to fulfill this responsibility by conducting study-specific training as appropriate for any given study. Study-specific training may be provided in various formats and for various durations depending on the training needs of the site and the study. The MTN staff mentioned above work closely with the Protocol Chair(s) and site IoRs to determine the optimal format and length of each study-site training.

The objectives of study-specific training are to:

- Ensure that study-staff members are informed of how the study should be conducted on a day-to-day basis, in accordance with the protocol, Study-Specific Procedures (SSP) manual and GCP guidelines
- Ensure standardization of study implementation across sites, so that data can be combined for analysis

During study-specific training, site staff and the MTN training team examine and discuss in detail the study protocol, regulatory requirements, procedural requirements and data-collection specifications. Broad responsibilities for planning and conducting study-specific training are

shown in Table 12.1. Documentation of all study-specific training must be maintained in each site's Essential Document files.

Table 12.1 Responsibilities for Study-Specific Training

Task	Responsible Persons
Schedule training	MTN LOC (FHI 360) Clinical Research Manager (CRM) or BRWG representative/designee for non-clinical studies, with input from study training team, key site staff and Protocol Chair(s), as applicable
Arrange training logistics	MTN LOC (FHI 360) CRM or BRWG representative/designee for non-clinical studies, designated site staff
Develop training agenda and training materials, conduct training	MTN LOC (FHI 360) CRM or BRWG representative/designee for non-clinical studies, with input from study training team and study-site staff
Translate training materials (if applicable)	Study-site staff
Arrange for specialized procedural training (if applicable)	MTN LOC (FHI 360) CRM or BRWG representative/designee for non-clinical studies, study-site staff
Evaluate training	Study-site staff training participants
Document training participation and maintain this documentation	MTN LOC (FHI 360) CRM or BRWG representative/designee for non-clinical studies, study-site staff

12.2.3.8.1 Scheduling Study-Specific Training

The MTN LOC (FHI 360) CRM, or BRWG representative/designee for non-clinical studies, develops the study-specific training agenda and schedules training for each site in coordination with the MTN Director of Pharmacy Affairs, a BRWG representative/designee (if applicable), the SDMC Clinical Data Manager (CDM) (if applicable), the LC designee, other MTN LOC (Pitt) and DAIDS personnel and key site staff. Protocol Chair(s) are also informed and involved as needed in developing the training agenda and schedule.

The MTN makes every effort to conduct site training as close as possible to the initiation of the anticipated study to maximize its effectiveness in preparing site staff. To achieve this goal, each site must complete certain study-activation requirements before it can reserve training dates. The remaining activation requirements must be met prior to the actual conduct of study-specific site training (see Table 12.2). In cases where the reserved training dates are approaching, and a site has not met all the requirements needed to proceed with the training, a revised set of training dates may be reserved. Any deviation from this process requires approval from the MTN PI and co-PI.

Table 12.2 Guidelines for Scheduling MTN Study-Specific Training

To be completed prior to reserving (assigning) dates for study-specific training:	
1	Current Federal Wide Assurance(s) should be in place for the study-site institution(s).
2	The FDA 30-day review period/Safe to Proceed Notice (if applicable) should be completed.
3	Review dates should be set for all required, local regulatory authority reviews (such as the Institutional Review Board (IRB), Independent Ethics Committee (IEC), medical control boards, etc.). All applicable drug import, specimen export and other applicable approvals should be in process.

4	Hiring of adequate staff should be completed or in-process and expected to be completed by time of training.
5	Ideally the Clinical Trial Agreement between DAIDS and the drug company and/or study sponsor should be finalized and signed.
To be completed prior to the training dates (Day 1 of study-specific training). If not, new (later) training dates may be reserved for the site.	
6	HSP and GCP training for all key personnel. (For studies subject to FDA regulations, this training must include relevant aspects of 21 CFR parts 11, 50, 54, 56 and 312).
7	Pharmacy requirements (if applicable) should be approved, based on: • The approval of a DAIDS Pharmacy Establishment Plan (PEP) by DAIDS Pharmaceutical Affairs Branch or an MTN PEP by the MTN Director of Pharmacy Affairs • Draft SOPs for managing, dispensing and accounting for study products (if applicable) (final versions required before activation) • Import and export approvals for study products (if applicable) should be in progress
8	The SDMC requirement for sufficient internet access and connection, and successful installation of required internet-enabled equipment, for study data collection and management, should be completed.
9	The LC approval of local laboratory requirements has been obtained, including approval or confirmation of the following: • GCLP training completed by at least one key on-site laboratory staff member with responsibility for laboratory QA • Established local laboratory back-up arrangements • CLIA certification (as appropriate) • Completed validation of study-specific testing-methods (if applicable) • Proficiency in performing all protocol-required tests • Documented validation of reference ranges for all protocol-required tests, and process for annual review • Draft SOPs for performing all protocol-required tests (final versions required before activation) • Draft SOPs for specimen management and chain of custody (final versions required before activation) • Well-developed QA/QC procedures (final versions required before activation) • Well-established Internet connectivity to Frontier Science and Technology Research Foundation, Inc. (FSTRF) for LDMS • International Air Transport Association (IATA) specimen-shipping certification within the last 24 months for all laboratory staff members who transport, ship or receive infectious substances and diagnostic specimens • Laboratory safety training within the last 12 months for all laboratory staff members
10	If required, the site-initiation visit by the DAIDS Clinical Site Monitoring Group has been made.
11	Well-developed drafts of required site or study-specific SOPs as defined in the study activation checklist have been completed (See Section 11 of this Manual for more information on site-specific study activation requirements).
12	The study-staff roster, signature sheet and delegation of duties log should be drafted (Signatures should not be collected until after staff complete training requirements, including Study-Specific Training).
13	If IRB/IEC approval has been obtained, a submitted DAIDS Protocol Registration package is expected, including, but not limited to: • U.S. and in-country IRB/IEC approvals of protocol and approved informed consent forms (ICF) (local language and back-translation, where applicable) • Signed *FDA Form 1572* or *DAIDS IoR Agreement* • Curriculum vitae of the IoR Protocol registration approval is not required prior to scheduling training; but if IRB/IEC approval has been obtained, the DAIDS Protocol Registration package must be submitted or the training may be postponed.
14	A training version of the SSP Manual should be available on site.

12.2.3.8.2 Site Preparation for Training

In addition to completing requirements for scheduling and conducting study-specific training, site staff must conduct other activities in preparation for study-specific training and conducting the study. Under the supervision of the IoR and other designated staff member(s), site staff will:

- Work with the MTN LOC (FHI 360) CRM, or BRWG representative/designee for non-clinical studies, to schedule the training, finalize the training agenda and identify and meet needs for translations and interpreters
- Arrange access to training facilities and any required training equipment
- Hire staff (if needed)
- Designate staff members' study-specific roles and responsibilities
- Assess local training needs
- Provide orientation and background training as needed, including:
  - Local staffing and organizational plan (including roles and responsibilities)
  - Local site operations and SOPs
  - Local role-specific training/certification
  - Other local requirements
- Review and become thoroughly familiar with the study protocol, ICFs, case report forms, training materials and other materials for study implementation
- Discuss and develop study-specific SOPs and other study-implementation plans and materials
- Complete mock visits using materials for study implementation, ideally in the facilities that will be used for the study (may also be scheduled after the training)
- Identify issues and questions that require input from the training team
- Prepare site-specific training modules, presentations and materials per the training agenda
- Ensure availability of relevant staff to attend training sessions

12.2.3.8.3 Conduct of Study-Specific Training

As applicable, the MTN Director of Pharmacy Affairs, the BRWG representative/designee, the SDMC CDM, the MTN LOC (FHI 360) CRM and the LC designee are responsible for providing the training and training materials. Additional MTN members, such as MTN Safety Physician(s), DAIDS representatives, and Protocol Chair(s), may also provide components of the training, as needed.

All site staff members who have been delegated duties or responsibilities for an MTN study will take part in study-specific training. This includes the IoR, study coordinator, clinical staff (such as physicians, clinicians and nurses), counseling staff, pharmacy staff, laboratory staff, data management staff, QA/QC staff, participant recruitment and retention (outreach) staff, community education staff and administrative staff.

It is especially important that site staff members make every effort to attend all the sessions or modules, particularly those that are most relevant to their responsibilities. Failure to attend required relevant training sessions in their entirety will result in a delay of site-specific study activation, and additional training will be required before study activation can be approved. If it is not possible for study staff to attend all sessions or modules of study-specific training, it is the responsibility of the IoR to ensure that training is provided to those staff who could not attend, using materials provided at the training.

During training, site staff are expected to:

- Present training sessions or modules as outlined in the training agenda
- Present local study-implementation plans, SOPs and other such materials
- Fully engage in the training: ask questions; identify issues requiring additional clarification; and identify best site-specific study-implementation plans, materials and tools
- Complete a training evaluation

The MTN LOC (FHI 360) CRM, or BRWG representative/designee for non-clinical studies, will provide a study-specific training report to the site following the training. This documentation as well as a copy of the agenda, training materials and staff attendance list, must be maintained in the on-site Essential Document files. Documentation of training for key staff who did not attend study-specific training, but were trained by the IoR, must also be maintained in on-site Essential Document files.

12.2.3.8.4 Continuing Study-Specific Training

It is the IoR's responsibility to ensure that study staff members are adequately trained and prepared to serve in their designated study roles. The study training team does not routinely conduct on-site training for site staff who are hired after the initial study-specific training has taken place. The training team will, however, ensure that study-specific training materials are provided for training future staff and will make every effort to answer questions for and provide technical assistance to new study staff members. The study training team also will participate in one or more additional training sessions via teleconference, if requested by the site. If a new study coordinator or lead clinician joins a site after the initial study-specific training, the MTN LOC (FHI 360) CRM will consider visiting the site to assess study implementation and possibly provide targeted training soon after the new staff member begins work on a study.

Once a study is underway, the MTN Director of Pharmacy Affairs, the SDMC, MTN LOC and LC staff will issue study-related communications, answers to frequently asked questions, data communiqués and other similar documents to clarify and guide study implementation at each site. The IoR or designee — typically, the study coordinator — must inform study staff when such documents are issued, provide training on them (as needed) and incorporate their content into day-to-day study operations. Designated site staff also should file such documents with other study training and implementation materials for future reference.

When considered useful and timely, the MTN Director of Pharmacy Affairs, the SDMC, MTN LOC (FHI 360), BRWG, and/or LC staff provide study-specific refresher training to site staff in the context of routine site visits and other MTN meetings (such as annual and regional meetings). Other methods, such as videos of previous training sessions, teleconferences and web-based training, also may be used for continuing training.

12.2.4 Research Ethics Training (Recommended)

The *Research Ethics Training Curriculum* (developed by FHI 360) is recommended for use at MTN study sites. This curriculum is accessible at the following website: http://www.fhi360.org/sites/all/libraries/webpages/fhi-retc2/.

12.3 Research Ethics Training for Community Representatives

The purpose of the FHI 360 *Research Ethics Training Curriculum for Community Representatives* is to educate community representatives about their roles and responsibilities, as well as the roles and responsibilities of a research team and IRBs/IECs, as they relate to the principles of research ethics. The curriculum includes easy-to-use materials, such as slides, case studies, activities, facilitator notes and a training certificate. Community-education staff, community advisors and partners are encouraged to complete this training. The curriculum can be accessed at the following website: http://www.fhi360.org/sites/default/files/webpages/RETC-CR/en/RH/Training/trainmat/ethicscurr/RETCCREn/index.html. Additional education/training materials for community representatives are available under *Community Clinical Research Training Documents* at the following site: http://mtnstopshiv.org/node/1425