

MTN Manual of Operational Procedures (MOP)

Section 8: External Communications

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8 EXTERNAL COMMUNICATIONS

8.1 Overview, Roles and Responsibilities

Communications and media relations for the Microbicide Trials Network (MTN) are managed by the MTN Leadership and Operations Center [LOC (Pitt)] Communications and External Relations Team, in conjunction with the U.S. National Institute of Allergy and Infectious Diseases (NIAID) Office of Communications and Government Relations (OCGR), News and Public Information Branch (NPIB) and the NIAID Division of AIDS (DAIDS) Workforce Operations, Communications and Reporting Branch (WOCRb).

The role of the MTN LOC (Pitt) Communications and External Relations Team includes developing and implementing study-related communications plans, supporting the communications and media relations efforts of MTN Clinical Trial Units (CTUs) and affiliated Clinical Research Sites (CRSs) and seeking opportunities to engage with, and inform, national and global stakeholders about MTN's research agenda and related topics.

These activities are performed in collaboration with DAIDS Leadership, the MTN Principal Investigator (PI) and MTN co-PI, Protocol Chair(s) and when applicable, the U.S. National Institute of Mental Health (NIMH) and *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD), as well as with Investigational New Drug (IND) Sponsors and/or Product Developers.

The MTN LOC (Pitt) Communications and External Relations Team's specific responsibilities include the following:

- Developing and implementing study-related communications plans and ensuring accurate and timely dissemination of relevant information to news media, advocacy groups, civil society and other key stakeholders
- Ensuring communications preparedness of CTUs/CRSs by advising sites in the development of communications and stakeholder outreach plans, and providing relevant training, guidance and oversight
- Preparing news releases, fact sheets, backgrounders, web content and other materials intended for external audiences
- Planning and conducting consultations and meetings with in-country and international stakeholders, civil society and advocates to solicit views on design, implementation and implications of specific studies and/or proposed research endeavors
- Raising awareness about MTN studies and broader issues through workshops, satellite sessions and special presentations at major national and international conferences
- Maintaining MTN's active presence and engagement on social media platforms

8.2 Press Releases, Statements and Communications Materials

The development and review of press releases, statements and communications materials is coordinated by the MTN LOC (Pitt) Communications and External Relations Team to ensure compliance with expected communications standards and principles, and U.S. National Institutes of Health (NIH) policies and agreements with IND Sponsors or Product Developers. The review process for different types of press releases and communications materials is described below.

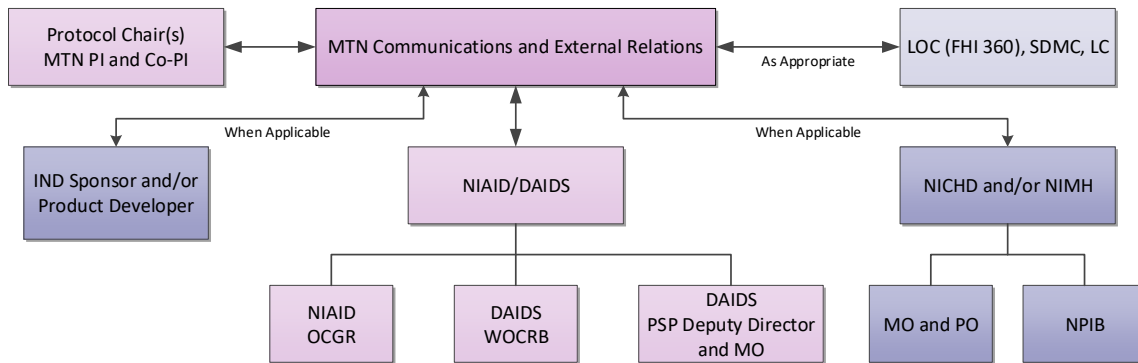
8.2.1 Press Releases and Statements on MTN Studies

Press releases and statements on MTN studies are reviewed by the DAIDS Prevention Sciences Program (PSP) Deputy Director, the DAIDS Medical Officer (MO) for the study, NIAID OCGR and DAIDS WOCRB; and, when applicable, NIMH and NICHD program officers (POs) and their respective communications office or news and public information branch. When feasible, the Protocol Chair(s) and the MTN PI and co-PI will approve study-related press releases and materials prior to DAIDS/NIAID review. In some circumstances, reviews occur simultaneously (see Figure 8.1).

MTN press releases and statements for studies that are conducted under a Clinical Trials Agreement (CTA) with an IND Sponsor and/or Product Developer must also be reviewed by

these parties in accordance with the terms of the CTA. NIAID/DAIDS is responsible for ensuring that specific terms of a CTA are met, although the review process may be coordinated by the DAIDS PSP Deputy Director, DAIDS MO, NIAID's OCGR or the MTN LOC (Pitt) Communications and External Relations Team (see Figure 8.1).

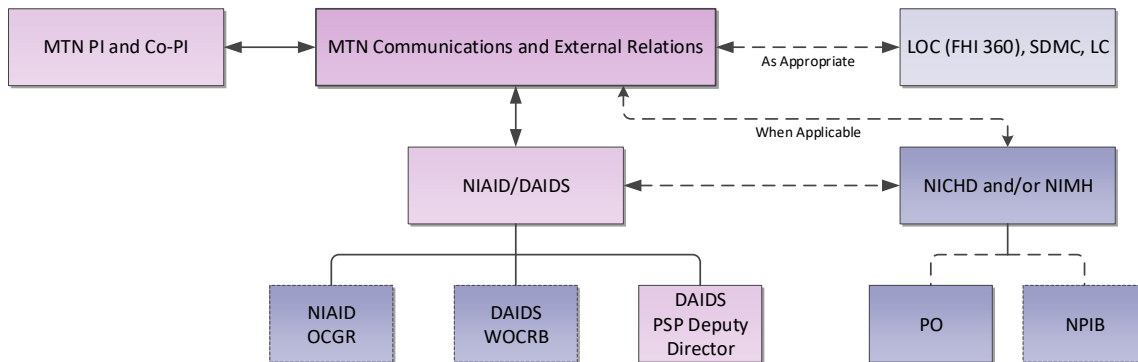
Figure 8.1 MTN Study-Related Press Releases and Statements



8.2.2 General MTN Press Releases and Statements

General (non-study specific) MTN press releases and statements are reviewed and approved by the MTN PI and co-PI and the DAIDS PSP Deputy Director, and as appropriate, by the NICHD and/or NIMH PO. Reviews by the NIAID OCGR and WOCRB are not necessarily required (see Figure 8.2).

Figure 8.2 General MTN Press Releases and Statements



8.2.3 Other MTN Communications Materials

In addition to press releases and statements, other communications materials developed by the MTN LOC (Pitt) Communications and External Relations Team, such as fact sheets and Q&A documents, may be subject to review by NIAID, DAIDS and/or NIMH and NICHD. Table 8.1 summarizes the review process for both press releases and different types of communications materials.

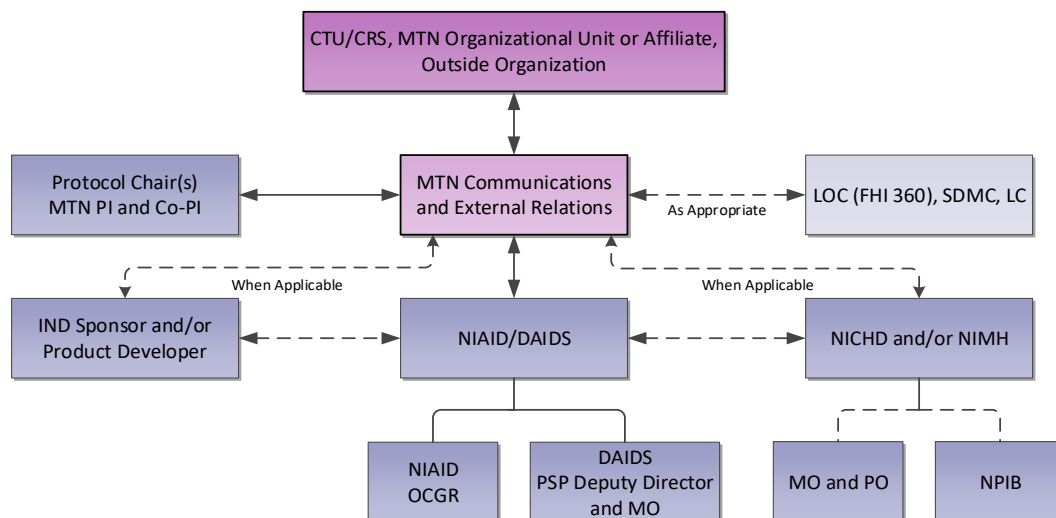
Table 8.1 Communications Materials Review Process for U.S. NIH

	DAIDS PSP Deputy Director/MO Review	DAIDS WOCR Review	NIAID OCGR Review	NIMH/NICHD
MTN study press release	YES	YES	YES	YES When applicable
MTN general release, statement	YES	For information only	For information only	For information only When applicable
MTN study Q&A	YES	For information only	YES	YES When applicable
MTN study fact sheets and backgrounders	YES	For information only	For information only	YES When applicable
General topic and MTN fact sheets and backgrounders	For information only	NO	NO	For information only When applicable
News release templates for sites	YES	For information only	For information only	YES When applicable
Scenarios and messages documents	YES	For information only	For information only	YES When applicable
“Dear Colleague” letter	YES (MO only)	NO	NO	YES When applicable

8.2.4 Press releases, Statements and Materials Developed by CTUs/CRSs, MTN Organizational Units, MTN Affiliates or Outside Organizations

The MTN LOC (Pitt) Director (or Associate Director) of Communications and External Relations must review MTN-related press releases, statements and any other forms of public communication developed by CTUs/CRSs, MTN organizational units (LOC, Laboratory Center [LC], Statistical and Data Management Center [SDMC]), MTN affiliates and/or other outside organizations. This is to ensure accuracy of information, proper identification of MTN, NIAID and other funding sources, and compliance with any relevant CTA. As necessary or appropriate, the MTN LOC (Pitt) Communications and External Relations Team will coordinate additional reviews by NIAID, and, when applicable, NIMH and NICHD and/or the IND Sponsor or Product Developer (see Figure 8.3). NIAID/DAIDS and the NIAID OCGR must review materials that involve studies for which CTAs are in place.

Figure 8.3 Press releases, Statements and other Materials Developed by CTUs/CRSs, MTN Organizational Units, MTN Affiliates or Outside Organizations



8.2.5 Acknowledgment Requirements and Boilerplate Language

All press releases, statements and materials intended for public dissemination must properly acknowledge in the main text that MTN activities are performed in cooperation with NIAID, NIMH and NICHD.

The Award Number must also be included, although this information is not required to be in the actual text of a press release. The following language should be used:

MTN is funded by the U.S. National Institutes of Health grants UM1AI068633, UM1AI068615 and UM1AI106707.

News releases and other materials often include a boilerplate statement that appears after the document's main content, sometimes under the heading, about the MTN.

The MTN's full boilerplate statement follows:

The Microbicide Trials Network (MTN) is an HIV/AIDS clinical trials network established in 2006 by the National Institute of Allergy and Infectious Diseases with co-funding from the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development and the National Institute of Mental Health, all components of the U.S. National Institutes of Health. Based at Magee-Womens Research Institute and the University of Pittsburgh, the MTN brings together international investigators and community and industry partners whose work is focused on the rigorous evaluation of promising microbicides – products applied inside the vagina or rectum to prevent the sexual transmission of HIV – in studies designed specifically to support the potential licensure of these products for widespread use. More information about the MTN is available at www.mtnstopshiv.org.

Boilerplate language and funding acknowledgments for use in scientific publications and presentations may be found on the MTN website (<http://www.mtnstopshiv.org/resources>). See also Section 20 of this Manual.

8.3 Communications Planning for Public Release of Study Results

The public dissemination of study results provides an opportunity to share findings that could influence the standard of care in the communities served by MTN or the design and/or conduct of ongoing or future HIV-prevention studies. Advance planning is essential, with an emphasis on the need for accurate, timely and well-controlled communication of results to different stakeholder groups.

NIAID (and NIMH and NICHD, when applicable) is responsible for determining the manner and timing in which results are shared with study participants and local communities, as well as publicly disseminated. NIAID also ensures that the process meets the terms of a study's specific CTA with the IND Sponsor and/or Product Developer. Because primary results are typically reported in a peer-reviewed journal and/or at a scientific meeting, the specific timeline for public dissemination of study results must also consider the embargo policies of the journal and/or meeting.

The MTN LOC (Pitt) Communications and External Relations Team works closely with the NIAID OCGR and DAIDS WOCR and IND Sponsor and/or Product Developer in the development of coordinated communications plans that meet CTA requirements and/or news embargo policies, should they exist, and with the study's Protocol Chair(s), the MTN PI and co-PI, the MTN LOC (FHI 360) Clinical Research Manager (CRM) for the study and others as appropriate.

For large and/or high-profile trials, such as Phase IIb, Phase III and Phase IIIb studies, the MTN LOC (Pitt) Communications and External Relations Team works directly with CTUs and CRSs on the development of site-specific plans and provides guidance and technical support throughout the planning and dissemination process. In preparation for results dissemination, CTUs/CRSs are required to complete and/or update specific communications planning documents, which may include a Results Dissemination Calendar, Communications Plan Template, Stakeholders Directory and Media Relations Standard Operating Procedures (SOP).

Typically, results dissemination communications plans for large studies and/or high profile studies will need to consider several different results scenarios to ensure trial sites are adequately prepared to implement appropriate strategies when the actual results become known. While the site's Investigator of Record (IoR) may have been unblinded to the study's results (see Section 19 of this Manual), others at the site may not be unblinded until shortly before public release, even if they had been intimately involved in communications planning and preparedness. Effort is made to provide ample notice to key site staff; although, how far in advance of public release this can occur depends on the CTA agreement, embargo restrictions and considerations specific to the situation. The MTN LOC (Pitt) Communications and External Relations Team works to ensure that site communications plans still allow for the timely dissemination of results so that study participants, Community Advisory Board (CAB) members, Institutional Review Boards/Institutional Ethics Committees (IRB/IECs), regulatory authorities and other key stakeholders are among the first to know.

At the discretion of MTN Leadership, NIAID/DAIDS and the IND Sponsor and/or Product Developer, select individuals or groups may be briefed about study results prior to public release, i.e., before the embargo lifts. Signed confidentiality disclosure agreements may be required.

For Phase I and Phase II studies and Ancillary and/or Sub-studies, the MTN LOC (Pitt) Communications and External Relations Team, Protocol Chair(s), and MTN Leadership will determine the most suitable process for disseminating results with input from NIAID OCGR, DAIDS WOICRB, DAIDS PSP Deputy Director and MO, and as appropriate, NIMH and NICHD.

8.4 Communications Planning for Data and Safety Monitoring Board (DSMB) Reviews

The MTN LOC (Pitt) Communications and External Relations Team and MTN LOC (FHI 360) CRM of the study ensure that each study site and investigator is adequately prepared in advance of routine Data and Safety Monitoring Board (DSMB) reviews.

At least eight weeks prior to a scheduled DSMB review, the MTN LOC (FHI 360) CRM for the study, in consultation with the Protocol Chair(s), Protocol Statistician, DAIDS PSP Deputy Director and MO, and the MTN LOC (Pitt) Director of Communications and External Relations will prepare a draft *Schedule of Events* planning document. Concurrent with this activity, the MTN LOC (Pitt) Director of Communications and External Relations prepares a *Communications Plan Task List* in coordination with NIAID's OCGR and DAIDS WOICRB.

The MTN LOC (Pitt) Director of Communications and External Relations prepares a document describing the most probable DSMB review-outcome scenarios with input from the DAIDS PSP Deputy Director and MO, Protocol Chair(s), Protocol Statistician, MTN LOC (FHI 360) CRM for the study and MTN PI and MTN co-PI. The scenarios document, draft messages and other supporting materials, such as backgrounders or Q&A documents, are provided to sites in advance of the DSMB review.

The NIAID OCGR, in consultation with the DAIDS WOICRB, the DAIDS PSP Deputy Director and MO and the MTN LOC (Pitt) Director of Communications and External Relations, prepares NIAID draft statements and Q&A documents for news media. All NIAID press releases and public statements must undergo standard review with clearance granted by the Office of the Director, NIAID; Office of the Director, NIH; and the U.S. Department of Health and Human Services (DHHS). NIAID is under no obligation to provide protocol team members draft press releases/statements in advance of their official release, but confidential drafts may be provided in special circumstances.

The MTN and NIAID ensure coordinated planning with the IND Sponsor and/or Product Developer. Coordinated communications planning is especially important when an MTN DSMB review is scheduled at or around the same time as a review of another study of the same product. On communications matters, the NIAID OCGR, in conjunction with the MTN LOC (Pitt) Director of Communications and External Relations, will determine the terms of engaging in joint or coordinated planning with the communications representative of the other study and/or co-sponsor.

Immediately following a DSMB review, the Director of DAIDS communicates the DSMB's recommendation to the Director of NIAID, who decides whether to adopt the recommendation. NIAID has overall responsibility for the public release of information following DSMB reviews of MTN studies.

As the outcome warrants, only the NIAID OCGR may issue an official statement or press release on behalf of NIAID concerning an NIAID DSMB review of an MTN study. The MTN press release and IND Sponsor/Product Developer press release will coincide with the timing of,

or immediately follow, NIAID’s press release. Other public announcements may not be issued until after this time. CTUs/CRSs are encouraged to use localized or template versions of the MTN news release and materials. The use of other materials must be approved by the MTN LOC (Pitt) Director of Communications and External Relations (see Section 8.2.4 of this Manual).

As needed, the MTN LOC (FHI 360) CRM will assist the MTN LOC (Pitt) Communications and External Relations Team and CTUs/CRSs in implementing communications strategies at the site level. The MTN LOC (FHI 360) Community Program Manager (CPM) helps to facilitate communication with the study-specific Community Working Group (CWG).

The general communications process for DSMB reviews is described in Table 8.2.

Table 8.2 General MTN Communications Process for DSMB Reviews

Task	Responsible Party	Timeline
Prior to DSMB Review		
Prepare draft “Schedule of Events”	MTN LOC (FHI 360) CRM, in consultation with Protocol Chair(s), Protocol Statistician, MTN LOC (Pitt) Director of Communications and External Relations and DAIDS MO	At least 8 weeks in advance
Prepare communications plan tasks list	MTN LOC (Pitt) Director of Communications and External Relations, in consultation with WOCR and OCGR	At least 8 weeks in advance
Draft possible outcome scenarios and messages	MTN LOC (Pitt) Director of Communications and External Relations, in consultation with Protocol Chair(s), MTN PI and co-PI, DAIDS PSP Deputy Director and MO, and NIAID OCGR	At least 7 weeks in advance
Communicate with study sites about general plan and timeline	MTN LOC (FHI 360) CRM and MTN LOC (Pitt) Director of Communications and External Relations	At least 6 weeks in advance
Distribute documents to study sites (e.g., scenarios and messages)	MTN LOC (Pitt) Director of Communications and External Relations and MTN LOC (FHI 360) CRM	At least 5 weeks in advance
Work with CRSs on completion of communication plans and related documents	MTN LOC (Pitt) Director of Communications and External Relations	At least 3 to 5 weeks in advance
NIAID prepares and obtains approval of holding statements/press releases for each DSMB review outcome scenario	OCGR, in consultation with WOCR, DAIDS PSP Deputy Director and MO, and MTN LOC (Pitt) Director of Communications and External Relations	At least 2 weeks in advance
<i>Subject to approval</i> Confidentially inform other investigators and stakeholders of upcoming DSMB review	Protocol Chair(s), in consultation with MTN LOC (Pitt) Director of Communications and External Relations, DAIDS PSP Deputy Director and MO, NIAID OCGR, DAIDS WOCR	Within 1 week prior
Following DSMB Review		
Proceed with planned communications activities per actual DSMB review outcome	NIAID OCGR and MTN LOC (Pitt) Director of Communications and External Relations	TBD per NIAID and schedule of events
Provide materials and documents to sites as appropriate for actual DSMB review outcome	MTN LOC (Pitt) Director of Communications and External Relations, in consultation with NIAID OCGR, DAIDS WOCR, DAIDS PSP Deputy Director and MO, Protocol Chair(s), LOC (FHI 360) CRM and CPM, MTN PI/co-PI	TBD per NIAID and schedule of events
Communicate DSMB outcome to stakeholders, news media and other groups as appropriate	Protocol Chair(s), NIAID OCGR and MTN LOC (Pitt) Director of Communications and External Relations (depending on outcome)	TBD per NIAID and schedule of events
Coordinate site-level communication	MTN LOC (Pitt) Director of Communications and External Relations and MTN LOC (FHI 360) CRM (and study CPM, as appropriate)	TBD per NIAID and schedule of events

8.5 Media Relations

All sites must adhere to MTN-specific media relations policies and procedures in conjunction with any MTN study being conducted at the site.

8.5.1 Media Relations Standard Operating Procedures

Clinical research sites can expect to receive inquiries from news media about MTN studies or related research. Maintaining transparency with news media is extremely important, and investigators are encouraged to cultivate credible relationships with media representatives. In order to ensure appropriate, consistent messaging among study sites and across the MTN, CTUs/CRSs should have an SOP describing how media inquiries are to be managed at their site. This SOP should be updated regularly to reflect any changes in staffing or procedures at the study site.

Sites conducting large and/or high profile MTN studies are asked to complete a template Media Relations SOP provided by MTN LOC (Pitt) Communications and External Relations Team. Completion of the MTN template is required even if the CTU or CRS already has an existing SOP or media relations policy.

8.5.2 Responding to Media Inquiries

Each site should designate a primary media point person to manage and triage MTN study-related media inquiries. A back-up contact should also be identified should the primary person not be available. While some organizations have a dedicated communications person on staff, this is not the case at many clinical trial sites. As such, sites may choose to designate a study coordinator, site coordinator or a community educator to serve as the point of contact for news media.

The media point person screens media inquiries, and when warranted, coordinates a response with the appropriate spokesperson. Under some circumstances, the point person(s) will notify the MTN Director of Communications and External Relations (see Crisis Communications, section 8.5.3).

Each site should designate two to three individuals to serve as spokespersons. Spokespersons may be the CRS Leader; study IoR or another key investigator. Designated spokespersons should be thoroughly familiar with relevant study background and materials, and should be able to speak articulately about MTN studies, oftentimes on short notice.

Media inquiries can be expected in conjunction with different events or study milestones, such as when study results are being reported for the first time. However, when inquiries occur outside these windows, particularly when results are under embargo, extreme caution is advised. As such, investigators should refrain from providing comments to news media, community groups or other external audiences that relate to study outcomes, study participants or adverse events without first consulting the Protocol Chair(s) and the MTN LOC (Pitt) Director (or Associate Director) of Communications and External Relations. Investigators should not discuss or publicly release information about proprietary study products that have not yet been reviewed by or received approval from a drug regulatory authority for the indication being evaluated in the study without the explicit (written) permission of the IND Sponsor and/or Product Developer.

Press inquiries generally or specifically about the MTN should be referred to the MTN LOC (Pitt) Director (or Associate Director) of Communications and External Relations, who will coordinate an appropriate response with NIAID's OCGR, if necessary.

Requests by news media to interview or photograph study participants are handled according to the discretion of site investigators and in accordance with institutional policy and the site's IRB/IEC requirements and/or procedures. Sites that permit study participants (or former participants) to be interviewed or photographed should ensure the study participant is fully informed of the process and potential ramifications and social harms that may unwittingly occur. A specific media informed consent document is strongly advised.

The MTN provides guidance and training to individuals who have little or no prior experience dealing with the media.

8.5.3 Crisis Communications

In situations of crisis or breaking news involving an MTN study, the MTN LOC (Pitt) Director of Communications and External Relations is responsible for managing the response in consultation with the NIAID OCGR, DAIDS program leadership, MTN PI and co-PI, Protocol Chair(s) and, as appropriate, the IND Sponsor and/or Product Developer and NIMH and NICHD Program Leadership.

All CRSs should have a designated crisis communications team, which may include the CTU PI, CRS leader, site IoR, designated media contact and others, as per their MTN media relations SOP or other procedures already in place at the CTU.

The MTN LOC (Pitt) Director (or Associate Director) of Communications and External Relations must be notified about any urgent or potentially negative communications situation so that an appropriate response and course of action can be developed in coordination with site CTU and CRS leadership, NIAID/DAIDS and other partners as appropriate.

- Lisa Rossi (Director of Communications and External Relations), mobile: +1-412-916-3315; rossil@upmc.edu
- Clare Collins (Associate Director of Communications and External Relations), mobile: +1-412-770-8643; collcx@upmc.edu

8.5.4 Resource Information for News Media and External Audiences

The MTN LOC (Pitt) Communications and External Relations Team develops materials about studies and general topic areas that are intended for lay audiences, including news media. These are publicly available in the News Room section of the MTN website (<http://www.mtnstopshiv.org/news>). As a matter of routine, the site media point person(s) should direct media representatives to the News Room to access background information, news releases and other materials.

8.5.5 Tracking Media Activities

Media inquiries and contacts should be documented to the extent possible by the CRS media point person(s) and resulting media coverage shared with the MTN LOC (Pitt) Communications and External Relations Team in a timely fashion. The MTN Communications Team aggregates media coverage and shares news stories and links with MTN leadership and other interested parties via periodic "MTN in the News" email distributions.

8.6 Social Media

The use of social media as a communications tool has changed the dynamics of how information is shared and how researchers, study participants and communities can engage. For purposes of this manual, social media is defined as digital (mobile or web-based) technologies, such as Facebook, YouTube and Twitter, that may be used to create general awareness about HIV prevention, disseminate information about a study milestone and/or to aid in the recruitment of participants into a specific MTN study. Social media also includes blogs, listservs and bulk text messages.

The MTN hosts a Facebook page ([MTNfacebook@mtnstopshiv.org](https://www.facebook.com/MTNfacebook@mtnstopshiv.org)) and a Twitter account (@HIVMTN) to keep internal and external audiences up-to-date on MTN activities and upcoming meetings, study launches and results, and more general HIV-related news. Content for both social media outlets is managed by the MTN LOC (Pitt) Communications and External Relations Team, who is responsible for ongoing monitoring of the sites.

With social media, information can be shared quickly. Although messages may be targeted to specific audiences, they can easily be shared more broadly and indiscriminately. Vigilant monitoring and managing of incoming messages and posts is necessary to prevent negative or inaccurate information from undermining the credibility and reputation of the site, MTN and NIAID. The MTN LOC (Pitt) Director (or Associate Director) of Communications and External Relations should be immediately notified about any negative or potentially negative situation that involves the use of social media (see Crisis Communications, section 8.5.3).

The use of social media to recruit potential study participants for an MTN study or to communicate with participants already enrolled in an MTN study is likely to be subject to IRB/IEC approval. Sites considering using social media in the context of an MTN study should contact their IRB/IEC for guidance as well as the MTN LOC (Pitt) Communications and External Relations Team and/or the MTN LOC (FHI 360) CRM for that study.

8.7 Stakeholder Engagement

The MTN LOC (Pitt) Communications and External Relations Team is responsible for planning and coordinating consultations and meetings with national in-country and international stakeholders to solicit their views on proposed studies or protocols in development, discuss key issues related to study conduct and implementation and/or to prepare for potential study outcomes and possible implications. Stakeholder consultations and meetings help to establish new ties and strengthen existing relationships between researchers and key in-country stakeholders concerned with HIV prevention and to create a framework for continued and broader engagement on issues of concern and/or relevance within each country or across large regions.

Whenever possible, the MTN partners work with key civil society groups and NGOs in planning and conducting consultations, and coordinate these activities in close collaboration with the MTN PI and co-PI and Protocol Chair(s) as well as MTN trial site investigators.

8.8 MTN Engagement at National and International Conferences

Working closely with the MTN PI and co-PI, the MTN Communications and External Team seeks opportunities for engagement at major national and international conferences through development of workshops, satellite sessions or presentations on timely and emerging topics of interest to the broader HIV prevention community. These activities are often performed in collaboration with civil society, advocacy organizations and other research groups, including other DAIDS-funded HIV/AIDS Clinical Trials Networks.