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6 NETWORK MEETINGS AND COMMUNICATIONS

Communications and information dissemination are critical to the successful management of a large, international, multicenter network such as IMPAACT. IMPAACT uses a variety of approaches to enhance communication within the Network about study-specific and Network-wide research initiatives. The Operations Center supports and coordinates much of the communications within IMPAACT through conference calls, in-person meetings, electronic and written materials, and announcements and postings through IMPAACT’s website. The website serves as a main driver of general and public communication, where study-specific information and postings about Network-wide activities can be found. The Network also distributes a newsletter and utilizes social media platforms for communication purposes.

6.1 Meetings

6.1.1 Annual Network Meeting

In collaboration with IMPAACT leadership, the Operations Center organizes an annual Network meeting to bring together IMPAACT members and collaborators to discuss study designs and research goals, review data from ongoing trials, examine cross-cutting issues, and provide an overview of the IMPAACT scientific agenda. In addition, the meeting provides opportunities for training, identifying key issues, defining and discussing Network procedures, and clarifying roles and responsibilities of IMPAACT members. The meeting generally includes plenary sessions to update IMPAACT members on the latest scientific research related to the Network’s mission and agenda. The Network Scientific Leadership Group (SLG), Management Oversight Group (MOG), Scientific Committees (SCs), IMPAACT Community Advisory Board (ICAB), and protocol teams schedule meetings in conjunction with this yearly event. Additionally, the annual Network meeting may provide National Institutes of Health (NIH) training opportunities.

The Operations Center is responsible for the overall logistics of the meeting, preparation of agendas and background materials and, subsequently, dissemination of any required materials for the SLG, MOG, SCs, protocol teams, and protocol-specific sessions in collaboration with the chair of the respective group, committee, board, or team.

6.1.2 In-Person Meetings

Network leadership groups, protocol teams, and other groups may meet in person at the Annual Meeting, on some other set schedule, or at key times, such as during protocol development (see Section 9 for more information about the appropriate timing of protocol development meetings). In-person meetings may

require adaptation to or replacement by a virtual meeting format, if needed, due to travel restrictions, social distancing requirements, or other unforeseen circumstances.

In-person meetings of Network leadership groups (SLG, MOG, and SCs) are generally convened annually. The purpose of these meetings is to discuss the priorities and direction of the IMPAACT Network. The Operations Center is responsible for the overall logistics of the meetings including preparation of agendas and background materials.

The clinical research manager (CRM) assigned to the protocol, with assistance from other Operations Center staff, is responsible for the overall logistics of any in-person protocol team meetings, including identifying times and assisting with the development and distribution of agendas and background materials. Documentation needs and requirements will vary based on the meeting and may include attendee rosters, written summaries, audio and/or video recordings, emailed summaries of action items, or other methods.

Ad hoc meetings of other groups can also be coordinated, based on need, with assistance from the Operations Center.

6.1.3 Conference Calls

In between or in lieu of in-person meetings, conference calls are used extensively to facilitate the Network's research activities. Joining conference calls over the internet using web-based platforms is the preferred approach, and when appropriate, webinar technology should be utilized to facilitate interactive slide presentations and other media-rich methods for sharing information and data. Organizers of each call should aim to provide toll-free numbers to all US participants and, when available, to international participants. Where a toll-free number is not available, alternate arrangements for connecting international participants should be made (e.g., dialing out to participants).

Routine call schedules may be established for IMPAACT study teams, groups, and committees, depending on project needs and the availability of key IMPAACT members involved in protocol or committee work. Prompt responses to these scheduling requests is required for efficient set-up of conference calls. Depending on the purpose and content of the call, quorum requirements as outlined in Table 12-2 of this MOP may apply. For protocol-related calls, prior to any call, participants should agree on a plan for documentation, including whose responsibility it is, as described in Section 4. Documentation needs and requirements will vary based on the call and may include written call summaries, audio and/or video recordings, emailed summaries of action items, or other methods.

As with in-person meetings, the Operations Center can provide a broad range of administrative and technical support for conference calls, if needed.

6.2 Communication Mechanisms and Material Distribution

Staff of the IMPAACT central resources (Leadership and Operations Center, Statistical and Data Management Center [SDMC], and Laboratory Center) disseminate IMPAACT information and study materials using a variety of methods including email, website postings, mail, and express mail services. To help ensure the successful transfer of information, each Network organization must:

- Have the capacity to send, access, and receive materials distributed using the above methods
- Ensure that IMPAACT communications and materials are distributed to all appropriate staff members
- Maintain all key study and IMPAACT communications in a well-organized filing system

Key IMPAACT information is posted on the [IMPAACT website](#) for access by all Network members and the public. Information from central resources and from the NIH is included and maintained regularly to ensure the timeliness of materials availability and dissemination. Other websites with information relevant to the Network include:

- DAIDS Regulatory Support Center (RSC): <https://rsc.niaid.nih.gov/>
- Office of Human Research Protections (OHRP): <https://www.hhs.gov/ohrp/>
- US Food and Drug Administration (FDA): <http://www.fda.gov/>
- National Institutes of Health (NIH): <https://www.nih.gov/>
 - National Institute of Allergy and Infectious Diseases (NIAID): <https://www.niaid.nih.gov/>
 - Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD): <https://www.nichd.nih.gov/>
 - National Institute of Mental Health (NIMH): <https://www.nimh.nih.gov/>
- HIV/AIDS Network Coordination (HANC): <https://www.hanc.info/>
- US Centers for Disease Control and Prevention (CDC): https://www.cdc.gov
- World Health Organization (WHO): <https://www.who.int/>

6.2.1 Network Website

The IMPAACT website (<http://impaactnetwork.org>) provides a wide range of materials.

The general philosophy governing the design, maintenance, and content of the website is to provide a site that: (1) contains useful and up-to-date information on the Network organization and studies; and (2) accommodates various internet connections and software and hardware limitations across this multinational Network.

When materials are posted on the IMPAACT website, an appropriate file type will be chosen based upon the document. If an alternate file type is needed (e.g., if a file is posted as a PDF, but a Word version is required), requests can be sent to the Operations Center. Documents generally open in new tabs, thus providing viewers with easy access back to the main website. Information on the IMPAACT website is updated frequently. This may include IMPAACT protocols, letters of amendment, full protocol amendments, and study-specific materials including laboratory processing charts, manuals of procedures, training presentations, and study implementation materials. Study-specific pages are developed to suit the needs of each particular study. An updated list of site names and numbers and a list of protocols (numbers and titles) that includes participating sites and the status of each study is also posted. The website also features a searchable IMPAACT publications database.

The design and maintenance of the IMPAACT website is the responsibility of the Operations Center. Document posting requests or design/structure update requests are sent to the website manager. Questions and comments on the website may be sent to: IMPAACT.webcontact@fstrf.org.

6.2.2 Newsletter and Social Media

The IMPAACT Network routinely distributes a newsletter to members, which generally includes study and other updates, a listing of new publications, ICAB updates, and a staff spotlight.

The Network also utilizes social media to keep members and the public aware of news and content related to the Network's scientific agenda. IMPAACT has a presence on Facebook, Twitter, and LinkedIn.

6.3 Release of Information to the Public

This section describes the public information policy of the Network as well as procedures and guidance related to press releases and public announcements. Policies and procedures related to dissemination of study results and the Network's compliance and support of the NIH Public Access Policy can be found in Section 19.

6.3.1 Public Information Policy

Investigators and site staff may have access to proprietary and sensitive information as a result of their participation in IMPAACT studies. The following guidelines relate to disclosure of product and study-related information to the public. These guidelines are in keeping with the policies and procedures of the DAIDS Office of Program Operations and Scientific Information, the NIAID Office of Communications and Government Relations (OCGR), and the NIAID News and Public Information Branch (NPIB).

Inquiries from the press, community representatives, and public officials concerning general study status may be addressed by the study investigators to whom questions are directed; however, investigators may not provide public comments related to study outcomes or adverse events, except in coordination with the protocol team and the sponsor.

Press inquiries more specifically or generally about IMPAACT activities should be referred to the IMPAACT Operations Center (IMPAACT.OperationsCenter@fstrf.org) in consultation with Network leadership and NIH.

Proprietary information about study products in development or used in a trial conducted under an Investigational New Drug (IND) application may not be discussed publicly by anyone without written permission of the product's manufacturer.

6.3.2 Disclosure of Study Results

The release of study results provides an opportunity to share findings that could influence the standard of care in the communities where IMPAACT studies are conducted or the design and/or conduct of ongoing or future trials. As outlined in Section 19, the protocol team, in coordination with Network leadership and NIH, develop materials and plans for results dissemination.

6.3.3 Press Releases and Public Announcements

All Network-related press releases and public statements will be developed or approved by NIAID, NICHD, and NIMH and, as appropriate, by its co-sponsors. When such materials are developed by the sponsor(s), the DAIDS Medical Officer and IMPAACT Operations Center will coordinate review by Network and/or study leaders as needed. When these materials are developed within the Network, the DAIDS Medical Officer and IMPAACT Operations Center will ensure that they are reviewed and approved by required groups, including representation from the relevant protocol team. Before any materials undergo NIH review, the IMPAACT Operations Center ensures they have been reviewed and/or approved by relevant parties within the Network. Study-related press releases and materials must be approved by the protocol chair and the IMPAACT Network chair.

To ensure accuracy of information and proper identification of IMPAACT, NIH, and other funding sources, all press releases generated by the Network must be reviewed by the IMPAACT Operations Center, which will coordinate additional review by the appropriate funding institutes, as necessary. Investigators should allow sufficient time for this process.

When study results are to be published or presented at a scientific meeting, the IMPAACT Operations Center, in collaboration with NIH and other relevant sponsors, may coordinate press announcements with the authors and the publishing journal or scientific meeting organizer to comply with all required embargo guidelines. For studies conducted under a Clinical Trials Agreement (CTA) with a product manufacturer, the publication guidelines and procedures described in the CTA must also be followed. In cases of specific points of discordance between CTA requirements and this policy, the CTA requirements shall be followed.

Review and issuance of press releases developed outside the IMPAACT Network (e.g., pharmaceutical, biomedical industry, or external collaborators) will follow the terms included in any applicable CTAs with DAIDS.

All press releases, statements, and public announcements must properly acknowledge that the activities of the IMPAACT Network are performed cooperatively with NIAID, NICHD, and NIMH.