5   COMMUNITY PARTICIPATION AND ENGAGEMENT IN THE IMPAACT NETWORK

Community participation and engagement are critical in scientific research. There is mutual benefit to communities and researchers when all parties work together throughout the scientific research process. In the IMPAACT Network, community participation occurs at the Network, community, and site levels through various mechanisms that include representation on the Network committees, protocols teams, and cross network community activities.

The IMPAACT Operations Center Community Engagement Program staff oversee IMPAACT's community engagement activities. Local engagement is typically done by clinical research sites with community partners who operate on a local level.

The IMPAACT Operations Community Engagement Program staff are responsible for the following:

- Ensuring an IMPAACT Community Program Manager (CPM) is assigned to each protocol team and Scientific Committees (SCs)
- Facilitating appropriate community input into the scientific agenda and the research process with Network leadership, including the Scientific Leadership Group and Scientific Committees, as well as within protocol teams
- Developing mechanisms for sharing experiences, lessons learned, and best practices in community involvement in research
- Building capacity for local communities to provide input into research at IMPAACT sites
- Facilitating training and capacity building sessions for community staff and CAB members
- Working with other IMPAACT Operations Center staff to ensure that community representatives are adequately prepared prior to launch of new studies, study milestones and results, to assist them in managing expectations and communicating study outcomes at the community level.

5.1   Confidentiality

All IMPAACT Community Advisory Board (ICAB) members are required to adhere to confidentiality standards and may be asked to sign confidentiality agreements. Members must agree to acknowledge the sensitive nature of IMPAACT discussion by refraining from:

- Disclosing confidential information, including concept sheets, protocols in development, study participant data and identifiers, and unpublished study results
- Sharing unpublished product data or other confidential proprietary information
- Sharing or distributing personal usernames and passwords to IMPAACT-related websites
- Sharing or distributing draft ICAB documents. Members can share documents for community review once approved timelines for such review have been set

Members are responsible for making certain an item can be shared or made public. If a member is in doubt, that member MUST clarify the issue of confidentiality. Clarification can come from the provider of the information, the chair of the relevant IMPAACT committee or protocol, or the chairs of the ICAB. Members must also respect confidentiality of disclosures by any member of the clinical trials networks (for example, the sharing of photographs, personal stories, HIV status, etc.).

Breach of confidentiality by any member may result in disciplinary action, up to and including loss of membership privileges. Disciplinary actions are determined by ICAB leadership.

5.2   IMPAACT Community Advisory Board (ICAB)

The ICAB includes representatives from areas in which IMPAACT works, including Asia, Africa, and the Americas, and assists clinical research site (CRS) Community Advisory Boards (CABs) with capacity building, training, and development. The role of the ICAB is to provide HIV/AIDS live experience expertise that positively impacts the formulation and implementation of research by community representation at the Network and cross- network levels.

The purpose of the ICAB is to ensure that community participation is the foundation of all community engagement activities at a CRS and to facilitate community participation throughout the research process (concept development, protocol development, study implementation, results dissemination, and post-trial access to interventions that are found to be effective).

The ICAB's goals are to:

- Provide HIV/AIDS lived experience that assists in the development and implementation of research
- Develop ways to share challenges and solutions, best practices, experience, and lessons learned
- Build community capacity to provide input and support to the IMPAACT scientific agenda
- Foster involvement of community members who represent diverse study communities within the Scientific Leadership Group (SLG), SCs, and protocol teams
- Provide information and guidance regarding community-related matters to the SLG, SCs, and protocol teams
- Provide guidance and actively promote Network initiatives related to research and training that focus on community participation across all levels of IMPAACT research

5.2.1 ICAB Membership

There are two ICAB representatives from each IMPAACT CRS – one a local CAB member and the other a site staff liaison (commonly a community educator/community liaison [CE/CL]). Typically, the local CAB elects or nominates the CAB member to serve on the ICAB while the CRS Leader or designee appoints the CE/CL. The CE/CL supports and facilitates the CAB member's participation in the ICAB.

Standing membership in the ICAB includes:

- Voting members (one vote each)
    - ICAB chair
    - ICAB vice chair
    - One CAB representative from each CRS
- Non-voting members
    - One CE/CL from each CRS
    - Emeritus ICAB chair (unless the Emeritus ICAB chair is an ICAB representative for their CRS)
    - IMPAACT Operations Center Community Engagement Program staff

5.2.2 ICAB Roles and Responsibilities

The roles and responsibilities of the ICAB include:

- Advocating for IMPAACT scientific priorities that reflect the needs of people living with HIV/AIDS, including community research priorities
- Advocating for innovative, efficient, and timely clinical trials
- Protecting the interests of research participants
- Promoting effective CAB(s) at every IMPAACT site
- Facilitating information flow between the sites and Network, including new and emerging research and study results, when available
- Bringing site and regional community issues to the ICAB Leadership Group (ILG) for further discussion with the IMPAACT Network
- Participating on protocol teams, when applicable
- Training and mentoring CAB members with assistance from site staff, the ILG, and IMPAACT Operations Center
- Electing the membership of the ILG

5.2.3 ICAB Participation Requirements

Active participation is expected and necessary to achieve the goals of the ICAB. Members of the ICAB are expected to attend and contribute to scheduled conference calls and/or webinars. If neither of a CRS's ICAB representatives is available, another site staff member or local CAB representative should be identified to participate on the call/webinar and report back to the CRS's ICAB representatives.

ICAB members are expected to attend the annual IMPAACT Network Meeting and the ICAB face-to-face meetings. Upon their return, they should report on both the community-specific and scientific content of those meetings to the local CAB and other site staff.

Participation in protocol team and other Network committee conference calls and meetings occur as appropriate. Additionally, study-specific ICABs may be established for some IMPAACT studies. See Section 5.6.1 for more information.

5.3 ICAB Leadership Group (ILG)

The ILG provides guidance and support to the ICAB and advises IMPAACT leadership on matters concerning community engagement in the IMPAACT research agenda. The ILG serves as a conduit of information between the IMPAACT ICAB, IMPAACT leadership, and IMPAACT SCs.

The ILG's goals are to:

- Respond to time-sensitive requests for community input
- Inform and guide the development of a community-centered, relevant, effective, and ethical research agenda
- Proactively identify challenges related to community engagement and/or research implementation to uphold scientific integrity and ethical standards
- Through the ICAB chair,
    - Inform the IMPAACT SLG of the ICAB's decisions, concerns, and activities
    - Advise the IMPAACT SLG on strategies to address challenges and issues of concern
- Develop mechanisms for sharing experiences, lessons learned, and best practices for community engagement in IMPAACT research

5.3.1 ILG Standing Membership

The standing membership of the ILG includes:

- Voting ILG members
    - ICAB chair
    - ICAB vice chair
    - Two at-large members for each of the IMPAACT SCs
- Non-voting ILG members
    - IMPAACT Operations Center Community Engagement Program staff
    - Emeritus ICAB chair

5.3.2 ILG Membership Requirements

While membership in the ILG is open to all ICAB members, it is important that the ILG is representative of the IMPAACT research communities. Therefore, people living with or affected by HIV are encouraged to join, including:

- Women and people who are pregnant and postpartum
- Parents/caregivers of infants, children, and young people
- Adolescents and young people

The qualifications of ILG members include:

- The ability to provide daily life experience-based expertise on living with HIV/AIDS
- The ability to read, speak, and write English at a conversational or fluent level
- Access to a device (e.g., computer, smart phone, tablet) with dependable internet capability, whether at home or the research site
- Time flexibility for participation in international conference calls (US time zones)

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- A history of positive ICAB contributions, if applicable
- Strong public speaking and presentation skills
- A basic understanding of scientific protocols
- The ability to quickly respond to time-limited requests

Regional and Site Representation on the ILG
It is important that the ILG impartially represent communities from the geographical regions that participate in IMPAACT research. For this reason, only one ICAB representative from any one CRS can serve on the ILG. This policy is ensured during the ILG solicitation and election process by:

- Alternating geographic representation between the ICAB chair and ICAB vice chair (see Section 5.3.4 for more information)
- Making ineligible the participation in the ILG by the second ICAB representative from the same site as an elected ILG member. If the ICAB vice chair chooses to become the ICAB chair, the second ICAB representative from the site is not eligible to apply for a position on the ICAB until the ICAB chair's one term of two years expires.
- When both the community representative and site liaison apply for a position within the ILG, both may be entered into the open election. The applicant with the most votes will be appointed to the ILG.

If the ILG's membership is not composed of at least one representative from each geographical region, the ILG may petition volunteers from the unrepresented region(s) for assistance and guidance to ensure that input and feedback into IMPAACT research and projects include the perspective of communities from all regions.

5.3.3 ILG Member Term Limits

ICAB Chair
After one term of two years, the ICAB chair moves into an emeritus chair role where they continue to actively participate in the leadership and direction of the ILG but through mentorship and guidance.

ICAB Vice Chair
After one term of two years, the ICAB vice chair may choose to be automatically moved into the position of ICAB chair where they will serve a two-year term. If the ICAB vice chair chooses not to move forward in the role of ICAB chair, the position of ICAB chair will be opened to receive applications followed by an election from the ICAB.

At-Large Members
At the end of one term of two years, an elected at-large ILG member may re-apply for a second term. At-large members may only serve up to two consecutive two-year terms. Members who have served two consecutive terms must rotate off the ILG for two years.

Emeritus Chair
The emeritus chair serves for one, one-year term in which they actively participate in the leadership and direction of the ILG through mentorship and guidance. The emeritus chair is not a voting member of the ILG. If re-elected as the ICAB representative of their CRS, they may, after rotating off the ILG for two years, seek election as an ILG at-large member.

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5.3.4 ILG Membership Selection Process

The positions of ICAB vice chair and the at-large membership of the ILG are filled through an open solicitation made to the full ICAB. Those interested in serving as an ILG member must complete a multi-component application process. This process is designed to identify the best qualified individuals from the pool of applicants.

The process may include:

1. Completion of an application form which assesses the desired qualifications for the position.
2. Submission of a performance checklist that is to be completed by either the CE/CL, CRS leader, or designee. The performance checklist evaluates the ICAB member's performance and interaction with their site and site CAB by assessing:
   - Active participation and regular attendance in site CAB meetings.
   - Responsiveness to emails and requests made by the site and/or CAB.
3. Submission of a one-page Statement of Interest that clearly describes the candidate's experience with HIV/AIDS, history working within a community advisory board structure, and any other information the candidate feels relevant and important to this selection process.

The IMPAACT Operations Center Community Engagement Program staff review all application packets for completeness. Applications that meet all requirements will advance to the final stage of the application process, which is a popular vote, open election.

The voting membership of the ICAB are asked to vote for their preferred leadership group members by selecting their top choices.

The ICAB representative may base their vote solely upon their own preferences or discuss the qualifications of candidates with their site's CE/CL or site CAB. CEs/CLs are responsible for ensuring that their site's voting ICAB member votes when requested. If necessary, the CE/CL may consult the voting ICAB member and submit a ballot on their behalf.

If the ICAB vice chair opts to move into the position of ICAB chair, the candidate with the most votes from an alternate geographic region becomes the new ICAB vice chair. For example, if the person moving into the ICAB chair is from the Americas region, the candidate with the most votes from the Asia or Africa region would be eligible for the position.

If the ICAB vice chair opts NOT to move into the position of the ICAB chair, the candidate who receives the highest number of votes will fill the position of the new ICAB chair. The candidate with the next highest number of votes from an alternate geographic region will become the new ICAB vice chair.

5.3.5 ILG Roles and Responsibilities

The roles and responsibilities of the ICAB Leadership Group include:

- Participating in monthly ILG calls and periodic face-to-face meetings
- Developing ICAB agendas
- Planning trainings with the ICAB and IMPAACT Operations Center
- Seeking opportunities that allow ICAB members to actively participate in the process of generating science as well as collaborate more closely with the various committees, working groups, and

protocol teams in supporting community-focused HIV, tuberculosis, and any other emergent areas of research
- For at-large members, participating in SCs
- For the ICAB chair and vice chair, participating in the SLG and leading ICAB meetings

If ILG members are unable to meet these roles and responsibilities, they may be asked to consider stepping down, and an election may be held to replace the ILG member to ensure adequate community representation.

5.3.6   ILG Scientific Committee Representation

Each at-large ILG member serves as an ICAB representative to one of the SCs. The roles and responsibilities of the SC representatives are to:

- Review and provide feedback on all new concepts within the SC
- Inform and advise the ILG on issues of concern
- Regularly participate in virtual and periodic face-to-face meetings

5.4   IMPAACT Site Community Advisory Boards

Typically, a CRS obtains community input into the research process through its CAB, although a CRS may refer to this structure by any locally chosen name or establish an alternative structure. Community representatives provide input to protocol teams, particularly in reviewing protocols in development, adapting sample consent forms for local use, and developing other study-related materials.

ICAB representatives may be asked to submit site update report forms to the Operations Center Community Engagement Program staff. The site update report form captures the site CAB's activities, accomplishments, and challenges that can be shared with the full ICAB for cross-learning and development. Routine CAB updates are also provided on ICAB conference calls.

To ensure their autonomy and to reduce possible conflicts of interest, CAB members are volunteers from the CRS community and are not paid staff members at the site. They must adhere to CAB by-laws and governance regarding roles, responsibilities, and meeting attendance. They are expected to participate meaningfully so that issues requiring community dialogue receive appropriate attention. CAB members and community partners involved in review of protocols and related documents sign a statement of confidentiality to ensure the confidentiality of proprietary information and to protect members and study participants from HIV-related stigma.

The CRS supports CAB members as they share their community expertise and gain new skills through face-to-face meetings and conference calls. CAB members are reimbursed for legitimate costs associated with participating in the advisory process, such as transportation, childcare, and meals, at a level deemed appropriate by the individual CRS. This reimbursement should not be construed as payment. The CRS staff and other IMPAACT members (such as Clinical Research Managers [CRMs], protocol chair, protocol team members, the IMPAACT Statistical and Data Management Center or the IMPAACT Laboratory Center) who are conducting training or assessment visits at study sites should be available to participate in CAB meetings as needed. The CRS is expected to support representatives of the CAB to participate in the IMPAACT meetings, protocol-specific training, and community workshops.

5.5   Community Input Throughout the Study Lifecycle

Community input and consultation is obtained throughout the study life cycle, with specific reviews and processes during concept development, protocol development, study implementation, and results dissemination.

5.5.1   Concept Development

When a concept is initially received for SC review, the assigned Operations Center representative(s) works with the assigned Community Program Manager (CPM) to determine an appropriate timeline for community review, depending on the date scheduled for SC review of the concept as well as the concept's scope. The ILG review of the concept may occur concurrent with or following SC review but must be reviewed by the ILG prior to submission for Scientific Leadership Review (SLG). Regardless of the timing, the ICAB SC representatives are responsible for providing feedback as part of the SC review of the concept.

The ILG will typically review a concept during a conference call where the proposing investigator(s) are invited to join the call to briefly introduce the concept, providing additional information that may help facilitate ILG feedback. The CPM will work with the ILG to determine call scheduling, as part of routine calls or ad hoc. Following the call, the ICAB SC representatives, with assistance from the CPM, summarize and provide the ILG feedback to the proposing investigators; this feedback is also shared with the ILG.

The ICAB chair, serving as the ICAB representative on the IMPAACT SLG, shares the community's feedback with the SLG during their review of the concept.

5.5.2   Protocol Development

As further described in Section 9, critical input is sought from site representatives, community representatives, and other stakeholders throughout the protocol development process, as needed, to ensure both the appropriateness and the operational feasibility of the study. Community input from representative sites is initiated once a protocol team has completed site selection. The assigned CPM will solicit 1-2 ICAB representatives from participating sites to serve as community representatives on the protocol team; primary roles and responsibilities for the community representatives are described in Section 4.

Prior to or concurrent with the IMPAACT Multidisciplinary Protocol Review Group (MPRG), the CPM in collaboration with the CRM(s) and community representatives sends the draft protocol to the ILG and to the ICAB representatives from selected sites for review and comment. Written review comments are generally requested within 10 working days. During this time, the CPM, with the CRMs, may arrange a conference call with the protocol chairs or designees and the ILG and ICAB site representatives to discuss the protocol and obtain community feedback. The CPM consolidates and provides the ICAB comments to the protocol chairs and CRMs as well as to the ICAB representative to the MPRG (generally the ICAB chair). The ICAB representative to the MPRG may use the comments to inform their response during the MPRG review.

If community input is requested before site selection is complete, the ILG and select ICAB representatives will provide feedback.

5.5.3   Study Implementation

The community representatives on the protocol team are actively engaged throughout the study lifecycle. In addition, a study-specific ICAB may be established as needed for studies that are larger or include more complex or unique procedures, populations, study designs, or interventions, depending on the study-specific community needs. They are generally comprised of ICAB members from the CRSs selected to conduct the study. Study-specific ICABs are responsible for enhancing study-specific community strategies and identifying possible study implementation challenges. They also assist in the following activities:

- Development of study-specific educational toolkits (e.g., informed consent flipcharts, flyers, Dear Participant letters)
- Development of plans to disseminate information intended to keep community members informed of protocol updates
- Support site-specific community involvement activities
- Facilitate community preparedness and ongoing engagement activities and ensure the successful conduct of studies through local or site-specific partnerships

5.5.4   Results Dissemination and Potential Next Steps

As described further in Section 19, 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. Protocol teams are responsible for determining appropriate plans and timing and generally include directions for CRSs to share with study participants, CAB members and other community partners, country officials, and other key stakeholders.

In addition to planned publications based on the study primary and secondary objectives, the CRS CE/CL and CAB members are encouraged to develop publications (such as abstracts, manuscripts and posters) describing community efforts that contributed to the successful implementation of the research.

5.6   Cross Network Collaborations and Community Partners

The ICAB works with other Division of Acquired Immune Deficiency Syndrome (DAIDS) research networks by having representation in the DAIDS Office of HIV/AIDS Network Collaboration (HANC) Community Partners (CP) group. Community Partners promotes effective representation of the many communities within which the National Institutes of Health (NIH)/National Institute of Allergy and Infectious Diseases-sponsored HIV clinical trials networks conduct research. ICAB members selected and appointed to the CP participate in monthly conference calls and utilize online tools such as email and a web portal system that allows for document collaboration and use of discussion boards.

The ICAB works with HANC CP and other research/community groups and organizations when it deems the partnership beneficial to IMPAACT. The ICAB identifies and selects members to work on these collaborations. Opportunities for cross-network collaborations are encouraged within the ICAB.

ICAB members may also collaborate with other community groups from NIH and non-governmental organizations. Through these relationships, the ICAB identifies HIV/AIDS research needs and issues across networks and institutes and works toward their effective resolution.