5   COMMUNITY PARTICIPATION AND ENGAGEMENT IN THE IMPAACT NETWORK

Community participation and engagement are critical in the conduct of scientific research. There is mutual benefit to communities and researchers when both 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.

5.1   Confidentiality

IMPAACT Community Advisory Board (ICAB) members are required to sign confidentiality agreements when requested. Members MUST agree to acknowledge the sensitive nature of IMPAACT discussion by refraining from:

- Disclosing confidential information, including but not limited to concept sheets, protocols in development, study participant data and identifiers, HIV status, and unpublished study results.
- Sharing unpublished product data or other confidential proprietary information.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 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 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 life experience-based 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 as a collective is to ensure that the principles of community participation are the foundation of all community engagement activities at a CRS and to facilitate community participation throughout the research process (concept 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 life 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.
- Evaluate value and effectiveness of community at Network, regional, and site levels.

To meet these goals, the ICAB works to:

- Integrate participation of community members who represent diverse HIV study communities and their advocates into Network committees and protocol teams.
- Promote understanding of community needs and issues among IMPAACT researchers and other Network members.
- Inform and advise the IMPAACT Scientific Leadership Group (SLG) on community-related issues of concern.
- Advise and advocate for Network efforts in research, evaluation, and training addressing community participation at 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 the CAB member to serve on the ICAB while the CRS Leader or designee appoints the CE/CL. The staff liaison supports and facilitates the CAB representative'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 chairs (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:

- Ensuring that IMPAACT scientific priorities reflect the needs of people living with HIV/AIDS, including community research priorities.
- Promoting the inclusion of all populations in clinical trials.
- Advocating for innovative, efficient, and timely clinical trials.
- Protecting the interests of research participants.
- Advocating for an effective CAB 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 site-specific 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 Election of ICAB Leadership Group Members

An important role of the ICAB is in electing the membership of the ILG. Positions for 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. See Section 5.3.4 for further details.

The IMPAACT Operations Center Community Engagement Program staff reviews all application packets using a rating checklist to convert responses into a numerical score. Candidates with the highest combined scores advance to the final stage of the application process, which is an open election.

There is only one voting ICAB representative from each CRS – the designated site CAB representative. Therefore, there is only one vote per site. The voting members of the ICAB vote for their preferred leadership group members by submitting a rated list of candidates (see Section 5.3.3 for information on the process of designating the chair). The rated list of candidates scores the most qualified/preferred candidate with a rating of #1, the second most qualified/preferred candidate with a rating of #2, and so forth. The ICAB representative may base their vote solely upon their own preferences or discuss the qualifications of candidates with their site's community liaison or site CAB.

Staff liaisons are responsible for ensuring that their site's voting ICAB member votes when requested. If necessary, the staff liaison may consult the voting ICAB member and submit a ballot on their behalf.

5.2.4 ICAB Participation Requirements

The ICAB facilitates information flow between community voices at the sites and the Network in a variety of ways. The ICAB brings site CAB members together for networking, training, and capacity building opportunities; 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 shall report on both the community and scientific content of those meetings to the local CAB and other site staff.

Additionally, protocol-specific CABs may be established for some IMPAACT studies and are generally comprised of ICAB members from the CRSs conducting the particular study. Study-specific ICAB calls take place on a routine basis. Participation in protocol team and other Network committee conference calls and meetings occurs as appropriate.

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 all aspects of the IMPAACT research agenda. The ILG serves as a conduit of information between the IMPAACT ICAB, IMPAACT leadership, and IMPAACT Scientific Committees (SCs).

The ILG's goals are to:

- Respond to time-sensitive requests for community input when it is not feasible to obtain a response from the full ICAB.
- Inform, facilitate, 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 ensure the ethical and scientific rigor of IMPAACT research.
- 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 Network's SCs
- Non-voting ILG members
  - IMPAACT Operations Center Community Engagement Program staff
  - Emeritus ICAB chairs

5.3.2   ILG Membership Requirements

Although any member of the ICAB may be a part of the ILG, it is important that individuals representing the following groups be included:

- Women of childbearing age who are living with HIV.
- Parents/caregivers of infants, children, and young people who are living with HIV or affected by HIV.
- Adolescents and young people living with HIV.

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 computer with dependable internet capability, whether at home or the research site.
- Access to a telephone with dependable service connection.
- Time flexibility for participation in international conference calls (US time zones).
- 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 each geographical region that participates in IMPAACT research (Africa, Asia, South America, and the US). 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.
- 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:
  - Only the community representative, when both applicants from the same site are equally qualified based upon the scoring results of the application and performance checklist, is included in the open election.
  - Only the applicant with the higher totaled score, when the applicants from the same site are not equally qualified based upon the results of the application and performance checklist, is included in the open election.

If the ILG's membership is not composed of at least one representative from each geographical region, the ILG will petition volunteers from the unrepresented region(s) for assistance and guidance to ensure that any input and feedback into IMPAACT research and projects include the perspective of communities within 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 of the ILG for two years, seek election as an ILG at-large member.

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:
   - Identifies in which position(s) (i.e., chair, vice chair, or at-large membership) the applicant is interested in serving.
   - Assesses the desired qualification requirements for the position(s).
2. Submission of a performance checklist that is to be completed by either the site liaison, site principal investigator, or another 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 reviews all application packets using a rating checklist to convert responses into a numerical score. Candidates with the highest combined scores advance to the final stage of the application process, which is an open election.

The voting membership of the ICAB are asked to vote for their preferred leadership group members by submitting a rated list of candidates (with a rating of #1 for the most qualified/preferred candidate, #2 for the second most qualified/preferred candidate and so forth).

For the positions of ICAB chair and ICAB vice chair, the current ICAB vice chair may choose to move automatically into the position of ICAB chair.

- If moving automatically into the position of ICAB chair is selected and they are from the Americas region, the Africa or Asia region candidate with the most votes becomes the new ICAB vice chair. Likewise, if the current vice chair (now the new ICAB chair) is from the Africa or Asia region, the new vice chair is the candidate from the Americas with the most votes.

- If moving automatically into the position of the ICAB chair is <u>not</u> selected, then the candidate who receives the highest number of votes will fill the position of the new ICAB chair. If the new ICAB chair is from the Americas region, the Africa or Asia region candidate with the most votes becomes the new ICAB vice chair.

5.3.5 ILG Roles and Responsibilities

The roles and responsibilities of the ICAB Leadership Group include:

- Developing mechanisms for sharing experiences, lessons learned, and best practices for community engagement in IMPAACT research.
- Collaborating with others in the IMPAACT Network Leadership to develop measurement criteria and tools for the evaluation of the IMPAACT Community Engagement Program.
- Planning trainings in conjunction 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, such as COVID-19.

ILG members participate in routine conference calls and periodic face-to-face meetings. If ILG members are continually unable to continue their participation in their assigned conference calls for the ICAB, ILG, and/or SC, they may be asked to consider stepping down, and an election may be held to replace the ILG member to ensure adequate community representation in the IMPAACT Network Leadership and protocol development process.

5.3.6 ILG Scientific Committee Representation

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

- Review and provide feedback on all new capsules, concepts, and protocols that are in development within the SC.
- Inform and advise the ILG on issues of concern.
- Participate in face-to-face SC meetings.
- Regularly participate on all SC conference calls.

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 CRSs support 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 CRSs are expected to support representatives of the CAB participating in the IMPAACT meetings, protocol-specific training, and community workshops.

5.5   Community Input into the Protocol Development Process

Note: Please see Section 9 for full details of the IMPAACT protocol development process. Community reviews of developing IMPAACT research occur during each phase of the protocol development process.

5.5.1   Concept Development

The research development process begins within the IMPAACT SCs. Typically, a one-week review period is allotted for review and feedback within each SC prior to voting for further development. Once a concept is given to the SC for review, the ICAB SC representatives should immediately share the document with the ILG. ILG members then review and provide written feedback on the research document to the SC representative within five days of receipt. The SC representative summarizes all ILG comments and submits them to the SC chair/vice chair, CRMs, and proposing investigators through the electronic voting system. A written copy of the summarized comments 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 at the appropriate time.

5.5.2   Protocol Development

Critical input is sought from site representatives, community representatives, and other stakeholders throughout the process, as needed, to ensure both the appropriateness and the operational feasibility of the study. When a protocol has reached the stage of development where it is ready for submission to the IMPAACT Multidisciplinary Protocol Review Group (MPRG), the draft protocol is sent to the ILG and to the ICAB representatives for the sites identified for the proposed study for review and comment. ICAB comments are consolidated and provided to the protocol team leadership and to the ICAB representative to the MPRG. The MPRG representative submits the collective ICAB comments to the MPRG for consideration and response.

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.