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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 throughout 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

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 capsules, concept sheets, protocols in development, study participant data and identifiers, HIV infection status, and unpublished study results
- Sharing unpublished product data or other confidential proprietary information
- Sharing or distributing personal user names and passwords to IMPAACT-related websites
- Sharing or distributing draft IMPAACT Community Advisory Board (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 the ICAB leadership.

5.2 IMPAACT Community Advisory Board (ICAB)

The IMPAACT Community Advisory Board (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).

ICAB 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

From each IMPAACT CRS, both a CAB representative and a community educator/community liaison (CE/CL) are appointed to the ICAB. 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
 - ICAB chair
 - ICAB vice chair
 - ICAB Leadership Group members
 - One CAB member from each CRS
- Non-voting members
 - One Community Educator (CE) / Community Liaison (CL) from each CRS
 - Emeritus ICAB Chairs

- 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 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, ICAB Leadership Group, and IMPAACT Operations Center
- Electing the membership of the ICAB Leadership Group

5.2.2.1 Election of ICAB Leadership Group Members

An important role of the ICAB is in the election of the membership of the ICAB Leadership Group. Positions for the ICAB Leadership Group (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 5.3.1.4 for further details.

The IMPAACT Operations Center community program staff reviews all application packets using a rated 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 site – the designated site CAB representative. Therefore, there is only one vote per site. The voting membership of the ICAB votes for their preferred leadership group members (vice chair and five at-large members) by submitting a rated list of candidates (see Section 5.3.1.3 for 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 his/her behalf.

5.2.3 ICAB Participation Requirements

Members of the ICAB are expected to actively participate in bi-monthly conference calls. If the ICAB representative is unavailable, he or she should ensure that another site representative participates on the call.

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 that meeting to their CAB.

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 occur as appropriate.

The ICAB brings site CAB members together for networking, training and capacity building. The ICAB facilitates information flow between community voices at the sites and the network.

5.3 IMPAACT CAB (ICAB) Leadership Group (ILG)

The ICAB 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 ICAB Leadership Group serves as a conduit of information between the IMPAACT ICAB, IMPAACT leadership, and IMPAACT scientific committees.

The ICAB Leadership Group 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 ICAB ILG include:

- Voting ILG Members
 - ICAB Chair
 - ICAB Vice Chair
 - Five At-large Members
- Non-Voting ILG Members
 - Operations Center Community Program staff
 - Emeritus ICAB Chairs

5.3.2 ILG Membership Requirements

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

- HIV-infected women of child-bearing age
- Mothers, fathers, and caregivers of HIV-infected and affected babies, children, and young people
- HIV-infected adolescents and young adults

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 good history of past 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

5.3.3 ILG Member Term Limits

ICAB Chair

After one term of three years, the ICAB chair moves into an emeritus chair role where he/she continues to actively participate in the leadership and direction of the ICAB ILG but through mentorship and guidance.

ICAB Vice Chair

After one term of three years, the ICAB vice chair automatically moves into the position of ICAB Chair.

At-Large Members

At the end of one term of three years, an elected at-large ILG member may re-apply for a second term. At-large members may only serve up to two (2) consecutive three year terms. Members who have served two consecutive terms must rotate off the ILG.

Emeritus Chair

The emeritus chair serves for one three-year term in which he/she actively participates in the leadership and direction of the ICAB Leadership Group through mentorship and guidance. The emeritus chair is not a voting member of the ILG.

5.3.4 ILG Membership Selection Process

The positions of ICAB vice chair and the at-large membership of the ICAB 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 qualification requirements for the position.
2. Submission of a performance checklist that is to be completed by either the site liaison or site principal investigator. 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 (1) 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 program staff reviews all application packets using a rated 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). If the current ICAB chair is from the Americas region, the Africa or Asia region candidate with the most votes becomes the new ICAB vice chair. Likewise, if the current chair is from within the Africa or Asia region, the new vice chair is the candidate from the Americas with the most votes. The remaining candidate who receives the highest number of votes fills the position of 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 IMPAACT CRS community staff to actively participate in the process of generating science as well as collaborate more closely with the Biomedical Science Working Group, Behavioral Research Working Group and protocol teams in supporting community-focused HIV prevention research

ICAB Leadership Group members participate in routine conference calls and periodic face-to-face meetings.

5.3.6 ILG Scientific Committee Representation

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

1. Review and provide feedback on all new capsules, concepts, and protocols that in development within the SC
2. Inform and advise the ICAB ILG on issues of concern
3. Participate in face-to-face Scientific Committee meetings
4. Regularly participate on all SC conference

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 submit a bi-monthly site update report form 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 can 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 Trials Specialists, 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 IMPAACT MOP 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 Capsule and 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 capsule or 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 submit them to the SC chair/vice chair, clinical trials specialist (CTS), 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 full IMPAACT Community Advisory Board for review and comment. ICAB comments are consolidated and provided to the ICAB representative to the MPRG. The MPRG representative submits the collective ICAB committees 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 on the DAIDS's HIV/AIDS Network Collaboration (HANC) Community Partners group. Community Partners (CP) promotes effective representation of the many communities within which the NIH/NIAID-sponsored HIV clinical trials networks conduct research. ICAB members selected and appointed to CP participate in monthly conference calls and online tools such as email and a web portal system that allows for document collaboration and discussion boards.

The ICAB works with HANC Community Partners, 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 National Institutes of Health (NIH) and non-governmental organizations (NGOs). Through these relationships, the ICAB identifies HIV/AIDS research needs and issues across networks and institutes and works toward effective resolution of these needs and issues.