

# Recommendations for Community Engagement in HIV/AIDS Research



*A guide for communities and researchers*

**November 2020**

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## BACKGROUND

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The world of clinical trials research is highly regulated, with an array of documents guiding the conduct of clinical trials research. Policy documents and procedural guidelines, such as Good Clinical Practice (GCP) and Good Clinical Laboratory Practice (GCLP), cover most aspects of clinical research but none of these documents discuss standards for engaging community in the research process.

Community representatives working with research networks funded by the National Institute of Allergy and Infectious Diseases (NIAID) at the National Institutes of Health (NIH) had increasingly felt that this type of guidance was essential as a way to address good *community* practice and in 2009 first sought to develop a set recommendations. These recommendations were updated in 2014, and again in 2020, to help research staff and community representatives expand and deepen existing partnerships, and forge new ones, with the ultimate goal of facilitating effective community engagement in all aspects of clinical trials research.

Around the same time these recommendations were first being developed in 2009, [AVAC](#), an advocacy organization committed to accelerating the ethical development and global delivery of AIDS prevention tools, developed the [Good Participatory Practice \(GPP\) Guidelines for Biomedical HIV Prevention Trials](#) to address many of the same issues. GPP is intended to give trial funders, sponsors and implementers guidance on how to effectively engage with all community stakeholders in the design and conduct of biomedical HIV prevention research. GPP was specifically developed with biomedical prevention research in mind but provides a valuable framework for all clinical research. The Recommendations for Community Engagement and AVAC's GPP are highly complementary and can be used in combination along with site-specific or other guidance tools. Fundamental principles underlying these recommendations are the Belmont Report (Ethical Principles and Guidelines for the Protection of Human Subjects of Research) and the Denver Principles articulated in 1983.

Over the years, more tools and resources have become available to facilitate community engagement efforts. It is valuable for researchers, site staff and community to draw on all of these resources as they each have unique features that may be relevant to a given situation or need. Taken together they can greatly enhance community engagement practices and outcomes.

### Purpose

The NIH-funded HIV/AIDS clinical trials networks' community engagement practices have evolved over time and while they still rely heavily on the Community Advisory Board (CAB) model as a means of partnering with the community, the networks and sites also incorporate other approaches, such as consultations, focus groups, and forums, among others. While recognizing the value of different types of community and stakeholder engagement, this document focuses on best practices for the use of the CAB model. It is mainstay for NIH-funded networks and sites as it provides a comprehensive and ongoing means of engagement throughout the research process. The Recommendations document offers a step-by-step approach to developing and maintaining a CAB, but many of the principles can be applied to other types of community outreach and engagement. And while these recommendations were first developed for HIV/AIDS clinical trials networks and research sites; they can easily be adapted for use by research sites conducting COVID-19 and other emerging infectious disease research.

This updated guidance document<sup>1</sup> defines the roles and responsibilities of the community and research staff as partners engaged in the research process, and addresses all stages of the research process, from community entry through site closure. Reflecting the values of NIH and Community Partners, it takes into account the social and cultural context of the research, the need for sustainable engagement of community, and the inclusion of those who are often marginalized or historically underrepresented in research.

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## **PART I. COMMUNITY ENGAGEMENT**

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### **Defining “Community”**

Finding a common definition of “community” is not as simple as one might think, as the views and perspectives of what constitutes community and the role community should play in the research process are widely divergent. Communities are not homogeneous and may have competing interests and priorities; they may not always fit a single definition.

NIH tends to define community by the population in and for which the research is being conducted. The community may be further segmented into communities of adults, adolescents, and children, depending on the nature of the research, or people with co-infections, such as tuberculosis or heart disease, or other stakeholders, such as the media, policy makers, and faith-based organizations. There are also some communities that continue to be disproportionately affected by HIV, such as men who have sex with men (MSM), transgender, African American/Black, and Latinx communities.

Community-based, service and advocacy organizations, political leaders, and decision makers, comprise part of the larger community and are often included in educational and outreach activities so that they are informed about research plans, progress, goals, and potential impact. The contributions and active engagement of these community stakeholders is essential to the ongoing success of the clinical research process and can help foster the translation of the research into future practices and policies.

### **Rationale for Community Engagement**

Collaboration with and participation of community representatives and other stakeholders in the research process helps to build trust, contributes to the acceptability and use of the intervention, and increases the likelihood that affected communities are invested in and supportive of the research being done.

- People who form a community provide the most direct opportunity for making a difference within that community; public health research that aims to be successful cannot afford to overlook this resource when planning strategies
- Collaboration between communities and researchers facilitates research that is in alignment with the priorities of the community, as well as that of the researchers.
- Collaboration between researchers and communities helps to ensure that communities invest themselves in the research, making data and results more significant for the community, thereby increasing the likelihood for a successful project with mutual benefits.

- Community participation also helps researchers achieve better penetration of communities with more acceptable and culturally relevant messages, and greater sustainability of the intervention activities and effects.
- A common perception in many communities is that researchers disregard the perspectives and needs of the community. Community participation can help build trust between the researchers and potential research participants.

## Principles of Community Engagement

The following principles lay the foundation for effectively involving community representatives in the research process.

- **Set Clear Goals:** Community engagement must meet the needs of the populations and/or communities affected by the research, strengthening the community's role and capacity to actively address research priorities and helping to ensure the development and implementation of relevant, feasible, and ethical research.
- **Learn About the Community:** It is important to become knowledgeable about the social and cultural context of the community in terms of its economic conditions, political leadership, demographic trends, history (overall and regarding research), as well as its perceptions of and experience with engagement activities.
- **Develop Cultural Awareness and Humility:** Knowledge and understanding of the community's predominant attitudes, perceptions and practices will help ensure more effective and respectful communications and interactions, leading to culturally responsive engagement activities.
- **Foster Transparency:** The community should be encouraged to express itself independently during the community engagement process.
- **Build Partnerships and Trust:** Partnering with community stakeholders is necessary to create change, build mutual trust and improve health. Toward that end, it is important to seek commitments from community-based organizations' and to identify formal and informal leaders in the community.
- **Provide and Promote Capacity Building:** Sustainable community engagement can only be achieved by identifying and mobilizing the community and by developing the capacities and resources within the community.
- **Maintain a Long-Term Commitment:** Community collaboration requires an ongoing, long-term commitment by the research organization, its partners and the community.

## Community Advisory Board (CAB) Model

The CAB model was formally initiated at NIAID in 1990 after a group of AIDS activists were invited to participate in an annual meeting of the AIDS Clinical Trials Group (ACTG) in response to community demands. It was truly the first time that community representatives—AIDS activists—were invited to meet with research scientists to discuss specific aspects of the HIV/AIDS treatment research agenda. The nature of this group evolved over time and became a model for community involvement not only in HIV/AIDS research but in other areas of research as well. The group that was formally established at the time was known as the Community Constituency Group (CCG), and different networks came to simply refer to these groups as CABs or Community Working Groups. Over time, all of the NIH-funded HIV/AIDS research networks were required to demonstrate the inclusion of community in the research process as part of their application for funding; most chose the CCG or CAB model to accomplish this. By 1996, CABs were also a requirement of funding for the individual clinical trials sites as well.

A CAB is defined as a group of community members who represent the global or local population(s) impacted by HIV/AIDS. They work closely with the network and/or site investigators and research staff to provide a community perspective into research plans and studies.

The site CABs ensure that at the local level, the community involved in, or affected by research, learn firsthand about the research being planned, its potential impact on the community, and about the ethics and regulatory issues involved. They help ensure that those most affected locally have a channel through which to voice their needs and concerns and obtain information. Site CABs provide a forum for raising questions and concerns directly to research staff, and where community needs can be discussed. Importantly, CAB members can help build support among the broader community, help determine if protocols are feasible, and can share information that helps the community understand the research and the researchers better understand the community. CAB members can provide input to protocol teams, particularly in adapting consent forms for local use and in developing other study materials. With an open dialog, increased awareness, and mutual trust, the CAB and all other forms of community engagement can help create a supportive environment for the research, allaying fears and dispelling myths about research, and contributing to informed choices and decisions about the research project.

In addition, while volunteer recruitment and retention are not the responsibility of CAB members, the CAB's knowledge of how to best reach the community— where and how—can be of significant help to researchers and research staff as they seek to inform the community about ongoing and upcoming trials, and recruit potential study volunteers in the most culturally appropriate manner possible.

### **Who Participates on a CAB?**

CAB participants include volunteers from a broad range of backgrounds representing different groups within a community who have a stake in the research being conducted. This may include representatives of non-governmental and community-based or service organizations or advocacy groups, local government officials, health care workers, those most vulnerable to HIV, trial participants, family members, caregivers and others.

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## **PART II. ROLES AND RESPONSIBILITIES**

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### **Roles and Responsibilities of CAB members**

#### **CAB members need to be:**

- Culturally sensitive to populations traditionally underrepresented in clinical trials, i.e., women, people of color, transgender people, and injection drug users
- Knowledgeable about the medical and social aspects of the illness and willing to expand and maintain their knowledge base
- Self-motivated and committed to independently pursuing knowledge and information about trends in the treatment and/or prevention
- Willing to learn about clinical trials that are being conducted and the types of research questions relevant to the communities that are being planned for enrollment

- Volunteer without expectation of rewards or monetary gain

**Responsibilities of site CAB members may include:**

- Help the community understand the need for and goals of the research being conducted or planned, and its potential impact on future research and clinical care
- Provide information about communities' research needs and concerns based on knowledge of the community and feedback about the research (ongoing and planned)
- Provide information that may help researchers and research staff better understand the community so that they can devise effective strategies for outreach, recruitment, and retention and develop effective partnerships
- Provide information based on personal experience and knowledge of community-wide practices that will help researchers improve study participants' compliance and quality of life
- Participate in the protocol development process and study implementation, including review of study protocols, informed consent plans, and other related documents
- Provide linkages to key populations and facilitate researcher-community partnerships
- Help translate scientific information into lay language
- Provide information that will help the research site disseminate information about research results in a timely manner, which may include reviewing materials to ensure that they are culturally appropriate and understandable to the general community

### **Roles and Responsibilities of Researchers and Research Staff**

Each clinical trials site should identify a staff member who is responsible for working with the site CAB. In working to support the CAB, these individuals would, among other things:

- Coordinate CAB activities, including conference calls, forums, trainings, operational meetings, educational sessions, and briefings
- Update CAB of all relevant research plans—studies that are being considered, status of ongoing studies, and research results
- Facilitate exchange of information between community and research team
- Identify and address training needs of the CAB (e.g., plan appropriate sessions, assemble educational materials). This could include the provision of regular educational opportunities for CAB members as well as programs on clinical trials research for the benefit of the broader community
- Identify and address training needs of research team (e.g., cultural responsiveness, importance of community of engagement, transgender awareness, use of non-stigmatizing language) to ensure their effectiveness in working with the community
- Identify and address training needs of CAB members to help increase research and scientific literacy and understanding (e.g., clinical research process, research ethics and informed consent, research-specific training related to prevention, vaccine, treatment, and cure research)
- Develop strategies for recruiting and retaining CAB members

## Management and Support Needs

CAB members need resources and support from their respective research site so that they can participate as equal and valued members of the research team. However, many community representatives do not and cannot operate like individuals in academia, whether because of hierarchy, resources, knowledge base, or other constraints. Therefore, flexible support is critical. For example, if a CAB member is expected to participate on every protocol team call, they may need regular and reliable telephone access at a site. In order to assess and meet support needs, it is recommended that a staff person be assigned to work with the site CAB to assess and address the many issues that might impact a CAB's ability to operate and have meaningful participation. Because this support is essential to CAB effectiveness, adequate funding would ideally be integrated into site budgets.

### Management and support needs would ideally include:

- Site staff person(s) assigned as the point person to work with the CAB
- Dedicated staff person(s)' duties may include:
  - maintaining call and meeting schedules and CAB member contacts
  - coordinating CAB member transportation and travel needs
  - troubleshooting logistical and technical needs of CAB members
  - acting as general liaison to CAB
- Telephone and internet access availability for all CAB members. One option is to arrange for CAB members to access telephone and internet directly at the site, which may include transportation support to and from the site
- Language interpretation for CAB-related calls and meetings, as appropriate
- Travel needs for CAB members:
  - transportation to and from all local CAB meetings. May also include transportation to and from the site for CAB-related calls or internet access
  - travel, lodging, and per diem for regional and international CAB meetings
- Training of new CAB members
- Translation of materials and documents for all calls, meetings, and trainings
- Meeting costs, including meeting space facilities that are accessible to all, presentation equipment and materials, audio visual assistance, and refreshments
- General office supplies
- Child or family care support for participation at meetings
- Message or suggestion box, or other mechanism for collection of community responses
- Other technical support, such as evaluation of community activities



## Laying the Foundation

### Introduction

When an organization decides to conduct research in a given region or area, it should immediately begin to learn about the community and share information about its research plans. The research staff should develop community engagement plans and start to establish mechanisms or structures for ongoing, meaningful community engagement. While the term CAB is being used, it is recognized that these groups may go by other names, such as Community Working Group or Community Advisory Group; CAB is being used as the generic term and encompasses all of these groups. Researchers and community representatives may also want to become familiar with alternative models for community engagement that may be more appropriate in a given region or setting, or that may help address a specific aspect of the community/researcher partnership or specific need. Other mechanisms of community engagement, be it a consultation, community forum, focus group or other approach can supplement and enhance the input of CAB members and help broaden the reach into the community.

### Roles and Responsibilities:

#### Site CAB and Research Staff

Role	Site CAB Responsibilities	Research Staff Responsibilities
<p><i>Gather Information for Community Profile</i></p>	<ul style="list-style-type: none"> <li>▪ Help researchers and research staff to better understand the community (e.g., local cultural and community norms, characteristics and organization)</li> <li>▪ Identify key community leaders</li> <li>▪ Provide linkages that will help researchers build partnerships with community-based organizations</li> </ul>	<ul style="list-style-type: none"> <li>▪ Conduct formative research and stakeholder analyses to “map” the community, which includes identifying:               <ul style="list-style-type: none"> <li>○ community dynamics</li> <li>○ key decision makers and community leaders</li> <li>○ research needs and interests in the community</li> <li>○ with whom/and how best to build partnerships</li> </ul> </li> <li>▪ Facilitate community consultative meetings to solicit questions, opinions, and identify key concerns about the research, and address these in a transparent fashion</li> </ul>

Role	Site CAB Responsibilities	Research Staff Responsibilities
<i>Educate and Train</i>	<ul style="list-style-type: none"> <li>▪ Educate research staff about the needs of the community and best ways to reach specific segments of the population</li> <li>▪ Provide the research staff with simple, culturally appropriate terms for complex scientific language</li> <li>▪ Educate researchers about community concerns and research priorities</li> <li>▪ Share information with others in the community</li> </ul>	<ul style="list-style-type: none"> <li>▪ Provide overview of research and network</li> <li>▪ Educate community about research goals, potential benefits to the community, and overall public health issues</li> <li>▪ Provide opportunities to get involved in various aspects of the research process, e.g., study participant, CAB member</li> </ul>
<i>CAB Development and Recruitment</i>	<ul style="list-style-type: none"> <li>▪ Work with researchers and research staff to clarify the mission as well as roles and responsibilities of the CAB</li> <li>▪ Coordinate organization and governance of the CAB by addressing the: <ul style="list-style-type: none"> <li>○ frequency and facilitation of meetings</li> <li>○ agenda development</li> <li>○ engagement of broader community (non-CAB members)</li> </ul> </li> <li>▪ Identify training needs of CAB members and help organize and facilitate these trainings</li> <li>▪ Identify criteria for self-evaluation</li> <li>▪ Discuss evaluation criteria with researchers and research staff</li> </ul>	<ul style="list-style-type: none"> <li>▪ Ensure that CAB development is transparent and inclusive of all relevant community groups</li> <li>▪ Determine the most appropriate ways to recruit CAB members: <ul style="list-style-type: none"> <li>○ extend invitations to community members to participate in the CAB</li> <li>○ ask local organizations and/or community groups to nominate a representative</li> </ul> </li> <li>▪ Discuss CAB membership requirements, which might include knowledge and cultural understanding of the relevant and diverse communities</li> <li>▪ Distribute materials to the community with notification of the first CAB meeting</li> <li>▪ Work with the CAB to: <ul style="list-style-type: none"> <li>○ clarify its mission and role</li> <li>○ provide an orientation for all new CAB members</li> <li>○ provide training to ensure effective CAB engagement in the research process</li> <li>○ identify evaluation criteria and process</li> </ul> </li> </ul>

Role	Site CAB Responsibilities	Research Staff Responsibilities
<i>Sustain Community Structure</i>	<ul style="list-style-type: none"> <li>▪ Advocate for continued support of the CAB by researchers and research staff to ensure optimum output by CAB members</li> <li>▪ Advocate for research staff involvement in CAB activities</li> <li>▪ Hold regular meetings with set targets for frequency, attendance, and community feedback</li> </ul>	<ul style="list-style-type: none"> <li>▪ Support CAB activities and be actively engaged in meetings, trainings, and other programs</li> <li>▪ Help motivate and sustain CAB interest and development</li> </ul>

**Indicators of Success**

An evaluation tool could help identify and document CAB success and be used to guide future decisions related to support, training, or need for other resources. Documenting the CABs’ practices, particularly those that are effective, could also provide guidance to other CABs as they implement various aspects of their organization or role. Research staff and CAB members might discuss the purpose of an evaluation, the need for developing reasonable and fair evaluation criteria, and how evaluation results would be used to strengthen the CAB. Methods for evaluation could incorporate both external review processes and self-evaluation. Evaluation criteria should be established during the initial organization of the CAB. The evaluation process should always be transparent.

**Potential indicators of success:**

- Number of community events held to talk about CAB formation and role
- Establishment of a CAB
- Development of a CAB mission statement
- Implementation of a CAB orientation plan

**Implementing the Research Study**

**Introduction**

Once a research study has received regulatory approval, implementation can begin. Throughout study implementation, researchers and community representatives continue working together, providing each other feedback (e.g., addressing new questions or concerns that emerge, or reviewing study enrollment status) and ensuring that it is being implemented as planned (e.g., in accordance with local and national regulatory and ethical standards.) Training for research staff on how to effectively engage community in the research process should be ongoing.

## Roles and Responsibilities

### Site CAB and Research Staff

Role	Site CAB Responsibilities	Research Staff Responsibilities
<i>Inform</i>	<ul style="list-style-type: none"> <li>▪ Become informed about the research study, including the reason the study is being done, the products being tested, the study design, and the implementation plan</li> <li>▪ Share information with broader community and other stakeholders as appropriate</li> </ul>	<ul style="list-style-type: none"> <li>▪ Ensure that all study information has been provided to community representatives, including study implementation timelines</li> <li>▪ Inform community representatives about the research study, including the risks and benefits of participating in it, and the informed consent process</li> </ul>
<i>Educate</i>	<ul style="list-style-type: none"> <li>▪ Share information with and educate the community about the value of the research</li> <li>▪ Develop a tool (such as a suggestion box) to give researchers monthly feedback concerning the study's impact on the community</li> <li>▪ Advise researchers and research staff on how to improve outreach to the local target population</li> <li>▪ Identify and facilitate communication pathways with the local site target population(s)</li> <li>▪ Learn about myths and misconceptions about the trial and report back to the research staff</li> <li>▪ Learn about Study Monitoring Committees (SMCs) and Data and Safety Monitoring Boards (DSMBs)</li> <li>▪ Help inform the broader community about the role/importance of IRBs and DSMB recommendations</li> </ul>	<ul style="list-style-type: none"> <li>▪ Provide the CAB with training on research methods, local ethical and regulatory systems, role of the DSMB and SMC, and community roles and responsibilities in trials</li> <li>▪ Update community representatives about progress made with the ongoing research, including studies at the local site and other relevant studies</li> <li>▪ Update the community on concerns raised by participants and any resulting changes in study procedures</li> </ul>
<i>Advocate</i>	<ul style="list-style-type: none"> <li>▪ Ensure that concerns are addressed appropriately, including any issues with the informed consent process</li> </ul>	<ul style="list-style-type: none"> <li>▪ Discuss accrual and retention issues with community representatives</li> <li>▪ Consider any information and insights provided by community representatives about reaching local target populations and for addressing any potential recruitment and retention issues</li> <li>▪ Identify barriers to accrual and retention, and share information with protocol teams</li> </ul>

Role	Site CAB Responsibilities	Research Staff Responsibilities
<i>Oversight</i>	<ul style="list-style-type: none"> <li>Stay abreast of study progress, enrollment, and interim reports from the DSMB</li> <li>Share information with others in community as appropriate</li> </ul>	<ul style="list-style-type: none"> <li>Report study progress and unanticipated problems to the IRB and protocol team</li> <li>Share study progress, enrollment, and DSMB summary reports with the CAB</li> </ul>

**Indicators of Success**

- CAB meeting(s) held with community to discuss study design, eligibility, and implementation
- Number of outreach and education sessions conducted by researchers

**Communicating Research Results**

**Introduction**

CAB members play a critical role in ensuring that research results reach all members of the community, particularly those who will be most directly affected. Each site should develop a communications plan that includes how study results will be disseminated. The CAB can play an active part in these communications by reviewing the clarity of the language being used and by providing advice on appropriate and timely channels of communication.

**Roles and Responsibilities**

**Site CAB and Research Staff**

Role	Site CAB Responsibilities	Research Staff Responsibilities
<i>Gather Information</i>	<ul style="list-style-type: none"> <li>Participate in research updates; learn about the potential impact of study results</li> </ul>	<ul style="list-style-type: none"> <li>Update community representatives about the research study and the potential impact of study results</li> <li>Incorporate community input into communications plan</li> </ul>

Role	Site CAB Responsibilities	Research Staff Responsibilities
<i>Information Sharing</i>	<ul style="list-style-type: none"> <li>▪ Provide feedback to the broader community about:               <ul style="list-style-type: none"> <li>○ why the study was conducted</li> <li>○ findings of the study</li> <li>○ key messages</li> <li>○ impact on clinical care and/or prevention strategies and future research</li> </ul> </li> <li>▪ Work with site staff, as appropriate, to share information via newsletters, radio, or other media outlets</li> </ul>	<ul style="list-style-type: none"> <li>▪ Disseminate information about research progress/findings to the CAB and others in the community in a forum that allows for questions and answers that address:               <ul style="list-style-type: none"> <li>○ actual results and impact on clinical care</li> <li>○ whether additional studies will be needed to address specific questions that were not answered by this study</li> <li>○ whether product is unsafe or ineffective and, therefore, not to be studied further</li> <li>○ implications of results for other populations, such as children, adolescents, pregnant women, or men who have sex with men</li> <li>○ next steps</li> </ul> </li> </ul>
<i>Consult</i>	<ul style="list-style-type: none"> <li>▪ Consult key stakeholders on specific target audiences to reach with results, how best to link with local target populations, and how best to relay information about the trial results</li> <li>▪ Review communication materials to ensure they are written in clear, understandable lay language and/or are translated as needed</li> </ul>	<ul style="list-style-type: none"> <li>▪ Seek CAB input on key messages to ensure they easy to understand by lay audiences and utilize CAB members in conveying the key messages</li> </ul>
<i>Advocate</i>	<ul style="list-style-type: none"> <li>▪ Request information that will help CAB members understand the study results so that they can inform/discuss with others in the community and advocate for additional research or policy changes, as appropriate</li> </ul>	<ul style="list-style-type: none"> <li>▪ Outline key issues for community awareness and policy considerations</li> <li>▪ Work with leadership to facilitate timely release and dissemination of study findings</li> </ul>

**Indicators of Success**

Site staff are encouraged to document the methods used to disseminate research results to specific target communities and the community at large. This would not only facilitate evaluation but would help in documenting different approaches/activities that could then be shared with other sites.

Specific evaluation criteria may include:

- CAB meetings held with researchers and research staff to discuss research results
- Coverage of research results in local press, newsletters, and/or media discussing research results

### **Communicating Research Results Checklist**

Sites should develop a communications plan and stakeholder list (with contact information).

Possible action items include:

- Develop communication plan
- Develop stakeholder directory to ensure broad dissemination of information
- CAB and research staff meet to discuss ongoing studies and study completion timelines
- Identify target communities
- Plan meeting to discuss research results
- Formulate plan to disseminate targeted information (e.g., community forums, flyers)
- Schedule conference call/meeting with CAB and research staff to review results and key messages
- Develop materials for trial participants
- Develop materials for media (e.g., press release, Q and A, Web content, talking points)
- Develop community-specific materials (local language needs addressed)
- Identify and contact specific media outlets
- Contact the following:
  - Relevant government agencies (e.g., Dept. of Public Health)
  - Collaborating partners
  - Community stakeholders (national organizations, advocacy groups, community-based organizations)

### **Setting CAB Scientific Priorities**

The identification of the CAB's scientific priorities can help CAB members influence which scientific questions will be addressed. Specifically, the value of identifying CAB priorities is that they enable the CAB to:

- Clearly articulate areas of potential research of importance to the community
- Identify gaps within the existing research portfolio relative to perceived community needs

### **Process for Identifying Scientific Priorities:**

A potential approach for the identification of scientific priorities is described below.

- Distribute an overview of the research plan to ensure that CAB members have a clear understanding of the scope of the research, including current and planned studies
- Explore the current research plan with CAB members, addressing their questions or concerns; these suggestions and concerns will help to identify potential gaps in research
- Involve local CAB members in identifying issues and potential gaps in research that may impact priorities
- Determine which community issues and/or gaps in research should be of highest priority
- Ensure that leadership receives and understands the community scientific priorities

To facilitate the CAB's ability to set priorities, researchers and research staff should:

- Present current research information in a format and language that is accessible to a community audience and easily shared
- Acknowledge and take the CAB's scientific priorities into consideration for decision making

### **Considerations for Developing Research Priorities:**

The following issues might be considered when trying to establish research priorities:

- **Potential Impact** as measured by the size of the targeted population that would potentially benefit from the therapeutic or preventive intervention
- **Likelihood of Achieving the Potential Impact**, including persuasiveness of the proof-of-concept data regarding the likelihood that the drug, treatment strategy, or biologic/behavioral intervention will effectively impact the targeted patient population or transmission pathway
- **Feasibility, Affordability, and Practicality** of wide-spread implementation/use of the intervention so that the potential favorable effect is realized
- **Strength of Scientific Proposal**, including availability of supporting evidence from prior studies
- **Efficiency of the Research Proposal**, so that multiple questions can be answered in one trial
- **Consistency with Strengths**, core competencies, and mission including the uniqueness of the scientific and site resources for trial design, conduct, and analysis
- **Likelihood of the Scientific Question Being Addressed Elsewhere**, either by pharmaceutical companies, well-funded non-governmental organizations (NGOs), or other government-sponsored research networks
- **Timeliness or Urgency of the Research Proposal**; for example, sometimes a lower priority issue must be addressed in order to tackle a more important priority



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## PART III. APPENDIX

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### GLOSSARY

**AIDS Clinical Trials Group (ACTG):** The [ACTG](#) supports the largest network of expert clinical and translational investigators and therapeutic clinical trials units in the world. It plays a major role in setting standards of care for HIV infection and related co-infections including tuberculosis and viral hepatitis infection.

**AVAC:** [AVAC](#) is a global advocacy organization that uses education, policy analysis, community mobilization and a network of worldwide collaborations to accelerate ethical development and global delivery of biomedical HIV prevention options.

**Community Advisory Board (CAB):** A CAB is a group of community members, representing the local population(s) impacted by HIV/AIDS that works in close collaboration with researchers and staff. NIH supports CABs that work at the global network level (network CAB) and at the site level.

**Community Partners (CP):** A community group that works across the NIH-funded HIV/AIDS research networks to improve community input at all levels of the research enterprise by identifying and developing programs and materials to meet the training needs, participation of community members from resource-limited settings and vulnerable populations, and address challenges to clinical trials participation.

**Concept:** The general idea for a research study. It is usually generated as a result of previous research findings, pre-existing clinical practice and observation, or from the existing public health needs/concerns of a community/society.

**Data and Safety Monitoring Board (DSMB):** An independent panel of experts established by NIAID and charged with the responsibility of monitoring the progress of trials, the safety of participants, and the efficacy of treatments or prevention methods being tested. A DSMB makes recommendations to NIAID and other study sponsors concerning continuation, termination, or modification of each study based on observed beneficial or adverse effects of the intervention being studied. DSMBs are funded by NIAID separately from the research networks.

**Division of AIDS (DAIDS):** The Division within NIAID that has primary responsibility for basic and clinical prevention and therapeutic research on HIV/AIDS within the National Institutes of Health.

**Good Clinical Practices (GCP):** An international standard established to guide the design, conduct, performance, monitoring, auditing, recording, analysis, and reporting of clinical trials. It is designed to provide assurance that the data and reported results are credible and accurate and that the rights, integrity, and confidentiality of trial subjects are protected.

**Good Participatory Practice (GPP):** [The Good Participatory Practice Guidelines for Biomedical HIV Prevention Trials](#) are designed to provide systematic guidance on the roles and responsibilities of trial sponsors and trial implementers towards participants and their communities. GPP identifies core principles, essential issues, and minimum elements of how stakeholders should plan, conduct, and evaluate community engagement in biomedical HIV prevention trials.

**HIV Prevention Trials Network (HPTN):** [The HIV Prevention Trials Network](#) is a worldwide collaborative clinical trials network that develops and tests the safety and efficacy of interventions designed to prevent the transmission of HIV.

**HIV Vaccine Trials Network (HVTN):** [The HIV Vaccine Trials Network](#) is a global network of clinical research sites whose mission is to fully characterize the safety, immunogenicity, and efficacy of HIV vaccine candidates with the goal of developing a safe, effective vaccine as rapidly as possible for prevention of HIV infections globally.

**Informed Consent:** A process by which a participant voluntarily confirms his or her willingness to participate in a particular study after having been informed of all aspects of the study that are believed by the researcher to be relevant to the participant's decision to participate.

**International Maternal Pediatric Adolescent AIDS Clinical Trials (IMPAACT):** [The IMPAACT Network](#) is a cooperative group of institutions, investigators, and other collaborators focused on evaluating potential therapies for HIV infection and its related symptoms in infants, children, adolescents, and pregnant women, including clinical trials of HIV/AIDS interventions for and prevention of mother-to-child transmission.

**National Institute of Allergy and Infectious Diseases (NIAID):** [NIAID](#), a component of the U.S. Department of Health and Human Services, National Institutes of Health, conducts and supports basic and applied research to better understand, treat, and ultimately prevent infectious, immunologic, and allergic diseases.

**Network:** A cooperative of institutions conducting clinical trials under a common research agenda, including an Operations Center, Statistical and Data Management Center (SDMC), Network Laboratory, and Clinical Research Sites.

**Protocol:** A descriptive document that presents a synopsis of the science supporting the study, details the scientific objectives, and describes the methods to achieve these objectives.

**Study Design:** Describes in detail how the research question will be answered, including methods used to collect data, where the study will be conducted, the number and type of people required for the study, how the study will be implemented, and when the research will be conducted.

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<sup>i</sup> The content of this updated version of the Recommendations for Community Engagement has not been significantly altered; some of the language has been revised and sections have been omitted to streamline and make it more practical for site and community use.