

Recommendations for Community Engagement in HIV/AIDS Research



A guide for communities and researchers
Version 2.0

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The [Recommendations for Community Engagement in HIV/AIDS Research](#) was developed by Community Partners, a global group of community representatives affiliated with the HIV/AIDS clinical trials networks funded by the National Institutes of Health (NIH). The Office of HIV/AIDS Network Coordination (HANC) coordinates Community Partners across the five NIH-funded HIV/AIDS clinical trials networks and the document is available on the [HANC public site](#).

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Background

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 the National Institute of Allergy and Infectious Diseases (NIAID) at the NIH increasingly felt that this type of guidance was essential and in 2009 sought to develop recommendations as a way to address good community practice. These recommendations are intended as a tool 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, [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 together and in combination with site-specific or other guidance tools.

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

This document is focused on best practices for engaging community using a Community Advisory Board (CAB) model, although NIH recognizes that this is not the only form of community engagement. The NIH-funded networks' community engagement practices have evolved over time and while they still rely heavily on the CAB model to partner with the community, they also incorporate other approaches, such as consultations, focus groups, and forums, among others. The Recommendations document offers a step-by-step approach to community engagement, which can be applied to the CAB model as well as other community engagement approaches. The recommendations are geared toward the global needs and experiences of NIH's HIV/AIDS clinical trials networks and sites, although they will undoubtedly benefit other research entities.

This guidance document is designed to help community members and research staff work collaboratively toward the common goal of finding, preventing, treating, and curing HIV/AIDS. It 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.

Overview: NIH Networks and Community

NIH and its HIV/AIDS Networks

The Division of AIDS (DAIDS) is a component of NIAID at NIH. It was established in 1986 to develop and implement a national research agenda to address the burgeoning HIV/AIDS epidemic. Today, DAIDS, NIAID and the NIH envision an “AIDS-free Generation” and toward that end, have the following primary goals:

- Halt the spread of HIV infection by defining highly effective prevention strategies, including a preventive HIV vaccine
- Cure HIV Infection
- Establish treatment and prevention strategies for HIV-associated infections of highest morbidity and mortality, especially TB and hepatitis
- Improve outcomes of treated HIV disease.

To accomplish these goals, DAIDS/NIAID supports research on the pathogenesis, natural history, and transmission of HIV through fundamental, basic, and epidemiological research as well as pre-clinical research, and clinical research in adults, adolescents and children for the treatment and prevention of HIV.

National Institutes of Health HIV/AIDS Clinical Trials Networks
<p>AIDS Clinical Trials Group (ACTG)</p> <p><i>Develop and conduct scientifically rigorous translational research and clinical trials to investigate pathogenesis and improve the care and treatment of HIV and associated complications and infections</i></p>
<p>HIV Prevention Trials Network (HPTN)</p> <p><i>Discover and develop new and innovative research strategies to reduce the acquisition and transmission of HIV</i></p>
<p>HIV Vaccine Trials Network (HVTN)</p> <p><i>Conduct all phases of clinical trials in search of an effective and safe HIV vaccine</i></p>
<p>Microbicide Trials Network (MTN)</p> <p><i>Evaluate the safety, effectiveness, and acceptability of microbicide candidates to prevent HIV infection</i></p>
<p>International Maternal Pediatric Adolescent AIDS Clinical Trials (IMPAACT)</p> <p><i>Decrease the mortality and morbidity associated with HIV disease in children, adolescents and pregnant women</i></p>

Through DAIDS/NIAID, the NIH has established a number of clinical trials networks and other programs to address to specific areas of research (e.g., vaccines, treatment, microbicides and other prevention modalities) and/or the specific issues related to the treatment or prevention of AIDS in specific populations (e.g. women, children and adolescents).

As a result of the most recent competitive process (awards made in December 2013) there are five [NIH HIV/AIDS clinical trials networks](#):

- [AIDS Clinical Trials Group \(ACTG\)](#)
- [HIV Prevention Trials Network \(HPTN\)](#)
- [HIV Vaccine Trials Network \(HVTN\)](#)
- [International Maternal Pediatric Adolescent AIDS Clinical Trials \(IMPAACT\)](#)
- [Microbicide Trials Network \(MTN\)](#)

While these networks are overseen and funded primarily by DAIDS/NIAID, other NIH offices and institutes collaborate with and/or fund one or more of the HIV/AIDS clinical trials networks, including: the Office of AIDS Research (OAR), the Eunice Kennedy Shriver National Institute of Child Health and Human Development, the National Institute of Mental Health, the National Institute on Drug Abuse, the National Institute of Dental and Craniofacial Research, the National Institute of Neurological Disorders and Stroke and the National Cancer Institute. [More information about NIH HIV/AIDS research can be found on NIAID's website.](#)

The networks have the overall responsibility for developing, implementing and adapting clinical research agendas to address NIAID's HIV/AIDS scientific priorities, including:

- Therapeutics for HIV/AIDS and HIV-associated infections in adults (including HIV cure, as well as co-occurring noninfectious and infectious diseases, such as hepatitis and tuberculosis)
- HIV/AIDS and HIV-associated infections in children and mothers
- Integrated strategies to prevent HIV infection
- Vaccines to prevent HIV infection
- Microbicides to prevent HIV infection

Community

A unique component of NIAID's clinical trials enterprise is Community Partners, which was created in 2006. Community Partners is an overarching body of community representatives conceived of to address cross-network concerns and the needs of the diverse communities working within each of the clinical trials networks. Community Partners establishes a formal role for community members across all of the networks to work to together; it provides an opportunity for regular interaction and communication between community and network/NIAID leadership. Oversight and coordination of Community Partners is provided by HANC, which works with the NIH HIV/AIDS clinical trials networks to create a more integrated, collaborative and flexible research enterprise.

In addition to Community Partners, each of the HIV/AIDS research networks and their affiliated clinical research sites are required to have community engagement throughout their organization and at all stages of the research process. At the network level, the community is involved in developing research plans, setting research priorities and serving on scientific committees and protocol teams. At the site level, community-research partnerships help facilitate an exchange of information to ensure that community opinions and suggestions are discussed and addressed by the research team. This also allows for an ongoing exchange of information on all research projects. One of the ways to accomplish

this has been through the establishment of a network-level CAB and a local CAB at the clinical trials unit (CTU) or clinical research site (CRS). Alternative approaches for community engagement have also been used to ensure that the broader community is engaged and aware of the research plans. These may include focus group discussions or consultations with stakeholders at Town Hall meetings, forums, health fairs, or other venues. The research networks and sites may also form partnerships with local or national advocacy, civil society, and provider organizations. The combination of approaches contributes to building trust in the community and ensuring effective collaborations and dissemination of information.

Part I. Community Engagement¹

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 and its funded HIV/AIDS clinical trials networks and sites tend to define community by the population in and for which the research is being conducted. HIV vaccine and other prevention research focus on healthy uninfected volunteers. Specific studies may be conducted in areas with low or high incidence of HIV. For therapeutic research, the community clearly encompasses HIV-infected individuals and others who may be affected by HIV and/or the research 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 hepatitis C virus, or other stakeholders.

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.

¹ The information in this section is based on excerpts from a comprehensive literature review on community involvement in HIV/AIDS clinical trials research compiled by Benjamin Weil, MIA, LaHoma Smith Romocki, MPH, PhD, and Stella Kirkendale, MPH.

- 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 (Merzel and D’Afflitti 2003).
- 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 “increas[ing] the likelihood for a successful project with mutual benefits” (Leung et al. 2004).
- 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” (Beeker et al. 1998).
- Community participation in HIV/AIDS research can be instrumental in raising awareness about influences on HIV transmission within the community, producing attitude changes in community leaders and strengthening leadership capacity in the parts of the community most affected by HIV/AIDS.
- 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 Competency:** 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 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 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 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 later 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 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.

The global network level CABs work with the network leadership on scientific, operational and oversight committees, and as such help shape the network research plans and priorities. They can also participate as members of protocol teams and in so doing, play an important role in the conduct of research by providing ongoing feedback and constructive suggestions on study design and procedures.

The site CABs ensure that 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 at the local level have a channel through which to voice their needs and concerns, and obtain information. The CABs provides a forum through which questions and concerns can be expressed to and addressed directly by research staff, and community needs can be discussed. As importantly, the CAB members can help build support among the broader community, help determine if protocols are feasible in a given community and share information that helps the community understand the research and the researchers better understand the community. With shared information, increased awareness and mutual trust, the CAB and all methods of community engagement can help create a supportive environment for the research, allay fears and dispel myths about research, and most importantly, contribute 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 competent 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, HIV-infected individuals, or those at risk of HIV infection, trial participants, family members, caregivers and others.

PART II. Roles and Responsibilities

Overview

Community engagement is required by all NIH HIV/AIDS clinical trials networks and sites. It helps ensure that research priorities are responsive to community needs and that the community is fully aware of planned and ongoing research activities. Effective community engagement has to be very intentional and involves time and resources from community volunteers.

The recommendations provided in the following sections are organized around the clinical research process. The NIH networks often use CABs as a means of linking researchers, site staff, trial participants, and the broader community. CAB members can perform a broad range of activities, and no individual CAB member can, or is expected to, do them all. It is recognized that CAB members' time is extremely valuable and often limited. Thus, CABs will need to set priorities for how they will participate in the research process, and these priorities may change over time. Researchers and study implementers must be sensitive to the nature of the CABs – volunteers who may or may not be well versed in the clinical trials research process and may or may not have a high level of scientific literacy in HIV treatment or prevention. Some of the goals delineated in these sections can be accomplished through other means of community engagement; it is perfectly acceptable and sometimes preferable to combine approaches for community input and involvement.

Whether at the network or site level, CAB members need to be:

- Culturally sensitive to populations traditionally underrepresented in HIV/AIDS clinical trials, i.e., women, people of color, transgender, youth, and injection drug users
- Knowledgeable about the medical and social aspects of HIV 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 of HIV/AIDS
- Willing to learn about, clinical trials that are being conducted and the types of research questions relevant to the communities that are being targeted by their network or site
- Volunteer without expectation of rewards or monetary gain

Responsibilities of network and 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 targeted communities; facilitate researcher-community partnerships
- Help translate scientific information into lay language
- Provide information that will help the research site or network 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 network should ideally have an identifiable employee serving as the liaison to the network CAB; similarly, 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 or on various aspects of HIV/AIDS for the benefit of the broader community
- Identify and address training needs of research team (e.g. cultural competency, importance of community of engagement) to ensure their effectiveness in working with the community
- Develop strategies for recruiting and retaining CAB members

Role of the Network Leadership and NIAID

Each network is responsible for evaluating its clinical research sites, and community involvement should be one of the many evaluation criteria. It is not enough for a site to simply have a CAB; having an active, effective CAB with adequate resources to function in partnership with researchers and research staff is the goal.

Management and Support Needs

CAB members need resources and support from their respective network or 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 or network 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 network and site budgets.

Management and support needs would ideally include:

- Network and/or CTU/CRS 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
 - travel, lodging, and per diem for CAB leadership participation at all network meetings
 - Visa and passport application and fee assistance
- Training of new CAB members, at the site, regional, and network level
- 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

1. 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. Because NIAID relies heavily on the CAB model, the following recommendations pertain to establishing a CAB at a clinical trials unit or clinical research site. 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 a 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.

2. Roles and Responsibilities:

2.1 Site CAB and Research Staff

Role	Site CAB Responsibilities	Research Staff Responsibilities
<i>Gather Information for Community Profile</i>	<ul style="list-style-type: none"> ▪ Help researchers and research staff to better understand the community (e.g., local cultural and community norms, characteristics and organization) ▪ Identify key community leaders ▪ Provide linkages that will help researchers build partnerships with community-based organizations 	<ul style="list-style-type: none"> ▪ Conduct formative research and stakeholder analyses to “map” the community, which includes identifying: <ul style="list-style-type: none"> ○ community dynamics ○ key decision makers and community leaders ○ research needs and interests in the community ○ with whom/and how best to build partnerships ▪ Facilitate community consultative meetings to solicit questions, opinions, and identify key concerns about the research, and address these in a transparent fashion
<i>Educate and Train</i>	<ul style="list-style-type: none"> ▪ Educate research staff about the needs of the community and best ways to reach specific segments of the population ▪ Provide the research staff with simple, culturally appropriate terms for complex scientific language ▪ Educate researchers about community concerns and research priorities ▪ Share information with others in the community 	<ul style="list-style-type: none"> ▪ Provide overview of research and network ▪ Educate community about research goals, potential benefits to the community, and overall public health issues ▪ Provide opportunities to get involved in various aspects of the research process, e.g., study participant, CAB member

Role	Site CAB Responsibilities	Research Staff Responsibilities
<i>CAB Development and Recruitment</i>	<ul style="list-style-type: none"> ▪ Work with researchers and research staff to clarify the mission as well as roles and responsibilities of the CAB ▪ Coordinate organization and governance of the CAB by addressing the: <ul style="list-style-type: none"> ○ frequency and facilitation of meetings ○ agenda development ○ engagement of broader community (non-CAB members) ▪ Identify training needs of CAB members and help organize and facilitate these trainings ▪ Identify criteria for self-evaluation ▪ Discuss evaluation criteria with researchers and research staff 	<ul style="list-style-type: none"> ▪ Ensure that CAB development is transparent and inclusive of all relevant community groups ▪ Determine the most appropriate ways to recruit CAB members: <ul style="list-style-type: none"> ○ extend invitations to community members to participate in the CAB ○ ask local organizations and/or community groups to nominate a representative ▪ Discuss CAB membership requirements, which might include knowledge and cultural understanding of the relevant and diverse communities ▪ Distribute materials to the community with notification of the first CAB meeting ▪ Work with the CAB to: <ul style="list-style-type: none"> ○ clarify its mission and role ○ provide an orientation for all new CAB members ○ provide training to ensure effective CAB engagement in the research process ○ identify evaluation criteria and process
<i>Sustain Community Structure</i>	<ul style="list-style-type: none"> ▪ Advocate for continued support of the CAB by researchers and research staff to ensure optimum output by CAB members ▪ Advocate for research staff involvement in CAB activities ▪ Hold regular meetings with set targets for frequency, attendance, and community feedback 	<ul style="list-style-type: none"> ▪ Support CAB activities and be actively engaged in meetings, trainings, and other programs ▪ Help motivate and sustain CAB interest and development

2.2 Network CAB, Research Network, and NIAID

Role	Network/Global CAB Responsibilities	Network Leadership Responsibilities	NIAID Responsibilities
<i>Guidance</i>	<ul style="list-style-type: none"> ▪ Provide local CABs with information about how other CABs are organized and methods for interacting with CTU/CRS staff and the broader community 	<ul style="list-style-type: none"> ▪ Provide CTU/CRS with guidance about the role of the CAB, recommended training needs, and level of support (for supplies, training, ongoing meetings, etc.) 	<ul style="list-style-type: none"> ▪ Ensure sufficient level of staff support and availability of resources needed to sustain CAB activities

3. Training

It is important to identify and utilize the skills that community representatives bring to the CAB and to provide training so that the CAB members can be more effective. To be most successful, CAB members would ideally have the following skills:

- Ability to communicate well and work in an inclusive and participatory way
- Open to constructive criticism and willing to be accountable to communities
- Capacity to listen to and learn from both community representatives and researchers to gain understanding about the local HIV epidemic, community concerns and priorities, clinical research plans and protocols, and ethical concepts and issues
- Strong and enduring interest in community involvement in research and commitment to advancement of ethics, scientific research, and prevention, treatment, and control of HIV/AIDS
- Understand the regulatory requirements that apply to HIV clinical research

3.1 Recommended training topics for CAB members:

- Communications training
- Presentation and public speaking skills
- Listening skills
- Report writing and information technology (IT) training
- HIV treatment and/or prevention (relevant to the research at the specific CTU/CRS and/or network), beginning with an introductory overview of HIV science and clinical research challenges
- Principles and structures for ensuring ethics and human rights, including processes for review and implementation of research plans
- Overview of NIH-funded clinical research structures, research priorities and plans, funding processes, and history of community involvement
- Other models of community participation
- Adult learning and education in order to better organize and facilitate meetings
- Building informal and formal mentoring relationships (within and across networks)

- Review of planned and current HIV clinical protocols as a way to train community representatives about how to read and evaluate a protocol
- Introduction to research design and analysis so that CAB members can better understand trial design and results
- Introduction to monitoring and assessment tools
- Interpreting research results and their impact on community

3.2 Recommended training topics for research staff:

- Value of community involvement and cultural fluency in research process
- History of community involvement in research and in NIAID-supported research
- How “community” is defined
- Different models of community involvement in the research process
- Potential role of the CAB in working with the site
- Role of the CAB at network level and role of Community Partners

4. Indicators of Success

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. The value of using the evaluation to identify and document CAB success and to help guide future decisions related to support, training, or need for other resources should be emphasized. Documenting the CABs’ practices, particularly those that are effective, will also help provide guidance to other CABs as they implement various aspects of their organization or role. 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.

4.1 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

Community Preparedness

1. Introduction

Community preparedness is a process whereby the researchers and community staff explore how the community may respond to a proposed study, how the community will obtain information, and how to reach out to potential volunteers. This is fundamental to allaying potential fears and misconceptions that may increase reluctance to participate in a study. Addressing these issues will enhance recruitment and retention of study participants.

Many factors should be taken into consideration when preparing a community for clinical research, including 1) size and type of trial(s) to be conducted; 2) location, language, and demographics of the

community; 3) socio-economic and cultural factors; 4) whether the community is new to, or experienced with, clinical trials research; and 5) whether the community has had previous involvement with a CAB or other means of community engagement in research. Additional factors to consider are whether the community is being prepared for one specific protocol or participation in the overall research agenda, and if multiple networks or study organizations will be involved.

2. Roles and Responsibilities

2.1 Site CAB and Research Staff

Role	Site CAB Responsibilities	Research Staff Responsibilities
<p><i>Consult:</i></p> <p><i>Communication streams between staff and CABs need to be open and transparent</i></p>	<p>Participate in discussions to learn about, and share community perspective on, proposed research. Discussions may include:</p> <ul style="list-style-type: none"> ▪ General information about research ▪ Research experiences in the community ▪ Overview of the research question ▪ Introduction of new research plan ▪ Difference between research and clinical care ▪ Potential research benefits and impact of proposed research ▪ Community perspective on need for HIV research in general and proposed research specifically 	<p>Address some or all of the following about proposed research:</p> <ul style="list-style-type: none"> ▪ Does the proposed research target a specific population in the community? If so, why is this important? ▪ How will the community be affected by the proposed research? ▪ Who else might be affected? ▪ Why is the proposed research important? ▪ What has been learned from earlier research? ▪ How will the community have input into the research process ▪ What are some of the community ethical concerns/issues?
<p><i>Strategize:</i></p> <p><i>Formulate a community involvement plan that serves to capture how the site will engage the community and the CAB</i></p>	<ul style="list-style-type: none"> ▪ Identify and meet with community members and community-based organizations ▪ Develop plans with research staff to increase awareness and understanding of research in the broader community; work with research staff to develop innovative ways to reach out to the community. 	<ul style="list-style-type: none"> ▪ Identify, establish, maintain, and nurture partnerships with local organizations such as clinics, churches, schools, non-profits, organizations, etc. ▪ Meet with various community groups and stakeholders to gather information ▪ Plan for community education sessions; encourage community input and suggestions on culturally accepted ways of conducting research ▪ Plan focus group discussions or community meetings for input that helps shape the research

Role	Site CAB Responsibilities	Research Staff Responsibilities
<i>Prepare</i>	<p>Help inform the broader community about:</p> <ul style="list-style-type: none"> ▪ Importance of this clinical trials research to public health ▪ Specific objectives of this research ▪ Possible impact, risks, and benefits of proposed research ▪ Role of a CAB 	<ul style="list-style-type: none"> ▪ Consider which training topics are most appropriate for, or of greatest interest to, CAB members; invite CAB representatives to participate in protocol-specific trainings so they can have a better understanding of the research ▪ Take an active role in providing information about the research to local organizations

2.2 Network CAB, Research Network, and NIAID

Role	Network/Global CAB Responsibilities	Network Leadership Responsibilities	NIAID Responsibilities
<i>Inform</i>	<ul style="list-style-type: none"> ▪ Help train site CABs in community preparedness strategy: what it is, how to do it, why it is important 	<ul style="list-style-type: none"> ▪ Support network CABs in their work with sites ▪ Support sites in utilizing NCAB expertise 	<ul style="list-style-type: none"> ▪ Require sites and networks to have community engagement and encourage community preparedness efforts
<i>Share Information</i>	<ul style="list-style-type: none"> ▪ Help sites share best practices, challenges, and successes they have experienced 	<ul style="list-style-type: none"> ▪ Share community preparedness best practices among CRS/CTU Principal Investigators (PIs) 	<ul style="list-style-type: none"> ▪ Promote cross-network sharing of community preparedness best practices
<i>Advocate</i>	<ul style="list-style-type: none"> ▪ Ensure that community preparedness activities are defined in the CTU's development plans and that they are budgeted for 	<ul style="list-style-type: none"> ▪ Advocate with DAIDS for adequate funding in the CTU budget to address community preparedness 	
<i>Evaluate</i>	<ul style="list-style-type: none"> ▪ Participate in evaluating site and network CABs and community engagement activities 	<ul style="list-style-type: none"> ▪ Evaluate sites' CABs and broader community engagement activities 	<ul style="list-style-type: none"> ▪ Ensure that networks assess their network sites' CABs and community engagement activities

3. Training

Training for network leadership and research staff on how to effectively engage diverse communities in the research process and/or GPP should be ongoing. Trainings should also address scientific literacy, including understanding basic scientific knowledge, clinical trials research; and as appropriate, biomedical prevention, HIV treatment, tuberculosis and viral hepatitis and/or cure/eradication research.

Staff training should address cultural competency and working with specific populations particularly those most disproportionately impacted, such as racial and ethnic minorities, men who have sex with men, transgender people and women.

4. Indicators of Success

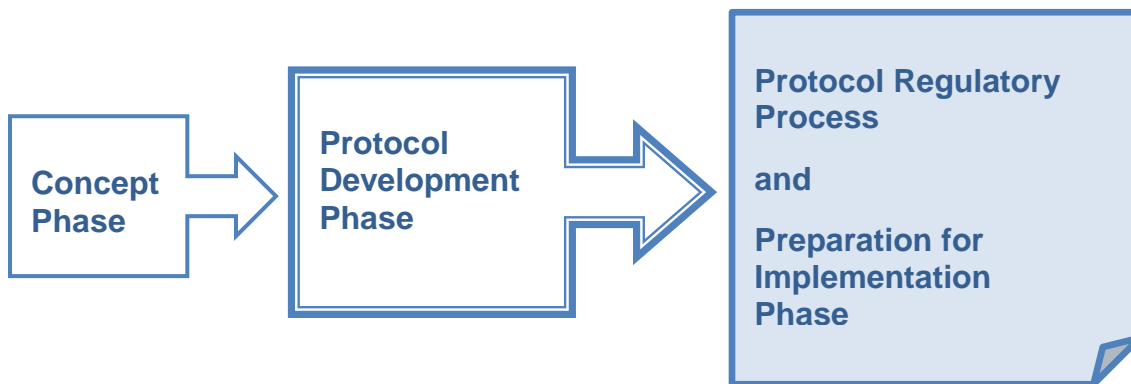
The success of community preparedness efforts can be evaluated by considering the following:

- Feedback from CAB about informed consent, protocol, and recruitment materials
- Community suggestions for conducting the study are shared with researchers and research staff
- Researchers and research staff respond to inquiries from the community about the study and address fears and suggestions
- Participation in educational events/forums
- Researchers and research staff know and understand target communities, including the socio-economic situation (through community mapping reports)
- Community knows where study is being conducted and who the key players are, most notably, the Principal Investigators
- Community understands research concepts such as the difference between research and care
- The community knows the importance of volunteers' contribution to the research process
- Partnerships have been established within the broader community and among other researchers

Developing the Research Protocol

1. Introduction

Ideally, community input begins before the research concept/question is developed and continues until the results are discussed and published. This section focuses on the role of the community in developing the research protocol.



2. Roles and Responsibilities

2.1 Site CAB and Research Staff

Role	Site CAB Responsibilities	Research Staff Responsibilities
CONCEPT PHASE		
<i>Community and Public Health Considerations</i>	<ul style="list-style-type: none"> ▪ Contribute public health and community information generated from interactions between the CAB and potential trial participants that will help researchers shape the research concept 	<ul style="list-style-type: none"> ▪ Investigate and prioritize research needs and develop a research plan accordingly
<i>Research Question Considerations</i>	<ul style="list-style-type: none"> ▪ Help determine the importance and relevance of the research being proposed to the community 	<ul style="list-style-type: none"> ▪ Provide context for the research concept and describe it in general terms so that the purpose and benefits of the research to the community are understood ▪ Meet with various community groups and stakeholders or provide community forums to ensure awareness of research plans in broader community
PROTOCOL DEVELOPMENT PHASE		
<i>Context for Research Question</i>	<ul style="list-style-type: none"> ▪ Learn what is known about the research question 	<ul style="list-style-type: none"> ▪ Share information related to the research questions/research area with the CAB
<i>Study Design</i>	<ul style="list-style-type: none"> ▪ Participate in relevant training (e.g., how to review a protocol, the clinical trials research process, etc.) that will facilitate protocol review and understanding, and increase ability to provide input throughout the research process ▪ Contribute community-relevant information that would help with designing a research protocol that would be feasible and acceptable to the community 	<ul style="list-style-type: none"> ▪ Address scientific/research literacy needs in the community ▪ Invite community input on study design and ethical considerations through CAB and/or other consultations, including: <ul style="list-style-type: none"> ○ target population, eligibility criteria, study design, primary and secondary endpoints, potential outcomes ○ potential role of CAB in preparing the community for the up-coming trial ○ ethical and regulatory issues and other community concerns

Role	Site CAB Responsibilities	Research Staff Responsibilities
PROTOCOL REGULATORY PROCESS AND PREPARATION FOR IMPLEMENTATION PHASE		
<i>Consents</i>	<ul style="list-style-type: none"> Understand the reason for the informed consent document and the implication of signing it Ensure that the informed consent document is understandable and in lay language Ensure that the informed consent clearly states that consent to participate in a study may be withdrawn anytime Help the community understand all aspects of informed consent 	<ul style="list-style-type: none"> Ensure that informed consent documents reflect the benefits and risks of participation Consider translating informed consent forms into the local language/ language of study participants and back-translating into English to ensure that the information is accurate Send informed consent to the CAB to ensure clear and understandable language Submit all versions of the document to the local ethical and regulatory bodies (i.e., Institutional Review Board or IRB) and implement only on approval
<i>Educational Materials</i>	<ul style="list-style-type: none"> Contribute to educational material by identifying gaps in existing material and suggesting needed topics for community education 	<ul style="list-style-type: none"> Provide adequate, relevant, and culturally appropriate educational material in as many of the local languages as possible Receive updates/training from the community on their norms and systems for addressing health issues and needs; use information to help guide study implementation and conduct

2.2 Network CAB, Research Network, and NIAID

Role	Network/Global CAB Responsibilities	Network/Global CAB Responsibilities	NIAID Responsibilities
<i>Participate on Scientific Committees</i>	<ul style="list-style-type: none"> Bring community perspective to all discussions; bring information to network CAB about scientific committee considerations 	<ul style="list-style-type: none"> Identify CAB members as part of protocol teams Seek out CAB members' opinions and consider their suggestions 	<ul style="list-style-type: none"> Encourage networks to incorporate community feedback into research and/or network/site activities Evaluate networks on community involvement

Role	Network/Global CAB Responsibilities	Network/Global CAB Responsibilities	NIAID Responsibilities
<i>Participate on Protocol Teams</i>	<ul style="list-style-type: none"> Help protocol team consider feasibility and participant issues when defining criteria for inclusion, exclusion, schedule of evaluations, etc. 	<ul style="list-style-type: none"> Ensure CAB representation and participation on protocol team Take CAB concerns into account as soon as protocol is developed, e.g., inclusion/exclusion criteria, study procedures, sample size, recruitment, data collection and management, and sample storage 	<ul style="list-style-type: none"> Evaluate networks on community involvement/

3. Training

Educational materials on the study and study products should be made accessible to potential participants and the community. The materials should be easy to understand and in the languages that are most used by the community in which the research is being conducted.

4. Indicators of Success

Whether working at the site or network level, CAB members should document their input, noting ways in which protocols have been modified to address their concerns or ideas. Examples may include:

- Informed consent language has been simplified into more appropriate lay language
- The study design has been revised so that it would be more acceptable in the community (specify what changes were made, e.g., number of tests or study visits required)
- Eligibility requirements for the study have been altered

Indicators of success at the local site level:

- CAB meetings held to review protocol design
- Depending on size and nature of study, CAB review of communication materials to announce study and/or promote study participation
- Review of informed consent forms by CAB

Indicators of success at the network level:

- CAB member(s)' participation on protocol teams and scientific committees

Implementing the Research Study

1. 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.)² Training for network leadership and research staff on how to effectively engage community in the research process should be ongoing.

2. Roles and Responsibilities

2.1 Site CAB and Research Staff

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

² DAIDS provides site monitors, independent of the site and the community, who regularly review site records to ensure that the highest scientific, regulatory, and ethical standards are being met throughout the implementation and conduct of the study.

Role	Site CAB Responsibilities	Research Staff Responsibilities
<i>Advocate</i>	<ul style="list-style-type: none"> Ensure that concerns are addressed appropriately, including any issues with the informed consent process 	<ul style="list-style-type: none"> Discuss accrual and retention issues with community representatives Consider any information and insights provided by community representatives about reaching local target populations and for addressing any potential recruitment and retention issues Identify barriers to accrual and retention, and share information with protocol teams
<i>Oversight</i>	<ul style="list-style-type: none"> Stay abreast of study progress, enrollment, and interim reports from the DSMB Share information with others in community as appropriate 	<ul style="list-style-type: none"> Report study progress and unanticipated problems to the IRB and protocol team Share study progress, enrollment, and DSMB reports with the CAB

2.2 Network CAB, Research Network, and NIAID

Role	Network CAB Responsibilities	Network Leadership Responsibilities	NIAID Responsibilities
<i>Oversight</i>	<ul style="list-style-type: none"> Stay abreast of study progress, enrollment, and interim reports from the DSMB 	<ul style="list-style-type: none"> Discuss any challenges that arise with the study, such as enrollment issues, and how they should be addressed 	<ul style="list-style-type: none"> Review all safety reports Support site monitoring activities to ensure participant safety and ethical study conduct Support independent DSMBs that conduct regularly scheduled reviews of data to ensure participant safety and study feasibility

3. Training

Ideally, there should be a structured training for CAB members before and during study implementation, including ethics training, the role of CABs, on Recommendations for Community Engagement and GPP. Training for network leadership and research staff on how to effectively engage community in the research process and on GPP should be ongoing.

4. 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

1. 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 helping to provide the right language and advice on appropriate and timely channels of communication.

2. Roles and Responsibilities

2.1 Site CAB and Research Staff

Role	Site CAB Responsibilities	Research Staff Responsibilities
<i>Gather Information</i>	<ul style="list-style-type: none"> ▪ Participate in research updates; learn about the potential impact of study results 	<ul style="list-style-type: none"> ▪ Update community representatives about the research study and the potential impact of study results ▪ Incorporate community input into communications plan
<i>Information Sharing</i>	<ul style="list-style-type: none"> ▪ Provide feedback to the broader community about: <ul style="list-style-type: none"> ○ why the study was conducted ○ findings of the study ○ key messages ○ impact on clinical care and/or prevention strategies and future research ▪ Work with CTU/CRS, as appropriate, to share information via newsletters, radio, or other media outlets 	<ul style="list-style-type: none"> ▪ 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"> ○ actual results and impact on clinical care ○ whether additional studies will be needed to address specific questions that were not answered by this study ○ whether product is unsafe or ineffective and, therefore, not to be studied further ○ implications of results for other populations, such as children, adolescents, pregnant women, or men who have sex with men ○ next steps

Role	Site CAB Responsibilities	Research Staff Responsibilities
<i>Consult</i>	<ul style="list-style-type: none"> 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 Review communication materials to ensure they are written in clear, understandable lay language and/or are translated as needed 	<ul style="list-style-type: none"> Seek CAB input on key messages to ensure they are easy to understand by lay audiences and utilize CAB members in conveying the key messages
<i>Advocate</i>	<ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> Outline key issues for community awareness and policy considerations Work with network leadership and DAIDS/NIAID to facilitate timely release and dissemination of study findings

2.2 Network CAB, Research Network, and NIAID

Role	Network CAB Responsibilities	Network Leadership Responsibilities	NIAID Responsibilities
<i>Inform Other Networks</i>	<ul style="list-style-type: none"> Inform/educate Community Partners about research findings 	<ul style="list-style-type: none"> Inform other networks of research results 	<ul style="list-style-type: none"> Plan for possible early trial termination due to favorable interim results, harm, efficacy, or lack of feasibility Inform collaborators, partners, relevant government agencies, international ministries of health and other key stakeholders of study results
<i>Share Information</i>	<ul style="list-style-type: none"> Work with community educators and/or network staff to review communication materials for community appropriateness With network staff, identify/develop other information sharing mechanisms (forums, workshops, op-eds) 	<ul style="list-style-type: none"> Develop appropriate communications materials to disseminate findings Post appropriate communications materials on network-specific Web sites Issue letters to clinicians and study participants if indicated by results 	<ul style="list-style-type: none"> Develop communications materials (press releases, Questions and Answers) to share with media outlets and others to broadly disseminate information Post materials on NIAID Web sites

3. Training

Communications skills training (e.g., listening skills, verbal and non-verbal communications) may be appropriate for both network and site CABs, as well as community liaison staff. The depth and nature of the trainings may vary depending upon the skills and responsibilities of the members at each level of the network enterprise

4. Indicators of Success

Site and network 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 and networks.

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

4.1 Communicating Research Results Checklist

Networks and 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
- Make contact with the following target audiences:
 - Relevant government agencies (e.g., regulatory, ministries of health)
 - Collaborating partners
 - Community stakeholders (national HIV/AIDS organizations, advocacy groups, community-based and AIDS service organizations)

Site Closures

1. Introduction

Site closures have a huge impact on the communities where research is being conducted and special attention should be given to how this information is conveyed to communities. Transparent communication is critical and should be ongoing with the community.

2. Roles and Responsibilities

2.1 Site CAB and Research Staff

Role	Site CAB Responsibilities	Research Staff Responsibilities
<i>Information Sharing</i>	<ul style="list-style-type: none"> ▪ Participate in site closure updates; provide feedback as to what and how information can be shared with communities and stakeholders ▪ Work with research staff to identify the various socially and culturally appropriate communication methods to be used for CABs and other specific audiences (local meetings or events) ▪ Discuss with research staff a timeline for study and CAB phase out ▪ Discuss with research staff the frequency of CAB meetings and CAB support 	<ul style="list-style-type: none"> ▪ Update community representatives about the site closure and the potential impact to study participants and to the community ▪ Develop key messages to be communicated about site closure ▪ Incorporate community input into communications plan Identify CAB members to help deliver and/or facilitate communications to the broader community ▪ Discuss frequency of delivering message ▪ Discuss chain of communication within the research team, CABs and stakeholders ▪ Discuss procedures to anticipate, monitor and address community concerns related to site closure ▪ Discuss procedures for keeping participants informed of trial results after site closure ▪ Discuss frequency of CAB meetings with CAB and CAB support ▪ Provide CAB with a timeline for study and CAB phase out ▪ Discuss ongoing communications with CAB if participants will remain on study after site closure for the duration of the study ▪ Discuss ongoing communication with the community post phase-out for the site to remain in good standing in the community and help ensure future community support and trust

Role	Site CAB Responsibilities	Research Staff Responsibilities
<i>Information Sharing</i>	<ul style="list-style-type: none"> ▪ Provide feedback to the broader community about: <ul style="list-style-type: none"> ○ why the site is closing ○ the impact to participants and the community ○ impact on clinical care and/or prevention strategies and future research ○ study results dissemination ▪ Identify CAB members to help deliver and/or facilitate communications to broader community ▪ Work with research staff, to share information via newsletters, radio, or other media outlets 	<ul style="list-style-type: none"> ▪ Express sincere gratitude for the time, commitment and energy of participants and CAB members ▪ Provide clear and accurate information about studies that will continue, patient referrals timeline, future CAB meetings and communications ▪ Explain reasons for site closure 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"> ○ impact to participants and community ○ communication mechanism for updates regarding site closure ○ communication mechanism to address community concerns related to site closure ○ procedures for keeping participants informed of trial results after site closure ○ next steps
<i>Consult</i>	<ul style="list-style-type: none"> ▪ Consult key stakeholders on specific target audiences regarding site closure, how best to link with local target populations, and how best to relay information about the site closure ▪ Ensure communication materials are written in clear, understandable lay language and/or are translated as needed 	<ul style="list-style-type: none"> ▪ Ensure that CAB members review key messages to ensure they easy to understand by lay audiences and utilize CAB members in conveying the key messages
<i>Advocate</i>	<ul style="list-style-type: none"> ▪ Ensure that CAB members understand site closure so that they can communicate effectively with the broader community 	<ul style="list-style-type: none"> ▪ Outline key issues for community awareness and policy considerations ▪ Work with network leadership and DAIDS to facilitate timely release and dissemination of site closure information

2.2 Network CAB, Research Network, and NIAID

Role	Network CAB Responsibilities	Network Leadership Responsibilities	NIAID Responsibilities
<i>Share Information</i>	<ul style="list-style-type: none"> ▪ Inform/educate Community Partners about site closures ▪ Work with community educators and/or network staff to review communication materials to ensure appropriateness for target population(s) ▪ Work with network staff to identify/develop other mechanisms for sharing information such as forums, workshops, op-eds 	<ul style="list-style-type: none"> ▪ Inform other networks of site closures ▪ Develop appropriate communications materials to disseminate site closure information ▪ Post appropriate communications materials on network-specific Web sites ▪ Issue letters to clinicians and study participants if needed 	<ul style="list-style-type: none"> ▪ Plan for possibility of early trial termination as a result of site closures ▪ Inform collaborators, partners, relevant government agencies, and international ministries of health and other key stakeholders of site closures ▪ Develop communications materials (press releases, Questions and Answers) to share with media outlets and others to broadly disseminate information ▪ Post materials on NIAID Web sites

Setting CAB Scientific Priorities

The identification of the network CAB’s scientific priorities can help CAB members influence which scientific questions their network addresses. At the cross-network level of Community Partners, representatives participate in the Strategic Working Group (SWG), which includes experts who advise NIAID and DAIDS in addition to the network leadership. These Community Partners representatives serve as a resource for this group, providing the community’s perspective as to the relative importance of the proposed studies and initiatives. This input is considered as decisions are made about which studies should proceed and in defining the scientific agenda and how it is implemented. Identifying the network CAB’s scientific priorities provides a foundation for CAB representatives when they are asked if they are in support or opposition to the proposed studies or initiatives being discussed.

Specifically, the value of identifying network CAB priorities is that they enable the network CAB and Community Partners to:

- Clearly articulate to DAIDS, the network leadership, and network investigators, 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 network's research plan to ensure that CAB members have a clear understanding of the scope of the network's 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 and network 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 network leadership receives and understands the community scientific priorities
- Share network priorities with Community Partners
- Community Partners can then set priorities taking all network CAB priorities into consideration

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 network CAB 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 Network Strengths**, core competencies, and mission including the uniqueness of the network's 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 trials 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

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.

Clinical Research Site (CRS): A CRS or site may be affiliated with one or more clinical trials unit and may conduct clinical trials associated with one or more network's clinical research plan.

Clinical Trials Unit (CTU): A CTU is a research entity comprising an administrative component and one or more clinical research sites. A CTU is a member of one or more clinical trials networks.

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 [HPTN](#) is an international collaborative clinical trials network whose mission is to discover and develop new and innovative research strategies to reduce the acquisition and transmission of HIV.

HIV Vaccine Trials Network (HVTN): The [HVTN](#) is an international collaboration of scientists and educators searching for a safe and effective HIV vaccine. It conducts all phases of clinical trials, from evaluating experimental vaccines for safety and the ability to stimulate immune responses to testing vaccine efficacy.

International Maternal Pediatric Adolescent AIDS Clinical Trials Group (IMPAACT): [IMPAACT](#) develops and evaluates safe and effective approaches to interrupting mother-to-child transmission of HIV; evaluates treatments for HIV-infected children, adolescents, and pregnant women, including prevention and treatment of co-infections; and evaluates vaccines for the prevention of HIV transmission to and among adolescents.

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.

Microbicide Trials Network (MTN): The [MTN](#) is a worldwide collaborative clinical trials network that evaluates the safety and efficacy of vaginal and rectal microbicides designed to prevent HIV transmission. It carries out its mission through a strong network of expert scientists and investigators from domestic and international sites.

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 a CORE Operations Center, Statistical and Data Management Center (SDMC), Network Laboratory, and the Clinical Trial Units 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.

From Subject to Participant: Ethics and the Evolving Role of Community in Health Research

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Belmont Report principles focus on the well-being of the research subject, yet community-engaged investigators often eschew the role of subject for that of participant. We conducted semistructured interviews with 29 community and academic investigators working on 10 community-engaged studies. Interviews elicited perspectives on ethical priorities and ethical challenges. Interviewees drew on the Belmont Report to describe 4 key principles of ethical community-engaged research (embodying ethical action, respecting participants, generalizing beneficence, and negotiating justice). However, novel aspects of the participant role were the source of most ethical challenges. We theorize that the shift in ethical focus from subject to participant will pose new ethical dilemmas for community-engaged investigators and for other constituents interested in increasing community involvement in health research. (*Am J Public Health*. 2015;105:900–908. doi: 10.2105/AJPH.2014.302403)

Patients, family members, health advocates, and health care agency leaders play substantially different roles in health services and public health research than they did just a few decades ago.^{1–3} Many major US health research funders today expect community involvement in research design, execution, or dissemination.^{4–7} For instance, engaging communities in research is a key goal of the National Center for Advancing Translational Science at the National Institutes of Health. The Patient-Centered Outcomes Research Institute prioritizes patient involvement in the development, governance, oversight, and dissemination of research.⁸ A report the Agency for Healthcare Research and Quality commissioned found that

stakeholder involvement . . . helps ensure that [Agency for Healthcare Research and Quality research] responds to relevant and important issues, . . . develops products that are accessible and user-friendly, and . . . ultimately reaches its intended audiences.^{9(pii)}

On the whole, community-engaged research asks community members with lived experience of the health problem under study—or with responsibility for populations with this lived experience (e.g., community-based agencies, advocates, payers)—to participate in planning, designing, conducting, interpreting, or disseminating research. Community

engagement in research can take numerous forms, from limited advisory roles in early stages (e.g., input on research priorities) to key leadership responsibilities at every stage, as in community-based participatory research.^{10–13} Consensus-building activities, shared control of data, and long-term partnerships can be key elements of community-engaged projects. These research approaches reflect the growing prominence of patient advocacy groups and the concept of participatory science.^{1,14,15}

Until the latter decades of the 20th century, community members primarily participated in research as subjects. Indeed, the construction of the role of the research subject is inextricable from the historical development of the human sciences generally and health research specifically.^{16–19} Researchers defined the research situation with reference to 3 aspects of the subject role. First, the role of the subject is context dependent: an individual becomes a subject by consenting to provide data for a specific study (e.g., in a particular laboratory). Second, the role of the subject is task focused: it centers on completing activities that generate data, such as giving biological samples or completing tests. Third, the role of the subject is time limited: once data collection is complete, the subject role ends, as does, typically, the researcher's relationship with the individual.

Once specified, the subject position allowed researchers to elaborate and refine key intellectual assumptions about research rigor, reliability, and validity. Among these were that one can generalize from data on individuals (e.g., those with particular diseases) to larger populations (e.g., others with the same disease); that an individual can be studied in isolation from social context; and that abstract attributes (e.g., intelligence, conscientiousness) can be reliably measured in artificial experimental settings.

The specification of the subject role also structured the concept of research ethics codified in the Belmont Report. The distinction between researcher and subject set the stage for “trust-based obligations” that are the foundation for what we understand as research ethics^{20(p542)} with the “protection of human subjects” as a core ethical goal.^{21(p5)} The experimental situation should maximize benefits and reduce risks to subjects as much as possible (the Belmont Report's basic ethical principle of beneficence),²² individuals should participate voluntarily (principle of respect for persons), and risks and benefits to potential research subjects should be fairly distributed (principle of justice).

To preserve the voluntarism at the heart of this relationship, both parties should expect the experiment to generate useful knowledge that could not be otherwise obtained,²³ and they should expect this knowledge to be free of fabrication and falsehood.²⁴ Institutional review boards (IRBs) assess whether subjects are adequately protected and insist on extra protections for those from vulnerable groups who may experience unusual constraints on voluntary decision-making or who may be less likely to receive the research benefits.²⁵

By contrast, community-engaged investigators enlist individuals in research as participants, advocating a transformation “from regarding individual community members as

research subjects to engaging community members and the organizations that represent them as research partners.^{10(p1)} Community-engaged investigators prefer the participant role because it “increases the possibility of overcoming the understandable distrust of research on the part of communities that have historically been the ‘subjects’ of such research.”^{26(p181)}

To community-engaged investigators, words like “subject” and “researcher” can signal exploitation rather than ethical protection because the subject role is seen to require passive acquiescence to others’ agendas.^{27,28} Community-engaged investigators also eschew the sharp distinction between subject and researcher and seek to minimize the distance between community and academic participants through the mutual exchange of knowledge and skills.²⁹ Community-engaged research is understood to be “with’ [the] community . . . rather than ‘for’ [the] community.”^{28(p321)} Community-engaged research participants may include enrolled individuals, research partners, social and constituent groups, funders and payers, study site staff, and others with some stake in the project.

Many investigators recognize the ethical implications of these new research relationships, but the theory and practice of ethical community-engaged research remain inchoate.³⁰ Although community-engaged investigators accept the continued relevance of the 3 Belmont principles,³¹ they articulate novel ethical priorities³⁰ and encounter new ethical challenges.^{32–34} Community-engaged investigators have developed innovative approaches to support ethical conduct,³⁵ yet investigators’ opinions about ethical priorities can vary.³⁶ Although many investigators view community engagement as a means for achieving ethical ends,³⁰ the field lacks objective criteria and shared guidelines for implementing ethical practices in community-engaged research.³⁷ Conceptualizing ethics in community-engaged research is important for developing normative guidelines, educating investigators, and monitoring research conduct.^{38,39}

We used interview data from community and academic investigators working on community-engaged projects to describe the ethical priorities and dilemmas in community-engaged research. We compared projects to outline 4 principles of ethical

community-engaged research and to advance theory that accounts for common ethical challenges. We have shown that most ethical challenges emerge as a result of the collapse of the subject position.

Community-engaged investigators’ ethical focus on the participant—a role that is less time limited, setting dependent, and task focused than is that of the subject—raises ethical dilemmas that resist resolution through traditional ethical frameworks. By directing attention to this shift from subject to participant, we characterize sources of ethical challenge, propose strategies that can support ethics in research engaging community members, and raise a set of fundamental questions for further study.

METHODS

We used a 3-step approach developed in previous studies to select interviewees.⁴⁰ First, we listed all academic investigators ($n = 17$) affiliated with the National Institute of Mental Health’s Partnered Research Center, a mental health services research center at the University of California, Los Angeles, whose mission is to improve care through academic and community partnerships.⁴¹ Second, we listed current projects of these investigators ($n = 22$) and identified each project’s main academic and community partners. Because some principal investigators led several projects, we randomly sampled 1 project per principal investigator to minimize burden. For each sampled project, we invited at least 1 lead academic and 1 community partner to participate in an individual phone or in-person interview. For projects involving more than 2 community agencies, we invited at least 2 academic and 2 community investigators.

Between January and June 2013, we interviewed 15 academic and 14 community investigators working together on 10 sampled projects. We obtained oral informed consent at the beginning of each interview. We interviewed at least 1 academic and 1 community investigator working on all but 1 sampled project (for which we could not contact a community partner). Typically, 2 authors conducted each interview. Interviews were audio recorded and professionally transcribed.

A semistructured interview guide included questions about research ethics and its practice on the project. Using open- and closed-ended questions, we elicited details about ethical priorities and ethical challenges. Academic and community members of the project’s advisory board reviewed and commented on the protocol. We tested the protocol with a community and an academic partner, modifying it for clarity and cultural competency.

Three authors analyzed interview data using both content coding and thematic analysis. We first developed a hierarchical codebook on the basis of the interview guide to mark topics (i.e., attributes of ethical research, ethical challenges), which we then counted and categorized. To ensure coding consistency, 2 experienced qualitative researchers performed coding independently on 20% of the data set, discussed disagreements until consensus was reached, and then coded the entire data set. Then, we used thematic coding to identify underlying concepts that linked recurrent and salient statements about ethical priorities and challenges.

To refine emergent themes, we used a constant comparative approach, comparing within and across interviewees to delineate connections between concepts.⁴² All authors discussed thematic coding results at several stages. We reviewed examples to reach consensus and then recoded and refined themes.

RESULTS

Ten sampled projects addressed such topics as community well-being and resilience and collaborative care models for the treatment of mental health and substance abuse. Interviewees included 22 women and 7 men; 16 interviewees were White, 5 Hispanic or Latino, 4 African American, and 4 Asian. Most academic principal investigators were affiliated with the University of California, Los Angeles, RAND, or the University of Southern California.

Community principal investigators came from advocacy agencies, faith-based organizations, school districts, the Veterans Health Administration, county and state departments of health and mental health, or payer agencies.

Content coding categories and counts for responses to the first interview question about attributes of ethical research (“What does it

mean to you to say that you are doing ethical research?") are shown in Table 1. Ethical challenges mentioned by interviewees are shown in Table 2.

Table 1 shows responses to the first question only, but interviewees elaborated on the meaning of ethical research throughout the interview. One community interviewee captured the viewpoint of many others with her summary of ethical community-engaged research:

The first word that comes to mind is doing the research with integrity. Where I'm respecting my participants. Their needs. I'm being culturally competent. Mainly because I work with African Americans and Latinos, to be appropriate in how I ask things and how I treat them. And then also making sure that I have integrity with everyone—with the partners, too, because of the [partnered research] model that we're doing also. Being clear and making sure that I'm following all procedures. Being ethical is respecting their identity 100%. And always putting myself in their shoes. Treat how I want to [be treated]—as a participant, right? And also as a researcher.

For this interviewee, ethical community-engaged research meant enacting respect in all interactions. She understood ethical protections to apply to enrolled participants but also aimed to uphold ethical priorities (e.g., cultural competence) with potential participants; the racial, ethnic, and cultural groups of which the participant was a member; and colleagues and coinvestigators.

Four themes recurred in interviewees' descriptions of ethical community-engaged research. These themes describe interviewees' overarching approach to conducting ethical research (i.e., embodying ethical action) as well 3 approaches they used to operationalize it (i.e., respecting all study participants; generalizing benefits while eliminating or mitigating various potential harms; and negotiating with participants—rather than determining a priori—what would count as efficacious and fair research). In adopting these approaches, interviewees focused ethical action on a new type of object, the participant, and encountered new ethical challenges.

Embodying Ethical Action

Interviewees understood a broad range of activities to have ethical importance. Their approach to conducting ethical community-engaged research involved a heightened attentiveness to the ethical implications of all research activities. We call this approach "embodying ethical action." For instance, interviewees described ethical community-engaged research as requiring more than compliance with routine protocols. As an academic interviewee said,

Doing ethical research means being impeccably in line with the Belmont recommendations and what the federal government wants us to be in line with. That's sort of a minimum standard [for] all projects.

As a community interviewee said, a contract such as a Memorandum of Understanding is only the scaffolding for an ethical project:

We've had things done in the past where people come and say, oh, this is a contract between [2 institutions]. And then they'll say, okay, well, this is all you need. And it's not all you need. It's just the beginning. . . . [The Memorandum of Understanding] just gives you a baseline to say, okay, this is what we agree upon at this level and we'll evolve.

Embodying ethical action entailed meeting the highest ethical standards in each action and interaction through exacting ethical choices and continuous ethical awareness. Interviewees understood themselves to be moral actors engaged in research as an ethical activity. Many described actuating a new type of ethical practice through mutuality, equity, and shared responsibility. These were valued ends in themselves—not just means to knowledge production. An academic interviewee explained that ethical practice entails not just procedures but a sensibility orienting all activity. This interviewee said that community-engaged investigators had to ask, "How do you break through the priors so that the ethics of it can be felt and . . . are a living, breathing entity?"

Many interviewees framed these expanded priorities as reparative. Academic and community interviewees mentioned instances of historical misconduct as challenges to current

TABLE 1—Attributes of Ethical Community-Engaged Research

	Total (n = 29)	Community (n = 14)	Academic (n = 15)
There is protection and fair treatment of enrolled participants and their data; enrolled participants are not harmed	22	8	14
The study results in community or policy benefit	14	6	8
The study is IRB, HIPAA, and Belmont compliant	11	4	7
There are appropriate informed consent procedures	8	3	5
Research team practices transparency	6	0	6
Research team practices respect	6	5	1
Research team practices trust or honesty and is personally ethical	5	4	1
Research protocols are sensitive to participants, not stigmatizing, and culturally appropriate	5	4	1
The benefits to enrolled participants outweigh the risks	4	1	3
Protocols are scientifically rigorous, valid, and objective	4	0	4
Study protocols are adhered to	4	3	1
The research aim is important to the community	4	3	1
The study is community partnered or engaged	4	2	2

Note. IRB = institutional review board; HIPAA = Health Insurance Portability and Accountability Act. The table shows the responses to interview question 1: "What does it mean to you to say that you are doing ethical research?"

TABLE 2—Challenges Associated With Upholding 4 Key Principles of Ethical Community-Engaged Research

Principle	Action
Embody ethical action	Address historical legacy of unethical research
Respect participants	Maintain confidentiality across participants' multiple roles Be sensitive and responsive to partners' perspectives and be culturally appropriate Pursue ongoing communication (e.g., deepen understanding, discuss disagreements)
Generalize beneficence	Achieve substantive roles for partners in research tasks and decision-making Manage conflicting priorities that compete with research activities Obtain funding for time needed to pursue partnering Devise alternatives or justifications for randomization or a control arm Manage work burden of community partners Modify survey instruments for cultural appropriateness Reach agreement on composition of partnership and compensation Address problems uncovered during research activities Achieve equitable benefits for all involved participants
Negotiate justice	Manage reluctance of community stakeholders to engage in research Stay aligned with study vision over time Ascertain the adequacy of success in partnering and trust Represent research aims and findings so all partners agree Maintain objectivity and scientific equipoise

Note. Each challenge was mentioned by at least 3 and fewer than 12 of the 29 interviewees. Challenges are listed from most to least frequent under each principle.

research (Table 2). As an academic interviewee said,

In almost every [community] setting that I've been in . . . they have had negative experiences . . . with researchers who come and gather information . . . and then they move on, and they don't necessarily give anything back to the community site. So . . . there is a lot that has to happen up front to build the relationship . . . so that they can feel like you're actually there to help them.

These interviewees held themselves accountable for other investigators' past misconduct in an effort to repair relationships with communities on behalf of participants harmed in the past.

Respecting All Study Participants

The Belmont Report defines respect for persons as enacted in the open communication of information relevant to study participation, including risks and benefits and ensuring voluntary enrollment in the research.⁴³ Interviewees generalized this principle to all participants, aiming to practice respect, truthfulness, and free choice with enrolled and potential participants, research partners, study site staff, community members, and the community as

a whole. As a community interviewee said, "Ethical research . . . does not invade one's space, does not disrespect anyone, does not do benefit to the community, does not stigmatize." Respecting participants meant ensuring a careful informed consent process. The study would, as an academic interviewee said, "go that extra mile to make sure that the consent process truly is an informative and collaborative process regardless of who the participant is." Interviewees also described an obligation to seek consent from the participant's community.

Interviewees described trust and relationship building in the team and in the community as critical enactments of respect for participants. As a community interviewee said,

Trust is a big piece. There's not, usually not a lot of time and planning to make sure that you give that relationship-building piece that is needed to build that trust for the participant and the community. And then it's often overlooked. So I think that that's the biggest. That relationship building and the trust area is a big aspect [of] ethical research for me.

Interviewees also described the importance of valuing all participants' perspectives. For one community interviewee, respecting participants

meant that her research partners valued the mission of her organization: "The academic groups really understanding that what I do and why I do it is not for a commercial purpose." She added, "Sometimes they are really surprised. They say, oh wow, I didn't know you guys did that." Respecting participants also applied to study site staff. An academic interviewee cited the need for respectful treatment of staff at community sites so there is a "pretty immediate, usually within 24 hours . . . investigation and intervention" that takes place when "a partner feels like a research assistant's been disrespectful."

Despite the clarity and commonality of this commitment, ensuring respect for participants frequently raised ethical challenges (Table 2). A difficulty in ensuring respect for participants was that participant tasks and involvement varied over time. Participants may function as coinvestigators, study advocates, clinical supervisors of study staff, friends of study leaders, or study enrollees. Participants might join, drop out, and then rejoin the study.²⁸ Inclusiveness was seen to further trust, but interviewees mentioned that personally close relationships among research team members raised concerns for coercion or unfair treatment. One community interviewee also questioned the validity of study data when relationships between investigators and enrolled participants were close:

Sometimes when you interview people that you know, it makes me wonder how accurate their opinion is gonna be . . . if you're asking, "Oh, you have HIV?" Are they gonna say the truth? Or any other things that might be very personal?

As one academic explained, "I think the most difficult piece of this has been: 'Are providers [at the study site] human subjects? And at what point are providers human subjects?'" A community interviewee said that her study team addressed this problem by distinguishing between planning and data collection. Some activities were termed quality improvement efforts not requiring voluntary consent:

We have made this distinction between what's research, because we're initiating it and we're collecting data, and it's totally voluntary to participants; and then what's quality improvement at the clinic [such as] . . . group planning that we've been doing for 6 months; and . . . quality improvement subgroups that are . . . testing the interventions. Now, we've had this

discussion with [the IRB] about what's research and what's not and who are the participants and subjects . . . and who aren't, so we decided with [the IRB] that people who are participating in data collection are subjects. That's totally voluntary.

These complex distinctions among research, planning, and quality improvement were needed to set expectations for voluntariness.

Interviewees also said that difficulties protecting confidentiality and privacy could undermine efforts to enact respect for participants.² One community interviewee mentioned that a provider's survey response was inappropriately shared with other stakeholders in an effort to facilitate planning activities. Another community interviewee discussed challenges clarifying when patient problems uncovered through research procedures can and cannot be shared with providers:

Research or not, if a provider knows the patient has the problem, no matter what study condition they're in, they're going to help the patient. . . . We've had to have, or we're developing it anyway, a kind of a hierarchy of, if it's an emergency, then of course you can't [protect privacy]. . . . And so it sort of [was] determined that patient care comes first and the study comes second.

Finally, a community interviewee described difficulty weighing the responsibility to uphold confidentiality with the need to support one's organization as an employee: "You're in a tricky position because there are pressures for you . . . to protect the clients and [you] might have experienced pressures from your organization to do more business." Thus, although practicing respect with all participants was a compelling ethical goal for interviewees, ethical challenges commonly arose from participants' multiple and evolving roles.

Generalizing Benefits While Mitigating Harms

The Belmont Report describes beneficence as maximizing benefits of the research project while minimizing harm to the subject. Benefits could include generating knowledge that will help individuals who share characteristics with the subject. Minimizing harm means ensuring that study procedures are as safe as possible for subjects.

Our interviewees agreed that protecting enrolled participants was a key attribute of ethical community-engaged research (Table 1).

Yet our interviewees also considered the potential benefit and harm of a variety of study activities and interactions, not just knowledge-production tasks. They also heightened the responsibility of generating benefits to constituents beyond enrolled participants. Interviewees described efforts to generalize benefits to all individuals touched by the study. Almost half stated that ethical community-engaged research must generate community or policy benefit (Table 1). Sound science and compensation for participation did not suffice.

Interviewees mentioned the need to address harm that might result from study procedures (e.g., modifying instruments to improve cultural sensitivity). They further described themselves as responsible for constructively addressing problems identified during the research (e.g., suicidality) even if unrelated to study procedures. A community interviewee said, "I don't feel that it's ethical not to provide services to a student population or school population that we identify as having needs." An academic interviewee added that community-engaged research includes an ethical obligation to address the needs of a community: "[Research] is not causing harm, but you have opportunities to intervene and being socially responsible when there's an opportunity at hand . . . and it's reasonably within your scope."

The process of generalizing benefits was associated with numerous challenges (Table 2). In particular, interviewees described challenges with maximizing benefit and minimizing harm to the research team. Interviewees described participation in the tasks of knowledge production (e.g., authoring articles) as a way to maximize partner benefit, but they also cited the need to identify substantive research roles for partners as an ethical challenge. Interviewees described the work burden for community partners and the difficulties achieving equitable community compensation as areas of potential harm. Moreover, interviewees said that balancing benefit and harm were complicated by the multiple roles participants played:

They've got their whole job to do and I'm asking them to take part in a research study. . . . They may be interested in the subject and . . . want to support what's going on and they certainly want us to come and ask them are you okay with this, or to give them suggestions, but it may be burdensome to them to give them a lot of

[research] responsibilities . . . if they're already stretched to the max just doing the[ir] job.

Another said, "People in partnered sites are busy and stressed . . . your project is not their priority."

Some community interviewees elaborated on the burden of research involvement. One described discomfort when asked to make a major decision about study design when she was new to leadership in her program and inexperienced in research. A second interviewee found her research responsibilities to be too challenging and insufficiently explained:

Our role is not to be a researcher [but] to provide supportive programs [for patients]. I just don't think maybe it was clearly put. . . . I wasn't sure whether I should take a lead role and say, "Okay, let's go on and do this, this and this." Or we were kind of waiting for . . . researchers to say, "Okay, here's what we need you guys to do."

A third summarized the risk–benefit trade-off:

It's really been great [participating in research], even though we're completely overwhelmed with the amount of work there is, but we signed up for that. We actually signed up not knowing how much work [participating in research would require].

In sum, as interviewees concerned themselves with participants of various types with multiple responsibilities, and as they took responsibility for mitigating several types of potential harms, they confronted challenges balancing risks and benefits.

Negotiating What Counts as Efficacious and Fair Research

The Belmont Report addresses the balance between the needs of society and research subjects through its principle of justice. This requires that research be nonexploitative and fair. Achieving justice involves considering whether the potential societal benefit from research justifies the cost to particular subjects. Moreover,

the selection of research subjects needs to be scrutinized to determine whether some classes . . . are being systematically selected simply because of their easy availability, their compromised position, or their manipulability.²²

The Belmont Report requires researchers to ensure justice through attention to the significance of study aims and through careful

choices in study design that generate rigorous findings without unduly burdening subjects.

Our interviewees took a different view of the strategies by which investigators could ensure that they generated scientifically important findings through nonexploitative procedures. Interviewees emphasized the need to negotiate with participants what would count as efficacious and fair research. They described these issues as being determined not ahead of time by researchers alone but in collaboration and over time as participants' perspectives were explored and understood. For instance, this interviewee expressed concern about a priori determinations about research aims and protocols:

A lot of White people come into our community . . . having already decided what they're going to do, what they're going to talk about, how they're going to talk about us. And we have no way to shut their mouth, close the door, or anything. They come in with the negative ideas and they use them automatically. And that's not ethical.

Another community interviewee, describing a problematic relationship with a researcher, agreed that fair procedures could only be established in discussion with the community:

This investigator is . . . putting their foot in their mouth constantly. And bypassing anybody else that doesn't agree with what they want to do. I was like, "That ain't how we do things down here." Because they're not taking the time. . . . They have a clear objective of what they want to do and they're not . . . trying to see from any other lens.

In community-engaged research, interviewees said, neither the value of the science nor the burden to the participants could be determined without community input. Interviewees noted that this deliberative approach meant that definitions of scientific validity could not be taken for granted. As a community interviewee said, it is not acceptable for a researcher to say:

It's just my agenda, what I think I know, and that's all. . . . It happens a lot with researchers . . . they feel that the data [are] valid and this is good, and it's evidence based and, I saw this and I've done this and that. And it may be true. I'm not saying it is or isn't. But when you come to work in the community, that value system is [different].

Interviewees saw the need for both sides to agree on a study design and on procedures for interpreting data. As an academic interviewee noted,

[Academic researchers] had to kind of try and work with [community members] so that they could understand our language, which is hard for outsiders who . . . haven't had all of the training in statistical methods and validity and stuff like that. And to kind of teach them and bring them along and get them up to speed and to listen to their opinion even when it goes against the face of everything you've learned in school.

In these ways, interviewees acknowledged that partners might bring differing assumptions about scientific practices to the project. One academic interviewee remarked on this issue by describing concerns raised in public presentations of findings:

Our community partner wants to talk about some research that we've done, but . . . oftentimes [we] put caveats on everything, because that's how we've been trained. The community partners haven't been trained that way and will oftentimes say things that wouldn't come out of our mouths because we would feel us uttering them would be an overstatement.

Another academic interviewee claimed a collaborative approach to science "has the chance of throwing off the scientific validity of your study if you really listen to what they say and do what they say." Another academic interviewee agreed, seeing collaborative design as a potential threat to objectivity. It may be that

the partners don't like what you're finding and then they want you to somehow change things so that you draw a different conclusion. . . . Some people are more willing to kind of slip more into an advocacy role. . . . I think that's very dangerous.

Without a partner "willing to understand and accept what research is . . . it does just become advocacy." As these quotations suggest, academic and community interviewees perceived that some of their core values were at stake in this negotiation.

Interviewees also described a challenge of establishing appropriate study aims and then staying aligned with the study's objectives over time. As an academic interviewee said,

People do have different expectations of what we're supposed to achieve and when we embark on something new, it often is very unwieldy. It takes a lot of time because you have so many different perspectives.

A community interviewee agreed that "we lost sight on a continuing basis of what we were trying to do." Another described the ongoing,

inclusive negotiation of justice: "What I hear [my boss] say [is] we've done so much more for [the] university in research than they've done for us."

Both academic and community interviewees were concerned about how well they achieved their goals of engagement and inclusion because they understood reluctance to participate in research and resultant gaps in inclusiveness as impediments to full resolution of this range of questions about justice. The approach our interviewees described of negotiating justice differs substantially from traditional research practices, in which researchers share assumptions about the value of science and establish the significance of study aims and the fairness of study procedures in advance of study implementation.

DISCUSSION

Our findings show that community-engaged investigators pursue an overarching aim of embodying ethical action through the practices of respecting all study participants, generalizing benefits while mitigating various potential harms, and negotiating to determine what counts as efficacious and fair research. In other words, interviewees' narratives demonstrate that ethical community-engaged research entails 4 key principles: embodying ethical action, respecting participants, generalizing beneficence, and negotiating justice. These principles are related to the principles of ethical research articulated in the Belmont Report.

As Shore says, in community-engaged research, "respect for persons could be renamed respect for partnerships."^{44(p12)} In many instances, interviewees explicitly described Belmont principles as the foundation of their ethical approach or the starting point for an ethical project. They considered their practices of shared responsibility in the research process and bidirectional learning to reflect commitments to autonomy, respect, and justice as described in the Belmont Report.

However, interviewees applied these principles to a new type of ethical object: the participant. Whereas the subject role is time limited (e.g., spanning data collection), setting dependent (e.g., in a specific lab), and task focused (e.g., as required to collect valid data), the participant role has multiple definitions,

unfolds in many settings, and is open ended. Participants may “wear ‘multiple hats’ . . . (e.g., investigator, advocate, volunteer, board member, etc.)”^{25(p40)} or shift roles over time. Participants might provide data but also advise, share expertise, advocate the study, or analyze data. Moreover, participants were understood to speak as individuals but also to represent or bring to the fore the needs of the groups or communities of which they were a part. As a result, interviewees deliberated issues such as respect, beneficence, and justice throughout a broad set of activities, and they often strove to extend respect, mitigation of harm, and just treatment to communities and groups.⁴⁵

By highlighting this shift from subject to participant, we have aimed to clarify that the Belmont principles and the role of the research subject are intricately intertwined. Many of our interviewees’ most common ethical challenges reflected the epistemological and phenomenological differences between the subject and participant roles. Opening roles for participants beyond providing data complicated maintaining confidentiality. Processes that generate benefits for participants (e.g., crafting substantive roles for community members) also carried risks (e.g., work burden).

Empowering participants to shape research procedures, a component of many community-engaged studies,^{46,47} sometimes precipitated new ethical challenges. Moreover, the ethical challenges interviewees encountered often resisted resolution through established ethical frameworks (e.g., Belmont principles) and procedures (e.g., IRB review).^{48,49} These procedures did not always help interviewees ensure protections for the varied participants with whom they were concerned. In these ways, the participant role may have heightened attention to ethical action, but it made the upholding of ethical priorities more complex.

Negotiating justice presented particularly charged ethical dilemmas for our interviewees. Community and academic interviewees suggested that some of their most closely held values were challenged in discussions about study aims, methods, and findings. Some academic interviewees expressed discomfort with blurred lines between advocacy and objectivity. Some community interviewees resented interactions with academic researchers who viewed themselves as arbiters of truth.

Interviewees described overt conflicts that ended research collaborations.

Some tensions appeared to reflect disagreements about the status of types of knowledge (e.g., experiential vs experimental). Their responses imply that community engagement could be difficult for those unwilling to engage in some epistemological debates. In community-engaged research models, not only data ownership^{30,50} but also questions of study design and data interpretation raise fundamental concerns about fairness.

Supporting and Monitoring Ethics in Community-Engaged Research

Some scholars have suggested that augmenting the Belmont Report with relational principles, such as reflexivity, reciprocity, and trust, can help support ethical practice in community-engaged research.^{44,51} We have argued that ethical conundrums emerge from redefinitions of the object of ethics rather than from uncertainty about ethical principles. Our interviewees mitigated ethical challenges by specifying their ethical focus.

One community interviewee weighed the ethical obligations associated with each role a participant played: “Research or not, if a provider knows the patient has the problem, no matter what study condition they’re in, they’re going to help the patient. [We] have this kind of hierarchy.” In the face of ethical challenges, community-engaged investigators may ask, for which type of participant are we most responsible in this instance? Is it the community as a whole, a community group, the investigator team, or an enrolled participant? Defining the object of ethical concern appeared more practically useful to our interviewees than did invoking abstract principles.

Although many practices described as ethically problematic in community-engaged research (e.g., breaches of trust) are difficult to measure and monitor,⁵² the 4 key principles we have described can be operationalized. Investigators can be asked in funding proposals and in community and university IRB applications to clarify potential risks to participants of many types. Investigators can detail plans for respecting participants by clarifying how they will facilitate communication and under what circumstances they may break confidentiality. IRBs can monitor the responsibility to generate benefits while minimizing harm to diverse

participants (i.e., the principle of generalizing beneficence) by asking investigators to clarify the potential risks and benefits of participation to research assistants, clinic staff, and community coinvestigators, as they would for enrolled subjects.

IRBs can request that the study team institute safeguards against potential harms (e.g., work burden). Investigators can outline plans for negotiating justice by describing procedures for communicating study aims and vetting questions about data interpretation. These oversight procedures may not be appropriate for every study. The detail of the safeguarding plan can be benchmarked to participants’ vulnerability and the degree of risk they assume, as IRBs do now in moderating protections according to study features.

Study Limitations

Our study has several limitations. First, our findings are derived from qualitative interviews conducted with a relatively small number of community and academic partners affiliated with a single research center, which limits their generalizability.

Second, the findings may reflect participants’ approval bias because some interviewees may have felt compelled to provide socially desirable responses to questions. However, we note that the open-ended, exploratory interview guide did not direct interviewees to give particular responses; participants shared positive, neutral, and negative experiences with conducting community-engaged research; and interviewees showed a high level of agreement on their ethical priorities.

Third, selection bias may limit the findings because a majority of interviewees conducted research related to mental health. Findings may reflect their awareness of the importance of psychosocial concerns and confidentiality or of the potential sensitivity of research inquiry. Although we are aware of the possible impact of these cognitive biases, we note that our interviewees’ responses are consistent with the literature on the ethical values practiced in community-engaged research.

Building a Community-Engaged Health Research Enterprise

Even with these limitations, our findings indicate that building a community-engaged

health research enterprise will require comprehensive ethical advances. The refractory ethical challenges our interviewees described suggest the need for more conceptual and operational clarity about the ethical implications of engaging diverse community stakeholders in health research.⁵³ We highlight 3 fundamental issues raised by the shift from subject to participant for further investigation.

First, the research community may need to reach consensus on the types of community-engaged research situations that trigger new ethical obligations. Overall, our interviewees agreed about the additional ethical obligations that community engagement entailed. Yet to what extent does our interviewees' consensus about ethical obligations apply to projects using other models of community engagement or addressing other health issues? Does a clinical trial that includes 1 patient representative on an advisory board need to generate direct benefits to her and her community? Do all intervention trials need to include iterative review of aims with study site staff to negotiate fair procedures? Can respect for participants be implemented sufficiently if community stakeholders prefer to help only with some research procedures, such as dissemination? These are only a few of the questions that warrant further exploration.

Second, our findings demonstrate that the epistemological and phenomenological differences between the subject and participant roles may have implications not only for research ethics but also for scientific knowledge and practice. For example, some strategies used to further ethics in community-engaged research can run counter to scientific norms, such as opening for debate the nature of valid evidence. Community-engaged investigators' attention to the social context of data collection implies a challenge to the assumption that valid data can be collected from an individual removed from her community context. Might investigators produce different knowledge from participants than from subjects? Our data suggest that adopting novel ethical approaches that meet the needs and expectations of academic and community partners may test accepted understandings of objectivity, clinical equipoise, and the superiority of randomized controlled clinical trials.

Finally, the shift from subject to participant may call into question current understandings of consent and autonomy. Family members,

advocates, and community members are vital to the research enterprise in part because they are understood to be capable of representing or standing in for others. In this way, the participant is an individual and a collective actor. However, the Belmont Report's principle of respect for persons emphasizes that an individual has the right to make decisions for herself alone. A subject chooses participation regardless of what others endorse, but a participant sometimes chooses for others, for example, by deciding which levels of risk are appropriate or which projects will be supported in a community.

The strategies for operationalizing ethical research described by our interviewees tend to sidestep this difference between individual and collective identities and do not resolve the question of who can decide for whom in research. These and other questions raised by the shift from subject to participant warrant further study if we hope to achieve the promise of participatory research approaches. ■

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E. Bromley supervised thematic analyses. E. Bromley and D. Khodyakov conceptualized the study, conducted content coding, and cowrote the article. L. Mikesell conducted content coding and thematic analyses. F. Jones revised interview guides and reviewed thematic analyses. D. Khodyakov supervised content coding. All authors contributed to the overall design of the study, drafting of interview guides, collection of interview data, review of other authors' analyses, and article revision.

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Human Participant Protection

The RAND Human Subjects Protection Committee approved this study. Research participants provided informed consent.

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HIV #LanguageMatters: Addressing Stigma by Using Preferred Language

[#NotYourInfection](#) is important to me because people living with HIV deserve respect. A word can be correct, but that doesn't make it nice. I am living with HIV, not an HIV-infected person. I am NOT an infection! –Mina, a teen living with HIV

The language we use to describe HIV can either empower or stigmatize people living with HIV (PLHIV). Researchers, clinicians, advocates and other professionals often use terms such as “HIV infected” and “HIV infections” which further stigmatize PLHIV. Being referred to as “infected” repeatedly by medical professionals, the media, and others begins to have negative consequences on a person's self-worth and confidence. Though these terms have been used for decades, a growing number of individuals in the HIV community have expressed concerns over the unintentional stigma conveyed by these terms. The language we use often does not reflect the current science or the ways that PLHIV feel about themselves. The use of preferred/less stigmatizing language is important in reducing stigma and empowering PLHIV. Reducing stigma can help reduce HIV transmission by increasing disclosure and encouraging HIV testing.

What language could I use to be more respectful?

One of the first steps would be to use *People First Language*, which puts the person before their diagnosis. A person is more than their medical diagnosis. *People First Language* puts the person before the illness or medical condition and describes what a person has, not who a person is. *People First Language* helps to eliminate prejudice and it removes value judgements about the person. When we describe people by labels or medical diagnoses, we devalue and disrespect them as individuals.

Another important factor is to be respectful of aspects of a person's identity that often coincide with elevated rates of HIV. For example, many people of color identify as same-gender loving (SGL) rather than “gay”. Transgender people or gender-diverse people may use a pronoun that is different from what you might assume, so asking *everyone* what pronouns they use can help show trans people they are welcome in your organization. Respecting people's core identity and the words they use to describe themselves is at the heart of putting *People First*.

Additionally, as numerous social determinants of health also impact HIV rates, particularly in marginalized groups such as women, youth, and people of color, it is important to use non-judgmental terminology to be inclusive of PLHIV whose lifestyle choices, relationships, household compositions, living arrangements, etc. may differ from that of more privileged groups.

We want to promote understanding, respect, and dignity for all people no matter what medical conditions they may be diagnosed with. Using appropriate language (Table 1) can help reduce

stigma and change the general public’s opinion about people living with HIV. The more awareness we bring to the issue the more change we can make for people *living* with HIV.

What can we do?

- [Sign on to this letter](#) committing yourself and/or your organization to using preferred, less stigmatizing language (Table 1).
- *Use People First Language when referring to people living with a medical condition.*
- Talk with colleagues and friends and educate others! Encourage use of People First Language and other preferred terminology.
- Change organizational documents and educational materials to reflect preferred language when possible.
- Create future organizational documents and educational materials that reflect preferred language.
- Include people with diverse backgrounds disproportionately impacted by HIV, such as MSM of color, transgender people, women, and youth in the creation of organizational documents and materials. This will help ensure that language is culturally appropriate beyond just the issue of HIV.

Table 1

Stigmatizing	Preferred
HIV infected person	Person living with HIV
HIV patient, AIDS patient	
Positives or HIVers	
AIDS or HIV carrier	
Died of AIDS, to die of AIDS	Died of AIDS-related illness, AIDS-related complications or end stage HIV
AIDS virus	HIV (AIDS is a diagnosis not a virus it cannot be transmitted)
Full-blown AIDS	There is no medical definition for this phrase, simply use the term AIDS, or Stage 3 HIV.
HIV virus	This is redundant; use HIV.

<i>Zero new infections</i>	<i>Zero new transmissions/new cases</i>
<i>HIV infections</i>	<i>HIV transmissions, diagnosed with HIV</i>
Number of infections	Number diagnosed with HIV/number of acquisitions
Became infected	Contracted/Acquired/Diagnosed
HIV-exposed infant	Infant exposed to HIV
Unprotected sex	Condomless sex; sex not protected by condoms or antiretroviral prevention methods
Serodiscordant couple	Serodifferent/magnetic/mixed status couple
Mother to child transmission	Vertical transmission, perinatal transmission
Victim, Innocent Victim, Sufferer, contaminated, infected	Person living with HIV (never use the term “infected” when referring to a person), survivor
AIDS orphans	Children orphaned by loss of parents or guardians who died of AIDS related complications
AIDS test	HIV test
To catch AIDS To contract AIDS To catch HIV	An AIDS diagnosis, developed AIDS, to contract HIV
Compliant	Adherent
Prostitute or prostitution	Sex worker, sale of sexual services, transactional sex
Promiscuous	This is a value judgment and should be avoided. Use “having multiple partners”.
Unprotected sex	Condomless sex with PrEP, Condomless sex without PrEP
Death Sentence, “HIV is not a death sentence anymore.”	HIV, chronic health condition, manageable health condition
Fatal condition or life-threatening condition: “HIV	

does not have to be a life-threatening condition.”	
“Tainted” blood; “dirty” needles	Blood containing HIV; shared needles
Scourge, "Right now we are on track to end the scourge of HIV/AIDS, that's within our grasp." @POTUS	“Right now we are on track to end HIV and AIDS, that's within our grasp.” @POTUS

“If we spoke a different language, we would perceive a somewhat different world” - Ludwig Wittgenstein

Resources Regarding the Appropriate Use of Language

Collins, S., Franquet, X., Swan, T. (2015). *HIV-positive vs HIV-infected: Reducing barriers to clinical research through appropriate and accurate language. Conference: AIDS 2010 - XVIII International AIDS Conference: Abstract no. THPE0516., At Vienna, Austria.*

Denver Principles (1983)

Dilmitis S, Edwards O, Hull B et al (2012). Why do we keep talking about the responsible and responsive use of language? Language matters. Journal of the International AIDS Society, 15(Suppl 2)

Kaiser Family Foundation. Reporting Manual on HIV/AIDS <http://kff.org/hivaids/reporting-manual-on-hivaids-updated-aids-organizations/>

UNAIDS (2015) Terminology Guidelines http://www.unaids.org/sites/default/files/media_asset/2015_terminology_guidelines_en.pdf

Unesco (2006) UNESCO Guidelines on Language and Content in HIV-and AIDS related Materials <http://unesdoc.unesco.org/images/0014/001447/144725e.pdf>

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Community-Oriented Summary/Conclusion Slide

Recognizing that keeping up with the scientific discussions can be a challenge given the highly technical methods described and terminology used in the field, the UW/Fred Hutch CFAR Community Action Board (CAB) ask that each scientific presentation include 1 summary/conclusion slide that is dedicated to the community – written in plain language that lays out the findings and implications of the work.

The slide should follow the template below, use plain language at a 6th-grade reading level, and not include undefined buzzwords or technical jargon.

Summary for Community

- Key question(s) of research
- Key finding(s) and take home message
- Why is this important?
- How is this related to cure?
- Why should we be excited (or not) about this?

For more information on plain language, visit the National Institutes of Health: Plain Language site: <http://www.nih.gov/clearcommunication/plainlanguage/gettingstarted/index.htm>

Thank you for your efforts to ensure that HIV/AIDS research is accessible to community!

Note: The UW/Fred Hutch CFAR CAB would like to thank the defeatHIV CAB for developing this concept and allowing us to adopt it!