

Executive Summary

Recommendations for Community Involvement in National Institute of Allergy and Infectious Diseases HIV/AIDS Clinical Trials Research



February 2009

The purpose of this Executive Summary is to provide an overview of the *Recommendations for Community Involvement in National Institute of Allergy and Infectious Diseases (NIAID) HIV/AIDS Clinical Trials Research* document. This Executive Summary is intended to serve as a reference for the recommendations on how to effectively involve the community in NIAID-funded HIV/AIDS clinical trials research. The full document provides history and background of Community Advisory Boards (CABs), and delineates recommendations for the roles and responsibilities of CABs and researchers, training needs, and measures of success. The document is organized along major aspects of protocol development and includes a collection of case narratives detailing specific community/researcher partnerships and lessons learned.

The mission of DAIDS is to help ensure an end to the HIV/AIDS epidemic.

The National Institute of Allergy and Infectious Diseases (NIAID) Division of AIDS (DAIDS) and Community Partners developed the document entitled *Recommendations for Community Involvement in NIAID HIV/AIDS Clinical Trials Research*. Together, they describe the history, progress, problems, and innovative solutions of community involvement, and delineate specific roles and responsibilities of the key individuals who directly impact community involvement in the research process—members of local and global Community Advisory Boards (CABs), clinical researchers and their staff, the leadership of NIAID's HIV/AIDS clinical trials research networks, and DAIDS.

While community representatives and advocates have been involved in NIAID's HIV/AIDS research endeavors for nearly 20 years, a unique component of NIAID's most recent restructuring of its clinical trials networks was the creation of Community Partners, an overarching body of community representatives affiliated with each of the clinical trials networks. The group's primary mission is to address cross-cutting concerns and the needs of the diverse communities working within each of the networks. Since there were no formal guidelines for community involvement among the many policies and procedures governing most other aspects of clinical trials research, Community Partners felt these recommendations were needed to help define and streamline the role of the community in the research process and to assist researchers as they seek community input and engagement.

As laid out in this Executive Summary, the recommendations are intended to help each clinical research site or network identify best practices for community involvement. Collaboration with, and inclusion of, community representatives in the research process help build trust and increase the likelihood that affected communities are invested in and supportive of the research being done. NIAID is committed to ensuring effective community involvement and, as such, requires CABs at all its HIV/AIDS clinical trials networks and sites. This helps ensure community input into the research process and fosters a partnership between researchers and the communities in which and with whom the research is being conducted.

CABs generally consist of community members who represent those who have a stake in the research being conducted. They may include representatives of non-governmental and community-based organizations, local government officials, members of patient advocacy groups, health care workers, trial participants, family members, and others.

General responsibilities of network and site CAB members

- Work with researchers and research staff to help the community understand the need for and goals of the research being planned or conducted
- Provide information about communities' research needs and concerns based on knowledge of the community and feedback about the research (planned and ongoing)
- Provide information that will help researchers improve study participants' compliance and quality of life through personal experience and knowledge of community-wide needs
- Review concepts for clinical trials, informed consent plans, and other related documents
- 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
- Participate in the protocol development process and study implementation
- Provide linkages to targeted communities and assistance in forming partnerships
- Translate scientific information into lay language
- Inform the broader community (for network CAB members this may encompass local CABs as well as others) about the various studies being conducted, their importance to the community, and their potential impact on treatment or prevention
- Advise on how best to disseminate information about research results in a timely manner and review materials to ensure that they are appropriately crafted

Laying the Foundation for Community Involvement

Because NIAID relies on the CAB model as a tool for community involvement, the following recommendations pertain to establishing a CAB at a clinical trials unit (CTU) or clinical research site (CRS). However, researchers and community representatives may want to become familiar with alternative models for community involvement that may be more appropriate in a given region or setting, or that may help address a specific aspect of the community/researcher partnership.

Laying the Foundation: Roles and Responsibilities of Site CAB and Research Staff

Role	Responsibilities of Site CAB	Responsibilities of Research Staff
<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., characteristics and organization) ▪ Identify key community leaders ▪ 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 	<ul style="list-style-type: none"> ▪ Educate community about research goals, potential benefits to the community, and overall public health ▪ Provide opportunities to get involved in various aspects of the research process, e.g., study participant, CAB member
<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

Role	Responsibilities of Site CAB	Responsibilities of Research Staff
<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

Laying the Foundation: Roles and Responsibilities of Network CAB, Research Network, and DAIDS

Role	Responsibilities of Network CAB	Responsibilities of Network Leadership	Responsibilities of DAIDS
<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

Community Preparedness

Community preparedness strategies should begin when the research question is being defined. Many factors should be taken into consideration when preparing a community for clinical research, including: 1) size and type of trials 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. 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.

Community Preparedness: Roles and Responsibilities of Site CAB and Research Staff

Role	Responsibilities of Site CAB	Responsibilities of Research Staff
<i>Consult: Communication streams between staff and CABs need to be open and transparent</i>	<p>Introduce the researchers and the community to one another. Discussions may include:</p> <ul style="list-style-type: none"> Overview of the organization/network General information about research Research experiences in the community Perceived research benefits Community perspective on need for HIV research, areas of research needed, etc. Overview of the research question Introduction of new research plan Difference between research and clinical care 	<p>Consider some or all the following questions:</p> <ul style="list-style-type: none"> Does the trial target a specific population in the community? What are the characteristics of the target population? How much information should be given to the community? Consider education requirements by evaluating information gaps and needs in the community How will the community be affected by the conduct of the trial? Who else might be affected by the conduct of this trial? What other trials are taking place in the same community? What role is the CAB going to play in preparing the community for the up-coming trial? What are some of the community ethical concerns/issues?

Role	Responsibilities of Site CAB	Responsibilities of Research Staff
<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 Conduct awareness campaigns and propose 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. 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
<p><i>Prepare</i></p>	<p>Educate the community about:</p> <ul style="list-style-type: none"> Importance of research to the public health Clinical trials research 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

Community Preparedness: Roles and Responsibilities of Network CAB, Research Network, and DAIDS

Role	Responsibilities of Network CAB	Responsibilities of Network Leadership	Responsibilities of DAIDS
<p><i>Inform</i></p>	<ul style="list-style-type: none"> 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 (NCAB) in their work with sites Support sites in utilizing NCAB expertise 	<ul style="list-style-type: none"> Require sites and networks to have CABs and encourage involving them in community preparedness efforts
<p><i>Share Information</i></p>	<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
<p><i>Advocate</i></p>	<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 	
<p><i>Evaluate</i></p>	<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

Developing the Research Protocol

Ideally, community involvement occurs at all levels of the research process in all NIAID-funded HIV/AIDS clinical trials networks. Community input starts when the research concept/question is first developed and continues until the results are discussed and published.

Developing the Research Protocol: Roles and Responsibilities of Site CAB and Research Staff

Concept Phase

Role	Responsibilities of Site CAB	Responsibilities of Research Staff
<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 of the research being proposed to the community 	<ul style="list-style-type: none"> Provide context for research concept and describe it in general terms so that the purpose and benefits of the research to the community are understood

Protocol Development Phase

Role	Responsibilities of Site CAB	Responsibilities of Research Staff
<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 question/research area with the CAB
<i>Study Design</i>	<ul style="list-style-type: none"> Contribute community-relevant information that would help with designing a research protocol that can be implemented within a proposed time frame 	<ul style="list-style-type: none"> Invite community input on study design through CAB involvement

Protocol Regulatory Process and Preparation for Implementation Phase

Role	Responsibilities of Site CAB	Responsibilities of Research Staff
<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 that clear, understandable language is used 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>Material: Education</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

**Developing the Research Protocol:
Roles and Responsibilities of Network CAB, Research Network, and DAIDS**

Role	Responsibilities of Network CAB	Responsibilities of Network Leadership	Responsibilities of DAIDS
<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
<i>Participate on Protocol Teams</i>	<ul style="list-style-type: none"> Help protocol team consider 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 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

Implementing the Research Study

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 and ensuring that the research study is being implemented as planned.

Implementing the Research Study: Roles and Responsibilities of Site CAB and Research Staff

Role	Responsibilities of Site CAB	Responsibilities of Research Staff
<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 	<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 Data and Safety Monitoring Boards (DSMB) 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

Role	Responsibilities of Site CAB	Responsibilities of Research Staff
<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 	<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

**Implementing the Research Study:
Roles and Responsibilities of Network CAB, Research Network, and DAIDS**

Role	Responsibilities of Network CAB	Responsibilities of Network Leadership	Responsibilities of DAIDS
<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

Communicating Research Results

CAB members play a critical role in ensuring that research results reach all members of the community, particularly those who may be most directly affected. Each site should consider developing a communications plan that includes how study results will be disseminated.

Communicating Research Results: Roles and Responsibilities of Site CAB and Research Staff

Role	Responsibilities of Site CAB	Responsibilities of Research Staff
<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
<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
<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 ▪ 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 are involved in creating and conveying the key messages
<i>Advocate</i>	<ul style="list-style-type: none"> ▪ Ensure that CAB members understand the study results so that they can advocate for additional research or policy changes 	<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 study findings

Communicating Research Results: Roles and Responsibilities of Network CAB, Research Network, and DAIDS

Role	Responsibilities of Network CAB	Responsibilities of Network Leadership	Responsibilities of DAIDS
<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 possibility of early trial termination as a result of favorable interim results, harm, efficacy, or lack of feasibility ▪ Inform collaborators, partners, relevant government agencies, and international ministries of health and other key stakeholders of study results

Role	Responsibilities of Network CAB	Responsibilities of Network Leadership	Responsibilities of DAIDS
Share Information	<ul style="list-style-type: none"> 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"> 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

Stories from the Frontlines

To illustrate how communities and NIAID-funded researchers have partnered over the years and what some of the outcomes have been, a number of community participants, researchers, and staff shared their observations and experiences of working in or with a CAB. The case narratives explore community contributions to treatment and prevention research and the impact of communities' increased knowledge of scientific research, disease concepts, treatment regimens, and health outcomes. These "Stories from the Frontlines" detail the experiences of the following community/researcher partnership participants:

Authors	Case Narrative and Network Affiliation
Apinun Aramrattana Nantapol Chuenchooklin Madeleine O'Hare	<i>Evolution of the Substance Abuse Community Advisory Board (S.A.CAB) for HIV Prevention Trials among Drug Users at Chiang Mai, Thailand, HPTN</i>
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Claire Schuster Dorothy Shaw	<i>International Maternal Pediatric Adolescent AIDS Clinical Trials (IMPAACT) Community Directs Research Responsive to Families' Needs, IMPAACT</i>
Julio Barros	<i>Community Involvement in HIV/AIDS Research in Brazil, HPTN</i>
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Neetha Morar Sbu Nhleko	<i>Women's Leadership and Gender Dynamics within a Rural-based Community Working Group (CWG), Kwazulu Natal, MTN</i>
Teopista Nakyanzi	<i>Challenges in Involving Ugandan Men in Prevention of Mother-to-Child Transmission (PMTCT), IMPAACT</i>

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Steve Morin	<i>Reflections on the Need for Community Participation in the Research Process from One of the Earliest HIV Treatment Trials: AZT Story (Introduction)</i>
Nalini Visvanathan	Editor