



Community Involvement Guidance

(draft)

A key factor of the overall HIV Prevention Trials Network (HPTN) strategy is the commitment to community participation at all levels of research. Directed by Federal guidelines, the HPTN has committed to community participation and collaboration as a key component in the Network's goal of effective public health research. As a result, a partnership of people who are affected and infected by the HIV epidemic will have input into the ideas that are developed, how the studies are designed, and the implementation of the actual research.

To ensure movement toward this goal, community participation must be facilitated to occur within the HPTN CORE, at the sites where research is to be implemented, and within the research communities. A system of information sharing and resources helps ensure information is shared between these levels of the Network. This document provides information and guidance for site staff and the community partners about community participation in the Network and how to develop and sustain it in the HIV prevention research conducted at the sites.

INTRODUCTION

The HPTN's commitment to community participation in research is based on the positive findings of research initiatives in the past that showed the science is better and communities benefit when the community is involved in the process. As stated in a 1997 UNAIDS guidance document for HIV vaccine research, community representatives should be involved in an early and sustained manner in the design, development, implementation and distribution of results of HIV vaccine research in order "...to ensure the ethical and scientific quality of the proposed research, its relevance to the affected community, and its acceptance by the affected community."

Community participation in decision-making will ensure that research participants and the community feel ownership of the research and have an interest in its success. Collaborations and partnerships encourage trust and mutual understanding of the research issues and implications. An additional benefit to the collaborative effort is that the prevention research developed will be based on respect for cultural and ethnic differences among participants. As stated in Fröhlich's paper on community participation in HIV research, "Where there is community participation in research, human capacity is built, with the ultimate results being self-determination, self-reliance, and a high self-esteem."

For the HPTN effort, the National Institutes of Health Request for Application (RFA) document guided applicants "...to ensure community input into the research process and to foster a partnership between researchers and the community, particularly the population served by the individual unit and/or research study."

Understanding what is expected in the community participation process is important. The Network proceeds with its community program based on guidelines given to us by the Division

of AIDS (DAIDS), US National Institutes of Health (NIH), and was initiated during the HIVNET trials. In the box below entitled, “Community Participation Charge from DAIDS, NIH,” the mandate for community participation in the Network was outlined in the original request for the Network proposal in 1999. Additional guidance from the HPTN CORE was added for HPTN Year One activities in 2000 to clearly articulate the HPTN’s commitment to a strong community involvement program.

Community Involvement Charge from the DAIDS, NIH

Revisions in *italics* reflect clarifications from the CORE Community Program Staff

From the NIH RFA:

Community Advisory Boards (CABs).

The awardee is required to establish a CAB (*or similar appropriate community advisory process*) to ensure community input into the research process and to foster a partnership between researchers and the community, particularly the population served by the individual unit and/or research study.

Budget Instructions:

- Support of a Community Advisory Board, including travel of CAB members to HPTN meetings (*see additional budgetary guidance for year 2*).

Sites initially reviewed for:

- **Adequacy of the plans:** Community Advisory Board (*or other advisory processes*) and community involvement is addressed sufficiently at the site and subsites (if applicable)
- **Innovation:** Does the project employ novel concepts, approaches or methods? Are the aims original and innovative? Does the project challenge existing paradigms or develop new methodologies or technologies?
- **Incorporation of effective strategies:** Evidence that the proposed plans for community education regarding HIV preventive interventions trials incorporates effective strategies

Guidance From the HPTN CORE for HPTU Priority Activities in First Year Activities:

The minimum requirements for participation in the HPTN must be developed and underwritten throughout:

- **Support for the HPTU community involvement program.** This should include salary for a HPTU community program coordinator/educator, development and maintenance of a HPTU community advisory board (CAB), including local travel expenses.

HPTU performance and level of continued funding will be evaluated on many dimensions, including contributions of participants to HPTN research trials, scientific contribution to SWGs, and **a strong community involvement program.**

Purpose / Objectives of this document:

The purpose of this guidance is to provide an outline of for both community advisory board members and site staff on what could and should be taking place to encourage collaborative decision-making and educational activities. In order to do this, some expectations need to be understood.

- At the **community level**, members of the community need to know they can safely share their experiences and ideas about what aspects of proposed research *will* and *will not* work in their communities.
- At the **site level**, HPTUs must invest appropriate resources in planning for and implementation of activities that develop and sustain community participation at each stage and all levels of the HPTN trials process while responding to community questions and concerns in a timely fashion.

- At the **CORE Network level**, there must be willingness to respond to identified needs and concerns regarding community involvement and decisions while facilitating the flow of this information to all levels.

Local community advisory mechanisms will incorporate common elements, and site staff will work to support the process that ensures these elements are in place.

- Community members will be involved early in discussing prevention research priorities; research design issues such as cohort selection criteria, questionnaire design, and follow-up plans; informed consent procedures; risk-reduction interventions; community education and outreach; and recruitment and retention planning and implementation.
- Sustained relationships and communication with community members will be the responsibility of each research site Principal Investigator. Community Educator Staff will develop a written plan to foster trust; to ensure respect of social, cultural, and political realities of the communities where recruitment will take place; and to maximize opportunities for dialogue about the implementation of research trials. This involvement and participation of community members must be supported as an integral part of the site operation plan.
- Clinical trials of HIV prevention interventions are most likely to succeed when all the parties concerned - researchers, government, manufacturers, and community - regard the trials as a collaborative process. Community members, particularly potential trial volunteers and people from the populations from which volunteers will be recruited, can and should play an integral role in advising on research trials.
- Community advisory mechanisms will be developed at all HPTN sites.
- The HPTN CORE will establish a Community Working Group (CWG) that will meet on a regular basis (preferably monthly.) Members from each research site will participate in conference calls and be ensured representation at an annual retreat. The CWG should minimally convene quarterly to review international issues and facilitate information exchange.
- The HPTN Core will outline steps to develop, maintain, support, and encourage the full participation of community representatives in all phases of the research process. This will include plans for recruitment, ongoing orientation, training and education, and facilitated access to participation on science direction working groups and network governance.

In the box labeled “**Community Participation ‘To Do’ Overview**,” is the basic guidance as to the community activities a site must be doing to prepare for and sustain their community participation in the Network.

Community Participation “To Do” Overview

- **Hire a Community Educator** (one or more staff members at a minimum of 50% full time equivalent – or about 20 hours per work week)
- **Create a Site Community Participation Plan (CPP)** that includes:
 - Measurable goals and objectives
 - Strategies to get community input into research
 - Community education section, based on assessment of local needs
 - Assessment of community resources regarding research
 - Building ownership of community advisory functions
 - Issues Management Plan
 - Budget for activities
 - Evaluation of the CPP
- **Build** positive and collaborative **community relationships** between HPTU members, community members and local non-governmental organizations that share similar goals.

I. HIRING A SITE COMMUNITY EDUCATOR

As indicated in the “**To Do Overview**,” hiring a site Community Educator is key to supporting community participation within the Network. The Community Educator’s focus is to work with the HPTU staff to develop and maintain the site’s relationship with the community where the research will be taking place, facilitating the development of a Community Participation Plan (CPP), as well as ensuring that the Principal Investigator knows what necessary resources are needed to support community participation and education activities based on guidance from the community. Basically, the Community Educator will act as a facilitator of community participation activities.

Each site is encouraged to develop the Community Educator position as it feels is appropriate with the minimum requirement to have at least 50% full time equivalent (FTE) for staff responsible for coordinating the community participation efforts at the site. This percentage of time can be divided among more than one staff person, and the 50% FTE is only the required *minimum*. Additional staff time can be budgeted to address site activities outlined in the site Community Participation Plan as work load increased with the onset of research activities.

Activities typical of the Community Educator include supporting efforts to educate and develop collaboration with community members and appropriate non-governmental organizations (NGOs), coordinate community advisory functions (CABs, town meetings, focus groups, etc.), participate in the development and implementation of the site Community Participation Plan and advise site staff on community needs, and represent the site’s community participation activities and concerns within the Network.

II. COMMUNITY PARTICIPATION PLAN (CPP)

The importance of having a planning document cannot be stated strongly enough. The collaborative process required to create and sustain the Community Participation Plan (CPP) is at

the heart of ensuring community participation in the HIV Prevention Trials Network, as well as being a requirement by the HPTN for each site.

The Community Educator should be responsible for facilitating the development of the CPP that will include input from the community and site staff, the HPTU Principal Investigator, and HPTN CORE Community Program Staff.

The CPP will need to be reviewed and possibly revised annually. This is to ensure forward movement on the plan and appropriate revisions are made to keep the site Plan a useful and relevant document.

What is “Participation” in a Prevention Research Setting?

Participation is a process through which stakeholders influence and share responsibility and control over research initiatives in their communities and the decisions and resources that affect them. (See section III. B. on Community Relationships for definition of stakeholders)

Writing clear and appropriate goals and objectives for community participation at the HPTN site is critical to integrating *planning* activities with *implementation* and *evaluation* of the plan:

- Planning – Identifying and developing a course of action to be conducted by site staff and community advisors to ensure a collaborative community participation process.
- Implementation – Preparing an implementation schedule that lays out the sequence, timeline and individual responsibilities for project activities.
- Evaluation – Measuring your achievements based on the goals and objectives that were initially set up. All of the HPTN sites will be evaluated on many different measures, some of them specific to community participation.

Make sure to build in evaluation measures as you plan activities that are based on the implementation schedule. When planning is based on looking for answers to key questions identified by the community advisory process and site staff, evaluation helps determine how well the project is progressing and achieving its goals and objectives. As a benefit to developing the goals and objectives, evaluation leads into the continuous process by providing information for the next year’s round of planning.

The CPP functions as a guide for the community and the site staff to make sure the process moves forward. It will define what is to be done, by whom, how it will be measured, what questions need to be answered, and when all of these activities will occur.

To develop the CPP, the following components of the plan need to be addressed:

- A. Goals, Objectives and Measures
- B. Site Community Involvement Strategy
- C. Community Education
- D. Community Resources Inventory
- E. Building Autonomy
- F. Issues Management Plan
- G. Budgeting Process
- H. Evaluation

A. Goals, Objectives and Measures

Identifying clear goals for your Community Participation Plan is the foundation of the planning, implementation and evaluation of the site and community collaboration effort.

Goals identify the expected accomplishments of the activities. To meet these goals, specific objectives need to be identified to indicate how the goals are to be achieved.

- **Identify goals.** Goals are broad statements outlining what is going to be achieved. Goals are met by fulfilling objectives that are specifically designed to fulfill the goal. For example: To ensure community involvement in research conducted at __ site.
- **Set objectives.** An objective is a statement describing what you expect the project to accomplish within a given period to meet the goals of your project. Objectives are **activity-specific, time-specific and measurable** and answer the question, “What changes do you want to effect within what timeframe?” It is important that objectives address the gaps and needs identified through a community resources assessment (see section II.D).

There are two types of objectives – **process** and **outcome**.

➤ **Process Objectives:**

Process objectives define the activities or methods necessary to achieve a desired result. Process objectives form the basis of the workplan, and assist in monitoring progress during each stage of the project. Each process objective should state *what* intervention will be done, *by whom*, *where*, and *when*. How the project will document the accomplishment of the objective is described in the objective measure.

Process describes the steps taken to implement the program, for example:

- Number of educational materials distributed
- Number of presentations given and how many people attended
- Number of professional or outreach contacts made

Example:

- ◆ **Objective 1:** The community education staff (*by whom*) will conduct twenty (20) educational sessions (*what*) with 12-15 women per group with women attending antenatal clinics (*where*) between July 1, 2001 and December 1, 2001 (*when*).

➤ **Outcome Objectives:**

Outcome objectives state what measurable change has occurred as a result of the process or intervention. They describe the effect that a particular intervention has on the knowledge and behavior of the target audience over time. Outcome objectives should state *what change* would occur as a result of that activity done *to whom* and *by whom*. How the project will document the accomplishment of the objective is described in the objective measure.

Outcome describe the end results or benefits of the objective, for example:

- How did people respond to an educational program?
- Knowledge gained and attitudes changed
- Reported behavior change

Example:

- ◆ **Objective 2:** Site Community Educator (*by whom*) will ensure all new Community Advisory Board Members (*to whom*) will be adequately prepared to participate (*what change*) in discussion and decision-making.

- **Measures** are a description of what is produced by meeting the objective. Below are examples of measures for the example process and outcome objectives listed above.
 - **Process Objective:**
 - ◆ **Measure 1:** Educational training materials will be produced, documentation of individual trainings with a short report, and sign-in sheets for participants, and final report summary of all trainings
 - **Outcome Objective:**
 - ◆ **Measure 2:** Individual modules for CAB member orientation will be produced, roster identifying new members, signed training documentation log, pre- and post-test results for new members, training evaluation forms completed by the participants.

When creating the site's CPP goals and objectives, be sure to incorporate ways to gather measures of activity that is needed by the Network Evaluation Committee. For the specifics, see the evaluation section below (Item II.H).

B. Site Community Involvement Strategy

Community involvement can occur in many different ways, as described in Fröhlich's paper on community participation in HIV research. "Communities can interact with researchers, in the research process, and at the group, leadership, and individual level. There are usually existing community groups and through the social network these groups bring community knowledge and an existing infrastructure to the research process." She goes on to state the importance of recognizing that "Community leaders bring the respect of their community to the research process, whereas individuals bring their own expertise, skills and knowledge of their community."

When planning the site's community involvement strategy, it is important to assess what the different participants are bringing to the community participation process. Therefore, knowing what stage the research process is in and the level of readiness to participate by the site and the community must be taken into account.

- Research phase: Each phase of research has different community participation activities that are appropriate. In *preparedness trials*, the focus may be in identifying stakeholders, identifying networking partner organizations, and building trust of the site in the research community. In *Phase I/II/III trials*, a more established community advisory process needs to be in place, educational efforts can be implemented, and networking with other groups needs to have been solidified. For sites that may have *trials on-hold*, maintaining and sustaining good community relationships during any lulls in the process, educational efforts can be conducted and community mobilization efforts can be supported.
- Type of intended protocol: Some study protocols affect participants in a minimal way (e.g., adding an additional behavioral survey to patients already being seen in a clinic), while others may affect the individual or their community by administration of medical treatment, use of a new product (e.g., microbicides or antiretroviral therapies), or attempting to reduce HIV transmission risks by changing individual behavior or community norms. The type of intended protocol therefore shapes the response of potential research participants and needs to be considered.

- Site readiness: The site's readiness to participate in research can affect the level of community participation on many levels, and sites in the HPTN are working from a variety of levels of site readiness. Some sites are starting with no community participation infrastructure; others have established community infrastructure while running one HPTN protocol; other sites are running multiple HIV-related protocols and one HPTN trial; while others have ongoing multiple HIV-related studies including more than one HPTN trial. The level of established community participation in existing research, if any, affects how the community should be approached to build the research partnership.
- Community readiness: The types of existing community links in the HPTN also display a diversity of options. Some have had no previous collaborative partnership experience; some have worked collaboratively in education and recruitment; others have established community advisory capacity for one study; others have more complex networked advisory mechanisms for multiple studies; some sites have complex community advisory systems that include multiple Community Advisory Boards or a global CAB that works with "sub-CABs" for trial-specific populations; while others may have moved to integrated research with HIV treatment and care as the result of community input and work with related non-governmental organizations (NGOs).

Each of these four factors must be identified in the Community Participation Plan in order to establish where a site is starting and to plan where the community involvement process will be going in the future.

HIV prevention research is by necessity, a broad and interdisciplinary activity. The expertise to successfully conduct HIV prevention research requires more than a simple understanding of how to conduct the clinical aspects of trials. The range of behavioral, political, social, legal, and psychological issues requires not only broad expertise, but active collaborations with other community groups and resources which can assist trial sites, trial participants and communities affected by vaccine research in dealing with these issues. In particular, HIV prevention research often requires a close degree of communication and collaboration with stigmatized and disenfranchised communities which may have suffered from long-standing and diverse forms of harmful discrimination in both medical research and clinical practice, while also bearing a disproportionate burden of HIV infections.

The goals of community collaboration efforts will be somewhat different depending on the community. Overall, the goals of the community participation strategy should be to:

- Leave the communities better off than when the research began, regardless of the ultimate result of any particular HIV prevention trial
- Create community investment in research, and to take a long-term approach to fostering community relationships
- Make the research an activity that not only benefits the world, or science, but also the specific communities in which it takes place

In implementing an appropriate community participation strategy, research site staff must demonstrate their ability to maintain informal and/or formal ongoing and substantive relationships with community groups and advocates. They should realistically plan for how

they will work to nourish these relationships. This should include the sites quickly reporting relevant local data to interested local parties.

Keep in mind that evaluation of the identified strategy requires evidence of collaborative relationships showing the potential and actual results of these relationships. Success is demonstrated when the research site is known in the community in which it is located; civic leaders, local media and stakeholders in the community will value the site's presence in concrete ways, and the research site is known to work for the direct and immediate benefit of the community.

C. Community Resources Inventory

A resource inventory is a systematic process of obtaining and analyzing information to identify existing and needed resources of a specific population to reveal priorities for networking and research strategies. Attention to the community's needs also sends a message that the site is interested in the community's concerns and welfare. This is important in building trust and mutual understanding of intentions. Also, being aware of the research community's HIV prevention needs provides information to the site and the Network about important priorities that could be the focus of future research efforts.

The resources inventory provides a baseline level of information that lets site staff document what is available to community participants and where gaps may exist. Identifying these issues helps the site and the research communities understand the larger picture of HIV's effect and how HIV prevention trials in their community will affect their lives.

1. Conduct a **community analysis and resource inventory**

- What other HIV prevention and care programs exist, to reach what population?
- Who are key public and non-governmental agencies and referral groups which could be helpful?
- What local media resources might be potential partners?
- What resources are available (NGOs, other research, intervention and treatment initiatives)

2. Conduct **ongoing community assessment** of community education and prevention needs around HIV prevention research:

- **Focus groups** are a valuable information collection method, in which a small group of selected individuals express their opinions and reactions
- **Key informant interviews**, an in-depth information collection method that include open-ended questions
- **Town or Village meetings** to share information and get responses
- **Community outreach surveys** where staff and/or community advisors go to communities to ask specific questions of community members

3. Some **key questions** to consider include:

- What tools and strategies work best to educate your community about HIV prevention research?
- Who are the stakeholders in the community and where do linkages need to be forged?

D. Community Education

An effective infrastructure for a comprehensive community education initiative will be developed and implemented at each HPTU.

1. **Community educators** build support for HPTN research by developing relationships with local networks, community-based organizations, and key opinion leaders and advocates. They work to ensure ongoing communication with and endorsement by community decision-makers and institutions.

Based on assessment of local needs and the nature of the HPTN trial to be conducted, the **community education section of the plan** will include education of the community at large, the population from which study volunteers will be recruited, research staff and trial participants; this will include the development and use of culturally and linguistically appropriate educational and informational materials. A community education workplan should include the following activities:

2. **Identify your target audience.**

Target audiences are groups of people who have common characteristics related to disease transmission. The purpose of focusing on target groups is to develop specific messages that are relevant to the needs of each particular group. Some examples of commonly targeted audiences are women of childbearing age, adolescents, drug users, commercial sex workers, etc.

- **Some key questions to consider about the target audience include:**
 - What do they know about HIV/AIDS?
 - What do they understand about research / clinical trials?
 - What are their concerns about AIDS?
 - What are the special needs of this group?
- **Develop key messages** – identify all of the possible messages needed and emphasize the 3-4 most important. That way the audience will not become frustrated with information overload.
- **Select channels of communication** – which methods of communication can be used to reach the target audience most effectively with the needed information? Some examples include:
 1. Institutional or interpersonal networks –community groups, youth organizations, women’s groups, influential leaders, bars, truck stops
 2. Educational materials – pamphlets, posters, displays, stickers, displays
 3. Mass media – radio, newspaper, TV
 4. Service delivery systems – clinic or hospital-based education programs that involve counseling, condom distribution, etc.
 5. Town meetings or public forums – invite decision-makers, representatives from AIDS organizations and people affected by HIV/AIDS to share community advice and ways to proceed
 6. Creative techniques – drama, song, dance, drumming, role-plays

E. Building Ownership of the Community Advisory Process

It is generally accepted that a true community-based effort is one in which the local participants will say, “We did it ourselves.” This basic principle of community participation in research efforts can be forgotten among competing community health research and

initiatives, so it is important in the planning process to account for the need of community feelings of ownership that must be created and sustained. To do this, devoting resources or time may be necessary to meet the technical requirements of the site research effort. It may also require better communications with community opinion-makers or informal leaders to help address their specific concerns.

One of the most effective ways of encouraging ownership in the process is to work on some short-term and easily achievable objectives that involve as many people as possible. Small-scale but visible achievements are valuable ways to keep people's interest, spark more participation, and show people that their collective action can actually lead to success.

Take the time to accomplish smaller, achievable projects with your community advisory group to build this sense of ownership over the advisory process. To do this, community advisors must be provided the knowledge and tools needed to affect control over the process in which they are involved. This is done through training and creating collaborative relationships with site staff.

The eventual goal is that community advisory members develop a sense of autonomy in working with the HPTN site staff. Autonomy implies that the participants have the skills to do what is needed while having actual influence over the decision-making process.

F. Issues Management Action Plan

Although everyone wants things to go as discussed and planned, occasionally unexpected things happen. A product slated for use in a microbicide study may get pulled from the market or a new form of therapy to be studied may prove to be extremely effective and the trial ends sooner than expected.

The HPTN site and the research community are occasionally faced with conflicting forces of short-term and long-term goals. The relatively short-term issues of conducting research on a time-table might run counter to a community's long-term efforts for mobilizing on HIV prevention issues beyond the scope HPTN research agenda.

To prevent and actively address these situations when they arise, coalition-based groups need to think through how they will prepare for and react if something happens in the prevention research process that needs a rapid response. An *action plan for issues management* is important for the group so a process can be rapidly employed if issues occur.

- Each HPTN research site will develop a clear plan for managing unforeseen, difficult and/or controversial issues.
- Establishing a state of readiness requires site staff to engage in a process to create awareness of, and sensitivity to, potentially controversial issues. Sites conducting research will take the steps necessary to identify, confront, manage and resolve unforeseen issues that may impact public confidence in the site and the research being conducted throughout the course of the project.
- Working with staff and through community contacts, sites should try to determine any potential controversial issues and evaluate their capacity to respond appropriately.
- With a clear understanding of the site's state of preparedness, a written issues management plan should be developed that will outline a decision-tree for implementing the plan, the staff roles and responsibilities in managing issues including the key contact

for decision making, and the available and accessible mechanisms for rapid internal and external communication.

G. Budgeting Processes

In order to fully implement the Community Participation Plan, resources are needed to support the identified activities. The Principal Investigator is responsible for including a realistic community involvement budget in the HPTU's annual budget.

As the site Community Educator facilitates the Community Participation Plan process, a recommended budget for the identified activities needs to be created as well. Just as the complete site budget is separated into core and protocol items, so should the CPP budget.

- Activities identified in the basic support of CPP will have community participation funding outlined in the core budget. This includes activities before protocols actually begin, community education activities to build relationships between the community and the site, the funds necessary to maintain community advisory activities if no protocol is presently active, and travel expenses for community members to annual HPTN meetings.
- Any protocol-specific community activities will need to be included in the protocol budgets. This would include educational efforts for the community about participating in the trial, and the mandatory travel associated with face-to-face protocol team meetings.

The following are key points for the Community Participation Plan and the site's fiscal support of collaboration activities:

- Relationships with the community and other organizations that support the community are critical to build trust and must be developed. Funds are necessary to support community participation activities, such as community education (e.g., health fairs or community campaigns, bicycles for outreach workers).
- Community advisory activities can take forms other than Community Advisory Boards and will require funds to support the efforts. For example, convening focus groups with high-risk individuals for direct community input, conducting community forums with local leaders, conducting community outreach surveys, or working with existing support groups to elicit comments and ideas about the research.
- Funding support for community participation from each site is mandatory for protocol teams, as well as expected on the Working Groups (Science and Community). Community member participation on other HPTN committees (e.g., Protocol Review Committee and the Network Evaluation Committee) must be approved by the site Principal Investigator. The funds to cover these activities need to be included in the site's annual budget
- Support for at least two Community Participants to attend HPTN Regional Trainings must be included. Travel, lodging and per diem is necessary for this level of participation and must be covered by the site budget.
- Participation by site community representatives at non-HPTN meetings and conferences is recommended. Supporting participation in this way can indicate the value sites place on community participation and help develop community participants' facility in research settings.

For more information, a document providing specific budgetary guidance for community participation activities is available from the HPTN CORE Community Program Staff.

H. Evaluation

Evaluation of the CPP and activities supporting the plan are based on the goals and objectives established at the beginning of the community plan process. As it was mentioned, measures of objectives describing activities to be accomplished should be either **process** or **outcome** focused and focused to accomplish a specific goal. Evaluating the goals and objectives require that the necessary information and materials be collected to address the identified measures, and as system must be in place to manage the collection of these measures.

Attention needs to be paid to the specific measures outlined by the HPTN's Network Evaluation Committee. These measures are required of the site and must be included in the initial development of goals and objectives. The Network evaluation measures to include are listed in the box below.

Network Evaluation Measures for CPP Goals & Objectives (draft)

Activities and Support:

Indicator: Regular meetings and activities involving community advisory functions.

A. Measure: Number of meetings, activities or functions per year as reported in quarterly reports.

B. Measure: Receipt of quarterly reports from site on community advisory functions.

Components:

- List of attendees to meetings
- Number and date of meetings
- Updates of CPP adherence
- List of other activities.
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Indicator: Regular meetings and activities with community and HPTN investigator participation.

Measure: Number of community meetings or other activities with PI or site participation.

Indicator: Establish and support a community educator at site.

Measure: Presence of active community educator at site.

Planning:

Indicator: Finalized Community Participation Plan.

Measure: Date of receipt of finalized Community Participation Plan and date of updates including annual report on adherence to plan.

Components:

- Needs assessment
- Budget
- Partnering strategies
- Statement of objectives or milestones
- Annual update on plan adherence
- Timeline for community education activities.

Representation:

Indicator: Representation of community in HPTN activities.

A. Measure: Number of community representatives on Protocol Teams, SWGs and HPTN committees.

B. Measure: Percent of team calls/meetings attended.

C. Measure: Number of community representatives at HPTN meetings against standard.

III. COMMUNITY RELATIONSHIPS

Many cultural, economic, political, and educational barriers effectively prevent HIV-affected populations the ability to have any real stake in HIV prevention activities in their communities. Without special efforts by the research staff and the HPTN as a whole and without specific ways to address and overcome the local barriers, the voices of the research communities will not be heard and their participation will at best be token or even misrepresented. Reaching the research community, therefore, requires working with them to learn about their needs and lives when facing HIV's effect on their communities, and identifying organizations, institutions and mechanisms to get opportunities and resources into their own hands.

To help support community participation and mobilization around HIV prevention research, HPTN site staff needs to work toward building and maintaining a **long-term collaborative partnership** between the community and the research team. These community relationships work toward ensuring mutual support and trust which is critical in establishing an effective collaborative partnership. It becomes the role of the Community Educator to help facilitate an effective system of sharing information between the site and the community by identifying, developing and maintaining community relationships.

A key concept in developing community relationships is timing. Often, the HPTN's schedule can be a prolonged waiting process followed by a burst of activity with very short time lines. Just as the HPTN has cycles of activity, it should be recognized that communities have their own natural rhythm for doing things. Unless the site staff understands the community's natural rhythms of everyday life, efforts to build community relationships might be viewed as frustrating by the perception of lack of progress. At the same time, community members can be irritated, offended or simply confused by the expectations of the research team if not adequately prepared and informed about the status of the research effort.

The process of developing good community relationships can extend beyond the immediate scope of HPTN research goals. It is the HPTU's role to initiate the development of community connections with the research community (if not present) and further develop those that exist in an effort to support the HIV prevention trials to be conducted. While needing to maintain a focus on the trials, supporting community interactions beyond the scope of the HPTN research often results in stronger community support of the site and its activities. These efforts are done keeping in mind that the effect of what is created in the community will continue after the HPTN research is over.

As part of the Community Participation Plan, the following issues need to be identified and a process developed to implement efforts to develop community relationships. Discussed below are the main areas to consider when discussing, planning, initiating, and sustaining the HPTN site's relationship with the research community that include:

- Assess Existing Relationships
- Identify Stakeholders
- Network with non-governmental organizations (NGOs)
- Work Toward Community Mobilization

A. Assess Existing Relationships

Just as with other processes mentioned in this Guidance, developing community relationships can happen in different stages based on existing relationships and networks that have already been established. If no substantial community relationships exist when the HPTN site starts their work, the need is to find entrée into the community and start building connections. Sites that have developed extensive relationships over time and multiple research projects have the benefit of a combined history and can build on it to further develop opportunities for mobilization and identifying areas of research.

Institutional Mapping

A simple “institutional mapping” exercise would be useful. One way to do this is to ask community members to identify the community groups by drawing circles of differing sizes -- the bigger the circle the more important and influential the group it represents.

The nature of shared decision making among the groups can be represented by how circles are placed in relation to one another: the closer together and more overlapping, the greater the degree of interaction between the represented groups.

These graphics, sometimes called “*chapatti* diagrams” have proved effective in identifying informal groupings that are important safety nets for disenfranchised and stigmatized members of the community. They also reveal that some of the more obvious organizations are actually quite weak.

In any community, a range of organizations is operating that can affect community participation in HIV prevention research: formal or informal, traditional or modern, indigenous or externally established. All these organizations have different functions – productive, social, religious, or otherwise. It is often through these organizations that need is expressed, participatory processes organize, and prevention research can be conducted.

Some of the most active community organizations are informal. They may not be listed in any documents, and

they may be unknown even to people familiar with the communities. Learning about these groups requires visiting the communities and talking with inhabitants about how decisions are made and norms enforced. Understanding how the informal organizations work helps facilitate community input to the community participation process.

B. Identify Stakeholders :

Stakeholders such as teachers, informal community leaders, storeowners, traditional healers, brothel owners, etc. have been documented in literature as critical for influencing HIV-related risk behavior in different communities. These people have a stake in what the outcome of a particular action is in their community.

As mentioned in the boxed definition of “stakeholder,” there are directly affected groups as well as indirectly affected groups of stakeholders.

- **Directly Affected Stakeholders**: Those directly affected by a health issue or research study are clearly among the stakeholders. These individuals or groups are the ones who stand to benefit or lose from HIV prevention research in their communities. The marginalized and stigmatized are often among this group, and are often perceived as the most difficult to identify and involve in participatory efforts.

What is a Stakeholder?

Stakeholders are those people or organizations affected by the outcome of an action – negatively or positively – or those who can affect the outcome of proposed actions, interventions, or research in their community. Often stakeholders have immediate and direct impact while others may only have indirect interests.

- Indirectly Affected Groups: Many individuals, groups, or organizations may be indirectly involved or affected by efforts to conduct HIV prevention research, or they may be linked in some way to those who are directly affected. Such stakeholders may include NGOs, intermediary organizations, private sector businesses, and political structures. Identifying and enlisting the appropriate intermediary groups can prove tricky, and sometimes results in trial and error selection processes.

When looking for appropriate stakeholders, consideration needs to be given to the balance of participants directly affected and indirectly affected. A good way to identify appropriate stakeholders is ask questions that are appropriate to what representation needs are of the community advisory process. Although not exhaustive, below are some questions that will help to identify the specific questions needed for the present situation.

- Who might be affected (positively or negatively) by the HIV prevention trial to be conducted?
- Who are the people who have little or no voice in the process where special efforts may have to be made to include them?
- Who are representatives of those who are likely to be affected by the research?
- Who is likely to mobilize for or against the intended research trial?
- Who can make the intended research more effective through their participation?
- Who can make the research less effective by their nonparticipation or outright opposition?
- Who is contributing to HIV prevention efforts in the community?
- Whose behavior has to change for the HIV prevention research effort to succeed?

In any community-based effort, there is always the risk that an identified community leader or stakeholder – whether traditional or newly arisen – will not represent the whole community, but will focus on their own concerns or agendas. At the same time, certain groups within the larger community – whose participation can be highly important to HIV prevention research efforts – may be marginalized or ignored.

Depending on the local society, these groups may include regional ethnic minorities, people in stigmatized professions (e.g., sex workers), or people excluded from power because they are too young, too old, because they are women, or come from a particular economic status. Often they are reluctant to speak publicly for fear of reprisals or discrimination, or have no experience in doing so.

A word of caution: To many of the identified stakeholders, an outsider bringing offers of community participation in research may seem suspect. Prior experience with other organizations, groups and individuals may have created negative impressions that may affect how the HPTU is perceived in the community. If this is so, steps need to be taken to rectify the negative impressions by working with the communities to build common understanding of intent and staking steps to develop a trusting relationship.

C. Network with NGOs

Establishing good working relationships with non-governmental organizations that work with the HPTN prevention research communities are important as NGOs serve an intermediary function between outside resources and the community of interest. Although NGOs vary in their ability and commitment to working with HIV prevention research, in many cases they have advantages as intermediaries in reaching people -- including women, ethnic minorities,

the poor, intravenous drug using populations, commercial sex workers – who are not represented equitably by more formal organizations. Working with NGOs, particularly if the site is just initiating community relationships for research, may be an effective way to build off of others experiences.

A number of reasons make it worth investigating potential collaboration with NGOs:

- If the site is new to the research community, the NGO can provide entrée to the community
- HPTN processes can benefit from their experience with communities
- A desire to work with existing organizational structures helps establish trust in the community
- Information may be available about stakeholders, informal organizational structures, community politics, and decision making processes

Just as with any organization, the HPTN sites included, there may be limitations in working with NGOs if they work in isolation, communicate or coordinate little with other organizations and groups. Keep in mind if they are confined to a small focus as they may provide information and experience on a limited scale.

D. Work Toward Community Mobilization

As mentioned previously, extensive support of social change processes at an HPTN site may be beyond the scope of the site's HPTN scope, but opportunities to encourage communities to empowerment should be a key part of developing a trusting relationship. Community mobilization is an effort that can unify a community around a particular issue, and if adequately sustained can create long-term effects on HIV prevention. This far exceeds the focus of the HPTN's research efforts, but working with communities to solve their own health concerns is key in developing a true collaborative partnership in HIV prevention research.

Community building provides an important foundation for community mobilization. The goal of community building is to develop people's awareness that they are a part of a community. It may include activities such as: going home to home, community events or gatherings, news stories, flyers, small media with explicit messages, outreach to places identified by community members, and follow-up after initial contact.

Community mobilization is a process of social action in which people of a community:

- Get organized to make plans and get something done
- Define the goal they have as individuals and for their community
- Make group and individual plans to deal with their problems and build on their strengths
- Accomplish their goal, relying mostly on resources in their own community
- When needed, getting services, materials, and resources from agencies outside of their own community

What is Community Mobilization?

(excerpt from the UNAIDS technical Update, *Community mobilization and AIDS*, April 1997)

A community becomes mobilized when a particular group of people becomes aware of a shared concern or common need, and decides together to take action in order to create shared benefits. This action may be helped by the participation of an external facilitator – either a person or another organization. However, momentum for continued mobilization must come from within the concerned group or it will not be sustained over time.

Community mobilization gets people actively involved in looking at the issues in their own community and deciding on what seems like the best way to deal with these issues. The purpose is to increase awareness and interest in HIV prevention research to improve how these efforts actually prevent HIV. To do this, community mobilization encourages people and organizations within the community to connect with each other, and to connect with others outside the community, to do what they can to prevent HIV.

Although beyond the scope of the HPTU's involvement with the community, the HPTN efforts are strongly encouraged to collaborate with community mobilization efforts that are related and support the proposed HIV prevention research.

IV. COMMUNITY ADVISORY MECHANISMS

Community advisory processes are built into HPTN through organizational channels that -- when fully integrated into the process -- will provide input from the community on all levels of the HIV prevention research process.

- The base of our community advisory processes comes from the sites where the community and the site create their working relationship of identifying needs, developing plans, securing resources, and conducting training to prepare for prevention research activities.
- In creating the Network research agendas, community advisors participate as members of the Science Working Groups and the Protocol Development Teams.
- On the Network level, community advisors are part of multiple committees including the Executive Committee, Network Evaluation Committee, Protocol Review Committee, and the Ethics Committee.
- Helping to coordinate and support community advisory and participation activities throughout the network are the Community Working Group and the CORE Community Program Staff.

Together, these elements are designed to ensure community voices are heard and are a part of the decision making process regarding HIV prevention research throughout the Network.

A. HPTU Support of Community Advisory Process

The goal of all HPTUs regarding their community participation is to create a process that effectively supports community members to voice their opinions, suggestions and concerns about the HIV prevention research in a way they know they are being heard and their issues are being addressed. A common way to do this is for the site to work toward the development of a Community Advisory Board (CAB) where a group of stakeholders of the local HIV prevention research effort participate in a process to advise the site on key research issues.

CABs have been proven in the United States to be an effective way to organize and guarantee community participation in research efforts, however the HPTN recognizes there is diversity of needs and abilities throughout the Network. Although committed to the CAB model, the CORE Community Program is responsive to suggestions of alternative methods. The

endpoint of any site advisory process is to guarantee appropriate communities are engaged, informed and active in the HIV prevention research process however the process is created and implemented on the local level.

But consider a CAB!

B. Guiding Principles for Community Advisory Participation

Some key principles often used in HIV prevention planning have application when working to convene communities who will be collaborative advisory partners in HIV prevention research: They are inclusiveness, representation, and parity.

- ***Inclusiveness***: Assurance that all community members affected by the HIV prevention research are represented in the community participation process.
Key questions: Are all stakeholders involved? Has adequate effort been expended in identifying the critical perspectives that need to be included?
- ***Representation***: Assurance that those who are representing a specific group within a community truly reflect their values, norms and behaviors.
Key questions: Do participating community members understand and adequately represent the community and perspectives for which they were chosen? Are the participants informed about their community's needs?
- ***Parity***: The condition whereby all members of the community participation process have equal opportunity and capacity to provide input and to participate, as well as an equal voice in decision-making activities and self-direction of their participation process.
Key questions: Are all participants adequately prepared to participate fully? Is each member well versed and comfortable with group decision-making processes? Are all members able to attend meetings on a regular basis? Do all participants understand HIV prevention research and unique community perspectives on the research?

For a more thorough discussion of these principles, look to Chapter One of the *Handbook for HIV Prevention Community Planning* (AED, 1994).

C. Identifying Advisory Partners

Identifying the appropriate partners in community relationships is of critical importance, and energy must be invested to ensure optimal community representation. The site's efforts to identify stakeholders will be the mechanism in developing a formalized community advisory process. The participation of marginalized groups within the research population is an important part of this, particularly when they are among the most affected by the research question.

Whenever possible, widening the established discussion, and decision-making mechanisms of the community to accommodate stigmatized or marginalized study populations should be tried first. In some cases, reserving seats for them in structured community advisory processes may be all that is needed for them to participate fully.

In other cases, special efforts such as focus groups, support group presentations, or street outreach

"Advisors" and "Doers" – a Difference of Approach

Often people attracted to working with community concerns are there to **do something** about the issue. HPTN sites are looking for people to advise them on the community issues and concerns that is planning or advisory in nature. The site Community Educator has the task of balancing these two needs in a productive way. By supporting activities and education in the community, "Doers" may feel more comfortable participating in planning and advisory activities as long as there something is being done beyond talking about the issues.

surveys may be necessary to help people to voice their concerns in a setting that feels safe and supportive. The opinions in information brought out by these discussions can then be communicated to the larger community. Sites at any level of community readiness can use these methods of gathering community opinions and providing education. Inclusion of the varied community voices affected by the research efforts is needed to set up a truly representative community advisory mechanism at the HPTU.

For sites that do not have formal CABs, these tools provide a way of exchanging information between the community and the site in a way that can be documented and presented where appropriate in the HPTN processes. For sites that CABs in place, conducting focus group discussions or street surveying can provide timely information from special populations in their community who may not be represented at the CAB. An added level of complexity for these activities is when the CAB identifies the need for targeted input and education and works with the staff to implement, evaluate, and disseminate the information.

D. Expectations of Community Advisors

In order to establish truly representative community advisory mechanisms, it is expected that the advisory members will:

- Provide to investigators informed commentary regarding: study protocols including documents related to the informed consent process, informational and educational materials, recruitment and retention of research participants
- Collect and make available to study staff and to the HPTN information that can be used to address concerns likely to arise during research trials
- Support in the community judicious recruitment efforts, promote referral arrangements for participants in prevention intervention trials, and support ethical processes for retention and identifying participants lost to follow-up
- Address issues of discrimination and stigma that are related to the type of research study at the site
- Address issues of social aversion to HIV prevention measures, particularly within marginalized populations
- Voice community concerns or issues related to proposed and ongoing studies
- Provide recommendations regarding planning, review, and evaluation of the study objectives and implementation

E. Community Advisory Structures

The success of the HPTN's research mission depends upon active participation by the communities involved in the studies. Including community members at all levels of the research process helps build trust and mutual understanding of research issues and ensures that values and cultural differences among participants are respected. Creating and supporting a community advisory process with an established structure is the foundation for creating a solid, collaborative relationship between the community and the HPTU.

The HPTUs will be at different levels in their process regarding the HPTN research and community relationships, so it may not be appropriate for a site to create a fully functioning CAB at the present time. A site might be getting ready for a preparedness study that has little requirement for community input, so a small group of indirect stakeholders (NGO staff, concerned citizens, representatives of future research communities) who organize regular community street surveys to provide information and get community feedback on specific science issues. At the other end of the spectrum, a site may be engaged in multiple research

projects and the community decided that supporting sub-CABs representing specific communities were needed was needed to advise on HPTN studies with the one main CAB managing all the community research issues being conducted in the community.

From whatever starting point, a system must be established and maintained where the communities involved are getting information, offering their opinions on the research, making decisions about research issues that affect them, and having impact on the research process and their involvement in it.

If an HPTU believes an alternative advisory structure is needed instead of a CAB, alternative methods for gathering input from the community must be guaranteed. The alternative method must adequately support that a process of information exchange is in place to gather information important to the research community while sharing study information with the participating community. Different systems could be put in place to guarantee adequate and timely information exchange between the community and the site.

Before alternative methods for CABs are developed, please consult the HPTN CORE Community Program Managers!

- No CAB with central formalized system of assessing affected community communication (focus groups, street outreach surveys, work with existing support groups)
- CAB with indirect stakeholders and a system of communication with affected communities (focus groups, street outreach surveys, work with exiting support groups, an town meetings)
- Site CAB with direct and indirect stakeholders
- Site CAB with direct stakeholders only
- Multi-study CAB with formalized system of communication with affected communities (sub-CABs)

Although alternative advisory mechanisms can be implemented, an active CAB with a committed membership is an integral element in the effort to prevention HIV. CABs can also help strengthen local capacity to respond to critical research needs in the future.

G. Participation in Science and Protocol Development

In addition to the community advising the site, there is a need for site community members to participate in the development of the Network's scientific agenda. This can be done in two ways by participating as a Community Representative on one of the Science Working Groups (SWG) or on a protocol team.

- Science Working Group Representative: (Antiretroviral Therapies, Behavioral Science, Microbicides, Perinatal Science, Sexually Transmitted Diseases Control, and Substance Use Science). There are two community representatives on each of the science working groups, one from an international site and one from the U.S. Representatives will participate in conference calls and meetings to develop the scientific agenda for the SWG and identify important concepts to be developed for approval as a protocol. Participation in the SWG requires a basic understanding of HIV prevention research, and experience in an actual study would be helpful. The Representative will need to review research concepts and assess them on their

- experiences, but make comments based on broader community issues and concerns that may be beyond their own experiences.
- Site Community Protocol Team Representative: There will be one community representative from each site on every protocol team in order to act as a conduit for information about the study to the community advisory members as well as present community issues, concerns and questions to the protocol team. To help support the community representative in the process, the site Principal Investigator (PI) or Study Coordinator who is representing the site on the protocol team will work with the community representative in partnership. The Community Educator will help facilitate the information sharing between site, protocol team, and community by working with the Community Representative. Representatives will participate in conference calls and meetings to develop the protocol and ensure community input is incorporated into the final product. Participation on a protocol team requires a basic understanding of how research is conducted (although the PI/Study Coordinator can mentor the representative), the ability to share information with their community advisors and present information on calls and at meetings that accurately reflect the site specific concerns, issues and questions. The Representative will need to review the protocol and assess the impact of the protocol specifically on the site's community.

As community representatives become a part of the science and protocol development processes, the site Community Educator needs to help ensure the advisory participants:

- Have been adequately prepared and trained to provide feedback and suggestions on research methods
- Appreciate the implications of different forms of research that can be done in their communities
- Understand how ethics are a part of the research process
- Are able to freely advise the staff on how to ensure the protection of research subjects and their community
- Develop a sense of autonomy in their advisory process.
- Have access to the resources necessary to participate fully in the science review process
- Have open access to the site PI/Study Coordinator so they can work together in their participation

The HPTN CORE Community Program staffs is available for advising the sites and community advisory groups on creating a supportive environment for community participation as well as provide training and other technical assistance.

F. Community Participation in Trial Participant Recruitment and Retention

Recruitment and retention of participants in a research trial is an important issue to the success of the research. If community members do not want to participate, then the study cannot be conducted. If a prevention trial requires more than one visit over time, participants who do not show up for a scheduled visit make it more difficult to answer the research question. Obviously, if community members are not going to participate then there is no research trial. Community advisors certainly have an important role in reviewing site recruitment and retention plans to make sure they are culturally appropriate, ethical, and have the opportunity for success.

It is advised that Community Educators should not routinely take part in direct recruitment activities. Rather, they conduct community education activities as well as consult with the site staff dedicated to recruitment activities on their approach, techniques, materials, etc. The reason for this is to protect the integrity of the education and research efforts as well as remove any possible doubts of conflict of interest. There should be no doubt in the minds of community members when they talk with a Community Educator that they will receive information without any strings attached. By keeping the two roles distinct, the staff dedicated to recruitment is able to focus solely on the tasks associated with identifying interested individuals.

The role of Community Advisory Members is similar to the Community Educator's role. Even if a site's Community Advisory Members agree completely with the trial, it is better to maintain some distance between community advisory information gathering and the site's recruitment and retention efforts. There are, however, some appropriate instances when advisory members may volunteer to advocate for recruitment along with study staff. If this is done, all parties involved should consider carefully the implications of the advisory members supporting recruitment and efforts to retain participants.

H. Guidance for CAB Development and Maintenance

Developing and sustaining a Community Advisory Board has provided documented results in ensuring community participation in various types of HIV research. Although not the only way, CABs are the best documented method for research sites to build community participation into their research. As different ways are identified and documented for community input, additional guidance will be developed. Below are

➤ **Function of the CAB**

CABs are responsible for evaluating the impact of HPTN studies on local communities. They serve as a voice for the community and study participants. CABs bring specific, unique expertise to the research process, informing researchers of local issues or concerns that can affect the conduct and successful implementation of the scientific agenda. Each HPTN research site will be linked with and support an active CAB.

CAB members may contribute professional or personal experience. CABs provide advice on scientific and ethical issues regarding study design, recruitment and protection of study volunteers. Each CAB will develop their own mission statement and operating guidelines.

➤ **Responsibilities of CAB members**

- Attend local CAB meetings and provide feedback on issues under discussion.
- Voice concerns from the communities and study participants.
- Demonstrate commitment to developing an understanding on issues where they may have little expertise; attend workshops.
- Participate on HPTN scientific working groups and community working group.
- Assist in the development and implementation of community education activities (health fairs, community forums, media interviews, etc.).
- Advise the HPTN protocol team in the development of informed consent and other study related documents.

- Advise in the development and implementation of recruitment and retention strategies.
 - Provide real-life experiences.
 - Serve as a resource to community liaison officer and research team.
 - Disseminate study information to local community.
 - Recruit and orient new CAB members.
 - Advise the HPTU on necessary budget items needed to support community participation in the local HIV prevention research efforts
- **Responsibilities of the Site CAB Community Educator**
- Plan and coordinate CAB meetings.
 - Ensure that information is shared between the CAB, research study staff and working groups.
 - Assemble educational materials and handling administrative duties (i.e. minutes).
 - Coordinate regular educational opportunities for CAB members to update their knowledge.
 - Work with the current CAB to identify and recruit new members.
 - Maintain contact with other CAB liaisons at other sites.
 - Recruit and orient new CAB members.
 - Coordinate the submission of an annual budget for community participation.
- **Suggested CAB operating guidelines**
- The total membership should not exceed 20.
 - All members will have an equal voice and equal opportunity to express their opinions
 - Membership is open to all members of the community who successfully complete a CAB orientation.
 - A CAB should have at least half of the membership regularly participate in CAB activities to be considered "active."
 - A CAB member is considered non-active if he/she is absent from three meetings without contacting the CAB liaison.
- **How to build and maintain a successful CAB**
- Competent and committed site Community Educator.
 - Active participation and visibility of principal investigator (PI) and/or other senior HPTN staff in CAB meetings and activities.
 - Timely orientation of new members.
 - Clearly stated purpose for CAB involvement.
 - Inclusion of CAB members in development of HPTN research plans.
 - Provision of regular training and technical assistance to all CAB members.
 - Clearly stated standards, procedures.
 - Agreed upon norms and decision-making rules of conduct for the group.
 - Provision of administrative assistance.
 - Establish means of communication with CAB members.
 - Provision of transportation to meetings, conferences, workshops, if needed.
 - Skilled facilitation of regular meetings.
 - Provision of refreshments.

I. Network Community Representation

Beyond the local community participatory process, there are opportunities for community participation to occur with the network itself. Community representatives from the sites can provide valuable insight for the larger objectives of the science agenda, HIV prevention research ethics, and evaluation.

Presently there are community representatives on the following committees.

What sites can do to prepare community members to participate in the Network.

The **Prevention Leadership Group (PLG)** is responsible for operational decision-making and management of the Network. Representatives of the three leadership group organizations and Division of AIDS (DAIDS) serve on this committee.

The **Network Evaluation Committee (NEC)** tracks and reviews annually the functional, fiscal, and managerial performance of the Network, the Leadership Group, and the individual HPTUs.

Ethics Working Group (EWG)

V. SOURCE MATERIALS SUPPORTING THIS DOCUMENT

Many sources of materials and experiences went into the development of this guidance and were compiled by Wayne Wilson and Stella Kirkendale for the HIV Prevention Trials Network, Family Health International – www.hptn.org.

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3. *Ethical Considerations in HIV Preventive Vaccine Research*, UNAIDS Guidance Document, 1997
4. *Handbook for HIV Prevention Community Planning*, Academy for Educational Development, 1994
5. *HIV Prevention Trials Network Leadership Group – RFA AI-98-015*, National Institutes of Health
6. *HVTN Standard Operating Procedures*, HIV Vaccine Trial Network
7. *World Bank Participation Sourcebook*, World Bank, 1996