

# **HPTN Approach to Ensuring Community Involvement in Research HPTN Year One**

Community participation and collaboration are cornerstones of all effective public health action. Similarly, clinical trials of HIV and other prevention interventions are most likely to succeed if community members are involved from the inception in discussions of prevention research priorities, including but not limited to, protocol design, recruitment and follow-up plans, determining appropriate incentives for trial volunteers, informed consent issues, risk-reduction interventions, outreach to the community at large, and dissemination of research findings. Sustained relationships with the community are also important to foster trust; to ensure respect of social, cultural and political realities of the communities where the research will be conducted; and to maximize the opportunities for ongoing exchange of ideas and information. Active and informed community participation in HPTN research also lessens the potential for conflict between researchers and community.

An essential first step in developing genuine community participation is to define “community”, a fundamentally fluid concept. Community may be used to describe a geographic, functional or socio-cultural entity. Characteristics may include shared interests, values, experiences, common fate or cultural affinity. In the context of research, “community” can be clarified in terms of those whose participation is necessary for the implementation of the research and whose well-being is likely to be affected by the research. Key questions need to be addressed, such as who speaks for the community, whose voices need to be heard on the Community Advisory Boards (CABs), what is the CABs role in the research process?

The following framework of recommendations for community education and participation in the HPTN incorporates elements from the guidance document for the establishment of best practices developed by the HIVNET/AVEG transition team. It also recognizes the diversity and uniqueness among HIV Prevention Trial Units (HPTUs) – U.S. and international sites, and makes provision for site-specific planning and adaptation of the proposed principles.

## **1) Establishment of Community Advisory Boards**

Each HPTU will establish, support, maintain and monitor community participation through a community advisory board (CAB). Members may include but are not limited to representatives from the study population, prevention advocates, representatives of grassroots organizations, citizens, health care professionals, religious leaders and researchers. At international sites, representatives may also be drawn from indigenous non-governmental organizations (NGOs) and other community organizations, as appropriate. The HPTN will build on the experience of the domestic and international HIVNET sites and work with each HPTU to establish an effective, representative community advisory group to function in partnership with the research team. CAB member recruitment should be viewed as an ongoing process, wherein new members are added over time as attrition occurs.

### **Roles and Responsibilities of Community Advisory Boards:**

- Formulate recommendations and strategies regarding the HPTN scientific agenda
- Assess community impact and assure that community concerns are considered
- Serve as a voice for the communities and study participants
- Participate on HPTN scientific working groups and community working group

- Assist in the development and implementation of community education activities (community meetings and forums, workshops, health fairs, etc.)
- Advise protocol teams in the development of informed consent and other study related documents
- Advise in the development and implementation of recruitment and retention strategies.
- Provide input from real-life experience
- Serve as a resource to community liaison officer / community educator and research team
- Disseminate study information to the local communities
- Recruit and orient new CAB members

Each study site will designate a paid staff employee to serve as the liaison to the CAB. The most logical person to serve as the CAB liaison is the HPTU community educator.

**Structures for building and maintaining successful CABs** will be put in place within three months. Each HPTU will need to have in place appropriate support and operational structures to nurture a fully functioning CAB. This includes:

- Clearly articulated mission statement, bylaws and goals
- CAB member orientation and background materials
- PI involvement
- Parity, inclusion and representation (PIR) to reflect study community
- Training and technical assistance
- Good facilitation
- Logistics: monthly meetings organized correspondence, transportation assistance, refreshments, and comfortable meeting space.

### **Recommendations:**

Facilitate the institutionalization of **regular CAB/PI question and answer sessions** at each HPTU. As an advisory group, the CAB's role is defined by the amount of leverage the leadership team assigns to the group. This leverage will in turn impact the attractiveness of the CAB to potential and current members. CABs have expressed that the PI's involvement and responsiveness to CAB concerns acknowledges the value and significance of community input.

CORE community program staff will work with CABs to identify external funding **opportunities** to send the CAB liaison to additional meetings and conferences, which in turn builds local capacity. Resources need to be adequate to support the activities and infrastructure necessary to build and sustain the community-research partnership.

### **Community Representation in the HPTN**

As a research network, HPTN will be organized and governed by policies and procedures, with scientific and ethical review and decision-making at various levels. In addition to serving on CABs, community representatives will help shape the research agenda by actively participating at each organizational level of the HPTN as follows:

### **HPTN Community Working Group (CWG)**

The HPTN structure for community involvement will differ from HIVNET insofar that the global Community Working Group (CWG) will be the leadership voice for community issues within the HPTN research agenda. The membership will not exceed 20, and will be comprised of five to six ex officio members – including the CORE community program

officers, the Executive Committee liaison, an international and U.S. principal investigator, a social scientist, and nine to ten HPTU site representatives, who will each serve a two year term and then rotate off. The majority of the group will be comprised of community representatives at all times. The mix of representatives from U.S. and international sites will be proportional to the number of sites.

The group will remain small to allow interaction and participation of all members. The CWG's responsibilities include:

- To refine and shape the overall HPTN community involvement plan.
- To promote information exchange among the six scientific working groups, the EC and the HPTU CABs.
- To inform and advise the EC on emerging issues of concern.
- To provide leadership to HPTU community staff in addressing issues that cross-cut the culturally diverse populations, communities and technical areas that form the focus of HPTN research, including ethics.
- To share ideas for establishing successful community involvement programs at the site level and to assist the CORE in the training of investigators.
- To promote and develop research relevant to improving community involvement in the HPTN research agenda.
- In its role as an advisory body, the CWG's global focus will include site accountability, technical assistance, training and linkage with the scientific working groups. The CWG will work with CORE community program staff to develop a plan for monitoring and evaluation of the community involvement strategies at the site and network levels.

A routine schedule for communication via conference call will be established. In addition, the CWG will meet face-to-face at least twice a year, either in conjunction with other scheduled HPTN meetings or as a stand-alone meeting. CORE staff will coordinate CWG meetings and conference calls.

### **Science Working Groups (SWGs)**

In addition, two community representatives will be selected to serve on each of the six HPTN science working groups (SWGs). The six working groups are microbicides, behavioral, perinatal, STD control, antiretrovirals (ART), and substance use. The CWG and HPTU CABs will work together to identify members, with some SWGs more actively involved in naming their own members. Selection will be based on prospective members' individual backgrounds and include prevention advocates, NGO staff, people living with HIV disease, people who represent the study populations and researchers. This is important, as these categories are frequently not mutually exclusive. The commitment of community representatives to the SWGs is analogous to that of the CWG delineated above, and will average four hours per month, with two face-to-face meetings per year. All SWG community members will represent HPTU sites. Science working groups which span both international and U.S. studies will appoint one community representative each; community members from those SWGs most likely to have solely U.S. participation or solely international (i.e. perinatal) will reflect existing sites.

### **The HPTN Executive Committee (EC)**

Finally, two additional community representatives (non-voting) will be invited to join the HPTN Executive Committee (EC) - one U.S. and one international, to serve a two-year term, in addition to the voting EC liaison. Mechanisms to improve communication across HPTU

sites will need to be formalized and enhanced – resulting in a “virtual CAB.” Methods such as electronic newsletters and listserves, an international CAB directory, distribution of minutes from CWG and SWG meetings, and exchange of site updates will be employed and evaluated. An additional opportunity for CWG members and SWG community representatives to network and gain new skills is the annual HPTN face-to-face meetings, which is funded through the CORE budget.

## **2) Community Education / Relations**

An effective infrastructure for a comprehensive community education initiative will be developed and implemented at the HPTU site and HPTN network-wide level. Educational plans will be based on locally conducted needs assessments, and will include the development of culturally and linguistically appropriate educational and informational materials. CORE staff and HPTU CAB members will begin working with HPTU site coordinators and community program coordinators to plan and develop the community involvement strategy for their site. HPTU CABS in the U.S. will link with CDC – supported HIV Prevention community planning groups, where available, whose mandate includes community HIV prevention needs assessment. International sites will partner with indigenous NGOs and other potential collaborating projects.

Educational efforts will target the broader community, site and research staff, and trial participants. A HPTN community educators group (CEG) will be created to discuss roles, workplans, local challenges, training needs, communications, etc. by monthly conference call and email. Skills building needs of community educators and other staff involved in community education will be assessed soon after HPTUs are selected and educators have come on board. Regional workshops will be conducted annually to provide training in needs assessment plans, community workplans, participatory research, presentation skills, media relations and to lay the groundwork for and maintain a strong community educators network. The CORE community program staff will provide site-specific technical assistance, as well as develop linkages across sites.

### **The Needs Assessment Process**

Community members and HPTU site staff can play a valuable role in helping determine the scope and focus for a community-relevant community profile, particularly as a well-conducted assessment is necessary to guide resource allocation and policy decisions.

Key questions that should be addressed include

- What questions does the community have about the proposed research?
- What planned information collection approaches are appropriate? (i.e. focus groups, community meetings, individual interviews)
- What are the “bottom line” information requirements for this needs assessment?
- What existing (secondary) data can be used and what new information must be obtained?

#### **a) Community needs assessment**

A comprehensive needs assessment that uses both qualitative and quantitative techniques can yield valuable information about attitudes, beliefs and norms regarding sexual practices and condom use in target communities, specific issues or problems communities are facing, as well as information about the adequacy of existing health services. It will be important to obtain an understanding of social, political, economic and other structural

factors that can impede or support behavioral change.

**b) An epidemiological profile / secondary data collection**

Instrumental in conducting a profile of community needs is an assessment of country-specific available disease surveillance data on HIV/STD prevalence and transmission rates. Multiple data sources should be included, such as available behavioral data and surrogate indicators of HIV risk behaviors, such as other STD rates, fertility rates, etc. Utilization of WHO, UNDP, UNAIDS and other publications may provide good summary information about health, economic and social indicators at the developing country national level.

**Collaboration and Partnership Development**

In addition, it will be imperative for HPTUs to conduct **resource inventories** of local current HIV prevention efforts and activities. For example, in the U.S. it will be important to forge linkages with local CDC HIV community planning groups, whose mandate includes resource inventory; at international sites engagement of NGOs and other organizations, such as faith or school based initiatives will provide important information. This process is also essential to the identification of potential partners among community-based organizations that are known and respected within target communities. Particularly when studies seek to recruit from “hard to reach” and vulnerable populations, credibility can be achieved more readily when strong and interdisciplinary collaborations with organizations that have the community’s trust are forged. Resource inventories can answer some of the following questions:

- What interventions are being conducted, by whom, to reach what population?
- What interventions have been tried in the past that worked well / did not work well?
- What barriers to conducting interventions have been experienced?
- Are services available in adequate quantities – i.e. condoms, treatment for STDs?

**In addition, it will be important to know**

- What other information sources and networks, such as media outlets, do people turn to for information on HIV/AIDS?
- What technical assistance needs have been identified?

Once completed, the needs assessment becomes the substantive foundation for community education priorities. A central goal of community collaboration is the issue of community investment in research – how will the research benefit the community? This process of engagement will differ across communities and studies, and goes beyond delivery of objectives and data to communities. Attention to process and inclusion will be key to a successful and genuine partnership between researchers, government and non-government entities and community members, at all levels of the research agenda and operations of the network.

Collaborative relationships among other national, federal and international agencies such as NIH, CDC, NMAC, UNAIDS, and the HVTN will be encouraged and facilitated, with the ultimate goal of fostering support and awareness of the HPTN research agenda. It will also be important to identify key in-country public and nongovernmental agencies and referral groups to build sustainability of interventions beyond the life of the trial.

### **Training HPTU CAB Members, Research and Community Program Staff**

At the first annual HPTN-wide meeting, during the October 23-25, 2000 EC meeting, CORE staff and CWG members will organize an interactive community involvement session to include HPTU investigators, site coordinators, HPTU community program coordinators and CORE community program staff. This will provide an opportunity to underscore the importance of community involvement in all aspects of HPTN research and to share and seek input on the overall HPTN community involvement plan. It is critical that both researchers and community representatives understand and appreciate the nature and importance of their respective contributions to the successful development and evaluation of HIV prevention interventions. At this workshop, CORE staff and CWG members will provide information and materials on various approaches and key principles for ensuring successful community involvement in research and encourage the open exchange of ideas and concerns among all participants.

### **3) Materials Development / Dissemination**

Culturally and linguistically competent targeted educational materials will be developed and disseminated on the HPTN and HPTU site levels. Materials at the network level might include study-specific fact sheets and brochures, an HPTN informational package, and templates on clinical trial research, informed consent and other concerns related to participation. Training, needs assessment, and presentation materials development for community education purposes at the Network level will be ongoing. This includes development of a CAB orientation manual. In addition, the CORE community program staff will maintain a clearinghouse of educational materials, develop and distribute an electronic newsletter and, with input from HPTUs and the CWG, put together a site monitoring plan and checklist for the community program.

Another key communications method being developed, and which sites will be encouraged to contribute towards, is the HPTN webpage. A community education page will serve as a centralized repository for information, updates, and links to other HIV/AIDS prevention education and research sites.

HPTUs will have funds budgeted for site-specific educational materials. Materials will be developed in collaboration with local CABs which will provide accurate education of potential trial participants and the broader community about the process and technical aspects of the local research agenda, as well as general materials based on local community assessments. All materials will be reviewed, which includes translation and back-translation where appropriate, and pre-tested by community members to ensure acceptability and appropriateness prior to dissemination.

### **4) Protection of Human Subjects**

Protection of research subjects against physical, social and ethical harms is a major concern in clinical research. To build trust, communities need to experience direct benefit from their relationships with researchers and to know that accountability exists. The Office for Human Research Protection (OHRP, formerly OPRR), National Institutes of Health provides oversight, advice and safeguards for volunteers participating in federally funded research. OHRP certifies Institutional Review Boards (IRBs); interdisciplinary ethical review committees of proposed research plans.

The HPTN has also established a small ethics subcommittee, which is developing an ethical framework for the network. This document will incorporate universal ethical principles from

the Declaration of Helsinki, the Council for International Organizations of Medical Sciences (CIOMS) and UNAIDS guidance documents. The possibility of social harm resulting from research will be explicitly considered and guidelines developed on how to apply the concept of “do no harm” on a site and community-wide level. A commitment to ongoing and open dialogue about issues related to informed consent (and ongoing assessment thereof), standard of care, management of research-related harm incidents, incentives vs. inducements, etc. exists, and constitutes a priority for the HPTN Executive Committee. Mechanisms for identifying, reporting and resolving research harms will vary by country. Local ethics committees and CABs are responsible for reviewing and monitoring protocols proactively, to ensure maximum protection of study participants.

## **5) Media Relations**

A comprehensive and well thought out strategy for media relations at all levels is critical for the successful operations of the HPTN. This serves a two-fold purpose: to communicate accurate and timely information about research conducted to the public, and to pre-empt public circulation of misinformation about volatile issues in the media. Success in conducting this type of research requires a certain degree of public confidence and trust. Therefore, sites conducting research should take the steps necessary to identify, manage and resolve unforeseen issues that may impact public confidence in the site. Frequent bi-directional communication with study volunteers, their advocates and the community at large about the status of research is consistent with a commitment to genuine participatory research. In addition, the following recommendations can be made to support a state of readiness with respect to media relations and issues management:

- Conduct an organizational assessment of capacity to respond to issues (staff, resources, internal and external relationships)
- Invite a media representative to join the CAB
- Invite media to events and workshops
- Sponsor a media event
- Provide the media with a list of qualified spokespeople who can communicate information about the trials and conversely, maintain a list of media representatives who want regular information
- Provide a regular flow of information to the media in language and format that is appropriate (i.e. fact sheets, updates)
- Include information about other relevant HPTN protocols to provide a context
- Follow up by researchers and/or community leaders as appropriate to correct misinformation
- Consider alternative methods of communication such as paid media, letters to the editor, press releases and community forums, radio interviews

Recognition of the media as an integral partner in the community education process is a key component of strategic planning for community involvement.

## **6) Evaluation**

Monitoring and evaluation objectives that determine how well the project is achieving its goals and objectives comprise an integral part of program design. Indicators relevant to evaluation of overall HPTN community participation and CORE support function include

- Evidence that a CAB has been formed and has prepared a mission statement and bylaws;
- Preparation and at least annual review of a CAB recruitment and retention plan;

- A calendar of CAB meetings showing evidence of periodic meetings with attendance consistent with the meeting schedule and quorum requirements established in the CAB bylaws;
- Evidence that CAB meetings or other activities include education of CAB members in scientific issues related to the mission of the HPTN (prevention intervention concepts, clinical trial design issues);
- Evidence of a formal feedback mechanism to obtain input from CAB members on the content and quality of community participation at a local level, including CAB operations
- Participation of CAB members at HPTN-wide annual meetings and meetings of working groups and committees of which they are members;
- Summary data from logs of community education activities organized in categories consistent with the HPTU community education plan established in consultation with CORE community program staff;
- Consistency of participation by community working group representatives;
- Adherence to the publication schedule of CAB page in the HPTN newsletter;
- Consistency of participation on other community-related network-wide committees;
- Feedback from other HPTU staff, PIs, etc.

HPTUs will include both process and outcome objectives in their community education plans. Process objectives report what was done to implement the program, and are measured with concrete indicators:

- Number of people attending \_\_\_\_ many educational sessions / CAB meetings
- Number of professional contacts made