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Project Accept Standard Operating Procedures Manual: Community Preparedness and Involvement

Table of Contents

I. Introduction ........................................................................................................................................ 5
   A. Definition of Terms .................................................................................................................... 5
   B. Overall Goal of Community Preparedness and Involvement for NIMH Project Accept ....... 5
   C. Overview of Community Preparedness and Involvement Structure ..................................... 6
   D. Working with the Community Preparation and Involvement Subcommittee ....................... 7
   E. Benchmarks and Timelines ...................................................................................................... 8
   F. How to Use this Manual .......................................................................................................... 8
II. Paving the Way: Introducing the Study to National, Provincial, District, and Community Level 8
   Stakeholders .................................................................................................................................. 8
      A. Stakeholder Inventory and Diagrams .................................................................................... 9
      B. Creating Promotional Materials ......................................................................................... 10
      C. Explaining the Study ............................................................................................................ 10
         1. Explaining the Trial Design .............................................................................................. 10
         2. Explaining the Community-based VCT Intervention ......................................................... 12
      D. Creating the External Advisory Committee ....................................................................... 13
III. First Impressions: Getting Started in the Study Communities ................................................ 13
      A. Initial Visits ......................................................................................................................... 14
      B. Getting to Know the Communities ..................................................................................... 14
IV. Building the Community Advisory Structures ........................................................................ 15
    A. Establishing and Maintaining the Community Working Groups (CWGs) ......................... 16
       1. Purpose of the CWG ........................................................................................................... 16
       2. Roles of the CWG .............................................................................................................. 16
       3. CWG Constitution .............................................................................................................. 17
       4. CWG Membership ............................................................................................................. 17
       5. Training the CWGs ............................................................................................................ 17
       6. Maintaining the CWGs ..................................................................................................... 18
    B. Establishing and Maintaining the Study Advisory Committee (SAC) ................................. 19
       1. Purpose of the SAC ........................................................................................................... 19
       2. Roles of the SAC .............................................................................................................. 19
       3. SAC Constitution and Membership .................................................................................. 19
       4. Training the SAC ............................................................................................................. 19
       5. Maintenance of the SAC ................................................................................................. 20
V. Preparing the Communities for the Start of the Study ................................................................. 20
VI. Maintaining Community Involvement ........................................................................................ 22
    A. Creating Workplans .............................................................................................................. 24
    B. Detailed Reports of Activities ............................................................................................... 25
    C. Summary Quarterly Reports ................................................................................................. 25
APPENDIX A .................................................................................................................................... 27
APPENDIX B .................................................................................................................................... 28
APPENDIX C .................................................................................................................................... 32
APPENDIX D .................................................................................................................................... 33
APPENDIX E .................................................................................................................................... 34
APPENDIX F .................................................................................................................................... 35
I. Introduction

The purpose of this manual is to provide a guiding framework for conducting community preparedness and involvement activities for NIMH Project Accept. Project Accept will be conducted internationally at five sites.¹ This manual sets out guiding principles and procedures in order to ensure that all sites of the study achieve a uniformly high standard of community preparedness and involvement that is consistent with international and U.S. Federal guidelines. The guidelines and procedures presented in this manual are adaptations of those developed for and currently used by the HIV Prevention Trials Network (HPTN).²

A. Definition of Terms

What is community involvement?
Community involvement is a process through which communities influence and share responsibility and control over research initiatives and the decisions and resources that affect them. It is a process that begins before the research commences (see “community preparedness” below) and continues through the completion of the research.

What is community preparedness?
Community preparedness is the stage of the community involvement process when researchers gain entry into study communities, establish rapport, and prepare community members to participate as partners in the research activities.

Who are primary stakeholders?
Primary stakeholders are those people or organizations directly affected by the outcome of Project Accept (negatively or positively) and who can affect the outcome of the proposed research in their communities.

Who are secondary stakeholders?
Secondary stakeholders are individuals and organizations that are not directly affected by Project Accept, but are interested or who are invested in the outcome of the project. Such stakeholders may include representatives from large nongovernmental organizations (NGOs), the private sector, political structures, and local authorities.

B. Overall Goal of Community Preparedness and Involvement for Project Accept

Overall Goal: The overall goal of community preparedness and involvement is to build and maintain long-term collaborative partnerships between study communities and Project Accept researchers.

¹ 1) Chang Mai, Thailand 2) Dar es Salaam, Tanzania, 3) Mutoko, Zimbabwe, 3) Soweto, Johannesburg, South Africa and 5) Vulindlela, KwaZulu-Natal, South Africa
² The HPTN is a worldwide network of scientists collaboratively conducting a range of clinical and behavioral HIV prevention research studies under the auspices of the National Institutes of Health (NIH), which is part of the United States Department of Health and Human Services (for more information, visit http://www.hptn.org).
Why? These relationships will ensure the mutual support and trust that is critical in conducting research that is ethical, scientifically rigorous, and responsive to HIV prevention needs in the research communities.

How? It will be the role of the study staff to facilitate an effective system of sharing information between researchers and community members. Many cultural, economic, political, and educational barriers may prevent community members from having real input into HIV prevention activities or research in their communities. Without special efforts by the research staff and without specific procedures to address and overcome these barriers, the voices of community members will not be heard. This manual will describe the procedures Project Accept will use to establish and maintain effective community involvement in the research.

C. Overview of Community Preparedness and Involvement Structure
The community preparedness and involvement process will be based on a structure of 1) community advisory groups in each of the study communities, 2) an overarching study advisory committee for each site, 3) an external advisory committee for each site, 4) the members of the research team, most notably the Community Relations and Mobilization Coordinator and staff of outreach workers, and 5) the Community Preparedness and Involvement Subcommittee (see Appendix A for a diagram of the structure).

Community Working Groups (CWGs)
Each research community3 will establish a Community Working Group. The CWG will be made up of a range of primary stakeholders from the community who are residents of that community. Each of these groups will be the primary structure through which information will flow between the research team and members of the research communities.

Study Advisory Committee (SAC)
There will be one Study Advisory Committee for each site. The Study Advisory Committee will be made up of one or more representatives from each of the Community Working Groups. The Study Advisory Group will be the overall structure through which all study communities have opportunities to chart the progress of the study as a whole, network with each other, and report back to their CWGs.

External Advisory Committee (EAC)
The External Advisory Committee will be made up of secondary stakeholders who are not necessarily members of the study communities but who serve in positions of authority at the district, provincial, and national level and who can be instrumental in ensuring that the research is responsive to larger agendas. Should the intervention prove effective, members of this committee may also be instrumental in ensuring that the intervention is sustained in the research communities and scaled up nationally.

Study Staff
Each site will employ a Community Relations and Mobilization Coordinator and four outreach workers who will oversee the community preparation and involvement activities as well as the community mobilization element of the intervention. The Study Directors at each site will also

3 For all sites except Thailand, this will be 8 communities, each with its own CWG. For Thailand, this will be 14 communities, each with its own CWG.
play a pivotal role in supervising the Coordinator and assisting her/him to plan community preparedness and involvement activities and to represent the study effectively with community members and other stakeholders.

**Community Preparedness and Involvement Subcommittee**

The Subcommittee will take overall responsibility for establishing procedural guidelines and documenting the community preparation and involvement activities of Project Accept as a whole (see Section d below).

**D. Working with the Community Preparation and Involvement Subcommittee**

Project Accept has established a subcommittee to oversee and coordinate the community preparedness and involvement activities across all sites of the study. Committee members:

Katherine Fritz, PhD (Chair and contact person: fritzk@hivsa.com)
Janet Frohlich, DCur
Heidi Van Rooyen, MA
Precious Modiba, MSW
Vusi Lushaba
Simangele Zamisa
Nokulunga Thabethe
Agnès Fiamma, MIPH
Greg Szekeres
Suwat Chariyalertsak, MD, DrPH
Surinda Kawichai, PhD, MSc
Alfred Chingono, MSc
Tserayi Machinda
Thomas J. Coates, PhD
Glenda Gray, MBCH, FCpaeds (SA)
Gertrude Khumalo-Sakutukwa, MSW, MMS
Suzanne Maman, PhD
Jessie Mbwambo, MD
Matilda Mogale
John Mutsambi
Linda Richter, PhD
Onsri Short
Nokuthula Skhosana, MA

[Note: the subcommittee will expand to incorporate each of the site Community Relations and Mobilization Coordinators as they are hired]

The subcommittee will fill the following roles:

1) Recommend principles and procedures for achieving community preparedness and involvement across all study sites, including preparation of and revisions to this manual.

2) Recommend strategies for sites to document community preparedness and involvement activities.

3) Act as a repository and dissemination center for documentation on community preparedness and involvement activities taking place at all sites in order that sites can share their experiences, strategies, and challenges, and that best practices can be developed. Update the Project Accept website with quarterly information submitted from all sites on community preparedness and involvement activities, achievements, and lessons learned.

4) Organize regular debriefings with community-involvement staff from all sites.
E. Benchmarks and Timelines

Establishing timelines and benchmarks is enormously helpful in setting goals, charting progress, and generally making sure the community preparation and involvement activities are proceeding at a pace that allows the research team to meet the overall goals of the study on time. Each site’s community involvement process will proceed according to its own pace and requires a site-specific timeline; however, it should be noted that the overall timeline for Project Accept requires all sites to initiate community preparation activities by the third quarter of Year 1.

Benchmarks are an important aspect of activity planning and timeline development. They are helpful in allowing study staff to acknowledge the successful achievement of goals along the way. In this manual, we have broken down the process of community preparation and involvement into stages and sub-stages. Benchmarks can easily be established for each stage and sub-stage.

F. How to Use this Manual

This manual is meant to provide overall guidelines that sites may adapt to their local conditions and needs. The subcommittee intends for it to be used as a guide rather than as a strict recipe book. Each site PI and study staff already have significant expertise in conducting community-based research and this expertise should be brought to bear on all community preparatory and involvement activities for Project Accept. This manual does, however, provide a useful structure for PIs and study staff to organize their thinking around the principles and processes of community involvement as well as recommendations for how all sites can achieve some measure of structural uniformity, including important procedures for documentation and communication across sites. In order to ensure this manual is maximally useful to study PIs and staff, please read it carefully and direct suggestions for improvement and revision to Katherine Fritz.
II. Paving the Way: Introducing the Study to National, Provincial, District, and Community Level Stakeholders

The first step in preparing for the study is for each site to introduce itself and the study concept to both primary and secondary stakeholders. This will begin at the national level and then continue at the provincial, and district levels, and finally continue to the level of the communities in which the research will take place. In order to build a strong collaborative foundation for the research, each site must have a thorough knowledge of all the stakeholders at the various levels that may have an interest in the study or may be able to affect the research outcomes. As stated in the Definition of Terms (Section Ia), 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, intervention, or research in their community. Often stakeholders have immediate and direct impact while others may only have indirect interests.

A. Stakeholder Inventory and Diagrams

The stakeholder inventory is the first step in the process. It is both a discrete element of preparation, as well as a procedure that will continue throughout the community preparedness and involvement process (because it is natural for stakeholders to shift and change, some leaving while others arrive). At the beginning of the study, each study site should conduct a thorough stakeholder inventory and associated stakeholder diagrams\(^4\) that can be updated periodically. The purpose of creating visual diagrams of the stakeholders is to make evident the linkages between stakeholders or lines of authority, which if not respected by the study team could result in miscommunication. The inventory should also indicate which stakeholders must provide official permission or a letter of support before the research can proceed. Original letters of support or permission should be filed in the study office and copies of the letters kept in binders that study staff can carry with them as they meet with stakeholders and start visiting the study communities.

Separate diagrams can be created for each level of influence beginning with the national government and cascading down to the provincial and district levels, and finally the level of the research communities themselves. Both governmental and nongovernmental stakeholders should be included in the inventory and on the diagrams. A variety of sources of information can be used to complete the stakeholder diagrams. For example, existing organograms from the national government ministries may be very useful. For nongovernmental stakeholders, there are often a variety of directories available and these can be helpful; however, it is important to note that these directories can quickly become out of date and therefore care needs to be taken to conduct research to identify the groups and individuals who are currently active and relevant to the research.

Once the inventory is complete and the diagrams have been constructed, it should be fairly evident how to order meetings with individuals so that you move through the networks of stakeholders in a fashion that is logical and appropriate to your setting. The schedule of meetings in most cases will likely begin with governmental officials at the highest levels and progress to meetings with local-level officials in the proposed study communities; however, there may be notable exceptions to this rule. As you move through your schedule of meetings, it will also be

\(^4\) the computer software program called Visio is helpful in creating such diagrams
important to ask each person or group with whom you meet if they would suggest any other potential stakeholders you may have not included in your inventory but should talk to. In this way, the inventory will become more complete as you progress.

Based on the stakeholder inventory and diagrams, you may also want to create a database (for example, using Microsoft Access) that allows you to manage information about the stakeholders and to retrieve it easily. Information that is important to track, whether through a database or on written forms include: general information you gather about each stakeholder (their interests, characteristics, and sphere of influence), when you met with them, what was discussed at each meeting, any outcomes of the meetings, questions or concerns they had, recommendations they made, any follow-up needed.

B. Creating Promotional Materials

Promotional materials should be designed to disseminate information about the study to stakeholders, community members, health and policy authorities, and other relevant constituents. Materials should aim to provide background information about the study, to contextualize the study in lay language and to be site specific. Materials should also contain an overview of the study’s objectives, the study’s methodologies and outcomes as appropriate. The promotional materials in some sites will feature the study’s local name and logo, and will include a number of documents suited to different constituencies. Examples of promotional materials include the Project Accept 3-page description, which is included in Appendix B. This document can be used as a guide to create other materials appropriate to the site settings. These may include briefer one-page descriptions and a variety of brochures targeted to various stakeholder audiences as well as project logos that will help identify the study. Samples of such promotional documents from the South Africa sites are included in Appendices C, D, and E.

C. Explaining the Study

Project Accept is a complex study that will require careful explanation and description appropriate to an audience that will likely not be familiar with the terminology of randomized trials or behavioral HIV interventions. It will be important to educate stakeholders on both the trial design and the specific services that will be provided in both community-based VCT communities and clinic-based VCT communities.

1. Explaining the Trial Design

In describing the overall trial design, it will be important to address five fundamental questions that stakeholders may have about the way in which the study has been organized. The questions are listed below as well as possible responses that could be given. The responses are written in language accessible to those outside the research field. Study teams at the sites should feel free to further develop these explanations using analogies and metaphors that are appropriate to the culture, society, and educational background of the various stakeholder audiences the study team will be addressing.

1) What is a randomized trial and why is it the gold standard of health research?
Response: A randomized trial is the only way that researchers can accurately determine if a new type of treatment really works. In this study, the new treatment we are testing is a type of HIV prevention programme called community-based voluntary counseling and
testing (VCT). In a randomized trial design, random chance (like a lottery) is used to decide which individuals or groups of individuals are given the new community-based VCT programme (this group is called the treatment group) and which individuals or groups of individuals are not given the new programme but continue to receive the currently available clinic-based VCT (this group is called the comparison group). By using random chance to decide which people or groups of people receive the new programme, the research becomes fairer. The use of random chance also ensures that the new programme is tested with a wide range of people. If random chance is not used, it is possible that the new programme would only be tested with certain types of people who may not represent the whole population. When that happens, the research is flawed and the results can not be used to recommend the new programme for everyone. For this reason, randomized trials are considered by scientists to be the most reliable way (the gold standard) of testing if a new treatment really works.

2) Why will this study randomize communities instead of individuals?
Response: Previous research has already shown that HIV VCT helps individuals to reduce their risk-taking behavior and thus reduces the chance they will become infected with HIV (or if they already have HIV, from passing it on to others.) In this study, we want to know whether providing HIV VCT using a community-based approach actually makes whole communities change the way they think about and respond to HIV. For this reason, it is necessary to provide the programme to whole communities rather than to individuals. This is why communities rather than individuals are the target of the research and why whole communities will be randomly chosen to receive the programme.

3) How will we randomize communities?
Response: Eight (or fourteen in the case of Thailand) communities at each site are being selected to participate in the study. These eight (fourteen) communities will be selected based on certain characteristics such as age, population, and existing HIV infections. Four communities at each site will be randomly chosen to receive the new community-based VCT programme (the treatment group). The other four communities at each site will receive VCT services from a clinic or hospital (the comparison group). The process of randomly choosing which sites will be in which group will be done in two steps. Step 1: We will match up communities into pairs. The communities will be matched into pairs based on ways that the communities are alike (like twins). For example, communities that are matched together in a pair should be about the same size, have the same types of religions, have the same medical services available, have similar road infrastructure, etc.
Step 2: We will randomly choose (pick out of a hat, for example) which community in each pair will receive the new community-based VCT programme and which will receive VCT from a clinic or hospital.

4) How will we know if the community-based model of VCT is effective?
Response: It is by comparing the communities that received the new programme with the communities that didn’t receive the new programme that we can determine if the new programme was effective. We will do this comparison by taking measurements in all the study communities of things like sexual and other HIV risk behavior, attitudes toward HIV risk, attitudes about people living with HIV, and also by testing community members for HIV. If the new programme is effective, we would expect to see that those communities that received it have less sexual risk behavior, more positive attitudes about
reducing risk, less feelings of stigma against people living with HIV, and also fewer new HIV infections than in the communities that didn’t receive the new programme.

5) Isn’t the study design unfair to the communities that don’t receive the new community-based programme?
   We know that communities may have special concerns about the prospect of being randomly chosen NOT to receive the new community-based VCT programme. These concerns need to be handled sensitively. Clear information about all four aspects of the study design above will assist community members to appreciate the need for a “comparison” group in order to accurately assess the effectiveness of the community-based model. Further to that, however, it will be helpful to explain the following points:

   - Standard-of-care (clinic or hospital-based) VCT has already been shown in previous research to be an effective, low-risk, and cost-effective intervention for preventing HIV risk behavior among those who participate. All study communities will receive a very high standard of this type of VCT. Where clinic or hospital-based VCT already exists, the research team will help to improve it; where it doesn’t exist, it will be established. In every community, the service will be monitored for quality to ensure that members of the comparison communities receive the best standard of VCT services that can be provided.

   - We hypothesize that the community-based VCT model will be more effective than the clinic-based model of VCT at producing community-level HIV risk reduction, however, we don’t know yet if that will be the case. In the meanwhile, standard-of-care VCT, which we know is beneficial to individuals, will be provided in all study communities and the benefits of that service will be available for everyone who wishes to use it.

   - The research team will partner with key governmental and nongovernmental stakeholders throughout the course of the study. If the new community-based VCT programme is shown to be effective, the researchers will work with these agencies to provide the community-based VCT programme in the communities that did not receive it as part of the research study and potentially to implement it across the country.

2. Explaining the Community-based VCT Intervention

When describing the community-based VCT intervention, it will be important to describe it in terms of a behavioural intervention in its own right, that aims to effect change in whole communities. Care should be taken not to cast the community-based VCT as an entry point into ARV therapy or other studies so as not to dilute the importance of the study’s aims, namely, to increase communities’ knowledge of their HIV status, decrease HIV related stigma and HIV risk taking behaviours. The model is primarily one of community and behavioural change.
The study should be described as including these important elements:

- Extensive community preparation will be conducted in all study communities. This will include extensive education about the study’s aims and procedures, the establishment of community advisory groups in each study community to facilitate the communication between community members and the study staff, and regular community meetings to discuss the study progress and give/receive feedback.

- High-quality VCT services provided from local clinics or hospitals will be made available to members of all study communities (within a specified distance determined at each site), and additional mobile VCT will be provided in the community-based model. All VCT services will be closely monitored for quality assurance.

- Post-test support services will be established and/or enhanced in the communities receiving the community-based VCT. These services will be tailored to the sites’ specific needs. These may include stand-alone centers and/or referrals to existing community-based resources. Post-test support services that are pre-existing in the communities receiving clinic-based VCT will continue to operate; however, the study will not enhance these existing services nor will it establish new services in those communities.

- Community mobilization around VCT will be organized in the community-based VCT model. This will involve a team of study staff and community volunteers who organize outreach and educational events to promote interest in VCT among community members.

For more detailed explanations of the community-based VCT intervention and the clinic-based VCT services, please see the Project Access Procedure Manual (Intervention Subcommittee).

D. Creating the External Advisory Committee

External Advisory Committee members will be chosen from a broad base of authorities with oversight over health, policy, social welfare, social development, and any other sector relevant at the specific site. As such, they should be canvassed from a broad range of departments and fields to represent diverse interests of relevance to the study. Potential members should be approached by site PIs or Project Directors, as appropriate, and briefed on the study. Potential members who show an interest and a commitment to participating in the External Advisory Committee should be formally invited to join and should receive a description of their responsibilities. Regular meetings should be convened on a schedule decided upon by the EAC and the site PI and/or Study Director. Recommendations from the EAC should be disseminated to appropriate research and study staff and shared across sites via the Community Preparation and Involvement Subcommittee.
III. First Impressions: Getting Started in the Study Communities

A. Initial Visits

Initial visits to the study communities are an opportunity to make a good first impression and should be organized carefully with key stakeholders in the communities. Often it will be important to make these first visits in the company of stakeholders from the national, provincial, or district levels who can facilitate entry, although this depends on what is necessary and appropriate at each site. During these initial visits to the study communities, it will be important to clearly explain the study’s purpose and significance and begin to develop a thorough understanding of the social and political dynamics in the communities. This will assist in knowing how initial preparations can be accomplished without creating or exacerbating conflicts between stakeholders. The following visits may thus be critical initially:

- Visits to local government structures
- Visits to the regional department of health and the clinics – for orientation to the functioning of the HIV/AIDS services
- Visits to key HIV/AIDS (VCT) coordinating structures to mobilize support for the research

B. Getting to Know the Communities

Following initial introductory visits, the long process of getting to know the research communities can begin. This is a process that will be especially intense at the beginning of the research and will continue with varying levels of intensity throughout the study.

In getting to know the study communities, the community preparedness and involvement staff will work hand in hand with the social science staff in a process called “Geographic Mapping and Baseline Ethnography.” In the mapping and ethnographic data collection, the study staff are tasked with collecting data that will be used to help define the study communities socially, identify key variables for matching communities, and identify potential barriers and facilitators to the implementation of community-based and clinic-based VCT. This process will also assist the Community Preparedness and Involvement team to learn more about the study communities such that effective plans for collaboration and involvement can be made.5

See Geographic Mapping and Baseline Ethnography Operations Manual for procedures.6

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5 It should be noted that appropriate IRB approval for ethnographic work will need to be obtained prior to initiating this process. The Qualitative Research Subcommittee will provide guidance regarding this.

6 sent out by Suzanne Maman on 13 April, 2004.
IV. Building the Community Advisory Structures

After getting to know the communities socially and geographically, the study team can begin to build the community advisory structures, first by establishing the Community Working Groups (CWGs) and the Study Advisory Committee (SAC).

Since the onset of the HIV/AIDS epidemic, community participation in research activities has been an evolving process that has organized community action and been a spur to advocacy. Community participation in research is a social process where truly democratic dialogue between researchers and the affected community occurs. This dialogue facilitates community members to become actively involved in the decision-making and implementation of the research. Sensitization to research is an enabling process where communities are then able to take more responsibility for their own problems and issues affecting them, as well as share in the benefits of the research. Community advisory structures facilitate community participation in the research process.

For NIMH Project Accept, the community advisory architecture is composed of the Community Working Groups (CWGs) and the Study Advisory Committee (SAC). In each study community, the community advisory process is ensured through the development of a CWG. Each research community will establish a CWG and through their participation, the study will ensure information exchange and dissemination between the research team and members of the research communities. The CWG is a group of people selected by the community to foster a partnership between researchers, research participants, and the community. Several members of each CWG will also serve on the overarching Study Advisory Committee (SAC). Although these structures have a common purpose across sites, there may be tremendous diversity in how each site facilitates community participation in the research process. However, the overriding principles in the establishment of the CWGs and the SAC are:

- **Parity:** Equal opportunity for meaningful input and participation exists among community representatives.
- **Inclusivity:** The community is represented and involved in meaningful and purposeful ways.
- **Representation:** Diverse perspectives are sought and ongoing steps are taken to ensure that the research reflects the needs and concerns of the communities’ values, norms and behaviours.
A. Establishing and Maintaining the Community Working Groups (CWGs)

1. Purpose of the CWG

The purpose of the CWG is to ensure community input into the research process and to foster partnership between researchers and the community. As CWG members become more familiar and knowledgeable about Project Accept, there will be greater participation on study-specific issues where members may have a range of suggestions, concerns, and advice to offer.

2. Roles of the CWG

The CWG fulfills the following roles:

- Leads, facilitates, directs, and advocates for research communities to have meaningful input into research
- Represents the interests of the community and the rights of individuals to the research staff
- Educates the community about all aspects of the study and creates a supportive environment for study participants and their families
- Provides information for anyone interested in the study
- Assists the researchers to build networks with organizations offering services to the community
- Monitors the practices and the ethics of the study
- Participates in all levels of decision-making, including financial decisions such as compensation for study participants
- Acts as the interface between community and the trial site
- Has input into the information and communication aimed at the community
- Assists in resolution of conflicts that could arise between researchers, study participants, and the community
- Informs, facilitates, and guides the development of a centered, relevant, and ethical research agenda
- Increases understanding among community members of community collaboration in HIV prevention research
• Ensures partnership with a community by integrating community perspectives into the substance of the research

3. CWG Constitution

The stakeholder inventory and baseline ethnography should provide a good idea of who the key players in the community are in terms of organizing community activities and providing social or health services. These are among the people who should be considered for inclusion on the CWG. As a first step to constituting the CWG, however, it is advisable to approach key community leaders who are influential and ask them to help with identification of potential CWG members. It is always a good idea to recruit at least some individuals who have a proven track record in voluntary activity in the community or who are already involved in community health activities (such as community health workers). This will ensure a CWG with a core of committed members who will provide the stability the group will need in order to function. Such members may also put their wide and deep social networks to work on the behalf of the research.

4. CWG Membership

The CWG can include as many members as necessary to achieve appropriate representation of the community. However, very large groups can be difficult to manage and often 20 members is the maximum number for achieving productive meetings and meaningful involvement. Above all, members of the CWG have to be recruited to ensure optimal community representation. Strive to involve representatives from each of the following areas:

- Women’s groups
- Community-based organizations (CBOs)
- Nongovernmental organizations (NGOs)
- Health workers
- Volunteers
- Lay people
- Religious groups
- Traditional leaders and healers
- Political leaders
- Educators
- People living with HIV
- Youth leaders

5. Training the CWGs

The Community Relations and Mobilization Coordinator, other staff, and the CWG members must agree on the dates to conduct a one or two–day training workshop to orient the CWG members and to establish a positive working relationship between study staff and the CWG members. Training should cover the following topics:

- Roles and obligations of the CWG and its membership
Roles and obligations of the study staff
Defining the mission and importance of the CWG
Principles of community involvement in research
Basic principles of ethics in research involving human participants
Basic principles of HIV prevention
Background and significance of NIMH Project Accept
Basic principles of the research design
Aims and procedures of the study
The benefits and risks to the community from the study
Communication between the research team and the CWG
Rules of conduct for the CWG and the research team
Determining the frequency of meetings
Appointment of a chairperson/facilitator and a secretary

6. Maintaining the CWGs

The site Community Mobilization and Involvement Coordinator and staff in collaboration and consultation with the CWG will:

- Plan and coordinate CWG meetings, ensure that they are convened at the agreed-upon times and locations.
- Ensure that information is shared between the CWG and Project Accept staff at all levels.
- Assemble educational materials and handle administrative duties (i.e., notices and minutes of CWG meetings)
- Coordinate regular educational opportunities for CWG members to update their knowledge
- Work with the CWG to identify and recruit new members, as needed
- Provide training to new members
- Provide the CWG with logistical support including meeting space, office equipment, photocopying, typing, and other administrative support and travel expenses
- Promote active participation and visibility of the PI and or other senior Project Accept staff in CWG meetings and activities
- Ensure there is a clearly articulated purpose for CWG involvement in Project Accept
- Ensure there are clearly defined responsibilities of CWG members
- Ensure the inclusion of CWG members in the development and implementation of Project Accept
- Provide regular booster training to CWG members
- Provide secretariat support by site Community Mobilization Coordinator
- Establish appropriate means of communication with CWG members
- Provide transport expenses for representative CWG members to meetings, conferences and training/workshops if needed.
- Provide skilled facilitation of CWG meetings
- Provide refreshments at CWG meetings
B. Establishing and Maintaining the Study Advisory Committee (SAC)

1. Purpose of the SAC

The purpose of the SAC is to allow primary stakeholders to exercise leadership at a higher level of study coordination to ensure community involvement not only in the individual communities but also across the communities. The SAC will further facilitate partnership development between Project Accept researchers and the respective research communities and allow a level of networking between study communities that would not otherwise be possible. Networking among study communities will promote a feeling of ownership among all the communities in the study and instill a sense of working toward common goals.

2. Roles of the SAC

- To enhance networking, communication and co-ordination between the Community Working Groups (CWGs) in order to promote the HIV prevention interests of all study communities and the goals of the research study.

- To formulate recommendations and strategies that enhance the preparation for and implementation of both community-based and clinic-based VCT.

- To promote capacity-building among the CWGs.

- To recommend ways of improving community involvement in the overall study.

3. SAC Constitution and Membership

The SAC should include at least one representative from each CWG and a back-up representative. Depending upon site needs, there may be more than one representative from each CWG on the SAC but representation from each CWG should be equal. The SAC should aim to represent and reflect the diversity of the study communities including culture, ethnicity, age, and behavioural risk.

4. Training the SAC

All members of the SAC will have already undergone training as part of their orientation to their CWG membership. Thus, training for SAC membership should address additional responsibilities inherent in SAC membership as well as additional training in the study protocol. Training should include:

- Roles and obligations of the SAC and its membership
- Roles and obligations of the study staff
- Defining the mission and importance of the SAC
- Refresher on principles of community involvement in research
- Refresher on basic principles of ethics in research involving human participants
- Refresher on background and significance of NIMH Project Accept
- Refresher on basic principles of the research design
- The benefits and risks to the communities from the study
- Communication between the research team and the SAC
- Rules of conduct for the SAC and the research team
- Determining the frequency of meetings
- Appointment of a chairperson/facilitator and a secretary

5. Maintenance of the SAC

Technical support will be provided by the Community Relations and Mobilization Coordinator and staff in the same way as for the CWGs. In addition, it is necessary to plan for the following:

- Adequate budget for meetings and travel of key members to Steering Committee Meetings and/or other conferences
- Regular interaction and dialogue with study PI and other senior researchers
- To perform a needs assessment and appropriate training to build capacity of this group’s members

V. Preparing the Communities for the Start of the Study

Preparing communities for the initiation of the study begins with formative research. This research will be led by the social science staff at each site according to the *Geographic Mapping and Baseline Ethnography Operations Manual*. During this process the Community Mobilization and Involvement staff will have an opportunity to explore the following areas, which will be crucial for designing a plan to sensitize community members to the study:

- Define community in the context of Project Accept
- Explore local customs that need to be observed
- Develop lexicon of local phrases
- Identify community resources
- Explore community expectations

Community preparedness is along a continuum of building community awareness, understanding, and willingness to participate. When these three areas are actively attended to, the community becomes prepared to support the responsible and effective implementation of Project Accept. The ongoing task of the CWGs, the SAC, and the site Community Relations and Mobilization Coordinator and staff is to develop and implement community education strategies designed to address these areas, promote a collaborative researcher/community relationship, increase community awareness, and facilitate community participation in Project Accept.
A sample plan for preparing a community for the start of the research is shown in the following table.

<table>
<thead>
<tr>
<th>GOAL</th>
<th>METHOD</th>
<th>RESULT</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Build Community Awareness</strong></td>
<td>- Disseminate study information through door-to-door canvassing by CWG members and study staff</td>
<td>- Promotes curiosity about the study and a desire to learn more</td>
</tr>
</tbody>
</table>
| **Build Understanding about the study** | - Follow canvassing with a series of community meetings led by members of the CWG and study staff and PI. Agenda of meetings is to introduce the study, its aims, design and procedures, to solicit feedback from community members.  
  - Use of participatory facilitation techniques rather than lecture | - Establishes rapport between researchers and the community, establishes basis for open communication and builds trust, allows community members to see the role the CWG plays in the research.  
  - Demonstrates respect for community members’ views and expertise thus building basis for a collaborative relationship |
| **Build Willingness to Engage**    | - Ongoing outreach by community relations and mobilization study staff and CWG members to listen to community members concerns and feed this information back into the development and implementation of the community-based and clinic-based VCT programmes  
  - Ongoing community meetings scheduled as necessary.  
  - Collaborative development of informational materials (where literacy is high) to be distributed to community members such as a newsletter or brochures updating the community on the progress of the research and the community involvement process. | - Establishes pattern of on-going conversation about the study and encourages community members to listen, learn, ask questions, provide advice, continually learn about the research process and to remain engaged.  
  - Promotes collaborative spirit between community members and researchers as community members see their input is listened to and used to improve the research procedures. |
VI. Maintaining Community Involvement

There will be a continuous need to nurture the community involvement process and collaborative interaction between researchers and community members on Project Accept. If the preparatory phases have gone well and the community advisory structures have been built on a strong footing, this maintenance process will not be difficult but it will require substantial continuing attention from the study staff throughout every phase of the study. Once established, the CWGs and the SAC will need to feel supported and valued through regular communication and continuing training. In addition, new and creative ways will always be needed to keep the communities informed about and engaged in the study. It must be noted that all collaborative relationships have highs and lows. Keeping in tune with community members’ attitudes toward the study activities and study staff is an important part of the maintenance phase and allows the staff to trouble shoot problems before they become entrenched. The following are some suggestions for keeping the community collaborations well-maintained and productive:

- Hold regular community meetings or educational fairs for disseminating study results as they become available. Community members will have more trust in the research team if they feel well informed about its progress and know how the data collected is being analyzed. Study staff will also learn at these meetings about areas of concern to the community.
- Create and use communication channels outside of formal ones. For example, make casual visits to members of the CWG in between CWG meetings just to check in with them and establish a familiar and collegial relationship. This will also help the CWG members to know that they can also drop in on the staff at any time to talk about issues affecting the community.
- Facilitate linkages between CWG and SAC members and other community resources in order to strengthen networks within the community. Facilitating these linkages also helps prepare for the time when the research team will leave the study communities. The research team should aim to leave behind a stronger and more integrated network of community service.
- Encourage members of the CWGs to keep in close touch with their communities so that they can be effective representatives. Develop strategies for CWG members to meet with community members in the absence of the research team to hear feedback that the community might be reluctant to articulate in a larger forum where the researchers are present.
- Forge relationships with key informants outside of the CWG and SAC structures and check in with them on a regular basis to hear their perspectives on how community members are viewing the research and any problems that might need to be addressed.

In addition, here are some suggestions for detecting common problems often faced in the community involvement process as a study wears on:

- Monitor whether community members begin to feel threatened or resentful of the partnerships developed between the CWGs, the SAC, and the research team. The relationships between the study staff and the formal community advisory structures will be particularly intense. It can happen that community members at large begin to feel the members of the CWGs and the SAC are enjoying special privileges (such as allowances...
Monitor consensus between CWG and SAC members and between other stakeholders. Stakeholders will not always agree on every issue affecting the study and the community. However, where factions or cliques begin to develop and become entrenched, intervention from the study staff may be necessary to break down barriers and re-establish team dynamics.
VI. Documentation

Documentation of the community preparedness and involvement activities will be a crucial element in establishing and maintaining best practices for this element of the study. As one of the world’s largest community-based behavioral intervention trials, we have an opportunity to contribute greatly to lessons learned about making community involvement an integral part of the research process and to how research can be improved through the community involvement process. We can only make these contributions, however, by documenting our workplans, activities, and outcomes. The Community Relations and Mobilization Coordinator under the supervision of the Study Director at each site will be responsible for ensuring the documentation takes place. This section of the manual outlines three areas where documentation is needed.

A. Creating Workplans

Each stage of the community preparedness and involvement process needs a workplan. A workplan will thus be needed for the following areas and sub-areas:

A. Paving the Way
   1) Accomplishing the stakeholder inventory and diagrams
   2) Creating promotional materials
   3) Establishing the external advisory committee

B. Getting Started in the Study Communities
   1) Making initial visits
   2) Getting to know the communities (in conjunction with the social science team)

C. Building the community advisory structures
   1) Establishing and maintaining the CWGs
   2) Establishing and maintaining the SAC

D. Preparing the communities for the start of the research
   1) Creating a community sensitization plan

E. Maintaining the community advisory process

The workplans can be in any format the sites would like but should include the following information:

- Description of the activity
- Persons or groups coordinating the activity
- Goal of the activity. The goal describes the ultimate mission or purpose of the activity.
- Objective of the activity. Objectives describe the mileposts that must be met to achieve the goal. Objectives are activity-specific, time-specific and measurable and answer the question, “What changes do you want to effect within what timeframe?”
- Measures/Evidence of Accomplishment. Measures describe how the project documents the accomplishment of the objective. They are the end result of the objective or the product of the activity.
- Resources needed.
- Timeline for the activity.

Workplans are not static documents and need to be updated frequently to reflect the changing circumstances the study team will invariably face in implementing the study on the ground.

A sample workplan devised by the HPTN is included in Appendix F.

**B. Detailed Reports of Activities**

A detailed report of each activity that has been completed needs to be written up as soon as possible after the event. The report is based both on the workplan (how you expected the activity to go) and on notes or minutes taken during the activity (how the activity really went). Activities may include meetings with officials, community meetings, CWG meetings, and informal meetings as well as any activity that contributes to the community preparedness and involvement agenda. The reports should include the following elements:

- Description of the activity (including whether the activity was part of a series of activities or a one-off event)
- Goals and objectives of the activity (including the planned content of activity or agenda)
- Who participated in the activity (also include who was expected to participate but was absent)
- What happened (be specific and provide details that allow the reader to understand how the event unfolded on the ground).
- Any special arrangements that were necessary or unexpected turns of events
- Participants’ suggestions or recommendations for the way forward as a result of this event.
- Staff suggestions or recommendations for the way forward as a result of this event.
- Staff analysis of the event (were the objectives achieved, if not how will they be followed up?)
- Cost of the activity

These reports should be carefully stored in both hard copy form and electronic form at the study’s main office.

**C. Summary Quarterly Reports**

Summary quarterly reports will help the study team assess progress made and identify areas that may be posing challenges and which need extra attention. These quarterly reports should be prepared by the Community Relations and Mobilization Coordinator and submitted to the Study Director, Principal Investigator, and the Community Preparedness and Involvement Subcommittee chairperson. The Subcommittee chairperson will be responsible for reviewing all the reports and creating a synthesis that will be posted on the Project Accept website in order for all sites to share experiences and lessons learned as well as to keep track of the progress of the community involvement agenda across all the sites. The more detailed the quarterly reports are the more useful they will be both within sites and across sites. The quarterly reports should include the following elements:

- Progress to date in relationship to workplans
- Descriptions of activities undertaken
- Measures of accomplishment
- Challenges faced and how resolved—lessons learned
- Work plans for the coming quarter
- Analysis of budget to date
APPENDIX A

NIMH Project ACCEPT Community Advisory Structure

Study Advisory Committee (SAC) — External Advisory Committee (EAC)

Community Working Group (CWG)

Community Working Group (CWG)

Community Working Group (CWG)

Community Working Group (CWG)

Community Working Group (CWG)

Community Working Group (CWG)

Community Working Group (CWG)

Community Working Group (CWG)
APPENDIX B

NIMH Project Accept:
A Phase III Randomized Controlled Trial of
Community Mobilization, Mobile Testing, Same-Day Results, and Post-Test Support
for HIV in Sub-Saharan Africa and Thailand

Overview and Significance

There is no more compelling crisis in the world today than the HIV epidemic in sub-Saharan Africa. Since the epidemic began, more than 60 million people have been infected with HIV. With an estimated 3.4 million new HIV infections in sub-Saharan Africa in the past year alone, 28.1 million Africans are now living with the virus; in 2001, 2.3 million Africans died of AIDS. In addition to death and disease burden, the epidemic has had an enormous impact on economies and life expectancies, and left a legacy of millions of orphans. There is concern that this magnitude of epidemic burden could devastate parts of Asia as well.

Evidence-based strategies that mobilize communities are required to achieve significant and lasting reductions in the incidence of HIV in countries hit hard by the HIV/AIDS epidemic. This study is the first randomized controlled Phase III trial to determine the efficacy of a behavioral/social science intervention with an HIV incidence endpoint in the developing world.

In this HIV prevention trial sponsored by the National Institute of Mental Health (NIMH), 32 communities in Africa (in South Africa, Tanzania, and Zimbabwe) and 14 communities in Thailand will be randomized to receive either a community-based voluntary counseling and testing (CBVCT) intervention in addition to standard clinic-based VCT (SVCT) services, or SVCT services alone. The CBVCT intervention has three major strategies:

1. To make VCT more available in community settings
2. To engage the community through outreach
3. To provide post-test support

These strategies are designed to change community norms and reduce risk for HIV infection among all community members, irrespective of whether they participated directly in the intervention. Thus, a community-level sampling approach is used, as opposed to a cohort design.

Provided that we can document efficacy with regard to HIV incidence and incremental cost-effectiveness, we expect that resources for widespread implementation of CBVCT will become available from the U.S. Agency for International Development (USAID) or the Global Fund to Fight AIDS, Tuberculosis and Malaria. We have worked closely with representatives of national AIDS programs in the host countries to ensure that the intervention is sustainable even in countries with limited resources.
Study Objectives and Design

The primary objective of this study is to test the hypothesis that communities receiving 2-1/2 years of CBVCT, relative to communities receiving 2-1/2 years of SVCT, will have significantly lower prevalence of recent HIV-1 infection. This will be evaluated by comparing the post-intervention prevalence of recent infection in CBVCT and SVCT communities, measured by the sensitive/less sensitive HIV assay on all HIV-positive blood samples obtained from the post-intervention assessment.

The secondary objective of this study is to test the hypotheses that CBVCT communities, relative to SVCT communities, will at the end of the intervention period report significantly less HIV risk behavior, higher rates of HIV testing, more favorable social norms regarding HIV testing, more frequent discussions about HIV, more frequent disclosure of HIV status, less HIV-related stigma, and fewer HIV-related negative life events.

Cost-effectiveness analyses will be conducted to determine whether CBVCT is cost-effective compared to SVCT. This will be evaluated in terms of cost per HIV infection averted and disability-adjusted life years (DALYs) saved. Qualitative analyses will also be performed through community ethnography and in-depth interviews.

The assessment of efficacy is based on changes in communities using repeat cross sectional data collected using household probability samples. A baseline behavioral assessment will be conducted in all communities using a household probability sampling technique. Pairs of communities will be matched using one or more variables; each community in a pair will then be randomized to receive either CBVCT or SVCT (CBVCT communities will be provided with both CBVCT and SVCT services, while SVCT communities will only be provided with SVCT services). A qualitative cohort in each community will be recruited in order to collect data on how stigma changes over time in the communities, and will allow for an assessment of attitudes toward HIV-infected persons.

A post-intervention assessment will be conducted using the same household probability sampling technique as for the baseline behavioral assessment. Recruited individuals from each community will provide biological samples for HIV testing, with a subsample of individuals from each community receiving a second cross-sectional behavioral assessment.

The intervention component of the study will last 2.5 years. The entire study project, from planning work through data analysis, is scheduled to last 5 years.

Intervention

The CBVCT intervention consists of four components—Community Mobilization, Community-Based (mobile) VCT, Post-Test Support Services, and Quality Assurance. The intervention in each of the countries and sites will be derived from the same theoretical model and contain the same strategies. The implementation of the elements of the intervention will be tailored to each local culture and context. The CBVCT intervention is based on the premise that HIV sexual risk behavior and HIV incidence will decrease in communities with increased knowledge of HIV status and more supportive community norms.
Communities randomized to SVCT (the “standard-of-care”) will only receive the installment of clinic-based VCT services at existing facilities. The training for VCT counselors will be the same in the CBVCT and SVCT communities; however, no active outreach/community mobilization, mobile/enhanced-access VCT services, or special post-test clubs will be provided in the SVCT arm.

Communities randomized to CBCVT will receive, in addition to the SVCT services, deployment of a mobile or easily accessed VCT unit including a nurse or trained phlebotomist, coordinator/health educator, and two HIV test counselors. The counselors, health educators, and recruited volunteers will provide information on HIV/AIDS and the VCT process to the community to encourage people to consider testing. Post-test clubs run by study staff will be available to people who have tested, regardless of their test results, in order to provide support and offer health and social service referrals.

**Community Participation**

All aspects of the design and implementation of the study are determined through strong collaboration among host-country investigators and institutions and their U.S.-partner investigators and institutions.

A partnership with each study community and its leadership shall be established through Community Advisory Boards (CABs). Throughout the duration of the study, regular CAB meeting will be held to ensure ongoing two-way communication between the study team and the study communities. Communication with relevant local, district, and national leadership will also continue as needed throughout the study.

For the 4 African sites, it is expected that a total of approximately 64,000 participants will access CBVCT services through the study, with another 32,000 accessing SVCT services. The baseline and post-intervention assessments will each enroll 16,000 participants; 45,760 participants will be evaluated for the post-intervention biological assessment.

For the Thailand site, it is expected that a total of approximately 24,500 participants will access CBVCT services through the study, with another 19,600 accessing SVCT services. The baseline and post-intervention assessments will each enroll 4,200 participants; 7,000 participants will be evaluated for the post-intervention biological assessment.

**Collaborating Institutions and Investigators**

This trial is a National Institute of Mental Health (NIMH) Cooperative Agreement involving Johns Hopkins University (JHU) Bloomberg School of Public Health and the University of California at San Francisco (UCSF) and Los Angeles (UCLA). The Statistical Center for HIV/AIDS Research & Prevention (SCHARP) at Fred Hutchinson Cancer Research Center (FHCRC) in Seattle, and Charles University in Prague, Czech Republic, are also participating as the statistical and data management experts for the study. The host country institutions are Chiang Mai University in Thailand; Human Sciences Research Council (HSRC) and the University of KwaZulu-Natal Nelson R. Mandela School of Medicine in Durban/Vulindlela, South Africa; Perinatal HIV Research Unit and the University of the Witwatersrand in
Johannesburg, South Africa; Muhimbili Medical College of the University of Dar es Salaam, Tanzania; and UZ-UCSF Collaborative Programme in Women’s Health and the University of Zimbabwe.

Christopher M. Gordon, PhD, is the study’s project officer at NIMH’s Division of Mental Disorders, Behavioral Research and AIDS. The primary investigators from the United States are David Celentano, ScD, MHS (PI, JHU); Thomas J. Coates, PhD (PI, UCLA); Stephen F. Morin, PhD (PI, UCSF); and Michael Sweat, PhD (PI, JHU). Primary host-country investigators are Suwat Chariyalertsak, MD, DrPH (PI, Thailand); Alfred Chingono, MSc (PI, Zimbabwe); Glenda Gray, MBBCH, FCPaeds(SA) (PI, Soweto, South Africa); Jessie Mbwambo, MD (PI, Tanzania); Linda Richter, PhD (PI, Vulindlela, South Africa); G.P. Kilonzo, MBChB, Mmed, FRCP, MD (co-PI, Tanzania); James McIntyre, MBChB, MRCOG (co-PI, Soweto, South Africa); and Surasing Visrutaratna, PhD (co-PI, Thailand). Deborah Donnell, PhD, and Michal Kulich, PhD are providing statistical and data management expertise for the study.

The study is funded through NIMH grants 1U01MH066687-01A1, 1U01MH066688-01A1, 1U01MH066701-01A1, and 1U01MH066702-01A1.
The Community Based Voluntary Counseling and Testing (CBVCT) Project

- VCT is receiving increasing attention from both governmental and non-governmental sectors as a key strategy in the fight against HIV/AIDS in South Africa.

- CBVCT is built on previous work that has shown that VCT is both highly effective in reducing individual risk behaviour, and a cost-effective prevention intervention for developing countries.

- For many working in the field, it is clear that if we are to make any meaningful impact on the epidemic, then we need to move beyond individual level interventions and address the social, community and cultural contexts that shape individual risk behaviour.

- The CBVCT project is a community level intervention that uses VCT as a vehicle for mobilizing communities to create more favourable social conditions regarding HIV/AIDS.

- In this study, we will compare two approaches to VCT i.e. clinic-based VCT with community based VCT. Community based VCT will have three components: (1) taking VCT to people via mobile caravans (2) engaging the community through outreach; and (3) providing post-test support.

- The purpose of the study is to show how offering mobile, community-based voluntary counselling and testing combined with post-test support to communities could lead to both a reduction in recent HIV infections in those communities, and change the ways people in those communities think about and respond to HIV and AIDS.

- In the next year, we will engage in preparedness activities for the project. These activities will include engaging with key community, traditional, regional and provincial stakeholders to obtain permission for the study and to facilitate community entry. We will also conduct the pilot study during this time.

- Thereafter, the project will offer mobile VCT services for two and a half years. Before, during and after this we will conduct confidential surveys in the communities to find out what they think about HIV/AIDS, HIV risk behaviours, stigma, discrimination, and so on.

- At the end of the study, we will anonymously test a sample of community members to see if there has been a reduction in new HIV infections since we have been working in these communities.

- The Community Based Voluntary Counselling and Testing project will take place in two sites in South Africa: Urban Soweto (Gauteng) and rural Vulindlela (KZN). These two places were chosen to try to represent the different ways people live in South Africa so that the findings will be applicable across the country.

- In South Africa, the project is being conducted by Dr. Linda Richter of the Human Sciences Research Council and the University of KwaZulu Natal, Dr. Glenda Gray of the University of Witwatersrand, and Dr. Thomas Coates of the University of California, Los Angeles, USA.

- The CBVCT Project will also run in three other countries: Tanzania, Thailand and Zimbabwe.
APPENDIX D

The Community Based Voluntary Counseling and Testing (CBVCT) Project:
Implications for Service Providers

- In both Soweto and Vulindlela, we have identified possible communities where we hope to conduct the study. In some of these communities VCT services may exist, or may not exist or exist in a limited fashion in relation to study communities.

- Under any of these circumstances, the study team will consult with local service providers to determine how best to improve the access of study communities to VCT services.

- Both sets of communities (i.e. those receiving clinic-based VCT as well as those receiving community based VCT) will use a model of voluntary counseling and testing consistent with recommendations from the Centers for Disease Control and Prevention.

- This model of VCT with a strong risk reduction emphasis has been effective in bringing about individual behaviour change in a variety of resource-poor contexts.

- Existing clinic staff and counsellors, as well as new counsellors in study communities will be trained in this new model of VCT.

- Counsellors in both clinic VCT and community-based VCT sites will receive individual and group supervision sessions on a weekly basis from study staff. Supervision sessions plus regular observations of counseling sessions comprises the cornerstones of quality assurance for this study.

- We believe that the training of staff in this new model of counselling plus the adoption of the above quality assurance mechanisms will benefit services and lead to better quality, prevention-oriented VCT.

- The CBVCT study intends to build the capacity of local VCT services and to leave behind both a well-developed infrastructure and highly trained staff that could be incorporated into health structures in the long term.

- The study is designed to respond to the policy question regarding the cost-effectiveness of providing a community-level intervention including VCT as opposed to a clinic-based model of VCT.

- If the enhanced services under investigation are found to be effective and cost-effective, this service could be applied in a variety of contexts in South Africa.
APPENDIX E

The Community Based Voluntary Counseling and Testing (CBVCT) Project: Partnerships and Collaborations

This prevention trial involves collaboration between four U.S. universities (Johns Hopkins University; University of California, San Francisco; UCLA and University of Washington) and five non-U.S. institutions (Muhimbili Medical College of the University of Dar es Salaam; University of Zimbabwe; Human Sciences Research Council of the University of KwaZulu Natal; University of Witwatersrand; and Chiang Mai University).

Our scientific team has considerable experience in conducting multi-country studies, which require local tailoring while remaining faithful to a centralized protocol to allow for cross-country data analysis.

The Community Based Voluntary Counselling and Testing project will take place in two sites in South Africa: Urban Soweto (Gauteng) and rural Vulindlela (KZN). These two places were chosen to try to represent the different ways people live in South Africa so that the findings will be applicable across the country.

CBVCT will also run in three other countries: Tanzania, Thailand and Zimbabwe.

In South Africa, the project is being conducted by Dr. Linda Richter of the Human Sciences Research Council and the University of KwaZulu Natal, Dr. Glenda Gray of the University of Witwatersrand, and Dr. Thomas Coates of the University of California, Los Angeles, USA.

This study is interested in how to deliver effective VCT services. As such, initial activities will be geared towards consultation with key health service providers and planners at district, regional, provincial and national levels.

The successful implementation of the study will require a close collaborative and structural link between local VCT clinics, clinic staff, counsellors as well as other prevention, care and support services that may exist in these communities.

We view the early involvement of all stakeholders as key to sustainability at the end of the trial.

Other important community leaders and gatekeepers - for example local tribal authorities in Vulindlela - will be approached to obtain study endorsement and to facilitate community entry.

Communities are no longer seen as just sources of research subjects but as active partners in developing research ideas, plans and providing oversight to research projects.

In each of the sites, existing mechanisms, such as community advisory boards (CABs), or other similar structures, will be used or developed. The goal of CABs is to respond to the ethical and practical issues raised by the study through a partnership between researchers and potential participants in the trial or their representatives.
## APPENDIX F

### HPTN Objectives and Activities Workplan (example)

<table>
<thead>
<tr>
<th>Goal (larger issue to be addressed)</th>
<th>Objective</th>
<th>Activities</th>
<th>Who will do it</th>
<th>Measure of objective</th>
<th>Date completed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Increase community involvement in HIV prevention research.</td>
<td>Community Advisory: 1. By December 30, 2001 the site’s Community Advisory Board members will actively participate in research discussions and decision-making.</td>
<td>1.a. Determine the skills-building needs of CAB members at CAB meetings. 1.b. Set annual training plan with timelines 1.c. Implement scientific training for CAB members.</td>
<td>Community Educator</td>
<td>Written report of decisions and input made by CAB members.</td>
<td></td>
</tr>
<tr>
<td>Goal (larger issue to be addressed)</td>
<td>Objective</td>
<td>Activities</td>
<td>Who will do it</td>
<td>Measure of objective (end-product of the work that lets you know your objective is met)</td>
<td>Date completed</td>
</tr>
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<td>-------------------------------------</td>
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</tr>
</tbody>
</table>
| **Community Education:**            | 2. By December 31, 2002, twelve (6) community sensitization events will be held in area marketplaces. | 2.a. Set annual events plan with timelines  
2.b Create an event checklist to use  
2.c. Plan and conduct interactive role plays  
2.d. Distribute educational brochures. | Community Educator, CAB  
Community Educator  
Community Educator, CAB  
Community Educator, CAB | 2. Documentation of event with list of participants, materials and number distributed, date of event and where distributed | |

NIMH Project Accept  
Community Prep/Involvement Manual_15 April 2004
<table>
<thead>
<tr>
<th>Goal (larger issue to be addressed)</th>
<th>Objective</th>
<th>Activities</th>
<th>Who will do it</th>
<th>Measure of objective</th>
<th>Date completed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Needs Assessment:</td>
<td></td>
<td>1a. Determine information sources for the inventory</td>
<td>Community Educator, CAB</td>
<td>Completed resource directory</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>1b. Obtain information about local services and programs</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>1c. Share inventory as a directory</td>
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<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>1d. Update inventory annually</td>
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<tr>
<td>By March 31, 2001, the site will have completed a resource inventory</td>
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