Goal of this guidance document
This document aims to help guide each clinical research centre working with the International Partnership for Microbicides (IPM) through the development of a strategic one year plan to engage their local communities in the work of IPM and microbicide research and build general community support for study participants.

Community engagement plans and reports
Each year IPM’s Community Engagement Program (CEP) will ask research centres to report on previous year’s activities and develop a yearly plan for the coming year. A templates and guidance document will be provided to help facilitate this process. Reports and plans will need to be submitted to the IPM CEP for review and approvals.

As we are beginning this process for the first time in 2008, we will only ask for the research centres to create plans for 2008. Starting 2009, we will then ask for both a report and a plan to be submitted yearly.

What elements are required in the community engagement plan?

Clinical trials of microbicides and other prevention interventions are most likely to succeed when all parties concerned – study participants, researchers, government, microbicide developers, community leaders, community advisory boards (CABS) and community advisory groups (CAGs), advocates and the community-at-large – regard the trials as a collaborative process. An aware, knowledgeable, and engaged community throughout the research process and beyond is an imperative for successful conduct of these trials. Providing communities with the tools for engagement and a true partnership between researchers and the community requires that communities have access to up-to-date, culturally, and linguistically appropriate educational information; opportunities for ongoing learning and participation; and ongoing interaction with IPM staff. Community members, particularly potential study participants and individuals from the populations from which participants will be recruited, can and should play an integral role in advising on these research trials.

The following elements are required in a community engagement plan:

- One year work plan
- Use template and include ALL eight elements listed below when writing it. Using the template helps the IP CEP better evaluate and gather information around success of community engagement efforts across all IPM research centres
- Include the research centre’s community engagement budget.
- Obtain PI, clinic/study coordinator and CAB/CAG sign-off. Their sign-off on the document indicates their inclusion in its preparation. CAB/CAG sign-off can be from the elected chairs or presiding heads of the group.
Focus on general community education and avoid including recruitment specific activities (recruitment and retention activities should be included in the recruitment and retention specific plans).

Community engagement background
Sustained relationships and communication with community members is the responsibility of each IPM Principal Investigator and his/her team.

The community engagement plan
Each clinical trial research centre will develop and implement a research centre-specific community engagement plan to ensure broad community support for IPM research and studies. This plan should address how the research centre will foster trust with the community; ensure respect of social, cultural, and political realities of the communities where recruitment takes place; provide community education; and maximize opportunities for dialogue about the design and implementation of research trials. The plan should be supported by a community assessment that identifies community education needs on general HIV prevention, potential benefits and barriers to study participation, and appropriate educational strategies to raise awareness of communities and build support for clinical trials and trial participants. The plan also should include details of how the implementation of the plan is monitored and evaluated. Please note that recruitment and retention activities and relationship building with potential and enrolled study participants will be developed separately in the IPM Recruitment and Retention Plan.

Educational strategies
Educational strategies should focus on increasing the knowledge base of communities infected and affected by HIV about HIV prevention and microbicide research; scientific concerns in the design and development of clinical trials; and the overall work at IPM. Community education efforts should also include strategies that increase the knowledge of researchers and staff about the community’s historical, cultural, social, and political issues and needs, as well as facilitate ongoing reciprocal learning and interaction between community members and researchers. Overall, it should be noted that community education is not synonymous with recruitment, but rather it is an ongoing process that helps lay the foundation for recruitment, retention, and ongoing dialogue between community members and researchers.

Overseeing the community engagement process
The research centre PI oversees implementation of the community engagement plan. The research centre budget provides for financial and human resources for the ongoing development, implementation, and coordination of community engagement initiatives, and for obtaining community members’ participation in IPM activities. IPM research centre staff, as required, report on the community engagement plan. This role is normally led by the research centre staff member responsible for engaging the community. This person is often called either the lead Community Educator (CE) or Community Liaison Officer (CLO).
Defining the communities

The term *community* can be defined as broadly as all people in the recruitment area of the IPM trial research centre, or more precisely as those targeted groups within that area who are at risk for HIV infection. This includes HIV-affected people and potential study participants.

Community involvement is essential for the IPM because health policy is often dictated by public opinion—when the public (or community) does not accept vaginal microbicides, they cannot be effectively studied. The research centres will work to create a formalized community advisory mechanism in the form of a CAB or CAG. This formalized structure will help the research centre quickly consult with a diverse representation of the general population. CABs/CAGs should not replace on-going and continued consultation with various stakeholders in the general population.

Involving communities in the planning process

There are many different ways to plan to educate communities about microbicide research and trials. However, one of the most important aspects of planning is to gain buy-in by the community. One of the most successful ways is to make sure that any plans developed incorporate the voice of interested individuals and groups. In this case, incorporating community voice is equivalent to having active participation in the planning process by those individuals and groups. The more they become a part of the process and the plan, the more they become partial owners and stakeholders in the education of their own communities. A true plan for community engagement is not written by one or two people alone, but rather by many voices. It is recommended that the community engagement plan be created in collaboration with the research centre staff and volunteer CAB/CAG members or any other group that represents the community at the research centre.

Why do we write plans?

- To develop community education efforts that are real, sustainable, well-thought-out and involve the community.
- What is thoughtfully developed ahead of time can have a major part in the success of the trial. Education efforts can make or break a trial.
- Using many minds in the community and at the research centre to develop plans gives a greater sense of ownership by the community and will better ensure communities readiness to participate in microbicide trials.
- The educator can use the way in which the plan was put together (using many different people) as a tool when explaining to communities why certain educational activities were selected.
- The plan serves as a roadmap for the year, ensuring ongoing attention to community engagement. Further, the goals and strategies provide a tool to measure opportunities that arise during the year.

Creating goals and strategies

In the Plan, goals indicate a purpose, a means to an end. A goal is what one wishes to accomplish, change or eliminate. Goals can be short-term and long-term. They should be
challenging, written down, assigned and measurable. Consider the availability of necessary resources, knowledge/skill, and possible barriers. Consider a reasonable range of goals for the research centre to accomplish in a year: it is not meaningful to plan 15 goals to be accomplished in one year if only five can be realistically accomplished with current staffing and budgetary levels.

GOALS

Goals should be **SMART**:

- **S**pecific – Use clear language with enough detail so as to avoid ambiguity.

- **M**easurable – Give people something to work towards; provide tangible evidence that the goal was completed. Examples are “a 10% increase in participation” or “two fewer days to finish the process.”

- **A**ttractive – Goals are stated in a way that encourages and influences others to accept and agree to the goal and to be involved in its accomplishment.

- **R**ealistic – Goals are attainable and not “over the top.” They may take extra work and resources, but can in fact happen. The goal is credible to those who will be involved.

- **T**ime-framed – Include a final deadline and/or smaller incremental stopping points if applicable. Working towards a future date aids in planning the work that needs to happen, and when it should happen.

STRATEGIES

These are the steps, actions and activities that help to accomplish the research centre’s goals. These strategies should be actionable, specific and as detailed as possible. Some details could include: a description of the program or event, how many people will attend, who will give presentations, which materials will be distributed, etc.

For each strategy, the research centre should maintain a record of what occurred. These program records should be maintained at the research centre, and can be helpful when reassessing your program from year to year, and help with your subsequent engagement plans. These records can help you see change over time.

**Example Goals and their Strategies:**
The context behind this example is that the educator and research centre are relatively new to the community and clinical research. They realize that one of the most important first steps is to build relationships with stakeholders and leaders in the community. The goals may look something like this:

**Goal 1:**
To build collaborative relationships with key organizations and community leaders that result in the invitation of the IPM research centre to conduct at least 20 educational sessions to the constituents of those groups or individual leaders from January to April 2009 (four months).


Strategies to achieve goal 1:
1. Map the different community groups and leaders that exist in the surrounding community.
2. Collect all necessary information about the organizations and individuals and put it into an excel spreadsheet.
3. Contact the groups and individual leaders and identify all those that would be interested in having someone come to talk about microbicide research and the work of IPM and the research centre.
4. Use the basic IPM provided resources: IPM general presentation and IPM handout materials to present work face to face to contact person.
5. Identify those groups that would be willing to have the research centre come and talk to their constituents about the work of the centre and IPM.
6. Schedule speaking engagements and appropriate person from the research centre to do outreach.
7. Collect all questions, comments and misconceptions that arise at presentations.
8. By the end of April complete at least 20 speaking engagements and have a final list of all the questions, comments and misconceptions gathered at the speaking events.
9. Invite the group contact people and community leaders to an open house meeting at the research centre to thank them for their collaboration, show them around the clinic and present them with the findings of questions, comments and misconceptions out in the community. Use this opportunity to present microbicide research and the work of IPM again explaining why the misconceptions are not true, and get input from the group on ways to present appropriate and correct information back out to their communities.

Goal 2:
Organize at least twenty community events and present information out into the general community that builds support for the microbicide effort, for the work of IPM, and for the participants that volunteer for clinical trials. (April to December 2009)

Strategies to achieve goal 2:
1. Use information gathered from initial outreach to community groups and leaders to create culturally appropriate and accurate outreach materials about microbicides, the work of IPM and the important role that study participants play in helping find a way to end the HIV epidemic.
2. Have IPM CEP review materials.
3. Pull group of dedicated community leaders and/or CAG together and have them review materials for basic community comprehension, and accurate messaging.
4. Plan twenty outreach events at the research centre and out in the community incorporating, but not exclusively to the many important days in the year such as World AIDS Day.
5. Continue to gather questions, comments and misconceptions at each event.

Evaluation Mechanisms
IPM does not have a standardized evaluation tool for use at the research centres. The CEP recommends that research centres maintain records of each program goal and strategies identified in local plans. To help research centres incorporate program evaluation into their community engagement plans at this time, the following are some general concepts on
evaluation. These may be helpful as IPM research centres plan to evaluate their goals and objectives in the coming year.

Program evaluation is divided into three types: Process, Outcome and Impact. Under each evaluation type, there are Indicators. Indicators address criteria that will be used to judge the program (such as the program’s capacity to deliver services, participation rate, levels of client satisfaction, knowledge increase, etc.). In addition, sources of evidence are the people or observations that provide documented information on the results of the educational activity being evaluated, key word being “documented”. The research centre will need to be creative in its ways to documents outcomes of their activities to assess how successful they were in achieving their goal.

1. **Process Evaluation** – This is to assess the extent to which the program is operating as planned focusing on inputs and outputs. This section covers the means, tools and procedures by which the objectives are achieved.

   - **Indicators** – Staff capacity to implement an activity; activity type and frequency; materials used; number of educational materials handed out; type and number of partnerships created.

   *Example:* The community education staff will present at least 10 public speaking engagements with at least 10 different community groups in the community surrounding the research centre. We will provide each participant in these groups with a basic fact sheet on microbicide research and two informational brochures on the work of IPM and the research centre. At the end of the year we will calculate success as having had completed 10 events with at least 10 different groups, count the number of people receiving the information, and count the number of brochures handed out.

2. **Outcome Evaluation** – This is a measurement of the effectiveness of any intervention.

   - **Indicators** – The level of knowledge acquired by the audience after an educational activity; audience reactions or level of satisfaction after an activity.
     - a. Results – The direct product or output of program activities.
     - b. Quality – The measure by which the results obtained and the processes adopted by a program are considered successful.

   *Example:* We will conduct a pre- and post-test with five community groups to monitor changes in the community’s understanding of key concepts around HIV stigma, HIV microbicide trials and research. We will provide these tests at 3 different times throughout the year to gauge one time knowledge increase and retained knowledge over time of the specific groups.

3. **Impact Evaluation** – This is the measurement of the effect a program has beyond the program’s scope. The focus is on longer term outcomes of the overall program.

   - **Indicators** – changes in participant behavior, community norms, policies or practices, health status, and quality of life.
Example: After giving presentations and working with community groups, we will monitor and evaluate the increase in community support for HIV microbicide trials and research by documenting independent acts of support made by groups in the communities. Such acts may consist of a community group taking it upon themselves to host events or talks about HIV and HIV microbicide research with their constituents, organizing activities to build awareness, speaking out in public forums about HIV microbicides, etc.

**Role of IPM’s CEP in research centre plan development**

IPM’s CEP is located in the South Africa office. They work with local IPM research centres to develop and support centre specific community engagement plans adapted to local settings. The CEP provides oversight, training and operational management support to research centres to ensure coordinated development and dissemination of educational materials, development of collaborative partnership relationships, and ongoing education of study participants, researchers, and the community-at-large.

IPM has dedicated community engagement staff to assist in facilitating the ongoing development, implementation and coordination of community engagement initiatives at each IPM research centre. The research centres’ dedicated community staff should work directly with the IPM Community Engagement Manager or designated support person in developing and undertaking the activities in the research centre plans. An IPM CEP staff member will visit each research centre quarterly to monitor progress of community engagement plans and activities and provide any necessary support. Please direct all questions and queries to:

Andrew J. Lambert
IPM Community Engagement Manager
Email: alambert@ipm-microbicides.org
Phone: +27 21 860 2315
Mobile +27 79 881 9776
Developing a Plan

The community engagement plan is comprised of eight (8) different sections. Below you will find a general description of what information is sought in each of these sections. Please follow this template outline and include all 8 sections in your plan. This “standardization” of sections will help facilitate cross research centre mentoring and support as these plans will be posted on the IPM website and will be useful tools for others to see and use in thinking through their own specific activities and events.

1. Community Assessment
2. Building Relationship in the Community
3. Building Support for Microbicide Trials, Study participants and Raising Community Awareness
4. Tracking and Helping Mitigate Social Harms
5. Community Advisory Mechanism
6. Educational Materials and Training Needs
7. Budgeting
8. Sign-Off

1. Community Assessment

In thinking about the community education goals and activities for the next year, it is important to do a basic assessment of the community in which trials will be conducted. This is basically describing the community as it presently is and the work and/or relationships that have been done and built to date. A few items that will be important to take into consideration to include in this section of the plan are the following:

- The history of the research centre’s involvement in HIV prevention research including microbicide trials; history of other community outreach work non-research related.
- The basic demographics of the area.
- How are the communities defined geographically, socially, culturally economically, politically, etc.?
- What are the challenges to community education (historically and currently)? Consider literacy rates, myths and public misperceptions surrounding sex, research, HIV/AIDS, microbicides, etc.
- Who are the target populations for the trials conducted by your research centre?
- Consider doing a “needs assessment” of the community: What information regarding microbicides and research is well understood? What information is of particular concern to the community? Are there messages that the centre needs to do a better job of conveying?
- What are some ways in which the community learns about new initiatives, health topics or the work of organizations in the community?

2. Building Relationships in the Community

One of the most important aspects of engaging the community around research and trials is to build relationships with those who are most engaged and influential in the community.
Building relationships involves learning about what other are doing, getting involved in their activities and getting them involved in the research centres’ own activities. It is about involving these key people and/or organization in the work of the research centre.

One of the best ways to begin building relationships is to map the different groups and individuals in the area. The process of mapping (gathering information) involves contacting, meeting and gathering information around what each groups or individuals do in the community. The information can then be put into a data base for the research centre community team to use at later times. Meeting with the various groups and individuals can also have an added benefit of allowing the research centre to begin educating the community, through these groups and individuals, about what their plans are around research and microbicides.

These may include but are not limited to:

- **Community Leaders** – Leaders of each community can vary from one area to another. Any community could have a whole range of people that are perceived as leaders (chiefs, politicians, nurses, head of community organizations, elders). Leaders are basically those in the community who have a strong voice and/or influence on groups of people in the community.

- **AIDS Service Providers** -- (VCT centres, AIDS support groups, Hospices, Treatment Centres, HIV prevention education groups, etc). These are people who already work in the field of HIV/AIDS. These groups and individuals already know a lot about what people are thinking or doing about HIV in their community. These groups often do their own outreach into the community around HIV prevention, counseling, etc, and are therefore important to connect with in terms of understanding perceptions of the community and challenges to message delivery around anything HIV and AIDS.

- **Non-Governmental Organizations(NGO), Community-Based Organizations (CBO)** – These are groups that may or may not work directly with HIV, but may work in other fields such as women’s issues, youth, education, social welfare, etc. Many of these groups are funded by recognizable organizations, such as the United Nations, Red Cross, European Union, GTZ, and USAID, while others are small community-based organizations funded from local government projects.

- **Government Organizations** – These include medical clinics, family planning clinics, STI clinics, VCT centres, hospitals and other government supported entities. Local governments have their own plans for HIV related activities and it will be essential to identify and know who the key players are in any given community and to involve them early on in the planning process.

As stated earlier, this is not an exhaustive list of stakeholders in any given community. Each research centre should be creative in identifying those that are influential within the context of their own communities and should work early to help them better understand the work of the research centre.
3. Building Support for Microbicide Trials, Study participants and Raising Community Awareness

The primary goals of the educational outreach activities should be to:

-Raise community awareness and build support for the larger microbicide effort and more specifically the work of IPM.
-Build support in the general community for those women who volunteer to participate in microbicide trials. This would include specific activities focused on working to include the support of male partners of study participants and men in general.
-Support and help expand the overall HIV/AIDS prevention messaging current in the local community.

The research centre should be as creative as possible in identifying audiences, audience considerations, venues, and ways to present information to their communities. As our communities are diverse, there are just as many diverse ways in which people listen, learn and adopt new ideas. IPM will provide a basic standard power point presentation that can be used as the backbone for any outreach activity. But remember, power point may not be the best way to get the information across in all communities. Below are some ideas that have come forward from various organizations doing HIV research throughout Africa. Use these examples to stimulate ideas, but also reach out to you local community, CAG and research centre staff to be creative in identifying interesting teaching opportunities in your own community.

Different audiences or places where people gather:
- Youth groups, Hospital/clinic staff and health workers, Community Leaders forums, Churches/Templs/Mosques/Synagogues, Taverns/shabeens, University student organizations and classes, Women’s groups, Men’s groups, Government institutions, The media (print, TV, radio, internet, etc.), Sex workers, NGOs/CBOs, Traditional Healers, VCT Centres, Community halls and meetings, Stadiums – sporting events, Malls, Street vendors, Sporting or recreational groups, Private businesses, Trade Unions, Community concerts, Taxi ranks, Open spaces, Markets, Stalls/Shops

Audience Considerations:
- Age, Language, Religious Beliefs, Dress Code, Occupation, Manners, Educational Level, Literacy, Ethnicity/Race, Gender, Sexual Orientation, Venue, Seating, Cultural beliefs, Mood of the environment, Time, Venue location, Size of group, Accessibility, Provisions of refreshment.

Ways to present:
- Workshops, Talks, Drama/Plays, Seminars, Puppetry, Street Bash (music).

4. Tracking and Helping Mitigate Social Harms

Activities and outreach events focused on building support for trial participation is a way to try and build community support for the women who come to the clinic to participate in a study. The more we can help the community understand the effects of HIV on the
community and the important need for people to come forward to help their community and ultimately help the world find ways to curb or end the HIV epidemic, the more we will be able to help the communities appreciate the important role that women study participants from their community play in helping to do this.

There is always a possibility for misunderstanding of why people participate in clinical trials. In many cases, in many communities, simply being associated with anything HIV can often cause one to be labeled as having HIV, and discrimination, stigma, and/or social harms could follow. As such, we must always be on the look-out for negative comments towards our research and more importantly towards the women who participate in our clinical trials.

The research centres should:

- Develop a mechanism (tracking tool) by which to document what is heard and learned in the community vis-à-vis trial participation.
- Identify and develop basic strategies for what they would try and do to quickly address (mitigate) any negative views that could grow and potentially be aimed toward study participants specifically.
- Come up with some ideas of how they might work to mitigate social harms of participants if they occur out in the community.

5. Community Advisory Mechanism

Community advisory structures have become recognized as important sources of input for researchers. These structures take on various names and have traditionally in HIV prevention research been called Community Advisory Boards (CAB) or Community Advisory Groups (CAG). It is up to each research centre to help form, develop, train and support some type of organized community advisory structure.

These CAB/CAGs should be made up of a diverse representation of the general community, including a large percentage representing the specific study population. It will be important for the research centre team to think broadly and bring together as many key leaders and stakeholders from the many different groups that exist in the larger community. These could include but are not limited to: Spiritual, Business, Political, Educational, NGO/CBO, Traditional, Union, Market Associations, Women’s Groups, Men’s Groups, etc. It is important that the research team think broadly and begin by inviting as many of these stakeholders as possible to hold discussions about the work of the research centre.

The goals of the advisory structures include advising the researchers and study team on study design, protocol informed consents and study implementation, as well as results dissemination. They can also be helpful making sure messages and outreach materials are community accurate and culturally appropriate. This organized advisory structure is NOT the recruitment and retention team, however the members of this group typically provide important input on how to recruit and retain participants from various communities. An effective group is one in which members engage in discussion, listen, feel free to talk and to ask questions, and in which researchers are willing to discuss issues openly and solicit ideas.

Together with the research centres’ community educators and liaison officers, IPM has created some basic requirements and suggested elements that should be a part of working with a locally organized community advisory structure within IPM.
IPM requirements:

- Group meets at least once a month
- Have ad-hoc meeting process in place (both for research centre to call and CABs)
- Elected chairs with term limits
- Minutes of meetings
- Basic CAB by-laws or simple rules of conduct and functioning of the group. These should be created together by the advisory group and research centre

Suggested Elements:

- Yearly intensive training, educational retreat, or longer workshop
- Educational component as a component at each monthly meeting
- Number of members = around 20 optimal
- Some basic group ownership and self facilitation
- Meeting and training agendas set by both advisory group and research centre staff
- CLO or staff in charge of educational outreach in the community arranges all that is needed for the group to function well, primarily working together with chairs to facilitate preparations

6. Educational Materials and Training Needs

IPM has provided the research centre staff with a standard community presentation entitled, “The Search for Microbicides: A possible new HIV prevention tool for women.” This document can be used as the background educational tool for talking about Research, IPM and Microbicides in general. However, the research centres are also encouraged to develop locally and culturally specific educational materials for other purposes such as handouts, flyers, posters, etc. Research centre CLO and staff can work with IPM’s Community Engagement Program in developing these materials. Please note that all educational materials developed should be cleared with IPM simply to verify consistent and accurate messages about IPM’s clinical program.

Research Centres should think about training needs for its CLO and/or outreach staff. If research centres identify outside resources and would like to have the training in-house or send people for training, this should be put into the Community Engagement plan and budget with a justification. This would then need to be approved by IPM’s Community Engagement Manager via the community engagement plan submission. For approval, it will be important for the RC to justify how this training will improve the work of the CLO and/or outreach staff, and how the skills learned can be transferred to others in the network of IPM CLOs.

7. Budgeting

Please use the excel document entitled, “Community Engagement Budget.xls” to complete your community engagement plan budget. This template follows the same format of the community engagement plan guidance document. It is important to follow the budget template as it is designed in a way help us obtain and use funds from the appropriate IPM donor source. It will also allow us to track amounts spent across sites in the different designated areas. If you have any questions about how to use this excel budget template, please feel free to contact IPM’s Community Engagement Program.

8. Sign-Off

The signature sheet should be signed by the PI and the Clinic Coordinator and include the names of the CAB members who had reviewed the document. The signature sheet should be faxed to the IPM Community Engagement Program at +27 21 860 1000.