



*Plan and Budget for
Stakeholder Engagement*

Introduction

Before you go through the steps of stakeholder engagement, you need to start *here*. Planning ahead will ensure that you determine your “baseline” — one you can use to measure your progress later — and that you have the necessary resources and the appropriate personnel to engage stakeholders and sustain the relationships you develop.

The tools in this step provide a systematic way to evaluate your team's current capacity and to identify any gaps. Establishing your baseline will help you determine which steps in this toolkit may be the most important for your team. In this way, Step One provides direction to your team as you implement the stakeholder engagement process.

Once you have established your baseline, make sure that a budget is in place for stakeholder engagement. Without adequate funds, you may not be able to continue current engagement activities, much less fill in the gaps you identified at your baseline. Even the most constrained budget should provide some money for stakeholder engagement. This step provides sample budget tools for the most basic stakeholder engagement activities and also offers ideas if you have the benefit of a larger budget.

It is essential to have a realistic understanding of the resources you will have available for stakeholder engagement. As you build relationships, it is important not to overpromise or to suggest that you can provide support beyond your means.

Once your budget is determined, you will assemble your stakeholder engagement team and ensure that everyone has the training they need to move forward. In this step, you will find sample job descriptions, suggestions for training exercises and other resources to help you build a solid team with the capacity to identify and engage stakeholders.



Goals of Step One

- Identify — and provide direction to — the other steps of stakeholder engagement that will be most useful to your trial team.
- Develop a baseline: Take inventory of your organization's resources, knowledge and skills; identify your weaknesses and strengths.
- Determine your budget for stakeholder engagement and create your plan.
- Develop your staff's capacity to engage stakeholders; hire new staff members and provide training if appropriate.

Why you need to plan and budget for stakeholder engagement

A systematic approach in this step will make it easier for your team to:

- Know what is expected of them.
- Be aware of their strengths and weaknesses with regard to stakeholder engagement.
- Measure and assess the trial's future stakeholder engagement activities.
- Budget for stakeholder engagement, and account for the use of resources.
- Monitor progress.
- Maintain — and resist compromising — stakeholder engagement activities.
- Develop an organizational structure that supports stakeholder engagement.
- Ensure you are prepared to meet commitments.

Task list

1 Establish your team's baseline.

Action: Take a systematic inventory of your current capacities and practices.

Result: This process will make the trial's team — and eventually, the trial's stakeholders — realize that stakeholder engagement can be a regular, organized process with clearly definable results. Also, establishing your baseline will help to identify the other steps in the toolkit that may be most important for your team. For example, you may discover that your team's strength is describing the broad context but that you completely lack a system for keeping track of the team's interaction with stakeholders.

Explanation: Complete an *Organizational Self-Assessment* (the baseline assessment; see Tool 1A). You will answer questions about your staff's experience working with stakeholders, including processes, knowledge and current relationships. Keep this assessment handy, as it will show you where you need to build capacity. It will also guide you as you go through the other steps in this toolkit. Furthermore, you will come back to this assessment from time to time to evaluate the stakeholder engagement process. Your team can assess its performance (a) over time and (b) between locations and studies. All of your future work in stakeholder engagement — the remaining steps in this toolkit — will be compared to this baseline.

2 Determine what you still need, and identify opportunities.

Action: Looking at your baseline assessment, identify your weaknesses. Then, with your staff, think of upcoming opportunities that could help you address these weak areas.

Result: Determining your team's strengths and weaknesses and thinking strategically about upcoming opportunities will help you develop your plan for stakeholder engagement (see Task 3). This exercise will also help you to identify the skill set you will need when the time comes to hire a new person for your team.

Explanation: Identify weaknesses, write them down and brainstorm about ways to address them (see *Tool 1B: Gaps and Opportunities*). If you find, for example, that you have a system in place but you lack the staff members required for the work, you will know that you need

to build your team. You can then determine whether an upcoming conference, event or other occasion could help you address your team's needs. This is an important intermediate step between your baseline assessment and a plan for stakeholder engagement. Doing this task well will ensure that your team creates realistic goals and objectives, and that your plan incorporates the team's strengths and addresses any gaps. This will also help you identify and take advantage of opportunities — this will be important, especially if your trial has a limited budget (see the next task on budgeting).

3 Develop a budget for stakeholder engagement.

Action: Create a budget for stakeholder engagement. Make sure to include funds for key activities, staff, training and other items that are in line with your trial's budget.

Result: When you have a budget dedicated to stakeholder engagement, you bring about greater accountability for the use of resources. Furthermore, the trial is less likely to compromise stakeholder engagement activities if the activities are part of the plan and the budget from the beginning.

Explanation: Developing a budget ensures that stakeholder engagement activities are built into the trial's plan. The budget will probably need to be submitted early — even before you have hired additional staff or developed your strategic plan. Try not to rush this process; make sure you allow enough time to consider the sorts of activities you would like to pursue. Be sure to talk to the principal investigator of the trial, members of the research network (if applicable) and others about the funding that may be available to your team.

Even a tight budget should have some funds to support basic levels of engagement. It may be a major challenge to find funding that will allow for in-depth stakeholder involvement. Where funding is tight, you may need to streamline capacity building, the production of educational materials and the translation of these materials to local languages. Further, operational costs of community advisory boards (CABs) and similar structures — as well as advocacy and

When funders make the budgets, they usually put the bulk of the funding into the implementation phase, whereas stakeholder engagement needs to take place during the conceptualization phase.

— Community liaison officer for HIV prevention research projects in Tanzania



Tips

Ensuring that you have some funds for stakeholder engagement may mean being ready to defend your team’s activities: Be prepared to negotiate for an adequate budget to ensure the identification, engagement and capacity building of your stakeholders. Even a small amount of extra money can make a huge difference for your trial.

research literacy initiatives not related to specific trials — are often considered “extra” activities even though they are key to a trial’s success.

If funding is not simply tight but inadequate to meet basic stakeholder engagement needs, document the deficiencies so that funders, sponsors and trial investigators are aware of the limitations.

Once you have a better understanding of the funds available to your team, you should complete a budget tool. *Tool 1C:*

Budget for stakeholder engagement provides a template for a basic budget (the minimum package), which may be appropriate for a small trial or one with limited funding. This template provides the major line items you should include in your stakeholder engagement activities. *The tool also* offers suggestions for what to include if your trial has more funding available for stakeholder engagement. Once you have a budget in place, you will be able to determine the kind of activities you can plan for during your strategic planning phase (see Task 4).

You may want to develop a list of “needs” versus “wants.” Make sure that everything essential for stakeholder engagement — your “needs” — makes it into the budget. Then, if you have extra funding, you can add items from your list of “wants.”

Here is an example of such a list:

NEEDS	WANTS
Brochures	Videos
Translations	T-shirts
Printing	Capacity-building workshops
Meeting support (including transport, airtime for mobile phones, venue for meeting)	Roadshows
Staff training	Public address system (for events)
Training for community advisory group	Training and recruitment of community peer educators
Dedicated staff member	
Computer	

Thinking creatively: stakeholder engagement on a tight budget

If your trial has a very limited budget, you can still engage stakeholders. But you may need to think a bit more creatively.

A one-on-one meeting with a key stakeholder is often the most effective way to establish and sustain a relationship, and it usually requires minimal staff time and transportation costs. If you would like to reach more stakeholders at a single event but you do not have the budget for multiple large-scale meetings, your team can make use of existing community events. For example, with little more than staff time and a few promotional items, your team could participate at local events that commemorate World AIDS Day, International Women's Day and other occasions.

As a way to keep their own costs down, some research teams help to organize community events and ask community businesses for support. For example, the Microbicides Development Programme's (MDP) South Africa study team held a football tournament as part of their stakeholder engagement efforts for the MDP 301 trial. A local sports shop donated football uniforms for the winning team with the name of the study team's organization printed on the jersey. This was an effective way to engage stakeholders at the local level, and it did not require a large budget.

By participating in such events, you can get to know and educate your stakeholders (through materials or one-on-one conversations). Perhaps most important, your study will be known as part of the community, which can go a long way toward establishing and maintaining relationships with stakeholders.

4 Assemble your team.

Action: Establish who will be primarily responsible for stakeholder engagement for your trial or site, and then determine who will be on the stakeholder engagement team.

Result: Having a group of staff members working together on stakeholder engagement will ensure accountability, provide a range of expertise and knowledge and provide a backstop to the lead staff member on the team.

Explanation: It is important to have a clear leader — who will work closely with the principal investigator — who has a background in stakeholder engagement, community mobilization, public relations or communications. This may be a new staff member or a current one. If it is a new member, be sure to develop a proper job description with the skills needed to undertake the task of stakeholder engagement (see Task 6).

If your trial is part of a global or national research network, it may be important to include someone from the research network on this team. This may be especially important when it comes to working with global- or national-level stakeholders. You may also want to include some support staff or information technology staff on your team because you may need help setting up meetings, developing presentations, printing materials, creating a website, maintaining email lists and so on.

Often, the staff member who takes the lead for stakeholder engagement is the trial's community educator or CLO. It is preferable to have this staff member dedicated to stakeholder engagement on a full-time basis. This can be challenging because these individuals tend to have skills that make it tempting to pull them into other areas of the trial — such as recruitment, communications or other tasks — particularly if the trial is underfunded or understaffed.

In addition to dedicating a staff member to lead stakeholder engagement, it is vital to have a team working on stakeholder engagement to ensure that these activities are not pushed aside because of other pressing concerns. Having a team also ensures that stakeholder activities are not dropped when the leader is out of the office for travel, vacation, illness, family emergencies or other reasons.

Team members may have other responsibilities, but they should meet regularly. Meeting agendas should include updates on action items from previous meetings. The team's leader should work closely with other research team members, attend core leadership meetings, review trial materials and be aware of any changes in research implementation.

A team approach makes it easier to engage all stakeholders — including those beyond the local community — because you are tapping into the networks of staff members with diverse professional and personal relationships.

It is crucial to have a core group of people who have stakeholder engagement as an explicit part of their job responsibilities to ensure that the work will get done. Although you will probably make use of most members of the research team at some point, keep the core group to a manageable size — three or four people should be adequate for most studies.

5 Develop a plan for stakeholder engagement.

Action: Set goals and objectives for your trial's stakeholder engagement activities. Then develop your plan, which can be organized in a grid format that lists the stakeholder groups. You will also need to develop a work plan, an action plan and a timeline.

Result: A well thought out plan will ensure the involvement and buy-in of a broad cross section of stakeholders, and can ultimately lead to the success of not only your current trial but future trials as well.

Explanation: If you are developing a stakeholder engagement plan for the first time, creating your goals, objectives and action plans takes time. Remember that this work will pay off in the long run. Be patient. Don't rush the front end of this process. Also, remember that planning does not preclude doing some of the basic work. Stakeholder engagement activities and opportunities will occur concurrently with the planning process. Establishing the team's vision for stakeholder engagement early is critical so that this vision can guide individual actions. With that said, don't let planning become an obstacle to doing the work of stakeholder engagement!

If stakeholder engagement is to be a critical part of a research project, the commitment has to be very evident among the top levels of project management.

— Senior strategic planner for a research organization in Tanzania

Plan for stakeholder engagement

Goals and objectives

Develop your goals first. They will provide direction to your objectives, work plan, timeline and other planning materials. Goals are broad statements of what your team wants to accomplish, and goals focus on ends rather than means. Think of the large scale impact that your team is aiming for, but be realistic. You can have more than one goal, but try not to have more than a few — all should be achievable.

Here is an example of a well-written **goal** for a microbicide trial:

- Increase awareness of HIV/AIDS, clinical trials and microbicides.

Your objectives are steps that your team plans to take to achieve your goal(s). To develop your objectives, identify obstacles that can be overcome by engaging stakeholders.

Here is an example of **objectives** to support your goal:

- To assess the knowledge of stakeholders — at the local, national and global level — on clinical research, HIV prevention and microbicides
- To address any identified gaps through outreach and education efforts

Action plan and activity prioritization

Now that you have outlined your goals and objectives, you can plan specific activities (sometimes called “strategies”). See *Tool 1D* for a simple “action plan” matrix that itemizes the person(s) responsible, materials, indicators and outcomes.

Examples of **activities** to support your goal and objectives:

- Develop a needs assessment tool.
- Conduct a needs assessment at the local, national and global level.
- Analyze findings from the needs assessment,
- Share your findings with the stakeholder groups (among which they were conducted).

Once you have determined your activities (or strategies), you should prioritize the activities based on their importance and urgency (see *Tool 1E* for a template that will help your team think through this process).

Matrix of stakeholders

Next, your team should develop your matrix of stakeholders (see *Tool 1F*). Note that this matrix is different from a contact list of stakeholders (which you will develop later in *Step*

Five). The matrix is used for planning purposes, and it will focus on your overall strategy for engaging the five broad groups of stakeholders.

This matrix will guide the rest of your team's planning process. In developing this matrix, you will discuss the potential role of the stakeholders, the strategy for engaging them (such as face-to-face meetings and community events), the desired outcome (such as support from local leaders or global advocates), a follow-up strategy to ensure continued engagement and the timing of engagement. Some of these items may need to be left blank until you complete some of the later steps in this toolkit. For example, you probably have not identified all of your stakeholders this early, so you will need to wait until you complete *Step Five* to complete this grid. But you can at least set up your matrix and begin establishing the overarching strategy for stakeholder engagement in your trial.

Work plan

Now that you have completed your goals, objectives and action plan and prioritized your activities, you can create a written work plan. For a work plan template, refer to *Tool 1G*.

Exactly what is included in your trial (or site) work plan may be dictated by your research network or funder. Most work plans, however, have some combination of the following: basic information about the trial or site (including the name of the principal investigator); goals, objectives and planned activities; and a basic assessment of the trial community (including any current issues that the team should be aware of). A section may also be included about the involvement of a community advisory board (CAB) or community advisory group (CAG); these will be discussed in more detail in *Step Six*.

Timeline

After your work plan is complete, construct a timeline (see *Tool 1H*). A timeline can help your team ensure the completion of key stakeholder engagement activities, and it will help ensure that your work plan is realistic. First determine the month you will begin your activities; then plan your work for the upcoming year (and longer, if you choose).

Ideally, you will assemble your entire stakeholder engagement team to draft your timeline. You may want to write each activity on a note card. Then as a team, you can put the cards in order on a table (or taped to the wall) before deciding on the final timeline.

Some activities will need to be repeated more than once, and others may not yet have a place on the timeline. By the end of your exercise, though, you should have all of the cards in order and you will be ready to assign months (or years) to each activity. This is a good time to make sure that someone on your team is responsible for each activity.



Case Study

The importance of documentation

Based on: Kirkendale S, Omullo P, Agot K, Odhiambo J, Ratlhagana MJ, Malamatso R, Ahmed K, Van Damme L, Corneli A. Documenting community involvement in FEM-PrEP. IAS 2011 Conference, Rome, Italy. Poster MOPE392. Geneva: International Aids Society; 2011.

FEM-PrEP was a Phase III randomized, placebo-controlled, clinical trial designed to assess the safety and effectiveness of a daily oral dose of an antiretroviral drug (ARV) called Truvada for HIV prevention among women. HIV-negative women between the ages of 18 and 35 who were at high risk of HIV exposure volunteered to take part in FEM-PrEP at four sites in Kenya, South Africa and Tanzania.

At the Bondo, Kenya site, the community involvement activities included general community education in the chief's *barazas* (public meetings), in churches, with men's and women's groups and in meetings with key stakeholders, either individually or in groups. The community team also attended community meetings that were not organized by the study staff but to which they were invited to address the people gathered.

Stakeholder engagement activities were planned monthly, and *ad hoc* meetings were also conducted when needed. Meetings were coordinated by a community liaison officer and assisted by field staff members who took minutes, noting issues raised, questions asked and responses given. The notes were expanded at the end of each meeting.

During community outreach the team learned that some participants may not have informed their partners about their participation in the study. Male community members also expressed concern about not being informed about their partners' participation. For example, one male partner reported, "If I find my wife taking these pills without my knowledge, I will throw them away." A lack of support from a partner could impair a participant's ability to adhere to the study product or attend the study visits. In response, the team increased outreach efforts to meet with men and to address their concerns.

Stakeholder engagement at the Bondo site included these activities:

- More than 600 general community education meetings during the preparedness phase, during trial implementation and after trial closure
- Establishment of a community advisory board that held quarterly and ad hoc meetings to obtain community feedback
- More than 70 meetings to involve males (targeting men only)
- More than 36 well-attended stakeholder meetings in the local districts

The documentation and constant, timely and respectful feedback processes at the sites and communities contributed to the broad-based support of FEM-PrEP and an overall decrease in rumors and controversy. Many men who had misconceptions about the study were satisfied after they took advantage of opportunities for discussions and explanations of the research.

6 Develop job descriptions.

Action: Determine main job responsibilities and write position descriptions for staff members working on stakeholder engagement activities.

Result: With detailed job descriptions for new positions, your team will attract the right candidates. And you will ensure that you hire people with skills that can boost your stakeholder engagement activities. Writing job descriptions for staff members will make sure that staff members know what is expected of them and makes it more likely that they will be accountable for their various tasks. Having job descriptions in writing that are approved by the principal investigator and the rest of the trial's leadership will also ensure that the organizational structure of your trial team is supportive of stakeholder engagement and that a system is in place to continue this work, even in the case of staff turnover.

Explanation: You will need to write job descriptions for each person with direct responsibility for stakeholder engagement tasks — whether it is a current staff member or a new recruit (see Tool 11 for sample job descriptions).

How do you find the right staff members to implement stakeholder engagement? What should the skill set of a potential staff member look like? These are questions your team needs to address before developing job descriptions for each team member who will work on stakeholder engagement (including filled and open positions).

Make sure that your team has one or more people with the following skills:

- **Language proficiency:** It will be important for one or more people on your team to speak the main language(s) of the key trial stakeholders, including community members, global advocates and others. The ability to read, write and speak in the major international language of the region or research network — such as English, French or Spanish — as well as being fluent in local language(s) is crucial.
- **Public relations:** The staff selected will spend much of their time interacting with stakeholders who are important to your trial's success, so it is important that they have some previous experience in public relations. They can obtain on-the-job training (see the section on capacity building) to complement their experience, but it is important that they feel comfortable speaking in public and that they present themselves well. Remember that they will be ambassadors for your trial.
- **Communications:** One or more people should have the ability to write materials, plan and facilitate meetings and develop messages to share with the stakeholders. You may

wish to ask for writing samples from the potential candidates. You might ask them to give a presentation because the ability to communicate well in a group setting will be important.

- **Organization and project management:** Stakeholder engagement will involve many moving parts, including planning and implementing activities, keeping track of stakeholders at multiple levels, monitoring and evaluating the process and working with stakeholders to develop capacity. To keep track of your team's progress and your stakeholders, your team leader will need to be organized and should have experience managing collaborative projects.
- **Partnership building:** Someone who can build partnerships with stakeholders at all levels — from local to global — will be an asset to your team. Familiarity with the major stakeholders in the country or region — and the local community and customs — in which the team will be working is also important.
- **Technical knowledge:** Although all staff will have on-the-job training about the trial's protocol and any issues specific to the trial, it will serve the trial well to have stakeholder-engagement staff members with some technical knowledge of research, particularly HIV prevention research.
- **Teamwork:** Everyone must be a strong team player with the ability to function smoothly as a key member of the research team.
- **Consulting skills:** A broad range of consulting skills for those coordinating stakeholder engagement processes is essential. The following article on “Choosing a Consulting Role”¹ gives practical and realistic guidance for people in this role who need to decide on the most appropriate role(s) for them to fulfill:
<http://www.questia.com/library/1G1-8167764/choosing-a-consulting-role>

7 Ensure capacity building among the staff.

Action: Ensure that your staff members have the proper training and resources to undertake stakeholder engagement activities.

Result: Your stakeholder engagement staff will spend their time interacting with people who are crucial to the trial's success. As ambassadors for your trial — at the community, regional, national, and global levels — it is important that your staff have proper training and accurate information to adequately speak for the trial to stakeholder groups.

¹ Champion DP, Kiel DH, McLendon, JA. Choosing a consulting role [Internet]. Training & Development Journal; 1990 Feb 1 [cited 2012 April]. Alexandria (VA): ASTD. Available from: <http://www.accessmylibrary.com/article-1G1-8167764/choosing-consulting-role.html>

Explanation: All staff members who are involved in stakeholder engagement should be trained in the following areas:

- **Ethics:** Training in research ethics will be required for all staff members who will work on your research trial. The specifics will likely be dictated by your research network or sponsor, but there are a number of resources that can be used either as core training or to supplement required training. For example, FHI 360 offers an online training course in research ethics and a research ethics curriculum specifically for community representatives, which is well suited for face-to-face group training. (Please see the Additional Resources section at the end of this toolkit for a link to this course.)
- **Communications and public relations:** Your team should ensure that someone with appropriate expertise in communications and media skills provides training to each person working on stakeholder engagement. Even if your stakeholder-engagement staff members are not official spokespersons for the trial to the media, you should ensure that they have the proper training and that they are aware of any standard operating procedures related to communications and the media. You may want to collaborate with your trial's communications team for this training — or have the training provided by your communications staff (if possible). For more on training staff members in public relations and communications — including techniques staff members can use to practice delivering key messages about the trial — refer to Chapter 2 of the *Communications Handbook for Clinical Trials*. (Please see *Additional Resources* at the end of this toolkit for a link to this resource.)
- **Trial protocol:** Make sure that stakeholder engagement staff members understand the basics of HIV prevention research and that they are familiar with the trial protocol. The most efficient way to do this is to include stakeholder engagement staff in the basic protocol trainings offered to other members of the research team. This will ensure that everyone is hearing the same messages and benefiting from any discussions that occur during the training. You may need to arrange for HIV prevention research literacy training for stakeholder engagement staff prior to the protocol training if they do not have sufficient on-the-ground experience with such clinical research. As ambassadors of the trial to the larger community — and to stakeholders at the national and global levels — engagement staff should be prepared to answer questions about the trial and to speak accurately about research methods.



Checklist: Step One

Use this checklist to make sure that you accomplished all the tasks required in Step One.

- Establish your team's baseline for stakeholder engagement.
- Identify gaps and opportunities.
- Develop your budget.
- Create an overall plan for stakeholder engagement.
- Assemble your team, ensuring necessary capacity and organizational structure.



Appendix

Tools: Step One

Tool 1A: Organizational self-assessment

Tool 1B: Gaps and opportunities

Tool 1C: Budget for stakeholder engagement

Tool 1D: Action plan

Tool 1E: Activity prioritization grid

Tool 1F: Matrix of stakeholders

Tool 1G: Work plan

Tool 1H: Timeline

Tool 1I: Sample job descriptions

Tool 1A: Organizational self-assessment

This tool will help you assess the strength and consistency of the organization's commitment to stakeholder engagement.

You may wish to answer this questionnaire with several staff members; pooling your knowledge may increase the tool's validity. You could ask individuals who have differing perspectives on your organization — trial staff members, leaders of partner organizations and funders — to complete this with your trial in mind.

Tool 1A: Organizational self-assessment (baseline assessment)

Name of Organization: _____

Please answer yes or no to the following questions and provide additional details where relevant.

1. Does anyone on your staff have experience with stakeholder engagement?

Yes _____ No _____

If yes, please describe:

2. Does your team have a process for doing stakeholder engagement?

Yes _____ No _____

If yes, please describe or note where this process is documented:

3. Does your trial team follow a set of guiding principles for engaging with stakeholders in a research trial?

Yes _____ No _____

If yes, please describe or note where these principles are documented:

4. Has your trial team conducted an environmental scan, done formative research or otherwise identified and documented key features of the country, regional and local context (as appropriate) where the research is taking place?

Yes_____ No_____

If yes, please describe:

5. Does your trial team have the budget, staff and other resources necessary to support stakeholder engagement through the entire life cycle of the proposed research project — and even beyond that time frame?

Yes_____ No_____

If yes, please describe:

If no, please indicate which resources are lacking:

6. Has your trial team already identified stakeholders (in a systematic way) in the following stakeholder groups:

- | | | |
|--|----------|---------|
| a. Trial participants and their families and partners? | Yes_____ | No_____ |
| b. The local community? | Yes_____ | No_____ |
| c. Policymakers and advocates? | Yes_____ | No_____ |
| d. Other researchers, funders and sponsors? | Yes_____ | No_____ |
| e. Program and service providers? | Yes_____ | No_____ |

7. How would you rate your site's knowledge of the following groups?

a. Trial participants and their families and partners

Excellent _____ Good _____ Fair _____ Poor _____ Nonexistent _____

b. The local community

Excellent _____ Good _____ Fair _____ Poor _____ Nonexistent _____

c. Policymakers and advocates

Excellent _____ Good _____ Fair _____ Poor _____ Nonexistent _____

d. Other researchers, funders and sponsors

Excellent _____ Good _____ Fair _____ Poor _____ Nonexistent _____

e. Program and service providers

Excellent _____ Good _____ Fair _____ Poor _____ Nonexistent _____

8. How would you rate your site's relationships with the following groups?

a. Trial participants and their families and partners

Excellent _____ Good _____ Fair _____ Poor _____ Nonexistent _____

b. The local community

Excellent _____ Good _____ Fair _____ Poor _____ Nonexistent _____

c. Policymakers and advocates

Excellent _____ Good _____ Fair _____ Poor _____ Nonexistent _____

d. Other researchers, funders and sponsors

Excellent _____ Good _____ Fair _____ Poor _____ Nonexistent _____

e. Program and service providers

Excellent _____ Good _____ Fair _____ Poor _____ Nonexistent _____

9. Has your team ever undertaken a stakeholder analysis before?

Yes_____ No_____

If yes, please describe or note where this analysis is documented:

10. Do you have descriptive profiles of any stakeholders? Or has your organization ever created profiles for another trial?

Yes_____ No_____

If yes, please describe or note where these descriptive profiles are documented:

11. Does your organization monitor and evaluate the effectiveness and efficiency of stakeholder engagement?

Yes_____ No_____

If yes, please describe or note where the M&E activities are documented:

12. Do you begin stakeholder engagement during the conceptualization phase of a trial?

Yes_____ No_____

If yes, do you modify the engagement process during any other part of the trial (e.g., during the dissemination of the trial's results)?

Yes_____ No_____

If yes, please describe:

Tool 1B: Gaps and opportunities

This tool will help you pull information from your baseline assessment (Tool 1A) and determine how to address your team's weaknesses. You should complete this tool immediately after you conduct the baseline assessment, with the same group of people.

Gaps	Opportunities

Example — Completed Tool 1B: Gaps and opportunities

Gaps	Opportunities
We have identified stakeholders, but we have limited relationships, especially policymakers and other researchers.	Upcoming conference in Nairobi will offer our team the chance to develop relationships with other key researchers in the country — we will plan to attend. We will also hire a staff member who has experience working with the Ministry of Health — this should give us the chance to improve our relationships with policymakers.
Our team engages with stakeholders early on in the trial (the conceptualization phase), and sometimes during results dissemination, but does not keep engaging throughout the trial.	We will plan (and budget for) events to continually engage with stakeholders during the course of the trial. We will also work with our communications staff to develop materials for various audiences.
No one on the team has experience with M&E of stakeholder engagement.	Write M&E experience into new job description.

Tool 1C: Budget for stakeholder engagement

This template includes suggested line items for your stakeholder engagement budget. You can refer to your list of “needs” versus “wants,” and select some of the items in your “wants” list for your expanded budget if you have the benefit of a larger budget. If you are conducting a large trial — or simply have more funds for stakeholder engagement — we have included suggestions for some “extra” activities — “wants” — to help enhance your team’s portfolio. (Note the items that have been added to this budget are shown in **green text**.) When planning for staff time, be sure to consider all stages of the stakeholder engagement process, including work planning, ongoing engagement and capacity development.

Tool 1C: Budget for stakeholder engagement.

Black text indicates suggested basic items; green text indicates suggested extra activities.

Name of project:			
Protocol number:			
Date completed:			
Is this a revised version of an earlier budget? <input type="checkbox"/> Yes <input type="checkbox"/> No			
Budget categories			
Exchange rate: [funder currency] = [local currency]			
Salaries (title and effort)			
Director of stakeholder engagement (___ % for ___ months)			
Community educator/liaison (___ % for ___ months)			
Administrative support (___% for ___ months)			
Site PI (___% for ___ months)			
Other staff (___% for ___ months)			
Subtotal salaries \$			
Staff training			
Room rental			
Trainer/facilitator			
LCD projector; video camera, DVDs			
Training materials/duplication/printing/binders/etc.			
Travel and per diem, if necessary			
Catering, if necessary			
Subtotal training \$			

Promotional items			
Materials development (brochures, leaflets, thank-you cards, other items)			
Translation			
Printing costs			
T-shirts, condoms, bags, etc.			
Subtotal promotional items \$			
Stakeholder engagement meetings			
Room rental			
Trainer/facilitator			
LCD projector; video camera rental, tapes			
Travel and per diem, if necessary			
Catering, if necessary			
Subtotal meetings \$			
Stakeholder engagement roadshows			
Room rental			
Trainer/facilitator			
LCD projector; video camera, DVDs			
Travel and per diem, if necessary			
Catering, if necessary			
Subtotal roadshows \$			
Stakeholder engagement workshops			
Room rental			
Trainer/facilitator			
LCD projector; video camera, DVDs			
Travel and per diem, if necessary			
Catering, if necessary			
Subtotal workshops \$			
Operational costs			
Telephone (including minutes for mobile phones), Internet, fax, courier			
PA system (for events)			
Local travel to meet with stakeholders (gas, mileage)			
Postage			
Computer, printer, back-up drive, thumb drives, Internet access			
Digital recorders, cameras, video			
Subtotal operational \$			
Overhead \$			
TOTAL \$			

Tool 1D: Action plan

This tool should be completed after your team has developed its goals and objectives. Use this form to outline the activities that you will complete in support of your goals and objectives. You should complete a separate matrix for each objective, and you can outline persons responsible, materials needed, indicators and measurable outcomes (for M&E purposes). This tool was adapted from an activity grid created by the Microbicide Trial Network's VOICE trial.

Tool 1D: Action plan

Date completed:

Objective:

Activity	Responsible Persons	Materials	Indicators	Measurable Outcomes
1.1				
1.2				
1.3				

Example — Completed Tool 1D: Action plan

Date completed: 12 June 2011

Objective 1: To assess the knowledge of community volunteers and community members on clinical research, microbicides and PrEP through a needs assessment exercise.

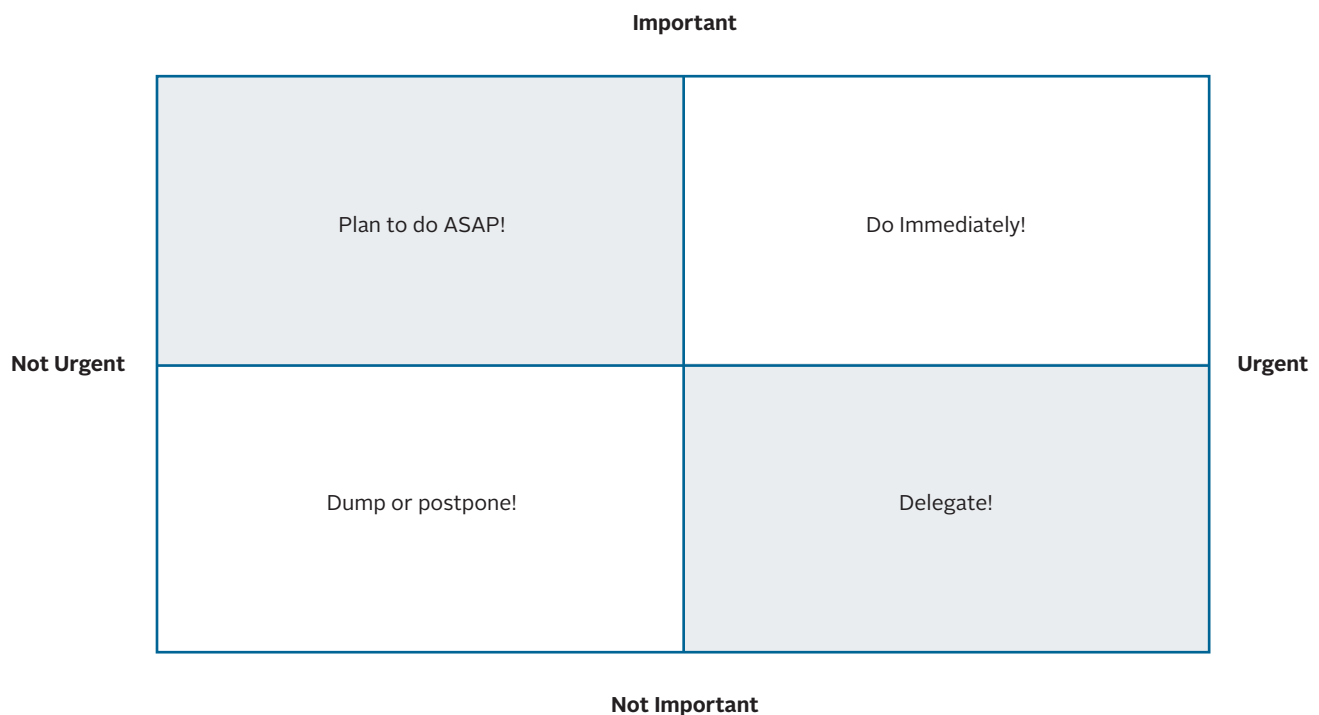
Activity	Responsible Persons	Materials	Indicators	Measurable Outcomes
1.1 Develop assessment tools	Community educator	Personnel Paper Pens	Tools developed	Various types of tools developed according to the target audiences.
1.2 Conduct needs assessment for CAB and Outreach Workers	Community education team	Personnel Paper Pens Hire of venue Transport refund Snacks/drinks Questionnaires Flip charts	Needs assessment conducted for all the CAB and outreach workers	Assessment conducted and knowledge gaps identified among CAB members and Outreach Workers.
1.3 Conduct needs assessment for stakeholders and general community members using questionnaires and small group discussions	Community education team with CAB members	Personnel Paper Pens Hire of venue Transport refund Snacks/drinks Questionnaires Flip charts Water for interviewers	Needs assessment conducted for all the stakeholders and randomly selected general community members in targeted communities	Assessment conducted and knowledge gaps identified among stakeholders and randomly selected general community members in targeted communities.

Tool 1E: Activity prioritization grid

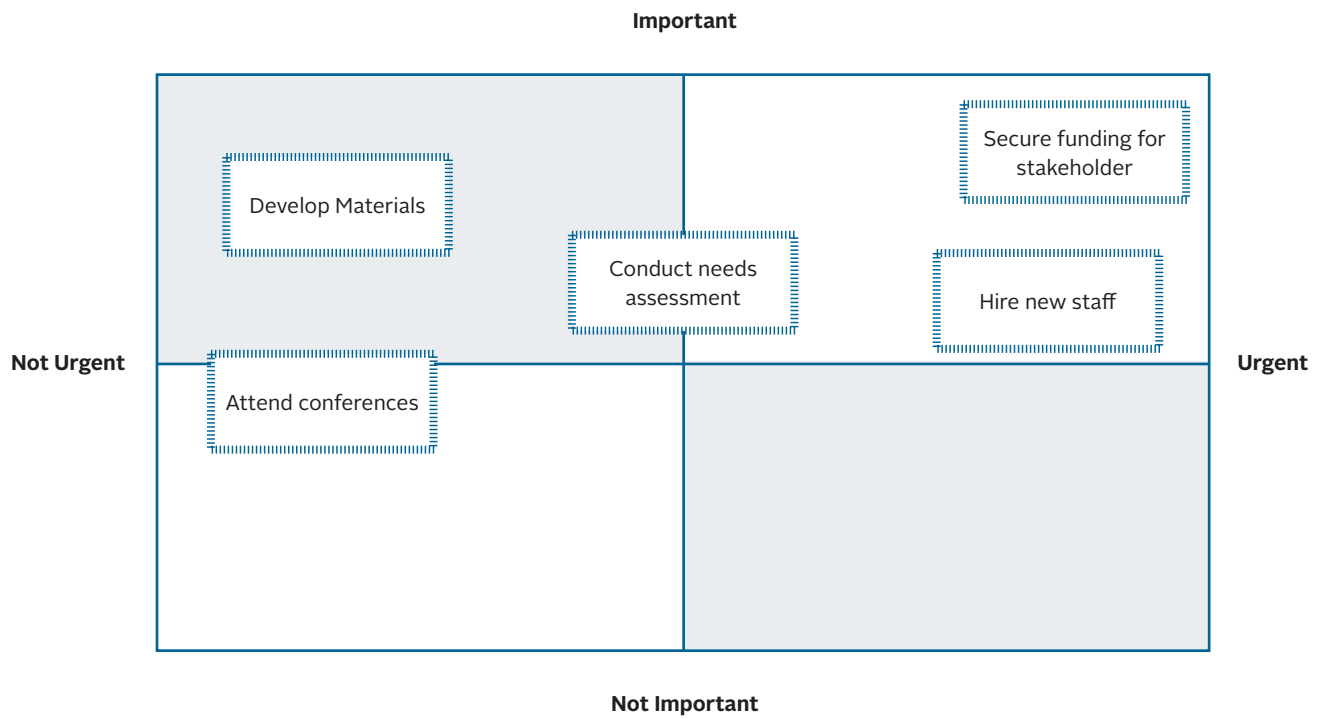
Once you have outlined your team's activities, you can use this simple grid to prioritize activities. For each task, decide how important and urgent it is. Tasks that are important and urgent will be placed in the upper right quadrant. These tasks should be completed first. Tasks that are less important, but still urgent, can be placed in the bottom right quadrant. These tasks should be completed second. Tasks that are important but not urgent should be placed in the upper left quadrant and should be completed third. Tasks that are neither urgent nor important should be placed in the bottom left quadrant. These tasks can be completed as time and resources allow.

As a team, write each activity on your grid in the appropriate spot. When you are finished, your team should have a clear idea of the order in which to complete each activity. This can feed into your timeline (see *Tool 1H: Timeline*).

Tool 1E: Activity prioritization grid



Example — Completed Tool 1E: Activity prioritization grid



Tool 1F: Matrix of stakeholders

The following tool can be used to plan your stakeholder strategy. This matrix is crucial to the rest of your planning process. Some items may need to be left blank until you complete some of the other steps in this toolkit, but you should set up your matrix and begin establishing the overarching strategy for stakeholder engagement in your trial. Adapted with permission from this resource: MEASURE Evaluation, USAID. Stakeholder engagement: An assessment and implementation tool for identifying stakeholders in a data collection initiative and engaging them as contributors and beneficiaries. Data demand and information use, part 2: Strategies and tools [Internet]. Available from: <http://www.cpc.unc.edu/measure>.

Tool 1F: Matrix of stakeholders — for overall plan

Date completed: _____

Stakeholder (organization, group or individual)	Potential role in the trial	Engagement strategy	Desired outcome	Follow-up strategy and plans for feedback or continued involvement	Timing of engagement
Trial participants, their families, partners, neighbors, co-workers					
Local community members					
Health care programs and service providers					
Researchers, funding agencies and regulatory bodies					
HIV and AIDS policymakers and advocates					

Example — Completed Tool 1F: Matrix of stakeholders for overall plan

Date completed: 15 June 2011

Stakeholder (organization, group or individual)	Potential role in the trial	Engagement strategy	Desired outcome	Follow-up strategy and plans for feedback or continued involvement	Timing of engagement
Trial participants, their families, partners, neighbors, co-workers					
	Ambassadors to community	Meetings, initial appointments (with participants and partners)	Represent accurate information about the trial to other community members	Regular meetings, appointments, brochures, other materials	Periodic engagement — from conceptualization until after results dissemination
Local community members					
		Meetings, presence at community events	Participate in trial planning, represent the study accurately to other stakeholders	Continue to participate in community events and hold regular CAB meetings (as well as larger meetings)	
Health care programs and service providers					
Researchers, funding agencies and regulatory bodies					
Researchers in other HIV prevention trials	Scientific partners	Conference calls, contact at scientific meetings and conferences	Support for current study, partnership in future trials	Monthly calls, regular emails and e-newsletters	Begin at trial launch, continue through dissemination and beyond
The X Foundation	Funder	Conference calls	Support during the study, support for future trials	Monthly check-in calls, regular emails	Early engagement and regular contact
HIV and AIDS policymakers and advocates					
Treatment Action Coalition (TAC)	Advocate for trial	Contact at meetings and conferences	Support for trials, advocacy for HIV prevention research	Semi-annual calls, regular emails and e-newsletters	

Tool 1G: Work plan

Use this template to create your team's work plan. What you include may be partially dictated by your research network or sponsor. However, you should make sure to include some background and basic details about the trial, along with information about your goals, objectives and activities. The previous tools you have completed (1A–1F) can be used to fill out your team's work plan. This work plan has been adapted with permission of the Microbicide Trials Network.

Tool 1G: Work plan

Stakeholder engagement work plan

Clinical research site: _____

[Relevant research network information]: _____

Staff member completing the work plan: _____

Community advisory board (CAB) chair/representative signature:

_____ **Date signed:** _____

Principal investigator (PI) or investigator of record (IoR) signature:

_____ **Date signed:** _____

Date submitted: _____

I. Stakeholder assessment

- a. Please provide the names and contact information (office and mobile numbers, and email addresses) for your site's stakeholder and/or community engagement staff.
- b. Describe any challenges that your site expects to experience with current or upcoming trials. Describe how your staff (and the CAB, if appropriate) plans to respond to these challenges.

- c. Have there been changes in the population of your community during the past year that might affect the site's education, awareness and sensitization efforts? If so, please describe.
- d. Describe any events happening in your community that might adversely affect participant accrual, retention, adherence or community ownership of current or upcoming studies.
- e. Are there new messages or information about upcoming trials that the site needs to consider in planning its education, awareness and sensitization efforts?

II. Stakeholder involvement

- a. New scientific information about HIV, HIV prevention strategies and microbicides (*or PrEP or other HIV prevention methods being studied*)
 - i. How will the stakeholders be kept up-to-date on new scientific information, HIV prevention strategies, and microbicides (or PrEP or other HIV prevention methods being studied)?
 - ii. Is there any stakeholder training planned for the upcoming year? If yes, please describe.
 - iii. Describe the structure of your CAB.
 - iv. In reaching out to the larger community, which groups does your team work with?
 - v. Are there groups that you have not previously been successful in reaching? How do you plan to reach out to these groups in the coming year?
- b. New stakeholder information about HIV, HIV prevention strategies and relevant research
 - i. How will the stakeholders keep the research team informed about new activities, programs, collaborations, etc.?
 - ii. Do research team members sit on key boards or otherwise participate in community groups so that they can learn from the stakeholders?

III. Goals/objectives/activities

a. Goal 1

i. Objective

1. Activity 1*
2. Activity 2
3. Activity 3
4. Activity 4

ii. Objective

1. Activity 1
2. Activity 2
3. Activity 3
4. Activity 4

b. Goal 2

i. Objective

1. Activity 1
2. Activity 2
3. Activity 3
4. Activity 4

ii. Objective

1. Activity 1
2. Activity 2
3. Activity 3
4. Activity 4

**For each activity, you may wish to provide the following details: responsible person(s), materials needed, indicators, measurable outcomes and estimated cost. This information can be obtained from your action plans (see Tool 1D) and your budget (see Tool 1C).*

Example: Completed Tool 1G: Work plan

(This is a fictitious example.)

Stakeholder Engagement Work Plan

Clinical Research Site: Lusaka, Zambia

Trial: Protocol 003

Staff member completing the work plan: Mary Demke

Community advisory board (CAB) chair/representative signature:

Pastor Nixon Mundia, CAB Chair

Principal investigator (PI) or investigator of record (IoR) signature: Dr. Francis Pilusa

Date submitted: 29 August 2010

I. Stakeholder assessment

- a. Please provide the names and contact information (office and mobile numbers, and email addresses) for your site's stakeholder and/or community engagement staff. Sena Chiti, community educator, (234) 123-456-789, sena@domain.org; Geradine Beta, recruitment nurse, (234) 987-654-321, geradine@domain.org
- b. Describe any challenges that your site expects to experience that are related to current or upcoming studies. Describe how your staff (and the CAB, if appropriate) plans to respond to these challenges. There were rumors in the last trial about the transmission of HIV to trial participants through blood draws. We did extensive education, but still expect some problems, so we will plan community education via community events, drama presentations and brochures.
- c. Have there been changes in the population in your community during the past year that might affect the site's education, awareness and sensitization efforts? If so, please describe. No
- d. Describe any events happening in your community that might adversely affect participant accrual, retention, and adherence, or community ownership of current or upcoming studies. We will have a new president soon and should keep this in mind when planning our engagement efforts.
- e. Are there new messages or information about upcoming trials that the site needs to consider in planning its education, awareness, and sensitization efforts? There are other gel trials going on at the same time, and we should consider this when developing messages in order to avoid confusion or conflation of the various trials.

II. Stakeholder involvement

- a. New scientific information about HIV, HIV prevention strategies, and microbicides (*or PrEP or other HIV prevention methods being studied*)
 - i. How will the stakeholders be kept up-to-date on new scientific information, HIV prevention strategies, and microbicides (*or PrEP or other HIV prevention methods being studied*)? Regular meetings and emails
 - ii. Is there any stakeholder training planned for the upcoming year? If yes, please describe. The CAB will have ethics training, as well as training on the transmission of HIV.
 - iii. Describe the structure of your CAB. We have 20 members, representing the diversity of trial participants.
 - iv. In reaching out to the larger community, what groups does your team work with? Churches, AIDS advocacy groups, district clinic staff, traditional healers, VCT clinics, schools
 - v. Are there groups that you have not reached successfully? How do you plan to reach out to these groups in the coming year? We had difficulty reaching larger (global) advocacy organizations, but we plan to attend conferences and participate regularly in open-forum email lists, conference calls, etc.

III. Goals/objectives/activities

- a. **Goal 1:** Increase awareness of HIV and AIDS, clinical research trials, PrEP and microbicides.
 - i. **Objective 1:** Assess the awareness of stakeholders about HIV and AIDS, clinical research trials, PrEP, and microbicides.
 - 1. Activity 1: Develop assessment tools.
 - 2. Activity 2: Conduct needs assessment among CAB members and other stakeholders.
 - 3. Activity 3: Analyze findings of the needs assessment.
 - 4. Activity 4: Share the findings with stakeholders.
 - ii. **Objective 2:** Fill the identified gaps from the needs assessment.
 - 1. Activity 1: Develop messages to be used with each stakeholder group.
 - 2. Activity 2: Print messages on brochures and fliers.
 - 3. Activity 3: Develop email newsletters with messages.
 - 4. Activity 4: Hold community meetings where messages are delivered and discussed.

- b. Goal 2:** Develop and strengthen relationships with stakeholders, especially global advocates.
- i. Objective 1:** Identify key stakeholders — especially global advocacy organizations — and deliver messages about HIV prevention research and our trial.
1. Activity 1: Identify stakeholder groups and obtain contact info.
 2. Activity 2: Arrange meetings or trainings for the identified groups.
 3. Activity 3: Provide ongoing trial updates to these groups.
- ii. Objective 2:** Partner with other trials to engage advocacy groups and other key global audiences.
1. Activity 1: Participate in regional and global HIV meetings.
 2. Activity 2: Participate in related conference calls.
 3. Activity 3: Participate in community events where global nongovernmental organizations may have a presence.
 4. Activity 4: Monitor global media and open-forum email lists.

Tool 1H: Timeline

This timeline should be filled out after your work plan is complete. You can fill out just the first year of the trial, or you can begin a multiyear timeline and fill it out as you go. You can use different colors to designate audience, person responsible or level of importance and urgency.

Tool 1H: Timeline

Date completed:

[Activity]					[Activity]			[Activity]				
Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	
	[Activity]			[Activity]					[Activity]			

Example — Completed Tool 1H: Timeline

Date completed: 11 August 2011

Staff		Conduct needs assessment						Fill gaps identified in needs				
Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	
	Ethics training with stakeholders		First CAB meeting						Regional conference			

Tool 1I: Sample job descriptions

Position title:

Director of stakeholder engagement

Position summary:

The director of stakeholder engagement is responsible for directing and managing the stakeholder engagement function in clinical studies that are conducted by *(insert name of research institution or name of large trial)*.

Accountability:

The director of stakeholder engagement is jointly accountable to (a) the director of research programs *(or similar title)* and (b) the principal Investigator(s) in specific research studies. The position holder will be a member of the executive management team and trial management teams.

Key roles and responsibilities:

1. Assures that assessments of the nature, extent, and quality of relationships with the following groups of stakeholders are undertaken: (a) trial participants and their partners, (b) local communities, (c) research colleagues and other staff members of the research enterprise, (d) policymakers and advocates and (e) service providers or program implementers
2. Identifies and explains enabling factors and barriers that are affecting the stakeholder engagement process — and makes recommendations for strengthening the enabling factors and removing the barriers.
3. Oversees the development, implementation and evaluation of strategies for (a) developing new relationships and (b) enhancing relationships with stakeholder groups during each phase of research — conceptualization and protocol development, clinical trial implementation and dissemination of research findings.
4. Develops and oversees the budgets for the stakeholder engagement component of research trials.
5. Develops, maintains and contributes to a database of “promising practices” in stakeholder engagement.
6. Identifies and develops opportunities for the testing of promising practices — and the subsequent identification and description of “best practices in stakeholder engagement.”
7. Develops strategies for ensuring that best practices in stakeholder engagement are (a) identified and (b) become institutionalized.
8. Collaborates closely with the communications manager.

9. Provides training and guidance on all aspects of stakeholder engagement.
10. Remains abreast of the current literature on stakeholder engagement — and assesses its applicability in HIV prevention research.
11. Participates in an online “community of the practice of stakeholder engagement” and maintains contact with colleagues working in this area.
12. Maintains an inventory of resources that are relevant to HIV prevention research (including audio-visual resources).
13. Supervises the stakeholder engagement specialist(s) and administrative staff.
14. Routinely reports to the executive board (*for those employed by institutions*) or the trial management team (*for those employed on a research project*).

Skills and experience required:

- management
- leadership
- community assessment
- community organization
- organizational development
- facilitation
- partnership building
- communications (verbal, written and audiovisual)
- public health

Position Title:

Stakeholder engagement specialist

Position Summary:

The stakeholder engagement specialist is responsible for building, supporting and sustaining positive and productive relationships with the stakeholders in research trials conducted by (*insert name of research institution*).

Accountability:

The stakeholder engagement specialist is accountable to the director of stakeholder engagement.

Key roles and responsibilities:

1. Assesses the nature, extent and quality of relationships with at least two of the following stakeholder groups: (a) trial participants and their partners, (b) local communities, (c) research colleagues and other staff members of the research enterprise, (d) policymakers and (e) service providers or program implementers
2. Identifies and explains enabling factors and barriers that are affecting the stakeholder engagement process — and makes recommendations for strengthening the enabling factors and removing the barriers.
3. Develops, implements and evaluates strategies for (a) developing new relationships and (b) enhancing existing relationships for at least two of the above stakeholder groups during each phase of the prevention science research continuum (PSRC) — conceptualization stage, clinical trial stage and application stage.
4. Develops, maintains and contributes to a database of “promising practices” in stakeholder engagement.
5. Identifies and develops opportunities for the testing of promising practices — and the subsequent identification and description of “best practices in stakeholder engagement.”
6. Develops strategies for ensuring that best practices in stakeholder engagement are (a) identified and (b) become institutionalized.
7. Collaborates closely with the communications manager.
8. Provides training and guidance on all aspects of stakeholder engagement.
9. Remains abreast of the current literature on stakeholder engagement — and assesses its applicability for HIV prevention research.
10. Participates in an online community of practice for stakeholder engagement and maintains contact with colleagues who are also working in this area.
11. Maintains an inventory of resources that are relevant to stakeholder engagement in HIV prevention research (including audiovisual resources).
12. Routinely reports to the director of stakeholder engagement.

Skills and experience required:

- community assessment
- community organization
- organizational development
- facilitation
- partnership building
- leadership
- communications (verbal, written and audiovisual)
- management
- public health