



Good Participatory Practice Tools

GPP Blueprint for Stakeholder Engagement

Background

The *GPP Blueprint for Stakeholder Engagement* is a step-by-step guide designed to help research teams develop an effective and comprehensive plan for engaging with a full range of stakeholders throughout the course of a biomedical HIV prevention trial or trials.

The blueprint is part of a suite of tools created by AVAC in collaboration with other trial stakeholders designed to help research teams implement good participatory practices in a clinical trial setting. The blueprint serves as a companion tool to the UNAIDS/AVAC *Good Participatory Practice (GPP) Guidelines for Biomedical HIV Prevention Trials, Second Edition*, a document providing trial funders, sponsors, and implementers with systematic guidance on best practices for stakeholder engagement. Familiarity with the *GPP Guidelines*, however, is not a prerequisite for use of this blueprint.

Intended Use

Ideally, research team members who are responsible for implementing and managing stakeholder engagement activities, including participants who are enrolled in the online GPP training course, will use the blueprint to produce a plan and put it into action *before* a trial begins. Investigators, other members of the clinical team, and other stakeholders should be encouraged to offer input and actively participate in the plan's development, as well, in order to optimize its alignment with research objectives and goals.

The blueprint can also be used to develop or update a plan for a trial that is already underway, to develop a plan or plans for multiple related trials, or to develop a plan for the intervals between trials in order to maintain support from existing stakeholders and cultivate relationships and support for future trials.

Purpose

A well-crafted plan allows research teams to collaborate with a broad range of stakeholders with clarity of purpose, facilitating a participatory approach to research, allowing for the design and implementation of effective and locally acceptable trials, paving the way for smooth trial conduct and reliable outcomes, and creating a supportive environment that extends beyond the lifespan of a specific trial.

The blueprint guides users in:

- Evaluating key aspects of the trial life cycle where gaps in experience, knowledge, and influence can be addressed through stakeholder engagement
- Pinpointing areas of strength that can be leveraged or built on through stakeholder engagement
- Clarifying what site leadership aims to achieve through an engagement program
- Thinking broadly and comprehensively about engagement opportunities and objectives
- Approaching stakeholder engagement challenges in the context of GPP
- Developing an engagement plan that complies with the GPP guidelines
- Organizing a comprehensive program of engagement activities that includes timelines, budgets, and ways to measure success and gauge impact on the community and the research

AVAC encourages users to customize the *GPP Blueprint* to best serve their needs. Users can share their adaptation and send feedback about the blueprint and other GPP tools to gpp@avac.org.



Blueprint Overview

Section 1: Assessment

Take stock of factors at the trial-site and on a local, national and international level that could impact the research and need to be addressed through stakeholder engagement.

Section 2: Goals, Objectives, and Stakeholders

Draft and prioritize a list of stakeholder engagement objectives and a list of potential stakeholders; then match stakeholders with the objectives they're best positioned to help meet.

Section 3: Stakeholder Engagement Plan

Design a plan (including events, timetables, metrics, budgets, etc.) for meeting the stakeholder engagement objectives laid out in Section 2.

Section 1: Assessment

In each part of Section 1, you will be assessing an area that needs to be considered in drafting a stakeholder engagement plan.

- 1.1 Trial-site inventory
- 1.2 Research readiness
- 1.3 Existing support
- 1.4 Sociocultural landscape
- 1.5 Legislation, guidelines, standards, and structural issues
- 1.6 Existing HIV program

Section 2: Goals, Objectives and Stakeholders

- 2.1 Engagement goals and objectives
- 2.2 Prioritize engagement objectives
- 2.3 Stakeholder list
- 2.4 Prioritize stakeholders
- 2.5 Match stakeholders with objectives

Section 3: Stakeholder Engagement Plan

Instructions for Online GPP Training Course

The GPP Blueprint is a companion tool to into the online GPP training course. Content from the blueprint is integrated into several of the course modules as well as the required work assignments.

It is recommended that users enrolled in the online training course print a copy of blueprint for reference and note taking, if necessary. All questions are hyperlinked to answer sheets at the back of the document, if additional writing space is required for responses.



To increase usability, this icon appears in each section of the document. It indicates the titles of GPP online training modules that correspond to the blueprint's content.



SECTION 1 Assessment

SECTION 1.1 Trial-site inventory

**Purpose:**

To gather information about the trial site's scientific agenda and activities to help ensure that the stakeholder engagement plan will be aligned with the site's goals

**GPP Online Training Modules**

Module 3: Formative Research Activities

Module 4: Stakeholder Advisory Mechanisms, Engagement, and Education Plan

Record your answers to the following in the space provided, or on the Answers Worksheet contained at the end of this document. Writing the answers out will provide a record of thought processes, ideas, and issues that you can return to either as a memory refresher or a source of inspiration. Many of these answers will expand and evolve as more stakeholders are consulted.

1) List the trial/s you wish to develop a stakeholder engagement plan for and note any details from the trial protocol that are relevant to stakeholder engagement (e.g., the number of participants, target population, trial objectives, and trial endpoints). * Consider copying sections from the protocol to save time!

2) What are the overarching goals of your team's research program?

3) How does the biomedical HIV prevention field stand to benefit from your research?



4) What kind of HIV-related work and activities take place at the trial site during intervals between trials?



SECTION 1.2

Research readiness



Purpose:

To gauge the level of research knowledge, experience, and preparedness among populations that will be involved in, affected by, or have influence over the proposed trial



GPP Online Training Modules

Module 3: Formative Research Activities

Module 4: Stakeholder Advisory Mechanisms, Engagement, and Education Plan



Circle one answer to each of the following questions. New sites/teams may not have answers to all of these questions. Leave blank questions that do not apply.

<u>TRIAL SITE/RESEARCH TEAM</u>			
1) How experienced is the research team in conducting clinical trials?	Not at all	Moderately	Extensively
2) How many HIV-related trials have been conducted at the site in the past 5 years?	0	1–3	3<
3) How many HIV networks or funding groups conduct trials at the site? List them below.	0	1–3	3<
-			
-			
-			
-			
4) How experienced is the research team in working with stakeholders?	Not at all	Moderately	Extensively
5) Has the research team been involved with stakeholder engagement efforts during previous trials?	NO		YES
6) Have community stakeholders responded favorably to past engagement efforts?	NO		YES
7) Have previous trials been successful in engaging a diverse range of stakeholders (e.g., with a variety of perspectives, backgrounds, experience, skills)?	NO		YES
8) How experienced is the research team in working with the population targeted for participation in the trial?	Minimally	Moderately	Extensively



9) How many trials involving the target population has the site conducted in the past 5 years?	0	1–3	3<
10) How often do members of the target population come to the site for non-trial services (e.g., events, information, education, health care)?	Never	Occasionally	Often

COMMUNITY ADVISORY BOARD (CAB OR OTHER SUCH GROUP)

1) How experienced is the CAB in clinical research?	Not at all	Moderately	Extensively
2) Has the CAB been involved in previous trials?	Never	Occasionally	Often
3) How knowledgeable are CAB members about the clinical research process?	Not at all	Moderately	Extensively
4) How knowledgeable are CAB members about HIV prevention?	Not at all	Moderately	Extensively
5) How knowledgeable are CAB members about HIV prevention research?	Not at all	Moderately	Extensively
6) How knowledgeable are CAB members about the science involved in the proposed research?	Not at all	Moderately	Extensively
7) How well does the current CAB composition reflect the community population?	Not at all	Moderately	Extensively
8) Have members of the CAB expressed negative views of the target population in the past?	Not at all	Moderately	Extensively

COMMUNITY AND OTHER STAKEHOLDERS

1) How familiar is the local community with clinical research?	Not at all	Moderately	Extensively
2) How well informed are members of the community about the clinical trial process?	Not at all	Moderately	Extensively
3) How well informed are members of the community about participant rights during a trial?	Not at all	Moderately	Extensively
4) How knowledgeable are members of the community about HIV?	Not at all	Moderately	Extensively
5) How knowledgeable are members of the community about how HIV is transmitted?	Not at all	Moderately	Extensively
6) How knowledgeable are members of the community about how HIV might be prevented?	Not at all	Moderately	Extensively



7) How knowledgeable are members of the community about HIV prevention research?	Not at all	Moderately	Extensively	
8) Are members of the community aware of how they can access HIV prevention options?	Not at all	Moderately	Extensively	
9) Are members of the community aware of the latest prevention options available in their area?	Not at all	Moderately	Extensively	
10) What percentage of the community has had risk-reduction counseling or is aware that it is available?	>25%	25%>50%	50%>75%	75%>100%



SECTION 1.3

Existing support



Purpose:

To get a basic sense of the trial site's past stakeholder relationships and engagement experience



GPP Online Training Modules:

Module 3: Formative Research Activities

Module 4: Stakeholder Advisory Mechanisms, Engagement, and Education Plan

Record your answers to the following in the space provided, or elsewhere if you'd prefer.

- 1) [Has the CAB been supportive of stakeholder engagement in past trials? What was the nature of its involvement? In what areas did CAB members take initiative? Were their efforts effective?](#)

- 2) [What are the CAB's strengths? What are its weaknesses?](#)



- 3) Is the CAB's membership appropriately representative of the potential trial population? If not, which group/s are over- and underrepresented? If there is under representation, do the majority of members have understanding, demonstrated through their work, leadership or conversations with site staff, about the potential scientific and social issues of the potential trial population?

- 4) List any stakeholders (individuals or organizations, groups, etc.) who have been engaged by the research team in related trials in the recent (previous five years) past.

- 5) List the stakeholder advisory mechanisms (e.g., focus groups, interviews, suggestion boxes) you have used in the past. Note which were effective, which weren't, and why.

- 6) List any factors that have impeded stakeholder engagement in the past (e.g., budgetary shortfalls, insufficient staffing, lack of experience, lack of coordination among groups).



7) [Does the trial site have a secure funding stream at present for a robust and ongoing stakeholder engagement program?](#)



SECTION 1.4

Sociocultural landscape



Purpose:

To assess local attitudes, beliefs, and practices related to HIV prevention and scientific research; to identify issues that stand to impact recruitment, trial conduct, and public perception of the trial.



GPP Online Training Modules:

Module 3: Formative Research Activities

Module 5: Communications and Issues Management Plans

Record your answers to the following in the space provided, or elsewhere if you'd prefer.

1) List attitudes, beliefs, or sociobehavioral factors in **the local community**(the population around the trial site) that could interfere with recruitment or trial conduct (e.g., social stigma, religious and traditional beliefs or practices, gender discrimination, misconceptions about research, mistrust of research and researchers).

2) List attitudes, beliefs, or sociobehavioral factors among **the potential trial population** that could interfere with recruitment or trial conduct (see examples above).



3) Has HIV prevention research received balanced coverage in the local and national media? Has the coverage been positive or negative? Are there aspects of the media coverage (past or ongoing) that might interfere with recruitment or trial conduct (e.g., adherence once the trial is in process)?

4) List local organizations (e.g., CBOs, advocacy groups) that might have a stake in or influence—whether positive or negative—over the proposed trial. Are they likely to support the research? Might they oppose it and present obstacles? How significant an impact might they have?

SECTION 1.5

Legislation, guidelines, standards, and structural issues



Purpose:

To assess local, national, and international rules, regulations, and standards that will have to be upheld in planning and conducting the proposed trial



GPP Online Training Modules:

Module 3: Formative Research Activities

Module 4: Stakeholder Advisory Mechanisms, Engagement, and Education

Module 5: Communications and Issues Management Plans

Record your answers to the following in the space provided, or elsewhere if you'd prefer.

1) [List the stakeholder engagement requirements of each of the trial's funders.](#)

2) [List any legislative, regulatory, and political issues that could impact recruitment, trial conduct, or other aspects of the research \(e.g., legislative issues, such as criminalization of homosexuality; political stances, such as opposition to the proposed research from influential leaders\).](#)



3) List any economic or structural issues (e.g., poverty, lack of education, unemployment) that may interfere with recruitment, adherence, or other aspects of the trial.

4) List any international and normative guidelines, statements, and policies that need to be accounted for in planning and conducting the trial (e.g., WHO guidelines).

5) Is the proposed trial likely to draw the scrutiny of any advocacy or activist groups? List the potential issues and possible reactions. Draw on previous trials, either at your site or globally, for examples.



6) List any regulatory bodies (e.g., institutional review boards, national ethics committees) that have authority to approve or reject clinical trial proposals, as well as those with the potential to impact trial conduct, product or strategy approval, or rollout. How experienced are they in reviewing research? How well versed are they in the research area of the proposed trial?



SECTION 1.6

Existing HIV prevention and treatment programs



Purpose:

To review national and local HIV prevention options, protocols, and practices to detect potential conflicts between the proposed research and existing policies and practices



GPP Online Training Modules:

Module 7: Standard of HIV Prevention and Access to HIV Care and Treatment

Module 8: Non-HIV Related Care and Trial Related Harms

Record your answers to the following in the space provided, or elsewhere if you'd prefer.

1) [Is there a robust HIV prevention program in the country where the trial is set? Which prevention strategies does it make available](#)

2) [Are there aspects of the proposed research that could conflict with national health care policies or programs \(particularly those related to HIV\)?](#)



3) [If there is a national HIV program, has it been implemented in the trial-site community? How do prevention services in the trial-site community differ from the national program? Which strategies are made available? e.g. If MTCT is part of the national program how many mothers are accessing services?](#)

4) [How equipped are health providers to explain and provide HIV prevention?](#)

5) [What kind of non-HIV-related health care services are available to members of the local community?](#)



SECTION 2 Goals, Objectives, and Stakeholders

SECTION 2.1

Engagement goals and objectives



Purpose:

To define the trial site's goals and objectives for engaging with stakeholders



GPP Online Training Modules:

Module 2: GPP Scope and Structure

Goals vs. Objectives: An Overview

As you work through this section, it's important to keep the distinction between a **goal** and an **objective** in mind:

A goal is a general statement that describes the “big picture” or ultimate impact of a set of activities, based on an identified need (e.g., “to decrease HIV transmission among the MSM population in country X”). A goal is generally not specific to a single trial but rather to overall public health outcomes over time. Goals, however, should always be aligned with the research agenda.

Objectives are specific results that can be achieved through a set of actions; taken together, they can lead to the accomplishment of broader goals. Generally they will be tied to a specific trial or set of trials. Most important, objectives should be S.M.A.R.T.:

Specific: clear, well defined, and easily understood

Measurable: quantifiable (e.g., how many? how much?)

Achievable: realistic and attainable, using existing resources

Relevant: aligned with stakeholder and trial-site priorities

Time-bound: designated to take place within a specific time period

Here is an example of stakeholder engagement goals and objectives based on a hypothetical research scenario:



SCENARIO:

Young men who have sex with men (MSM) in your setting are at increased risk for HIV in a stigmatizing environment that includes discrimination and violence. There is a need for evidence-based MSM biomedical HIV prevention options that address HIV risk in the context of these psychosocial issues.

Examples of stakeholder engagement goal: To benefit from the expertise of MSM community stakeholders in order to better inform and improve aspects of the research, such as recruitment into and retention in the trial

Stakeholder engagement objectives: To increase participation of adolescent MSM in formative research activities and trial protocol design, during Quarter 1 of trial planning stage.

Record your answers to the following in the space provided, or on the Answers Worksheet contained at the end of this document.

1) [Review your answers from Section 1.1, and use them as a basis to draft a list of the goals you hope to meet through stakeholder engagement.](#)

2) [Review your responses from Sections 1.2 through 1.6, highlighting, circling, or otherwise noting any issues of concern that can be addressed through stakeholder engagement](#) (e.g., “research team lacks experience working with target population”, “an influential community leader has reservations about the proposed research”, or “a specific aspect of the trial protocol could be seen to conflict with national HIV prevention practices”).

3) [For each issue you’ve noted, consider the following points](#) (you don’t need to write down your answers):

- » How can engaging stakeholders help address this issue?
- » How might engagement affect how the research affects the community and/or local populations?
- » How might engagement impact the overall course of the research?
- » How might engagement affect future trials and trial-site activities?
- » What are the risks of not engaging stakeholders on this issue?



4) List S.M.A.R.T. objectives for each issue you've determined calls for stakeholder engagement. (It's not necessary to come up with unique objectives for every issue; look for areas of overlap that will allow you to streamline your engagement efforts.)



SECTION 2.2

Prioritize engagement objectives



Purpose:

To rank each stakeholder engagement objective by urgency, both in terms of the trial stage it's relevant to and its significance (i.e., the importance of addressing it)



GPP Online Training Modules:

Module 2: GPP Scope and Structure

Module 4: Stakeholder Advisory Mechanisms, Engagement, and Education Plan

Record your answers to the following on your stakeholder engagement objectives list.

1) [Assign each item on your list of stakeholder engagement objectives a number, according to the corresponding stage of the research life cycle](#) (refer to [Diagram 1: GPP Guideline Topic Areas](#), below as a guide):

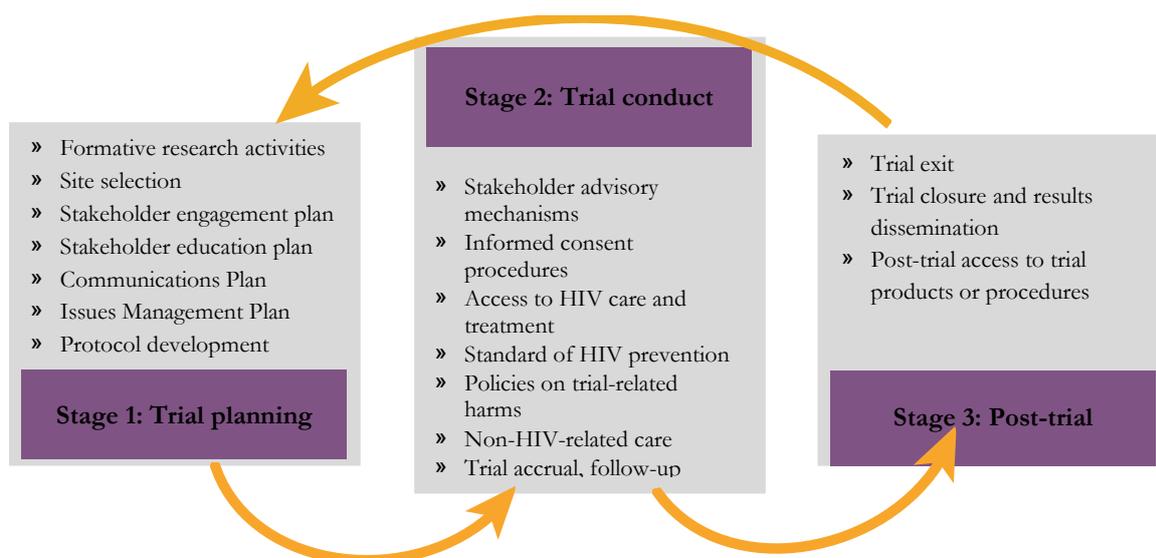
Use a “1” to indicate issues related to **trial planning**.

Use a “2” to indicate issues related to **trial conduct**.

Use a “3” to indicate issues related to **post-trial activity**.

Use the lowest applicable number for issues related to more than one stage of research.

Diagram 1: GPP Guideline Topic Areas



This graphic is based on Section 3 of *Good Participatory Practice (GPP) Guidelines for Biomedical HIV Prevention Trials, Second Edition*, which outlines best practices for stakeholder engagement in each of 16 “topic areas”, covering every aspect of a biomedical HIV prevention trial from planning stage to post-trial activity.



Here, the topic areas are organized according to three stages of the research life cycle. (See Section 3 of the *GPP Guidelines* for detailed coverage of each topic area.)

2) [Review the GPP topic areas in the graph above and look for issues you may have missed in drafting your objectives. Add any new objectives to your list and assign them a trial-stage number.](#)

3) [Read through your objectives once more, this time assigning each item a letter—A, B, C, or D—based on the following:](#)

Use an “**A**” to indicate **highest priority** (i.e., failure to address this issue is likely to have significant negative consequences for the research).

Use a “**B**” to indicate **high priority** (i.e., it’s important to address this issue; not doing so could have negative consequences).

Use a “**C**” to indicate **medium priority** (i.e., this issue should be addressed, if possible; doing so is likely to help the research proceed smoothly; the consequences of not doing so are minimal).

Use a “**D**” to indicate **low priority** (i.e., consider addressing this issue if time and resources allow; the consequences for not doing so are insignificant).



SECTION 2.3

Stakeholder list



Purpose:

To draft a list of potential stakeholders who can assist in trying to meet the trial site's goals and objectives



GPP Online Training Modules:

Module 4: Stakeholder Advisory Mechanisms, Engagement, and Education Plan

Other Modules to Consider:

Module 3: Formative Research Activities

Module 5: Communications and Issues Management Plans

Module 6: Site Selection, Protocol Development and Informed Consent

Module 7: Standard of HIV Prevention and Access to HIV Care and Treatment

Module 8: Non-HIV Related Care and Trial Related Harms

Module 9: Trial Accrual, Follow-up, and Exit

Module 10: Trial Closure, Results Dissemination, and Post-trial Access to Trial Products and Procedures

Draft a list of potential stakeholders in the table below or create your own template.

1) [Building on your list of past stakeholders from Section 1.3, compile a list of potential stakeholders for your upcoming trial in the table below.](#) (You can list them as individuals or by group, organization, etc.)



Tips:

- Don't expect all stakeholders to be supportive of the research. Some may take issue with the research agenda or be opposed to the trial and even take steps to try to stop the research from moving forward. Your list should contain both potential supporters and potential critics.

- Seek recommendations from a wide range of sources, including investigators and other trial-site staff, CAB members, and current stakeholders.

2) [Fill in the first four columns](#) (the remaining two will be addressed in the next section). Limit your answers in the second column to areas relevant to the research or the community (e.g., advocacy at high levels of government; influential voice in national media; extensive experience in technical aspects of trial-related procedures).



SECTION 2.4

Prioritize stakeholders



Purpose:

To evaluate potential stakeholders in terms of their importance, influence, interest, and investment in the research in order to determine an appropriate level of engagement



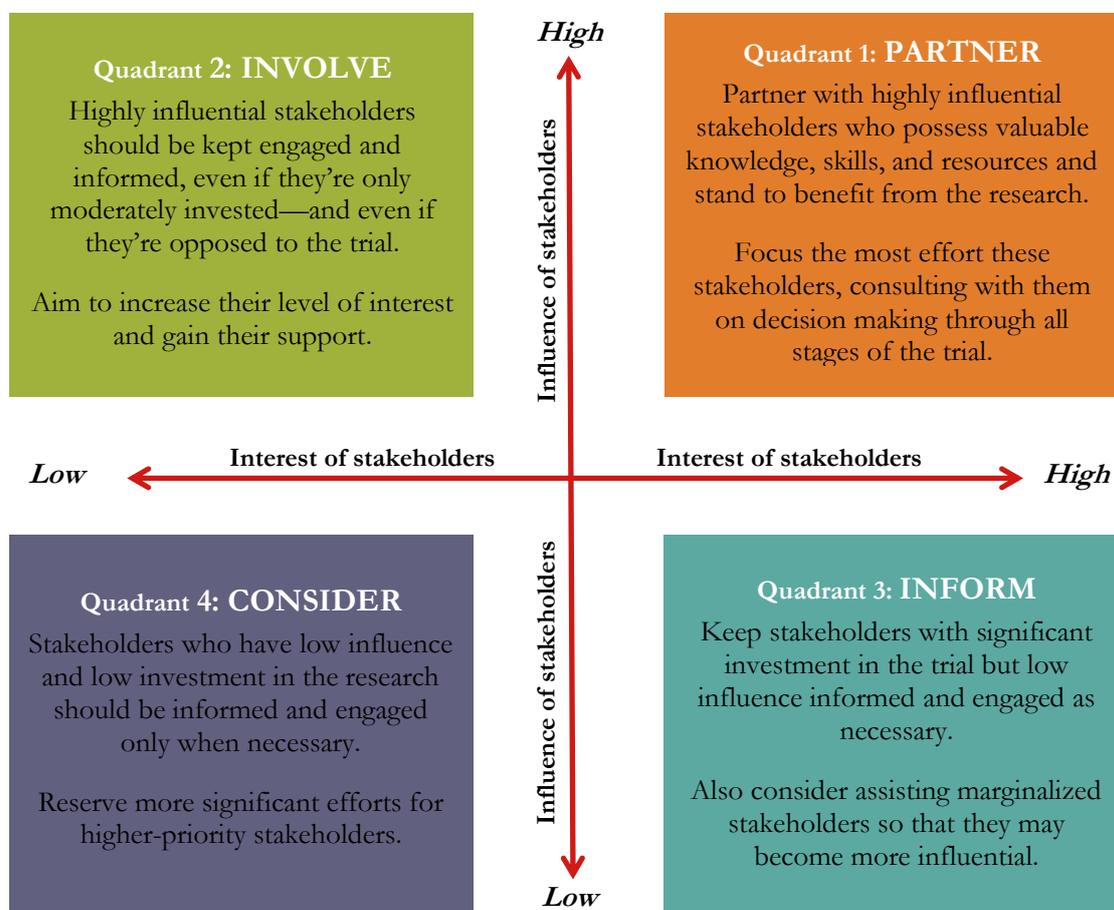
GPP Online Training Modules:

Module 4: Stakeholder Advisory Mechanisms, Engagement, and Education Plan

Module 5: Communication and Issues Management Plan

Record your answers to the following on your stakeholder list (from Section 2.3).

- 1) [Prioritize your list of stakeholders, assigning each a number \(1 through 4\) based on where they fall in the priority grid below.](#)



SECTION 2.5

Match stakeholders with objectives



Purpose:

To match stakeholders with the objectives they're best positioned to help you meet



Corresponds with GPP Online Training Modules:

Module 4: Stakeholder Advisory Mechanisms, Engagement, and Education Plan

Record your answers to the following on your stakeholder list (from Section 2.3).

1) [With your list of stakeholders and list of objectives side by side, look for individuals and/or groups that would be good candidates for helping you meet each of your objectives. Whenever possible, try to match your partner-level stakeholders with your highest-priority objectives.](#)



Tip: Keep in mind that factors such as stakeholders' power, influence, abilities, competencies, interests, values, and motivation may change during the course of the trial. It's important to re-evaluate your stakeholders and their roles periodically and be prepared to adjust your plan, as needed.



SECTION 3 Stakeholder Engagement Plan



Purpose:

To build on the information collected thus far to create a strategic and comprehensive stakeholder engagement plan



GPP Online Training Modules:

Module 4: Stakeholder Advisory Mechanisms, Engagement, and Education Plan

Other Modules to Consider:

Module 3: Formative Research Activities

Module 5: Communications and Issues Management Plans

Module 6: Site Selection, Protocol Development and Informed Consent

Module 7: Standard of HIV Prevention and Access to HIV Care and Treatment

Module 8: Non-HIV Related Care and Trial Related Harms

Module 9: Trial Accrual, Follow-up, and Exit

Module 10: Trial Closure, Results Dissemination, and Post-trial Access to Trial Products and Procedures

Provide the requested information in the template provided, or you can create your own.

1) Beginning with your objectives for **trial planning** (stage 1), fill in the template below, based on the following definitions:

- » **Goal:** a broad statement (or statements) that describes the overall purpose of your stakeholder engagement efforts. List the goals you drafted in Section 2.1 at the top of the template.
- » **Objective:** the specific results that will help you achieve your goals within a designated time frame using available resources. Begin by listing your highest-priority objectives for the stage you're addressing, and work your way through to those you've determined are less essential.
- » **Activity:** specific actions taken to meet the objective, such as convening forums, conducting focus groups, facilitating workshops, and distributing newsletters. Under each objective, list the activities required to carry it out.

For each activity, list the following:

- **Stakeholder:** the group or individual/s you are seeking to engage
- **Timeline:** time frame for carrying out the activity
- **Deliverable:** the report or other tangible that will be delivered upon completion of the activity
- **Related GPP topic area/s:** the GPP topic area/s on which you are seeking stakeholder input and expertise
- **Indicator of success:** an agreed upon measure of the activity's impact
- **Estimated budget:** financial resources required for the activity



2) Using a separate sheet for each trial stage, fill out a template for **trial conduct** (stage 2) and then **post-trial activity** (stage 3). (You may also want to designate a sheet for activities that span more than one trial stage or will extend beyond the post-trial period.)



Stakeholder Engagement Goals						
»						
»						
»						
Activity	Stakeholder	Timeline	Deliverable	Related GPP topic areas	Indicator of success	Estimated budget
Objective 1:						
Objective 2:						
Objective 3:						



ANSWER SHEET

Questions from Section 1 and Section 2

SECTION 1

Assessment

SECTION 1.1

Trial-site inventory

1) List the trial/s you wish to develop a stakeholder engagement plan for and note any details from the trial protocol that are relevant to stakeholder engagement (e.g., the number of participants, target population, trial objectives, and trial endpoints). * Consider copying sections from the protocol to save time!

2) What are the overarching goals of your team's research program?



Good Participatory Practice Tools

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3) How does the biomedical HIV prevention field stand to benefit from your research?

4) What kind of HIV-related work and activities take place at the trial site during intervals between trials?

SECTION 1.2
Research readiness

TRIAL SITE/RESEARCH TEAM			
1) How experienced is the research team in conducting clinical trials?	Not at all	Moderately	Extensively
2) How many HIV-related trials have been conducted at the site in the past 5 years?	0	1–3	3<



3) How many HIV networks or funding groups conduct trials at the site? List them below.	0	1–3	3<
-			
-			
-			
-			
4) How experienced is the research team in working with stakeholders?	Not at all	Moderately	Extensively
5) Has the research team been involved with stakeholder engagement efforts during previous trials?	NO		YES
6) Have community stakeholders responded favorably to past engagement efforts?	NO		YES
7) Have previous trials been successful in engaging a diverse range of stakeholders (e.g., with a variety of perspectives, backgrounds, experience, skills)?	NO		YES
8) How experienced is the research team in working with the population targeted for participation in the trial?	Minimally	Moderately	Extensively
9) How many trials involving the target population has the site conducted in the past 5 years?	0	1–3	3<
10) How often do members of the target population come to the site for non-trial services (e.g., events, information, education, health care)?	Never	Occasionally	Often

COMMUNITY ADVISORY BOARD (CAB OR OTHER SUCH GROUP)

1) How experienced is the CAB in clinical research?	Not at all	Moderately	Extensively
2) Has the CAB been involved in previous trials?	Never	Occasionally	Often
3) How knowledgeable are CAB members about the clinical research process?	Not at all	Moderately	Extensively
4) How knowledgeable are CAB members about HIV prevention?	Not at all	Moderately	Extensively
5) How knowledgeable are CAB members about HIV prevention research?	Not at all	Moderately	Extensively
6) How knowledgeable are CAB members about the science involved in the proposed research?	Not at all	Moderately	Extensively
7) How well does the current CAB composition reflect the community population?	Not at all	Moderately	Extensively



8) Have members of the CAB expressed negative views of the target population in the past?	Not at all	Moderately	Extensively	
COMMUNITY AND OTHER STAKEHOLDERS				
1) How familiar is the local community with clinical research?	Not at all	Moderately	Extensively	
2) How well informed are members of the community about the clinical trial process?	Not at all	Moderately	Extensively	
3) How well informed are members of the community about participant rights during a trial?	Not at all	Moderately	Extensively	
4) How knowledgeable are members of the community about HIV?	Not at all	Moderately	Extensively	
5) How knowledgeable are members of the community about how HIV is transmitted?	Not at all	Moderately	Extensively	
6) How knowledgeable are members of the community about how HIV might be prevented?	Not at all	Moderately	Extensively	
7) How knowledgeable are members of the community about HIV prevention research?	Not at all	Moderately	Extensively	
8) Are members of the community aware of how they can access HIV prevention options?	Not at all	Moderately	Extensively	
9) Are members of the community aware of the latest prevention options available in their area?	Not at all	Moderately	Extensively	
10) What percentage of the community has had risk-reduction counseling or is aware that it is available?	>25%	25%>50%	50%>75%	75%>100%



SECTION 1.3

Existing support

1) Has the CAB been supportive of stakeholder engagement in past trials? What was the nature of its involvement? In what areas did CAB members take initiative? Were their efforts effective?

2) What are the CAB's strengths? What are its weaknesses?

3) Is the CAB's membership appropriately representative of the potential trial population? If not, which group/s are over- and underrepresented? If there is under representation, do the majority of members have understanding, demonstrated through their work, leadership or conversations with site staff, about the potential scientific and social issues of the potential trial population?



4) List any stakeholders (individuals or organizations, groups, etc.) who have been engaged by the research team in related trials in the recent (previous five years) past.

5) List the stakeholder advisory mechanisms (e.g., focus groups, interviews, suggestion boxes) you have used in the past. Note which were effective, which weren't, and why.

6) List any factors that have impeded stakeholder engagement in the past (e.g., budgetary shortfalls, insufficient staffing, lack of experience, lack of coordination among groups).



7) Does the trial site have a secure funding stream at present for a robust and ongoing stakeholder engagement program?



SECTION 1.4

Sociocultural landscape

1) List attitudes, beliefs, or sociobehavioral factors in **the local community** (the population around the trial site) that could interfere with recruitment or trial conduct (e.g., social stigma, religious and traditional beliefs or practices, gender discrimination, misconceptions about research, mistrust of research and researchers).

2) List attitudes, beliefs, or sociobehavioral factors among **the potential trial population** that could interfere with recruitment or trial conduct (see examples above).



3) Has HIV prevention research received balanced coverage in the local and national media? Has the coverage been positive or negative? Are there aspects of the media coverage (past or ongoing) that might interfere with recruitment or trial conduct (e.g., adherence once the trial is in process)?

4) List local organizations (e.g., CBOs, advocacy groups) that might have a stake in or influence—whether positive or negative—over the proposed trial. Are they likely to support the research? Might they oppose it and present obstacles? How significant an impact might they have?



SECTION 1.5

Legislation, guidelines, standards, and structural issues

1) List the stakeholder engagement requirements of each of the trial's funders.

2) List any legislative, regulatory, and political issues that could impact recruitment, trial conduct, or other aspects of the research (e.g., legislative issues, such as criminalization of homosexuality; political stances, such as opposition to the proposed research from influential leaders).



3) List any economic or structural issues (e.g., poverty, lack of education, unemployment) that may interfere with recruitment, adherence, or other aspects of the trial.

4) List any international and normative guidelines, statements, and policies that need to be accounted for in planning and conducting the trial (e.g., WHO guidelines).



5) Is the proposed trial likely to draw the scrutiny of any advocacy or activist groups? List the potential issues and possible reactions. Draw on previous trials, either at your site or globally, for examples.

6) List any regulatory bodies (e.g., institutional review boards, national ethics committees) that have authority to approve or reject clinical trial proposals, as well as those with the potential to impact trial conduct, product or strategy approval, or rollout. How experienced are they in reviewing research? How well versed are they in the research area of the proposed trial?



SECTION 1.6

Existing HIV prevention and treatment programs

1) Is there a robust HIV prevention program in the country where the trial is set? Which prevention strategies does it make available

2) Are there aspects of the proposed research that could conflict with national health care policies or protocols (particularly those related to HIV)?

3) If there is a national HIV program, has it been implemented in the trial-site community? How do prevention services in the trial-site community differ from the national program? Which strategies are made available? e.g. If MTCT is part of the national program how many mothers are accessing services?



4) How equipped are health providers to explain and provide HIV prevention?

5) What kind of non-HIV-related health care services are available to members of the local community? This includes inpatient and outpatient services

6) List any regulatory bodies (e.g., institutional review boards, national ethics committees) that have authority to approve or reject clinical trial proposals, as well as those with the potential to impact trial conduct, product or strategy approval, or rollout. How experienced are they in reviewing research? How well versed are they in the research area of the proposed trial?



SECTION 2

Goals, Objectives, and Stakeholders

SECTION 2.1

Engagement goals and objectives

1) Review your answers from Section 1.1, and use them as a basis to draft a list of the **goals** you hope to meet through stakeholder engagement.

2) Review your responses from Sections 1.2 through 1.6, highlighting, circling, or otherwise noting any issues of concern that can be addressed through stakeholder engagement (e.g., “research team lacks experience working with target population”, “an influential community leader has reservations about the proposed research”, or “a specific aspect of the trial protocol could be seen to conflict with national HIV prevention practices”).



3) For each issue you've noted, consider the following points (you don't need to write down your answers):

- » How can engaging stakeholders help address this issue?
- » How might engagement affect how the research affects the community and/or local populations?
- » How might engagement impact the overall course of the research?
- » How might engagement affect future trials and trial-site activities?

What are the risks of not engaging stakeholders on this issue?

4) List S.M.A.R.T. **objectives** for each issue you've determined calls for stakeholder engagement. (It's not necessary to come up with unique objectives for every issue; look for areas of overlap that will allow you to streamline your engagement efforts.)



SECTION 2.2

Prioritize engagement objectives

1) Assign each item on your list of stakeholder engagement objectives a number, according to the corresponding stage of the research life cycle (refer to **Diagram 1: GPP Guideline Topic Areas, below as a guide**):

Use a “**1**” to indicate issues related to **trial planning**.

Use a “**2**” to indicate issues related to **trial conduct**.

Use a “**3**” to indicate issues related to **post-trial activity**.

Use the lowest applicable number for issues related to more than one stage of research

2) Review the GPP topic areas in the graph and look for issues you may have missed in drafting your objectives. Add any new objectives to your list and assign them a trial-stage number.



3) Read through your objectives once more, this time assigning each item a letter—A, B, C, or D—based on the following:

Use an “**A**” to indicate **highest priority** (i.e., failure to address this issue is likely to have significant negative consequences for the research).

Use a “**B**” to indicate **high priority** (i.e., it’s important to address this issue; not doing so could have negative consequences).

Use a “**C**” to indicate **medium priority** (i.e., this issue should be addressed, if possible; doing so is likely to help the research proceed smoothly; the consequences of not doing so are minimal).

Use a “**D**” to indicate **low priority** (i.e., consider addressing this issue if time and resources allow; the consequences for not doing so are insignificant).



SECTION 2.3

Stakeholder list

- 1) Building on your list of past stakeholders from Section 1.3, compile a list of potential stakeholders for your upcoming trial in the table below. (You can list them as individuals or by group, organization, etc.)



SECTION 2.4

Prioritize stakeholders

- 1) Prioritize your list of stakeholders, assigning each a number (1 through 4) based on where they fall in the priority grid below.

SECTION 2.5

Match stakeholders with objectives

- 1) With your list of stakeholders and list of objectives side by side, look for individuals and/or groups that would be good candidates for helping you meet each of your objectives. Whenever possible, try to match your partner-level stakeholders with your highest-priority objectives.

