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# Introduction

## What is the GPP Blueprint?

The UNAIDS/AVAC *Good Participatory Practice (GPP) guidelines for biomedical HIV prevention trials, Second Edition*, aim to provide trial funders, sponsors, and implementers with systematic guidance on how to effectively engage with all stakeholders in the design and conduct of biomedical HIV prevention trials, such as microbicides, vaccine, or PrEP clinical trials.

The **GPP Blueprint** serves as a companion tool to the GPP Guidelines.The **GPP Blueprint** is a step-by-step collaborative exercise for research teams and can act as a for implementing the GPP guidelines.

The **GPP Blueprint** contains seven sections, divided into two phases, for developing a GPP or stakeholder engagement workplan for a specific trial. Sections 1 through 4, contained in Phase 1 of the document, may be completed in any order. Sections 5 and 6, contained in Phase 2, entitled *Identifying Key Issues* and *Putting It All Together*, should ideally be done in the suggested sequence. The second phase is where key information is collated to create the final GPP workplan.

## How should the GPP Blueprint be used?

The **GPP Blueprint** can be used by a research team that is planning for or initiating a new clinical trial. It can assist the research team with the development of a strategic stakeholder engagement plan that is linked to the 16 topic areas, outlined in Section 3 of the GPP Guidelines.

The primary user of the **GPP Blueprint** is intended to be **community or stakeholder engagement trial site staff**. Investigator involvement, however, will enhance the process and overall outputs, and is highly encouraged. The **GPP Blueprint** should optimally address all trial stages – trial preparation and planning, trial conduct, and trial closure.

The GPP Blueprint can assist the research team with identification of:

* Goals and objectives for stakeholder engagement that align with research objectives
* Environmental needs (resources, social, political) of the trial site
* Potential challenges encountered during the research process
* Ways in which meaningful engagement can address challenges and strengthen the community

The **GPP Blueprint** may also be used in conjunction with, or be complementary to, the **GPP Roadmap**, that aims to assist trial site staff with the development of a longer term stakeholder engagement plan encompassing the site’s broader research agenda.

The **GPP Blueprint** is part of a suite of tools and resources being developed by AVAC, in collaboration with other trial stakeholders, to support and promote effective implementation of the GPP guidelines with trial sites conducting biomedical HIV research. Users should feel free to adapt and customize the tool, based on their specific needs and priorities. AVAC also encourages users to share their own adaptation and send their feedback about the GPP tools to: [**gpp@avac.org**](mailto:gpp@avac.org)

# PHASE 1

# SECTION 1

## Describing the Research Goals and Objectives

Stakeholder engagement goals and objectives must be directly related to and reflect the goals and objectives of the specific clinical trial in question. This section will describe what the trial site is aiming to accomplish through its research initiatives. Goals and objectives can reflect one or multiple trials.

| USER TIP: This section is not asking the user to develop a new set of research goals and objectives, or to propose a new study. It is simply asking for an outline of the existing research program or trial, on which the stakeholder engagement program will be based. |
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**Answer the following questions. Record your answers in the worksheet provided below.**

| Worksheet #1 **Question 1:** Describe the trial (or trials) that are planned for the trial site. For example, include the number of participants, phase, target population, and rial endpoints.   |  | | --- |   **Question 2:** Are there any additional or secondary objectives or key questions that the research should ideally address?   |  | | --- | |
| --- | --- | --- |

| **Question 3:** How do the intended research outcomes aim to further the field of biomedical HIV prevention research in general?   |  | | --- | |
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# SECTION 2

## Identifying Stakeholder Engagement Goals and Objectives

Strategic, specific, and concrete goals and objectives must be the starting point of the stakeholder engagement plan. When developing goals for stakeholder engagement, the following questions can act as a guide:

* How will engaging stakeholders change or benefit the course of the research?
* How will engaging stakeholders change the impact of research on the local community, where the research is being conducted?

A strategic set of goals and objectives will guide the development of the more detailed workplan, which will include stakeholder education, communication, issues management, results dissemination, and other participatory practices outlined in GPP. This section will take users through a process of identifying goals of stakeholder engagement based on three stages of the trial life cycle, which also correspond with the 16 GPP topic areas.

There is no need for objectives to be developed directly around the 16 GPP topic areas because they will naturally link. For instance, the objective to *ensure meaningful stakeholder input in decisions around standard of HIV prevention* may be linked to GPP topic areas protocol development, standard of HIV prevention, and stakeholder advisory mechanisms.

It is important to keep in mind the difference between a goal and an objective. A **goal is a general statement** that describes the “big picture” or ultimate impact of a set of engagement activities, based on the problem or identified need (e.g “To decrease HIV transmission or prevalence in a certain population”). A goal is not, and should not be tied to a single research trial but **should aim to improve the overall public health outcomes of the community.** The goal, however, should always be aligned with and add value to the research.

**Objectives are what will be achieved, by on-going actions or activities, that together will achieve the broader goals.** They should be specific, realistic, and measurable. Objectives need deliverables that can be achieved in a certain time frame. Action words are the best method to refer to the endpoint of the research**.** (e.g. “To increase the number of former vaccine trial participants being tested for HIV on site”). When developing specific objectives, it is important to be realistic – make sure that your proposed activities have achievable outputs that can be accomplished in a specific time period.

| **Objectives should be SMART:**   * **S**pecific – clear and easily understood * **M**easurable – quantifiable: how many? how much? * **A**chievable – realistic and attainable, within existing resources * **R**elevant – align with stakeholder and trial site priorities * **T**ime-bound – describe a specific time period |
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| EXAMPLESResearch problem to be addressed: Adolescent 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. Research goals:  * To strengthen nationally-owned HIV prevention health and health policies and systems for adolescent men who have sex with men (MSM) * To reduce incidence of HIV infections in adolescent MSM  Research objectives:  * To measure changes in HIV risk taking behaviour in adolescent MSM, ages 14-16 years, over the period of 12 months * To evaluate the safety of a rectal microbicide in adolescent MSM, used during anal sexual intercourse, over a period 12 months |
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| **USER TIP: Think about surveying the community’s feelings about the research! Use GPP case studies to help!** |
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# SECTION 3

## Assessing Potential Social, Cultural, and Community Implications

Community opinion and other social, cultural, and economic aspects can significantly impact a trial’s conduct and success. Before a plan, and possibly stakeholder engagement goals and objectives, can be created the community perceptions and understanding of the research must be taken. Having an understanding of potential societal harms will influence the development of policies on trial related harms among other areas of the trial.

Assessing the baseline for society opinion will help identify the gaps to achieving stakeholder engagement objectives.

**Think through the following questions related to the research environment. Record your answers here.**

| Worksheet #3 **Question 1:** What are some of the key characteristics of or expected challenges faced by the potential research population? Fro example, include stigma, economic strain, distance from the research site   |  | | --- |   **Question 2:** Is there any group or individual who has a significant effect on the trial population? Does the research team have mechanisms for engaging them?   |  | | --- | |
| --- | --- | --- |

| **Question 3:** What issues or reactions have come up with stakeholders (at all levels) about other HIV prevention trials over the past several years?   |  | | --- | |
| --- | --- |

What is the current standard of HIV care and treatment? Describe national guidelines on treatment and how they differ from what prevention modalities are available locally. Include barriers like limited knowledge of providers.

# SECTION 4

## Assessing the Community’s Research Preparedness

Before creating a work plan it is important to reflect on the engagement efforts conducted during previous trials. It doesn’t make sense to continue to use stakeholder engagement mechanisms that haven’t worked in the past, or haven’t achieved effective stakeholder engagement.

**Think through the following questions related to past or existing engagement efforts. Record your answers in the worksheet below.**

| Worksheet #4 **Question 1:** What site activities currently engage the potential trial population in question?   |  | | --- |   **Question 2:** Does the CAB independently initiate activities? Have they ever brought negative input from the community to the research team? Describe.   |  | | --- |   **Question 3:** What local organizations (CBO, advocacy group) are interested in this trial, and what kinds of engagement activity have they been conducting? This includes education and outreach activity.   |  | | --- | |
| --- | --- | --- | --- |

| **Question 4:** What is the research literacy level amongst potential participants and other relevant stakeholders regarding: general clinical trial process, rationale for research, HIV prevention, and the science behind this trial?   |  | | --- | |
| --- | --- |
| **Question 5:** Is the CAB a good representation of the population that is being courted for the trial?   |  | | --- | |
| **Question 6:** Are there other concerned stakeholders that should be involved in the CAB? Or in an alternate advisory mechanism?   |  | | --- | |



# PHASE 2

# SECTION 5

## Identifying Key Issues

Now that you completed Phase 1 of the GPP Blueprint, it’s time to identify the key issues that will have an effect (negative) on the research, and how to address or mitigate those negative effects. The key issues should be related to the trial but broader themes, like women’s healthcare, may emerge. In the final section, “Putting It All Together” these key issues will be the focus of the trial action items in the work plan.

**Think about the example in the box below. Record your answers in the worksheet below.**



**Answer the following questions here.**

| Worksheet #5 **Question 1:** Are there cultural challenges that will potentially affect the trial? During what stage of research will these challenges probably have the most impact?   |  | | --- | |
| --- | --- |
| **Question 2:** What, if any, are barriers to engaging the target population for this research?   |  | | --- | |
| **Question 3:** What are the resource constraints that have limited stakeholder engagement in the past? Resource constraints aren’t exclusively monetary, although they can be part of it. Resources might also be stakeholders and staff with the level of knowledge needed to communicate.   |  | | --- | |

# SECTION 6

## Stakeholder Identification and Selection

It is not practical, strategic, or necessary to engage all stakeholder groups with the same level intensity at all times. Some stakeholders will be important in every trial, but should not be engaged simply because they have been in the past. Stakeholder mapping will help assess the appropriate type of engagement and participation of different stakeholders during different stages of research.

| USER TIP: Use the GPP Community Mapping tool to see what stakeholders will be the most useful in the area! |
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Stakeholder mapping can be broken down into four parts:

1. **Identifying:** listing relevant groups, organizations, and people
2. **Analyzing:** understanding stakeholder perspectives and interests
3. **Prioritizing:** ranking stakeholder relevance and identifying key issues
4. **Mapping:** visualizing relationships to objectives and other stakeholders

## PART 1: Identifying

Make a list of stakeholders that can be engaged throughout the research process. Their level or frequency of involvement is not a concern at this time.

**It is important to remember that not all stakeholders are in favor of the research**. Some are actually individuals or groups with significant influence who oppose the trial and can negatively influence goals. This list should contain both stakeholders who are likely to support as well as those who may oppose the research.

## PART 2: Analyzing

Once a list of stakeholders has been generated, their strengths and weaknesses can be assessed. For example, different stakeholders may offer advocacy at high levels of government, greater public awareness of the trial through media communication, or technical inputs to the protocol or trial related procedures.

Think about the questions below and record your answers in the table provided

1. What stage or stages of the research will this stakeholder have the most influence?
2. What is their area of expertise regarding the research or community?
3. Do they have any conflict with this trial? Meaning do they have some opposition? What? Who?
4. Have they been a successful stakeholder in the past? What trial?

| Stakeholder | Stage of Influence | Area of Expertise | Opposition or support? | Successful stakeholder? Trial? |
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## PART 3: Prioritizing



Using the chart you just created and the stakeholder engagement goals and objectives you created earlier in the Blueprint, it’s time to prioritize stakeholders. Over the course of the trial lifecycle the focus on target objectives and goals will switch. So will the stakeholder priority chart, so this should be reevaluated often**. Key times include: the start of each new objective, when the engagement strategy is not going according to plan, if adverse events or news happens that shifts trial perceptions.**

## Key Definitions and Points:

**Quadrant 1 (Partner):**

Key stakeholders placed here have high influence and high importance need to be fully engaged in the research. A true partner brings knowledge, skills, and/or resources to the process, and typically stands to benefit in some way from the success of the research.

**Quadrant 2 (Involve):**

Stakeholders placed here can be highly important but  less invested or interested in the research-- what they stand to gain may not be tied directly to their contribution in the same way as that of partners. They should be kept engaged and informed through appropriate education and communication.

**Quadrant 3 (Consider):**

Stakeholders placed here can have potentially high  investment in the trial but low influence overall.

**Quadrant 4 (Inform):**

Stakeholders here have low influence and low investment in the research, but should be kept on board with regular communication.



## PART 4: Mapping

The last step is to map stakeholders to goals. Once again, like the priorities grid, the objectives maps will need to be evaluated often. When developing activities it’s crucial to have an understanding of what stakeholders will have the most influence toward achieving the stakeholder engagement goals and objectives.

# SECTION 7

## Putting It All Together: Building a Work Plan

The complete set of information collected through Steps 1-6 can now be put together into a strategic stakeholder engagement action or work plan. Include as much information in the plan as possible; the more detailed the plan, the easier it will be to follow.

Components of the work plan include:

* Goal: **A goal is a broad statement that describes the overall change** stakeholder engagement will bring about and serves as a foundation for the objectives.
* Objective:
* Activity:
* Stakeholder
* Deliverable
* Related GPP topic area(s)
* Budget needed
* GPP tool – there are suggestions throughout the Blueprint of supplementary GPP tools that can help with various Steps. The tools should be modified to fit your specific community needs. There may be no tool available; in these instances create an action item to achieve the objective/

| **Goal** | **Objective** | **Activity** | **Stakeholder** | **Deliverable** | **Related GPP  Topic Areas** | **Budget Needed** |
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