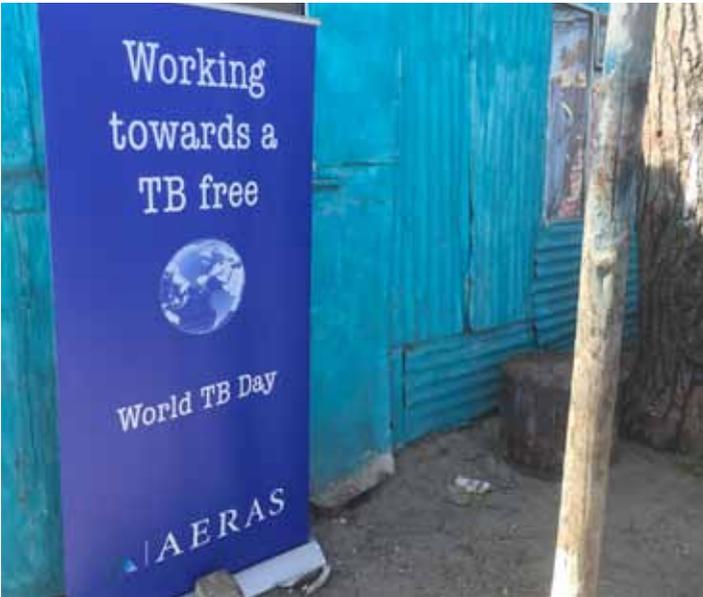


# Good Participatory Practice Guidelines for TB Vaccine Research 2017



The current version of *GPP-TB VACC* can be downloaded at the Aeras website:

[www.aeras.org](http://www.aeras.org)

For more information about these guidelines or to request printed copies of the guidelines, please email Aeras at:

[gpp@aeras.org](mailto:gpp@aeras.org)

For other related guidance and information about the global Good Participatory Practice initiative, please visit AVAC's website:

[www.avac.org](http://www.avac.org)

# **Good Participatory Practice**

Guidelines for TB Vaccine Research

*GPP-TB VACC*

July 2017

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## Preface

Tuberculosis (TB) remains an urgent global health problem, and the movement to eliminate TB is at a crossroads. Increasing evidence suggests that a new TB vaccine is an essential and feasible component of a comprehensive elimination strategy.

There have been profound advances in TB vaccine science and research in recent years, largely driven by innovative global platforms that have prioritized information sharing and collective decision-making about promising trial concepts and vaccine candidates. Eventual development and delivery of a vaccine depends on this global collaboration as well as significant financial support, which in turn requires political will and enduring advocacy from countries across the world.

Funders, sponsors, researchers, industry partners, national governments and community stakeholders must work together in accountable and mutually beneficial ways to ensure that TB vaccine trials are well-designed and conducted; that research objectives are relevant and acceptable to local communities; and that community stakeholders are ultimately empowered to participate in and advocate for the research agenda.

Rooted in our deep commitment to and belief in the unique power of partnerships and stakeholder cooperation to eliminate TB, Aeras has developed the *Good Participatory Practice Guidelines for TB Vaccine Research (GPP-TB VACC)* to support research teams in the pursuit of a new TB vaccine. *GPP-TB VACC* is a user-friendly framework that defines specific standards and key elements needed for creating effective partnerships with stakeholders throughout the entire research process. *GPP-TB VACC* is an adaptation of the *Good Participatory Practice Guidelines for Biomedical HIV Prevention Trials* and was heavily informed by the *Good Participatory Practice Guidelines for TB Drug Trials*.

Forged by a common cause, these guidelines are for the entire TB community and allies at every level who are involved in some manner with the opportunities and challenges concerning the urgent priority of TB elimination.

Jacqueline Shea  
Ph.D.  
**Chief Executive Officer**

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Particular gratitude goes to the entire AVAC team for their technical support, encouragement and inspiration, especially: **Mitchell Warren, Stacey Hannah and Jessica Salzwedel**.

We would also like to thank all of the **Community Advisory Board** members who provided input on the participatory practices and for their ongoing dedication to our collective pursuit of a new TB vaccine.

Lastly, we are grateful for the pioneering work of all of those responsible for the development of the *Good Participatory Practice Guidelines for Biomedical HIV Prevention Trials* and the *Good Participatory Practice Guidelines for TB Drug Trials*, most especially the affected communities and educators, advocates and allies on the ground who are working towards the goal of disease elimination. We couldn't do it without you!



# Introduction

## Objective of GPP-TB VACC

**Good Participatory Practice Guidelines for TB Vaccine Research (GPP-TB VACC)** provides systematic guidance on how to effectively engage stakeholders throughout the entire life cycle of research, including trial design, conduct, results analysis and dissemination.

## Intended audience for GPP-TB VACC

**GPP-TB VACC was developed to support research teams who are involved in any way with TB vaccine trials, particularly those team members who lead, implement and support stakeholder engagement programs and/or activities.** The composition of a “research team” may vary, depending on the setting and research context, but can include investigators, sponsors, clinical nurses, data managers, trial coordinators and community educators or other staff members who are responsible for community outreach and engagement.

These guidelines are essential reading for sponsors, funders and community representatives to better understand the rationale for good participatory practice in a TB vaccine research context and to learn more about their own roles in the development, maintenance and evaluation of an effective stakeholder engagement program.

The guidelines document can also serve as a resource for individuals or organizations who desire to learn more about the multifaceted issues that are specific to TB vaccine trials and how to effectively address some of them through meaningful involvement of stakeholders, including the communities most affected by the research.

## Scope of GPP-TB VACC

This document is not intended to provide research teams with guidance on scientific or ethical aspects of TB vaccine trials. Multiple guidance documents already exist to address these components of the biomedical research process. *GPP-TB VACC* outlines and promotes minimum standards for research teams to follow in order to ensure the early, sustained and effective participation of stakeholders in all stages of the TB vaccine research process. It is assumed that no single set of practices will work equally well in all contexts. Therefore, the guidelines have been developed for a global audience, and it is expected that research teams will adapt them to their local context.

## Development of GPP-TB VACC

The original *Good Participatory Practice Guidelines for Biomedical HIV Prevention Trials* were born out of a response to the controversies and debates that erupted in early safety and effectiveness trials for oral pre-exposure prophylaxis (PrEP). Trials in Cameroon and Cambodia, targeting HIV-negative women who engaged in commercial sex, were prematurely closed in 2004 and 2005 by local governments, due to concerns voiced by local and international advocates about ethics and proposed standards of care for trial participants. Although investigators obtained input from sex worker groups in numerous forums during the trial planning and formative research stages, divergent perspectives on critical issues between researchers and activists persisted and eventually evolved into protests and media firestorms, leaving a legacy of distrust in local communities. These controversies underscored a critical need for early relationship building with stakeholders and more meaningful involvement of stakeholders at the regional, national and international levels, beyond the trial community.

The setbacks and dramatic fallout generated intense dialogue in the HIV prevention field about ways to facilitate more effective and accountable relationships between researchers and stakeholders. As part of this consultative process, the United Nations Programme on HIV/AIDS (UNAIDS) and AVAC, a global research advocacy organization, established an international, multidisciplinary working group and developed the first normative guidelines for community engagement, published in 2007. These original GPP Guidelines also served as a companion document to *UNAIDS/WHO Ethical Considerations in Biomedical HIV Prevention Trials* and supported researchers with the operationalization of Guidance Point 2 on “Community Participation”: *To ensure the ethical and scientific quality and outcome of proposed research, its relevance to the affected community, and its acceptance by the affected community, researchers and trial sponsors should consult communities through a transparent and meaningful participatory process which involves them in an early and sustained manner in the design, development, implementation, monitoring, and distribution of results of biomedical HIV prevention trials.*

From 2007 onwards, the GPP Guidelines were applied in different contexts and became the subject of formal consultations involving a wide range of stakeholder groups in Africa, the Americas, Asia and Europe. Recommendations that arose from those consultations were incorporated into the second edition of the *Good Participatory Practice Guidelines for Biomedical HIV Prevention Trials (GPP-HIV)*, released in 2011.



Since their inception, the GPP Guidelines have been referenced, implemented and adapted in a variety of settings. Lessons learned from GPP implementation, especially in the HIV vaccine field, have been published in peer-reviewed journals and disseminated as case studies.<sup>1,2</sup> In 2011, US President Obama's Commission for Bioethics cited the GPP Guidelines in their official report, *Moral Science: Protecting Participants in Human Subjects Research*. This effort expanded the GPP Guidelines' relevance beyond HIV prevention research. In 2012, research entities in Thailand endorsed GPP as the standard for stakeholder engagement practice in all HIV prevention trials<sup>3</sup> and established a national Community Advisory Group, which continues to shape the country's research agenda.<sup>4</sup> Also in 2012, in response to demonstrated needs in the TB treatment research field, the Stakeholder and Community Engagement Workgroup of Critical Path to TB Drug Regimens (CPTDR) collaborated with AVAC and developed *Good Participatory Practice Guidelines for TB Drug Trials (GPP-TB)*, a principle-based framework for the development of effective relationships between researchers and stakeholders involved in TB drug trials.<sup>5</sup> Additionally, national regulatory authorities and ethics committees—in South Africa and Uganda—have formally recognized the value added by good participatory practice and are exploring ways to incorporate minimum standards for stakeholder engagement in biomedical trials into national oversight processes. GPP continues to be adapted in countries across the world and by researchers in other disease areas and disciplines, including emerging pathogen trials (*GPP-EP*), in order to ensure robust research design, successful trial conduct and understandable and credible results that are aligned with local health needs and priorities.

**The development of *Good Participatory Practice Guidelines for TB Vaccine Research*, led by Aeras with technical support from AVAC, evolved from a growing recognition about the criticality of, benefits of and unique opportunities for stakeholder engagement in the design, development and delivery of an acceptable, safe, new TB vaccine to eliminate the epidemic.**

A participatory development process was implemented to draft these guidelines, with contributions from international TB vaccine and HIV researchers, advocates, community and global advisory groups, funders and sponsors. Feedback was obtained through in-person consultations, email and telephone, and recommendations were comprehensively compiled and collectively analyzed. *GPP-TB VACC* is a dynamic document that may change over time.

Any feedback on the guidelines will be gratefully received and can be submitted directly to Aeras: [gpp@aeras.org](mailto:gpp@aeras.org)

## How to use these guidelines

GPP-TB VACC is presented in three main sections. Each section has a corresponding color and icon to enable easy navigation of the document.



### Section 1: Engaging Stakeholders in TB Vaccine Research

- Defines the terms “stakeholder” and “stakeholder engagement.”
- Describes the underlying determinants of TB.
- Offers a rationale for why a participatory approach is critical for the successful design and development of a new TB vaccine.



### Section 2: Guiding Principles for Good Participatory Practice

- Summarizes the core principles that form the foundation of relationships between research teams and stakeholders in biomedical trials.



### Section 3: GPP for TB Vaccine Research

- Introduces a process model for good participatory practice.
- Describes 13 topic areas that correspond to different parts of the TB vaccine research life cycle, with each topic area divided into the following sub-sections:
  - Definition** of the topic area.
  - Relevance** and benefits of stakeholder input into this aspect of TB vaccine research.
  - Special considerations** for stakeholder engagement in this area of TB vaccine research.
  - GPP for TB VACC**, which outlines the key participatory practices or “minimum standards” to be followed by research teams and that help ensure meaningful contributions from and involvement of stakeholders throughout the entire research process.
-  Lists key questions for each topic area to assist research teams in the design and implementation of their engagement strategies.



### Appendices

- Consist of acronyms, glossary and guidance documents that are relevant to biomedical and TB vaccine research.



**SECTION 1:**  
**Engaging Stakeholders in TB Vaccine Research**

Defines key terms.  
Describes important contextual factors for TB vaccine trials.  
Explains why good participatory practice is critical for TB vaccine research.

- Defining stakeholders
- Defining stakeholder engagement
- The wider context of TB vaccine research
- The dynamics of TB vaccine trials
- Rationale for GPP-TB VACC
- Applying GPP-TB VACC



**SECTION 2:**  
**Guiding Principles for Good Participatory Practice**

Summarizes core principles that are the foundation of relationships between research teams and stakeholders in biomedical trials.

- Respect
- Mutual understanding
- Integrity
- Transparency
- Accountability
- Community stakeholder autonomy



**SECTION 3:**  
**GPP for TB Vaccine Research**

Describes 13 topic areas that correspond to the TB vaccine research life cycle, and "minimum standards" for research teams to ensure meaningful participation of stakeholders.

- Stakeholder engagement plan and advisory mechanisms
- Stakeholder education plan
- Formative research activities
- Communications and issues management plans
- Site selection
- Protocol development
- Informed consent process
- Standards of prevention, care and treatment
- Non TB-related care
- Policies on trial-related harms
- Trial accrual, follow-up and exit
- Trial closure and results dissemination
- Post-trial access to TB vaccine candidates



# Section 1



## Engaging Stakeholders in TB Vaccine Research

# Section 1

## 1.1 Defining stakeholders

GPP-TB VACC defines a **stakeholder** as anyone who is directly or indirectly affected by TB vaccine research, who has an interest in the research and who can potentially influence the outcomes, whether positively or negatively.

A **key stakeholder** is an individual or group that is particularly important to the success of the research program. The selection of key stakeholders depends on the research team's engagement objectives as well as its analysis of each stakeholder's influence, interests and relevance to the research priorities.

TB vaccine research stakeholders can be organized according to community, broader, national and global levels. There are many instances when stakeholders can coalesce into different levels and when individuals can take on roles at multiple levels. The suggested categories are nonprescriptive, but research teams can use them as a basic framework to ensure representation of diverse perspectives throughout all stages of the research. Examples of generic TB vaccine research stakeholders are shown in *Figure 1: TB vaccine stakeholder layers*.

**Community stakeholders** include individuals and groups who are directly impacted by TB and by TB vaccine research, as well as representatives of people who participate in the research, such as family members of trial participants, local leaders, local advocates, community-based organizations (CBOs) and Community Advisory Boards (CABs). Research teams have direct influence on clinical trials and are considered to be stakeholders. However, they are a collective group in a professional setting and are not the direct beneficiaries of the research. Therefore, they are not categorized as "community stakeholders."

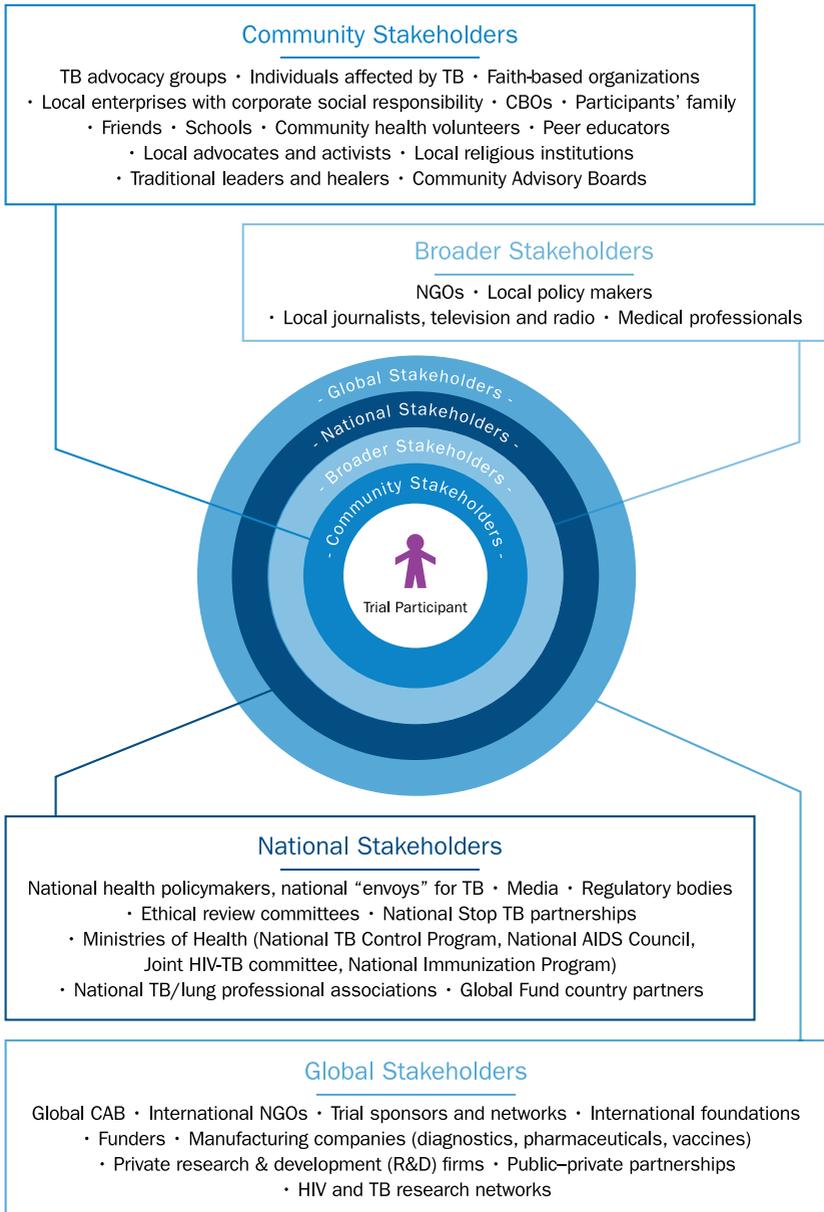
**Broader stakeholders** usually operate at the state, district or subnational level and may include district health teams, media outlets and nongovernmental organizations (NGOs).

**National stakeholders** are groups or individuals, such as national governments, NGO coalitions and regulatory authorities, who mobilize political will and influence and/or are responsible for country-level policy decisions and guidelines.

**Global stakeholders** are international bodies that influence the research agenda, such as funding agencies, normative bodies, global advisory committees and international advocacy organizations.

Figure 1: TB vaccine stakeholder layers.

The examples in each layer are generic and non-prescriptive. Research teams can use these categories as a framework for stakeholder identification and analysis.



## 1.2 Defining stakeholder engagement

*GPP-TB VACC* defines stakeholder engagement as a process by which research teams and key stakeholders build transparent, sustained, trusting and mutually beneficial partnerships, with the aim of shaping the TB vaccine research agenda collectively.

Good participatory practices are suggested actions (or standards) that research teams can apply in order to ensure the meaningful participation of stakeholders in different aspects of the research. Embedding good participatory practice in every stage of the TB vaccine research process helps facilitate local ownership of trials, enables more equitable relationships and increases the likelihood of successful research conduct, trial completion and application of research results.

## 1.3 The wider context of TB vaccine research

A new TB vaccine is both essential and possible. Since 2007, tremendous progress has been made in the development of new TB vaccine concepts, and many promising candidates continue to advance in the global clinical and preclinical pipelines. Nonetheless, despite this success, the field faces a unique combination of challenges, including

- **Knowledge gaps in basic science**, including the need for better understanding of immune mechanisms that control initial TB infection and disease and prevent reactivation of latent infection, as well as preclinical models to identify and prioritize the “best” vaccine candidates and to scale up comprehensive diagnostic technologies to detect TB infection;<sup>6</sup>
- **The need for robust, efficient clinical trial design concepts and approaches that can efficiently** determine the safety, efficacy and/or acceptability of TB vaccine candidates;
- **Requirements for sites with capacity for large-scale trials**, in settings with high TB incidence and adequate health and laboratory infrastructure;
- **Significant unmet funding needs to support the rigorous science and research necessary** to efficiently move the field forward in a manner commensurate with the extent of disease and death caused by TB.

## 1.4 The dynamics of TB vaccine trials

TB is a complex disease that is prevalent in poor and marginalized populations throughout the world. Poverty, social disruption, lack of education, barriers to health care, substance abuse, malnutrition, age and HIV infection are all risk factors for TB. TB is heavily stigmatized in most settings, which can discourage testing and adherence to treatment and can interact with social, economic and gender inequities that impact on health behavior. Groups who are especially vulnerable to TB vary according to context but can include migrant workers, prisoners, young adults and TB/HIV co-infected individuals. GPP is a framework for engaging community stakeholders as experts on their own culture and realities. Research teams can use this expertise to better understand the local determinants, risk factors and dynamics of the disease, avoid ethical pitfalls and improve the design and acceptability of the research itself.

## 1.5 Rationale for GPP-TB VACC

As a result of lessons learned from the implementation and evaluation of GPP in specific biomedical trials, there is an increasing awareness among trial implementers, sponsors, funders and communities about the advantages of early and constructive involvement of stakeholders in the research process.<sup>7</sup> Engagement is not an end in itself but a means to help build better relationships within the complicated contexts of a TB vaccine trial, ultimately resulting in the following:

- **Improvements in the design, conduct and outcomes of TB vaccine research**, due to stakeholder contributions to research questions and key trial procedures, ensuring they are culturally sensitive and appropriate and thus improving recruitment, retention, adherence, and other trial outcomes.
- **Greater awareness of and support for the TB vaccine research agenda amongst affected communities**, ultimately resulting in self-determination of health priorities and local advocacy for future TB vaccine trials and resource mobilization;
- **Greater and sustained political will among national policymakers and key decision makers** who facilitate, regulate and/or fund TB vaccine trials.



## 1.6 Applying GPP-TB VACC



Sponsors of TB vaccine trials can adopt *GPP-TB VACC* and provide adequate resources to support a long-term stakeholder engagement program. National governments and ethics committees can require that *GPP-TB VACC* be followed as part of their protocol review and research oversight processes. Even if the guidelines are not a requirement, community stakeholders can still assess a research team's engagement efforts against the practices described in Section 3.

For the full benefits of good participatory practice to be realized, stakeholder engagement must be embedded within the culture and core functions of a research program. Setting a vision and long-term goals for a stakeholder engagement program, building monitoring systems and conducting evaluations can help research teams clarify their desired results from stakeholder participation and demonstrate outcomes of their engagement effort to funders, communities and the wider research field.<sup>8</sup> Explicit engagement goals and evaluation frameworks are not stipulated in these guidelines but can be aligned with the GPP principles and benefits articulated in this document.

There is a variety of open-access resources to assist research teams with implementation and evaluation of GPP, including training materials, tools, case studies and journal articles. Research teams can consult AVAC's website to access these materials and to learn more about GPP implementation in other countries: [www.avac.org](http://www.avac.org)

## Section 2



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# Guiding Principles for Good Participatory Practice

## Section 2

Effective and ethical stakeholder engagement is anchored around six guiding principles: **respect**, **mutual understanding**, **integrity**, **transparency**, **accountability** and **community stakeholder autonomy**. These principles frame expectations for partnerships and are critical for building and maintaining trust between research teams and stakeholders.

### 2.1 Respect

Respect is the most basic and essential guiding principle that underlies all human relationships. For example, respect is demonstrated when a research team and community stakeholders act in ways that value and honor one another's perspectives and realities.

### 2.2 Mutual understanding

Mutual understanding requires that research teams develop an understanding of sociocultural issues in a particular location and that key stakeholders develop an understanding of the research process. Stakeholders and research teams engage in shared learning through two-way dialogue and ongoing opportunities for interaction and education that foster mutual understanding. See *Figure 2: Trial competency range*.

### 2.3 Integrity

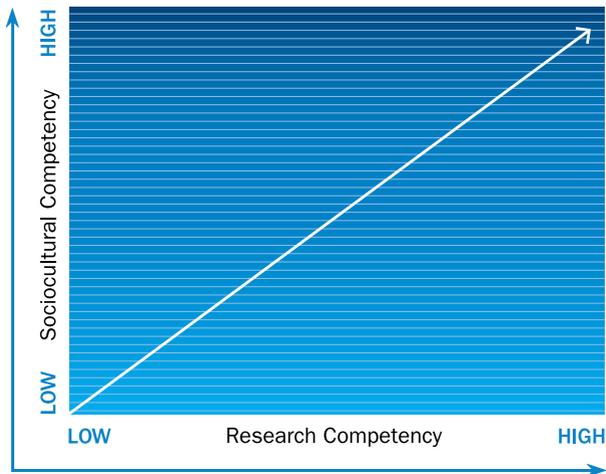
Integrity requires adherence to scientific standards and processes so that the research achieves valid results. The ethical aspect of this principle requires consideration of broader societal and ethical issues as well as adherence to ethical principles that include respect for persons, beneficence and justice.<sup>9</sup>

### 2.4 Transparency

Transparency means that there is clear communication among stakeholders throughout all stages of the research process, including open discussion about roles and responsibilities. Transparency enhances the trust that underpins relationships, and it means that stakeholders receive honest and understandable information about the research and that feedback from a broad range of stakeholders is acknowledged and addressed.

Figure 2: Trial competency range.

Sociocultural and research competency are shown as gradients along two axes. For example, a research team conducting a TB vaccine efficacy trial may have high research competency and understanding of TB vaccine science but low sociocultural competency or awareness of community norms and culture, especially if the target population is new for team members.



## 2.5 Accountability

Accountability indicates that trial funders, sponsors and implementers are expected to follow participatory practices when they conduct research and to ensure that funding and human resources are adequate to enable meaningful engagement. Stakeholders are accountable for ensuring that their input into the research process is constructive and respectful of the scientific process and is in the best self-identified interests of the community or entity they represent.

## 2.6 Community stakeholder autonomy

Community stakeholder autonomy means that community stakeholders have the right to support or to refuse trials proposed in their area. Although a wide range of stakeholders generally participates in the design, approval and implementation of a particular trial protocol, the self-identified interests of community stakeholders can ultimately determine whether a trial is conducted in a particular area.



## Section 3



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## GPP for TB Vaccine Research

## Section 3

### GPP process model

An effective, outcomes-driven engagement program relies on the research team and stakeholders having a shared understanding of the research priorities, the purpose for involving stakeholders and how they want to work together.

*GPP-TB VACC* uses a simple, five-step process model to help research teams approach stakeholder engagement in a structured and consistent way. See *Figure 3: GPP process model*. The model is broken down into five essential actions: **identify**, **analyze**, **prepare**, **engage** and **evaluate**. These actions can lead research teams from a loosely defined concept for GPP implementation to a strategic and participatory program with a measurable impact. In practice, the essential actions are also phases of an iterative learning cycle, which can be repeated numerous times during a particular activity or throughout the duration of the engagement program.

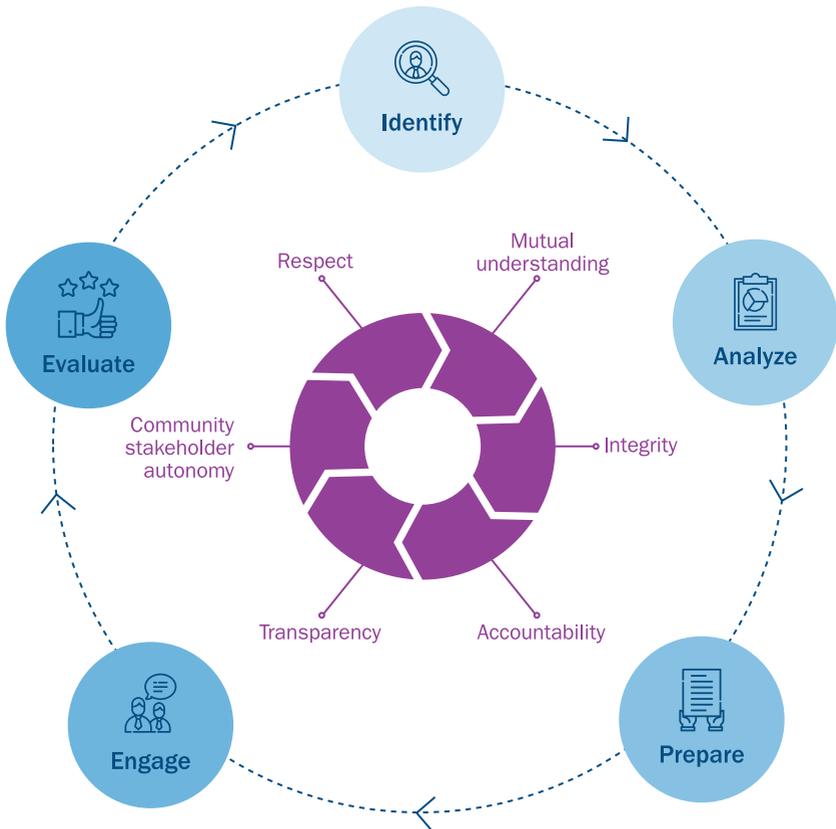
It is critical that research team members internally agree on and share a common purpose for stakeholder engagement, in order to clarify what change they are trying to achieve as a result of the process and what outcomes and outputs will be sought. This should be clearly stated to and discussed with stakeholders, detailing exactly what is sought from the process and should always remain the focus of the engagement, rather than the outputs of the process itself.

An effective process for stakeholder engagement is embedded within the wider context in which the research program operates. Therefore, the research team should always consider broader factors that are likely to affect their success and/or the choice of methods adopted, including

- The interest, commitment and/or involvement of trial site leadership and key decision-makers;
- How the stakeholder engagement program and process fit into the timelines, funding and decision-making systems for the wider research program;
- Previous experiences with stakeholder engagement, including lessons learned and their final outcomes;
- Characteristics and capabilities of the research team members to design, conduct and evaluate a stakeholder engagement program.

Figure 3: GPP process model.

Stakeholder engagement is a dynamic, ongoing process of creating, sustaining and evaluating relationships throughout the research life cycle.



## Topic areas for TB vaccine research

Appropriate and meaningful stakeholder engagement occurs at all stages of the research life cycle— from trial conceptualization to results dissemination. The TB vaccine research life cycle is divided into 13 topic areas.

See *Figure 4: Topic areas in the TB vaccine research life cycle.*

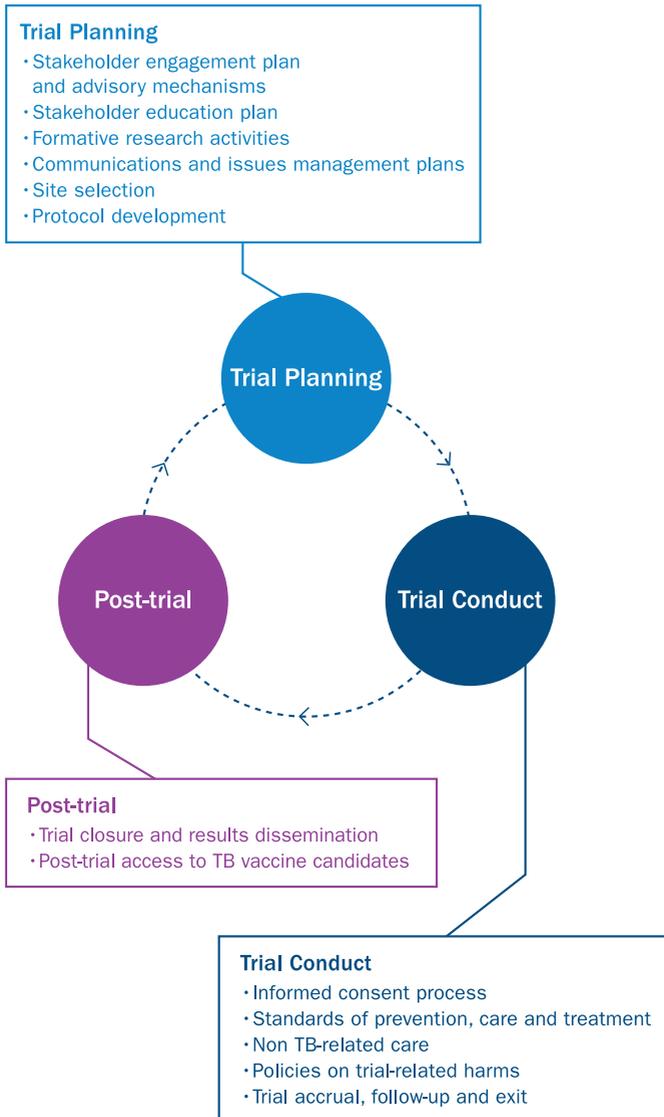
In Section 3, each of the 13 topic areas is defined and explained in terms of its relevance to TB vaccine research. Special considerations are highlighted for research teams, which describe the potential benefits of stakeholder participation in each area and the “value added” to a TB vaccine research program.

Key participatory practices are listed under each topic area and sequentially organized around the five essential actions of the GPP process model. These practices are suggested minimum standards for a research team to adopt and use to develop effective partnerships with relevant stakeholders in planning and conducting TB vaccine trials, as well as in monitoring good participatory practice. Practices are listed in the general sequence in which they may occur, although they are not necessarily sequential or time-limited and can take place as parallel, overlapping, or ongoing activities.

Application of each practice or set of practices will vary by location, the type of trial being conducted, and trial site experience with respect to previously established stakeholder engagement programs and activities.

Figure 4: Topic areas in the TB vaccine research life cycle.

The *GPP-TB VACC* topic areas encompass 13 aspects of the TB vaccine research life cycle, which are described in Section 3.



## Essential actions of stakeholder engagement

The key participatory practices for each topic area are listed in a sequential format around the five essential actions of the GPP process model. Some of the practices are cross-cutting and are considered to be the essential or “core” standards for research teams to follow in order to ensure meaningful participation of and high-quality contributions from stakeholders. They are

 <p>Identify</p>	<ul style="list-style-type: none"> <li>Identify <b>long-term goal(s)</b> for the stakeholder engagement program and <b>specific, measurable, achievable, relevant and timebound objectives</b> for the involvement of stakeholders, aligned to the research priorities.</li> <li><b>Identify stakeholders</b> at the community, broader, national and global levels, who are most affected by the research and who can achieve the objectives.</li> </ul>
 <p>Analyze</p>	<ul style="list-style-type: none"> <li><b>Analyze and prioritize key stakeholders</b> according to their interests, influence and relevance to the research and engagement objectives.</li> <li><b>Analyze the participation experience</b> amongst the identified stakeholders, including any barriers and ways these might be addressed.</li> </ul>
 <p>Prepare</p>	<ul style="list-style-type: none"> <li><b>Prepare an appropriately resourced strategy for engaging stakeholders</b> to achieve the objectives and desired outcomes.</li> <li>Prepare <b>methods and materials in alignment with the stakeholders’ interests and needs</b> and with consideration of the research team’s engagement skills.</li> <li>Communicate clear objectives, decision-making criteria and <b>two-way feedback processes</b> in advance of the engagement.</li> </ul>
 <p>Engage</p>	<ul style="list-style-type: none"> <li><b>Engage key stakeholders in the planning, implementation and evaluation of activities</b> with clearly defined roles and responsibilities for all parties.</li> <li>Employ <b>a range of informal and formal advisory mechanisms</b> to facilitate participation of stakeholders at multiple levels.</li> <li><b>Provide timely feedback</b> on recommendations, concerns and questions.</li> </ul>
 <p>Evaluate</p>	<ul style="list-style-type: none"> <li>Develop systems for joint <b>monitoring and evaluation of the engagement program and activities</b>.</li> <li><i>What do we need to achieve (goal and objectives)?</i></li> <li><i>What will we observe/document/evaluate (output and outcome indicators)?</i></li> <li><i>How will we gather evidence (methods and source of data)?</i></li> </ul>



## 3.1 Stakeholder engagement plan and advisory mechanisms

### 3.1.A Definition

A **stakeholder engagement plan** describes the overall goal, objectives and strategies for building and evaluating relationships with a broad range of community, regional, national and global stakeholders throughout the life cycle of the research.

**Stakeholder advisory mechanisms** are the informal and formal platforms or strategies that are used to facilitate stakeholder participation and involvement.

### 3.1.B Relevance

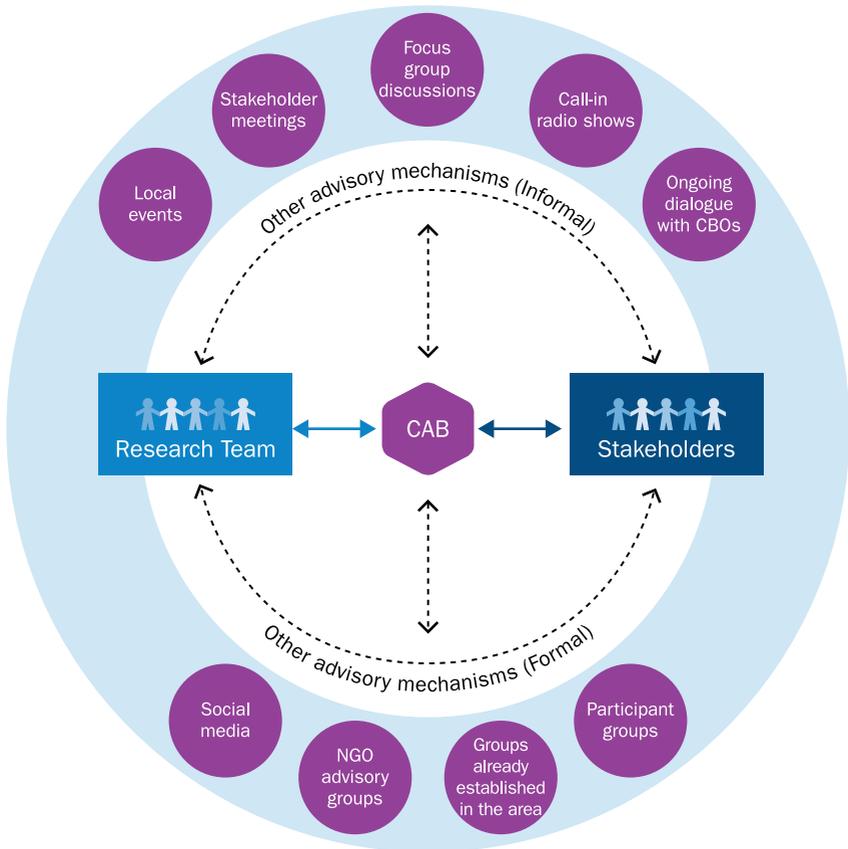
Meaningful and sustained partnership with stakeholders builds trust as well as understanding of and support for the TB vaccine research agenda, and local knowledge about culture, behavior and dynamics of the disease can enhance the design, conduct and outcomes of TB vaccine trials.

### 3.1.C Special considerations

1. A stakeholder engagement plan can be developed for a single trial or multiple trials. It is a living document that is routinely reviewed and revised as the engagement program and research agenda evolve. Additional plans for engaging individual topic areas, with supporting objectives, activities and indicators, can be developed as standalone work plans or can be incorporated into the broader engagement plan.
2. Community Advisory Boards are now a standard in clinical trials. CABs provide an independent advisory voice but should not be the sole mechanism for facilitating participation of community stakeholders in the research process. See *Figure 5: Stakeholder advisory mechanisms*.
3. There is a need for TB vaccine researchers to monitor and evaluate their stakeholder engagement programs, to ensure that engagement practices are aligned with standards in the guidelines. Evaluation can help research teams determine which engagement strategies are most effective in order to meet requirements set by funders and ethics committees and can inform decisions about resource allocation.

Figure 5: Stakeholder advisory mechanisms.

CABs have limitations and optimally should not be the only mechanism used to engage and solicit input from the local community. There are many formal and informal advisory mechanisms that research teams can build on and utilize in order to facilitate participation of key stakeholders. Formal stakeholder advisory mechanisms typically involve established groups or platforms that result in an ongoing relationship with the research team at a particular trial site. Informal stakeholder advisory mechanisms may be one-time events by which research teams seek relevant stakeholders' views on proposed or ongoing research.



### 3.1.D GPP for TB VACC: Stakeholder engagement plan and advisory mechanisms

 Identify	<ol style="list-style-type: none"> <li>1. Research teams and sponsors identify achievable and measurable goal(s) and specific objectives for stakeholder engagement, aligned to the priorities of the TB vaccine research program.</li> <li>2. Research teams identify key stakeholders in the community, as well as regionally, nationally and globally, who are most likely to be affected by and/or can affect aspects of TB vaccine research. See <a href="#">3.3.D GPP-TB VACC: Formative research activities</a> for other key practices that might apply.</li> </ol>
 Analyze	<ol style="list-style-type: none"> <li>3. Research teams analyze the following, as part of a routine planning process for their stakeholder engagement program:             <ol style="list-style-type: none"> <li>a. Effectiveness of previous engagement efforts;</li> <li>b. Potential role of each key stakeholder in the research process, with consideration of the research priorities and the stakeholder's influence, interests and capabilities and any significant barriers to participation;</li> <li>c. Existing mechanisms to facilitate the desired participation of each stakeholder. See <a href="#">Figure 6: Stakeholder engagement spectrum</a>;</li> <li>d. External funding opportunities, cost-sharing possibilities and other resource mobilization strategies to support a long-term engagement program.</li> </ol> </li> </ol>
 Prepare	<ol style="list-style-type: none"> <li>4. Research teams and sponsors allocate sufficient human and financial resources for a long-term stakeholder engagement program and explore multiple financing strategies.</li> <li>5. Research teams prepare an approach for seeking input on the engagement plan, using appropriate mechanisms and materials, aligned to their desired outcomes and with consideration of stakeholders' needs and preferences.</li> <li>6. Research teams clearly communicate their desired objectives, expectations for stakeholders, decision-making criteria and two-way feedback processes as early as possible.</li> </ol>



## Engage

7. Research teams and stakeholders discuss, develop and implement a plan for actively engaging stakeholders in the design, conduct and dissemination of the research and that encompasses
  - a. Specific, measurable, achievable, relevant and time-bound objectives for engaging stakeholders on aspects of the research;
  - b. Activities to achieve each objective, using a range of informal and formal advisory mechanisms to facilitate sustained participation of key stakeholders;
  - c. Specific roles and responsibilities of the research team and stakeholders;
  - d. Specific support that may be required for implementation of the plan and that can be feasibly provided by the research team;
  - e. Protocols for two-way communication and feedback between key stakeholders and the research team;
  - f. The process by which new relevant stakeholders will be identified and engaged;
  - g. The process by which the engagement program and key activities will be jointly monitored and evaluated.
8. Research teams and stakeholders establish and/or maintain a Community Advisory Board, with clear terms of reference.
9. Research teams routinely assess the membership of the CAB(s) to ensure that the composition is adequately diverse, gender-balanced and representative of the trial population and local community.



## Evaluate

10. Research teams and stakeholders routinely monitor and evaluate the quality and outcomes of the engagement plan, assess whether the objectives and expectations of stakeholders are being met and revise the plan as needed.
11. Research teams share and disseminate lessons learned about “high impact” engagement strategies to the greatest extent possible.





## Key questions for implementers

- Are all of the research team members in agreement about what they want to achieve through good participatory practice with stakeholders?
- Do the research team and key stakeholders have adequate resources and capabilities to fulfill their assigned roles and responsibilities?
- Have external funding opportunities for stakeholder engagement activities been explored by the sponsor and research team?
- Has a range of formal and informal advisory mechanisms been identified to ensure participation of stakeholders in each stage of the research process?

Figure 6: Stakeholder engagement spectrum.

The matrix describes the range of intended outcomes for stakeholder engagement and suggested mechanisms of participation associated with each. There are no prescribed mechanisms or activities. Research teams and stakeholders must jointly determine what mechanisms are most appropriate, depending on the objectives of the activity, timeframes and available resources as well as the interests and needs of the participating stakeholders.

	<b>INFORM</b>	<b>CONSULT</b>	<b>INVOLVE</b>	<b>COLLABORATE</b>	<b>EMPOWER</b>
	Stakeholders receive information without expectation of two-way dialogue.	Information is presented to stakeholders, who provide feedback.	Stakeholders are engaged in generating options and carrying out actions.	Stakeholders share responsibility for some decision-making, but most authority is retained by the research team.	Research teams and key stakeholders act together based upon shared goal and objectives.
<b>Advisory mechanisms</b>	<p>Community TB/HIV events</p> <p>Conferences</p> <p>Presentations</p> <p>Health talks</p>	<p>Surveys</p> <p>Key informant interviews</p> <p>Focus groups</p> <p>Radio call-in shows</p> <p>Online media platforms</p>	<p>Stakeholder advisory boards, forums or committees</p> <p>Workshops and trainings</p> <p>Existing meeting platforms (staff and health facility meetings)</p>	<p>Joint review and evaluation of engagement plan; stakeholders monitor to what extent their contributions are reflected in decision-making outcomes</p>	<p>Sustained partnerships, underpinned by education, training and role diversity, so stakeholders meaningfully and independently participate throughout all stages of the research</p>



## 3.2 Stakeholder education plan

### 3.2.A Definition

A **stakeholder education plan** describes ongoing strategies for enhancing stakeholders' understanding of the research and TB vaccine science and their abilities to participate in joint analysis and decision-making with the research team throughout the research process.

### 3.2.B Relevance

Sustained education of stakeholders, particularly those affected by TB, is essential for ensuring meaningful participation of stakeholders.

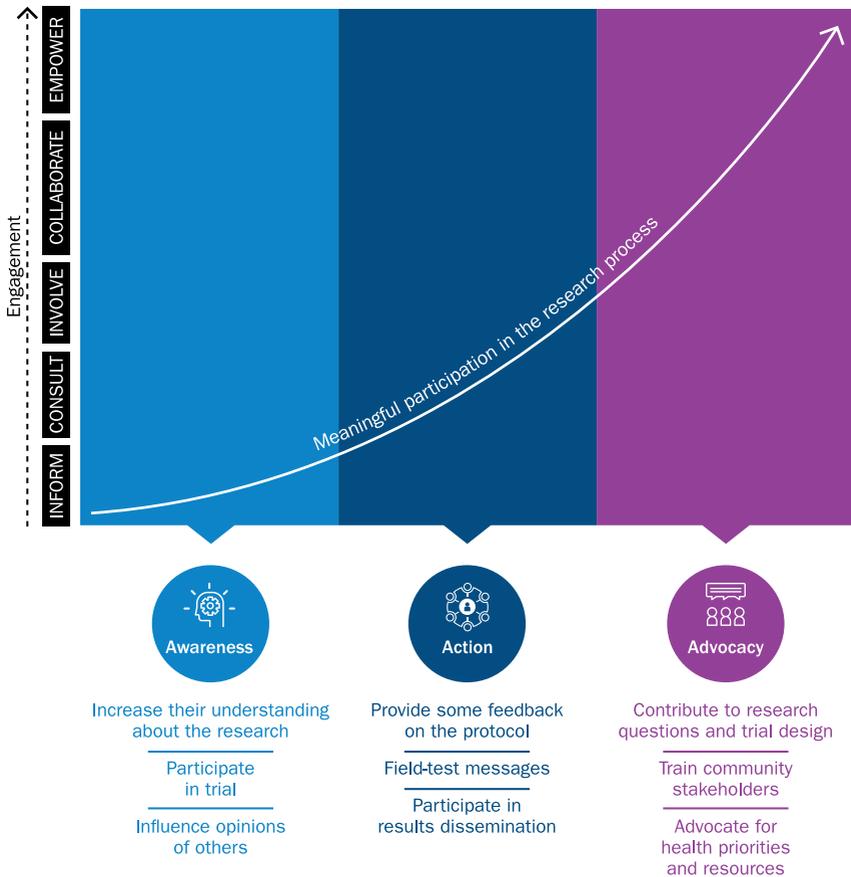
See *Figure 7: Community capacity building*.

### 3.2.C Special considerations

1. Stakeholders with a broad and deep community base, such as educators, religious leaders and community health cadres, can help researchers to sensitize “harder to reach” groups about TB and vaccines.
2. Research teams can work with schools and nongovernmental and community-based organizations, including those in the maternal health, nutrition and poverty-reduction sectors, to ensure that education about TB is included in curricula and program content.
3. Designing and implementing participatory education methods with community stakeholders such as drama, community, school events and workshops, can make concepts about TB and vaccines more accessible and simultaneously build important relationships.

Figure 7: Community capacity building.

Targeted and ongoing education about TB, clinical research and vaccine science can help stakeholders to participate more meaningfully in the research process. When community stakeholders are actively involved in the design, implementation and evaluation of activities with their peers, they can enhance their leadership and communication skills, resulting in greater mobilization and local advocacy for the TB vaccine research agenda.



## 3.2.D GPP for TB VACC: Stakeholder education plan

 <p>Identify</p>	<ol style="list-style-type: none"> <li>1. Research teams and stakeholders identify             <ol style="list-style-type: none"> <li>a. Groups in the community and at the regional, national and international levels who are most likely to be affected by and/or can affect specific aspects of TB vaccine research;</li> <li>b. Stakeholders who have broad community reach through channels for social mobilization, education and advocacy.</li> </ol> </li> </ol>
 <p>Analyze</p>	<ol style="list-style-type: none"> <li>2. Research teams analyze             <ol style="list-style-type: none"> <li>a. Research literacy needs and education priorities of community stakeholders;</li> <li>b. General knowledge of TB in the community, including common misconceptions and patterns of TB stigma;</li> <li>c. Local languages spoken and levels of literacy;</li> <li>d. Other factors that may impact learning or education of community stakeholders, such as age, gender dynamics and/or cultural issues;</li> <li>e. Skills and knowledge of research team members, related to their roles in engagement of the trial population and other key stakeholders.</li> </ol> </li> </ol>
 <p>Prepare</p>	<ol style="list-style-type: none"> <li>3. Research teams and sponsors allocate and continue to explore resources to support sustained education strategies.</li> <li>4. Research teams prepare an appropriate approach to involve key community stakeholders in the planning and implementation of activities, including groups who may be “harder to reach” for reasons such as language, culture, age or mobility.</li> <li>5. Research teams clearly communicate objectives and two-way feedback processes in the advance of any activity.</li> </ol>
 <p>Engage</p>	<ol style="list-style-type: none"> <li>6. Research teams and stakeholders design, adapt and implement appropriate educational strategies and supporting materials, aligned with the research priorities and stakeholders’ needs and preferences.</li> <li>7. Research teams and stakeholders discuss and design strategies for building awareness, knowledge and relevant skills of key community representatives to maximize their participation in each stage of the research.</li> </ol>

8. Research teams and stakeholders transparently discuss and agree on roles and responsibilities, including technical support and resource provision, in order to implement education activities throughout the entire research process.



Evaluate

9. Research teams and stakeholders monitor and evaluate the education activities, to assess whether objectives and expectations are being met, and collectively revise the plan as needed.



### Key questions for implementers

- Were the needs and participation barriers for “harder to reach” groups considered in the design process for stakeholder educational strategies?
- Do research teams and community stakeholders have access to the necessary training, materials and technical resources required for implementation of the education activities?
- Have indicators been developed to monitor the education activities and to evaluate their outcomes and impact on the research?

## 3.3 Formative research activities

### 3.3.A Definition

**Formative research activities** usually constitute the initial phase of stakeholder outreach and engagement. They enable research teams to gain an informed understanding of local populations who are directly affected by and able to influence TB vaccine research, including their needs and priorities, their sociocultural norms and practices, the history of research in the community, and more information about local TB epidemiology.

### 3.3.B Relevance

Early outreach and collaboration with community stakeholders helps to create ownership of the research and a foundation of trust. Participatory formative research with community stakeholders can be essential in the capacity-building process. Stakeholders can work with researchers to define methods that are in line with the research information needs and can contribute to results analysis and dissemination of findings back to the local community.

### 3.3.C Special considerations

1. Different TB vaccine trial sites will have specific needs regarding formative research activities. However, regardless of whether a research team has conducted previous clinical trials in the catchment area, some formative work is typically needed for stakeholder identification and early learning about local TB epidemiology, ethnography, existing levels of research literacy, health infrastructure, local resources and potential issues that may impact the trial(s).
2. When resources are insufficient for large-scale formative research activities, community stakeholders may help researchers to identify sources of reliable data, additional funding and strategies for meeting the needs of the larger trial(s) in an efficient and time-responsive manner. Stakeholders, such as the National TB Control Program (NTP) and special interest groups established by global vaccine funding agencies and/or academic institutions, may provide epidemiological data on TB and other diseases as well as other health, social and economic factors that affect the target communities.

### 3.3.D GPP for TB VACC: Formative research activities

 Identify	1. Research teams identify key stakeholders that can assist in planning, implementing and reviewing results of formative research activities for a TB vaccine trial(s).
 Analyze	2. Research teams analyze the research objectives, targeted population and trial environment, including any significant social, political, economic and cultural issues, laws, or norms that may impact the research outcomes.
 Prepare	3. Research teams work with internal/external stakeholders to prepare for engagement and identify any available resources, including existing data, published literature and/or funding to support formative work.
 Engage	4. Research teams work with stakeholders to design and implement a formative research plan that addresses <ol style="list-style-type: none"> <li>Key information and questions that need to be gathered and answered in order to support effective planning and implementation of the trial;</li> <li>The most appropriate methods to collect the required information;</li> <li>Research team members and community stakeholders best suited to collect the required information;</li> <li>Approval or notification processes and timelines for specific activities.</li> </ol>
 Evaluate	5. Research teams document and discuss the formative research findings with stakeholders, including techniques used, information collected, areas where additional clarification or attention is needed and how findings will inform planning and implementation processes. 6. Research teams use formative research findings to inform other components of their engagement plan, such as communications and message development, education and engagement approaches for certain groups, and identification of and planning for critical issues that may impact the research.





## Key questions for implementers

- In the initial outreach or formative activities, was consideration given to community stakeholders who may have less power or be harder to reach, such as youth and/or other vulnerable populations?
- Are there additional external funding avenues and/or partnerships that may support formative research activities?
- Were stakeholders, such as the National TB Control Program, academic groups and health authorities, consulted about existing epidemiological data or recent studies that could inform the formative work?



## 3.4. Communications and issues management plans

### 3.4.A Definition

The **communications and issues management** components of a stakeholder engagement plan describe strategies that will increase broad awareness of the research; facilitate dissemination, communication and understanding of correct information at each stage; and identify and manage issues of concern or unexpected developments that may emerge before, during and after the trial.

### 3.4.B Relevance

1. Ongoing and accurate communication with relevant stakeholders about TB vaccine trials is essential for building trust and support. Engaging community stakeholders in issues management planning prior to trial implementation can prepare research teams to address risks as they arise and can help avert crises.
2. Culturally relevant key messages and customized communication materials, developed with stakeholder input, can help ensure local understanding of TB science and vaccine trials, reduce potential for misunderstandings and enhance advocacy for the longer-term research agenda.

### 3.4.C Special considerations

1. Vaccine research has been influenced by many factors, including perceptions and fears of the general public. Communication strategies should be locally designed with input from community stakeholders about these influences.
2. Social media can be an important mechanism in the public discourse regarding vaccines. Studies suggest that monitoring and analysis of social media can provide research teams with key insights about emerging issues and community perceptions.
3. Stakeholders with experience conducting large-scale vaccination sensitization campaigns, such as media partners and United Nations (UN) agencies, can provide advice to researchers about effective messaging for different audiences, including groups who oppose vaccines.



## 3.4.D GPP for TB VACC: Communications and issues management plans

 Identify	<ol style="list-style-type: none"> <li>1. Research teams identify and prioritize key audiences that are essential for the success of a TB vaccine trial(s).</li> </ol>
 Analyze	<ol style="list-style-type: none"> <li>2. Research teams and sponsors analyze                     <ol style="list-style-type: none"> <li>a. Key time points during the research process at which data or results may be made available;</li> <li>b. Information needs for each audience at each time point, with consideration of their role and communication needs (including language and literacy level);</li> <li>c. Potential issues that may negatively impact the research;</li> <li>d. Competencies and skills gaps of research teams and stakeholders to be considered.</li> </ol> </li> </ol>
 Prepare	<ol style="list-style-type: none"> <li>3. Research teams review and consider any communication and issue-management protocols that are mandated by the sponsor and/or research network.</li> <li>4. Research teams prepare to consult key stakeholders about issues management and communication strategies, early in the trial planning stage, to ensure pre-approval of key messages.</li> </ol>
 Engage	<ol style="list-style-type: none"> <li>5. Research teams and stakeholders discuss and document                     <ol style="list-style-type: none"> <li>a. Milestones in the research process that require proactive updates to stakeholders;</li> <li>b. Communication strategies for each milestone, including communication preferences of or considerations for primary audiences;</li> <li>c. Potential issues that may impact the research and management strategies;</li> <li>d. Clear processes for two-way communication throughout the research process;</li> <li>e. Procedures and parameters for external communication, including media engagement and management of social media;</li> <li>f. Clear roles and responsibilities for the research team and stakeholders, aligned with the final plans.</li> </ol> </li> </ol>

6. Research teams and stakeholders develop key messages for primary audiences, aligned with the communication objectives and issues management strategies.
7. Sponsors and research teams provide communication training to the entire trial site, CAB members, trial participants and relevant stakeholders as needed.



Evaluate

8. Research teams and stakeholders jointly monitor the frequency and types of issues that emerge during the trial and the outcomes of any management strategies, in order to determine the effectiveness of their plans.



## Key questions for implementers

- Has a local media outlet been consulted for insights about how social, print and/or broadcast media are influencing community perceptions of and responses to the trial?
- Have local advocacy groups been engaged to provide ideas about potential concerns or objections to the trial and for help with strategizing about ways to improve communications?
- Do relevant research team members, CAB and trial spokespersons have the skills required to implement the communications and issues management plans?
- Are there practical ways for key stakeholders to share feedback and communicate (formally and informally) with the research team throughout the life cycle of the research?
- Have concerns about any previous trials been expressed by local authorities or the national government, that could impact the current research outcomes?

## 3.5 Site selection

### 3.5.A Definition

**Site selection** is the process by which funders, sponsors or networks evaluate new or existing sites for provision of funding for an investigator-led study, inclusion in a clinical trial or inclusion in a trial network.

### 3.5.B Relevance

Assessment of a site's stakeholder engagement program, or written plans to describe such processes, is critical to anticipating a site's ability to conduct robust TB vaccine research.

### 3.5.C Special considerations

New TB vaccine candidates will need to be studied in different geographic settings with high rates of TB infection and in different populations. This will require long-term, international collaborations with experienced trial sites in different disease areas and sustained engagement of communities between trials.

### 3.5.D GPP for TB VACC: Site selection

 Identify	1. Trial funders, sponsors and/or network representatives identify a potential site for TB vaccine research.
 Analyze	2. Trial funders, sponsors and/or network representatives analyze the trial site's previous research and engagement experience, with consideration of the trial design, the targeted population and the community's previous experience with clinical and vaccine research.
 Prepare	3. Trial funders, sponsors and/or network representatives communicate clear objectives for the assessment process and any requirements or expectations related to stakeholder engagement.
 Engage	4. Trial funders, sponsors and/or network representatives assess sites with respect to stakeholder engagement processes and programs, taking into account

- a. Evidence or plans for development and maintenance of stakeholder advisory mechanisms or commitment to establishing such mechanisms;
  - b. Evidence of previous stakeholder engagement activities;
  - c. Findings from formative research activities or a work plan for completing the activities;
  - d. Any evidence of cooperative arrangements with health care systems;
  - e. Demonstrated awareness and consideration of affected communities and human rights issues, particularly as they relate to vulnerable, marginalized or criminalized groups.
5. Trial funders, sponsors network representatives and trial site(s) transparently discuss and agree on roles, responsibilities, two-way feedback processes and timelines related to the development and maintenance of a stakeholder engagement program.



Evaluate

6. Trial funders, sponsors, and/or network representatives monitor the development and implementation of an appropriate stakeholder engagement plan, in alignment with good participatory practices.



## Key questions for implementers

- To what extent has the local CAB provided feedback on previous protocols, informed consent approaches or other key topic areas?
- Are multiple advisory mechanisms being used to facilitate stakeholder participation during the planning, conduct and post-trial stages of the research life cycle?
- How much time and potential support is required to develop a comprehensive stakeholder engagement plan, if one does not already exist?

## 3.6 Protocol development

### 3.6.A Definition

**Protocol development** is the process of creating and modifying a trial protocol. The protocol describes the rationale, objectives, design, methodology, statistical considerations, ethical considerations and key operations for a trial.

### 3.6.B Relevance

Participation of affected communities in the design of TB vaccine trials can ensure that research objectives reflect community needs, that trial procedures are acceptable to the targeted population and that potential issues are addressed early. See *Figure 8: Stakeholder engagement in protocol development*.

### 3.6.C Special considerations

1. Opportunities for protocol review by site staff and stakeholders vary by trial. In multicountry or multisite trials, protocol development may be centralized. In this case, research teams can consider documenting community stakeholder feedback about the protocol and sharing these recommendations with sponsors and protocol review bodies, even when not explicitly required to do so.
2. Protocols for TB vaccine trials may be designed in an adaptive fashion. The trial might be modified depending on interim results and subsequent protocol approval, and successful ongoing trial conduct would largely depend on efficient systems for rapid review and on input from key community stakeholders, including the CAB and trial participants.
3. It is vital for TB vaccine researchers to formally communicate challenges arising from trial design and operational lessons learned from implementation of the protocol, in order to inform future protocol development.

### 3.6.D GPP for TB VACC: Protocol development



#### Identify

1. Research teams identify key informants and relevant stakeholders that can assist in reviewing the protocol for a TB vaccine trial.

 <p>Analyze</p>	<ol style="list-style-type: none"> <li>2. Trial sponsors and local research teams analyze             <ol style="list-style-type: none"> <li>a. Local protocol development and review processes;</li> <li>b. Additional opportunities for key stakeholders, in particular community stakeholders, to contribute to research design, objectives, recruitment strategies, informed consent materials and procedures, reimbursement policies, counseling approaches, follow-up procedures and results dissemination strategies;</li> <li>c. Community stakeholders' levels of research experience, scientific knowledge or technical expertise to meaningfully contribute to protocol review and resources required to address these needs;</li> <li>d. Any stakeholder engagement strategies that require regulatory and/or ethics approval.</li> </ol> </li> </ol>
 <p>Prepare</p>	<ol style="list-style-type: none"> <li>3. Research teams prepare community stakeholders for protocol review with necessary research literacy, training and/or background information, such as translated protocol summaries.</li> <li>4. Research teams communicate the parameters of the protocol review process and the role of stakeholders, in advance of the review.</li> </ol>
 <p>Engage</p>	<ol style="list-style-type: none"> <li>5. Research teams explain approval timelines and processes for receiving and incorporating feedback into the protocol.</li> <li>6. Research teams and community stakeholders jointly review the protocol and document key comments, questions and/or concerns.</li> <li>7. Research teams provide regular updates to stakeholders about any changes to the protocol, including how comments were considered and/or incorporated.</li> <li>8. Research teams and sponsors make full, final protocols of trials available and easily accessible to key stakeholders.</li> </ol>
 <p>Evaluate</p>	<ol style="list-style-type: none"> <li>9. Research teams submit a summary of stakeholder comments, questions and concerns to the trial sponsor and site leadership for consideration (even if the protocol has been finalized prior to the review process).</li> </ol>





## Key questions for implementers

- How can community stakeholders provide feedback on trial procedures even if the protocol has been finalized before being sent to the site?
- Are there influential community stakeholders who require training and/or scientific knowledge in order to meaningfully contribute to discussions about the research agenda and the protocol?
- Are there confidentiality clauses that limit how trial protocols can be shared with stakeholders?

Figure 8: Stakeholder engagement in protocol development.

Stakeholder involvement during protocol development can help ensure that research questions and procedures are culturally sensitive and aligned with local health priorities. Community stakeholders can provide valuable input about effective recruitment and retention strategies and identify ethical considerations for vulnerable populations to be addressed in the protocol.



## 3.7 Informed consent process

### 3.7.A Definition

**Informed consent** is an ongoing education process that must occur before any clinical trial-related procedures are conducted. The process consists of a document (**informed consent form**) and a series of conversations between the trial participant and principal investigator (or delegated research team member) about the risks and benefits of the research and trial procedures as well as the understanding and expectations of the participant.

### 3.7.B Relevance

Community stakeholders can provide input on appropriateness of language and content and on comprehensibility of the informed consent form. They can also suggest practical approaches to assess participants' comprehension and ensure ethical decision-making during the informed consent process at enrollment and throughout the trial(s).

### 3.7.C Special considerations

1. There are ethical complexities regarding consent of groups who may participate in TB vaccine trials, such as diminished autonomy, language difficulties, literacy level and cultural barriers. Input from stakeholders with ethics expertise can help researchers ensure the protection and rights of children and/or adolescents, including in cases where the parents may themselves be minors.
2. It is critical to ensure that all elements of the informed consent process are included in the form and discussion as required by ICH E6 Guideline for Good Clinical Practice. However, detailed and lengthy consent forms can be challenging to administer. Ensuring comprehension about risks versus benefits of a TB vaccine candidate and certain trial procedures, such as biological sample storage (when future uses of samples and exact research objectives may not be known at the time of collection), can also be challenging. Research teams can consult with CABs and other trial sites about alternative approaches to consent that are ethically compliant but still effective.



## 3.7.D GPP for TB VACC: Informed consent process

 Identify	1. Research teams identify key stakeholders that can assist in planning for locally appropriate informed consent approaches.
 Analyze	2. Research teams analyze <ol style="list-style-type: none"> <li>Formative research findings related to literacy levels and local decision-making norms;</li> <li>National policies and guidance about age of consent for research and key trial procedures;</li> <li>Ethical considerations for the trial population.</li> </ol>
 Prepare	3. Research teams prepare an engagement approach with clearly communicated objectives as well as consideration of approval timelines and of stakeholders' abilities to participate in the discussion.
 Engage	4. Research teams and community stakeholders discuss and document feedback on <ol style="list-style-type: none"> <li>Cultural practices that may affect the decision-making ability of volunteers;</li> <li>Methods for assessment of literacy;</li> <li>Methods for age verification;</li> <li>Local determinations of "minor" and who can serve as a minor's legally acceptable representative;</li> <li>The prevalence of different languages in the area;</li> <li>Reimbursement and compensation in line with ethical guidelines;</li> <li>Strategies to ensure protection of participant rights;</li> <li>Strategies to ensure comprehension of the informed consent form and associated materials prior to and throughout trial participation;</li> <li>Preferred ways for participants to contact the research team;</li> <li>Any plans for field-testing the approaches.</li> </ol> 5. Research teams and stakeholders field-test and finalize approaches.
 Evaluate	6. Research teams maintain written records of discussions with stakeholders about informed consent, including recommendations, unresolved issues and actions to be taken by the research team and stakeholders.



## Key questions for implementers

- Have past trial participants, CAB members and civil society stakeholders been involved in the review and/or field-testing of the informed consent process?
- Have other researchers been consulted about existing informed consent templates and/or comprehension assessment tools that may be adapted for the trial?



## 3.8 Standards of prevention, care and treatment

### 3.8.A Definition

The **standards of prevention, care and treatment** refer to the package of services provided or made available to volunteers during the screening process of a TB vaccine trial, during trial conduct and/or after trial closure.

- **Prevention** refers to the provision of or linkage to screening, diagnostics, risk-reduction counseling and other prevention options for TB disease.
- **Care** includes counseling and other non-clinical management of TB disease.
- **Treatment** refers to provision of or linkage to medications and clinical disease management of TB disease, determined by local and/or international guidelines.

### 3.8.B Relevance

The standards of prevention, care and treatment provided to trial participants are likely to have a significant influence on community stakeholder perceptions of the research and are often at the forefront of community stakeholder concerns. Decisions about the type, range and duration of prevention, care and treatment options as well as who will finance and implement them should be negotiated with stakeholders in the early stage of trial design and planning.

### 3.8.C Special considerations

1. Decisions about the prevention, care and treatment services for a specific trial will be based on the characteristics of the trial population, such as prior TB vaccination status, TB infection status, and HIV infection status as well as national policies and protocols.
2. Health care providers, community volunteers and local leaders can strengthen linkages between the trial site and services for TB prevention, care and treatment. They can monitor referral outcomes for trial participants and assist research teams in understanding health-seeking behaviors and common barriers that affect access to services.

## 3.8.D GPP for TB VACC: Standards of prevention, care and treatment

 Identify	1. Research teams identify key stakeholders who have expertise related to local TB prevention, care and treatment standards and services.
 Analyze	2. During the trial design and planning stage, research teams and sponsors analyze <ol style="list-style-type: none"> <li>National guidelines, current research findings and local standards of prevention, care and treatment for TB;</li> <li>Anticipated number of people with TB/latent TB infection (LTBI) identified during the screening process and during the trial;</li> <li>Abilities of research team members and health care workers to provide appropriate clinical care to the trial participants, partners and family members, if applicable;</li> <li>Existing referral pathways and potential impacts of new referral streams on the local infrastructure.</li> </ol>
 Prepare	3. Research teams prepare an engagement approach with clearly communicated objectives, processes for two-way feedback and decision-making criteria as well as methods and materials aligned to stakeholders' needs.
 Engage	4. Research teams and stakeholders discuss, negotiate and document feedback on <ol style="list-style-type: none"> <li>Prevention, care and treatment services that will be offered to volunteers (during screening) and trial participants (including after trial exit) as well as partners and/or family members;</li> <li>Key counseling messages for participants who are diagnosed with LTBI, including their risk of developing active disease and treatment options in line with national or normative guidelines;</li> <li>Referral procedures for linking volunteers and participants to services;</li> <li>Cost and financing;</li> <li>Roles and responsibilities for referrals and service delivery;</li> <li>The duration of services being provided by each stakeholder.</li> </ol>



5. Research teams and stakeholders discuss the final service package (or any changes thereafter), clarify roles and responsibilities and agree on actions and timelines for outstanding issues.
6. Research teams describe standards of care in the informed consent forms for screening and enrollment.



## Evaluate

7. Research teams and stakeholders monitor and evaluate referral outcomes for screening volunteers and trial participants.
8. Research teams align their reporting with national systems for TB reporting, monitoring and data collection.



## Key questions for implementers

- Are there discrepancies among national policies, protocol requirements and available prevention, care and treatment options for TB/LTBI? If so, who should be consulted? How should the discrepancies be communicated to participants and communities?
- How will changes in standards of prevention, care and treatment for TB/LTBI be managed and communicated, if they occur during a trial?

## 3.9 Non TB-related care

### 3.9.A Definition

**Non TB-related care** refers to health, social protection and/or care services that may be made available to TB vaccine trial participants but are not directly related to TB prevention, care and treatment or trial-related harm. Examples could include provision of nutritional support, psychosocial services, antenatal care, family planning services, and clinical care and treatment for other diseases besides TB, such as HIV.

### 3.9.B Relevance

Individuals who are at risk for TB infection might require additional support due to social and/or economic vulnerabilities. Seeking input about these potential needs and transparently negotiating the range of services that will be made available to participants demonstrates responsiveness to affected communities and can result in better clinical outcomes for trial participants.

### 3.9.C Special considerations

1. Non TB-related care packages may vary, depending on the needs of the trial population, local health priorities and standards of care. Special consideration should be given to the economic, psychological and social needs of vulnerable trial populations, such as adolescents, children and infants and community experts can be engaged to provide relevant perspectives about needed services and referral pathways during the planning stage of the trial(s).
2. A synergistic relationship exists between TB and HIV. HIV infection is a risk factor for developing latent TB infection and for progression of latent TB to active TB disease. Additionally, HIV-positive individuals with active TB disease tend to have higher HIV viral loads. Trial sponsors and implementers are ethically obligated to provide information to trial participants to help them reduce their risk of acquiring TB and to ensure that participants who acquire TB and/or HIV during the trial have access to clinical evaluation and appropriate care and treatment.



### 3.9.D GPP for TB VACC: Non TB-related care

 Identify	1. Research teams identify community stakeholders and local providers who can offer advice about and/or facilitate referrals to non TB-related care and other support services necessary for the trial participants, should the need arise.
 Analyze	2. Research teams analyze <ol style="list-style-type: none"> <li>Factors driving the local community's vulnerability to TB;</li> <li>Available services to address these needs, including HIV testing, care and treatment;</li> <li>Potential impacts of additional referrals on local infrastructure.</li> </ol>
 Prepare	3. Research teams prepare an approach to support two-way dialogue and joint decision-making with key stakeholders about non TB-related care for trial participants.
 Engage	4. Research teams and stakeholders discuss and negotiate <ol style="list-style-type: none"> <li>Non TB-related care required by the trial protocol;</li> <li>Additional services (and rationale) for trial participants and their partners and family members, if applicable;</li> <li>Community expectations;</li> <li>Cost implications and financing strategies;</li> <li>Referral systems;</li> <li>Roles and responsibilities for service delivery;</li> <li>The duration of service provision.</li> </ol> 5. Research teams and stakeholders discuss the final service package (or any changes thereafter), confirm roles and responsibilities and agree on actions and timelines for outstanding issues.
 Evaluate	6. Research teams and stakeholders monitor and evaluate the effectiveness of referral pathways, including the referral outcomes for trial participants. 7. Research teams report relevant data to the NTP and/or local health authorities, as discussed and agreed during the trial planning stage.



## Key questions for implementers

- Can stakeholders assist with training for research staff on identification and management of non TB-related needs, such as addressing psychosocial issues faced by trial participants?
- Was the potential impact of a new referral stream on local systems addressed during the consultations with stakeholders?
- Have decisions (and rationale) about non TB-related services offered to trial participants been transparently communicated to key stakeholders?



## 3.10 Policies on trial-related harms

### 3.10.A Definition

**Policies on trial-related harms** describe how research teams will treat and compensate trial participants should they experience physical or social harm that is determined to be associated with TB vaccine trial participation, as well as how such harm will be addressed and mitigated.

### 3.10.B Relevance

1. A key ethical obligation of research teams is to maximize benefits and minimize harm for trial participants. Stakeholders can work with researchers to identify possible social harms and decide on strategies for prevention and management.
2. Discussing with stakeholders before a trial starts and clearly explaining how trial-related harm will be addressed and mitigated can significantly influence community stakeholder perceptions of the research.

### 3.10.C Definition

1. In many countries, TB is a “notifiable infectious disease.” This designation means that medical practitioners have a statutory duty to notify their health department or government of all suspected and diagnosed TB cases.
2. TB is also a stigmatized disease often associated with factors (HIV, poverty, drug and alcohol misuse, homelessness, incarceration and refugee status) that can create additional stigma for trial participants, partners and their families. Research teams can collaborate with stakeholders who are known for their work with marginalized and stigmatized populations, such as faith-based organizations.

### 3.10.D GPP for TB VACC: Policies on trial-related harms



Identify

1. Research teams and relevant stakeholders identify anticipated physical and social harms that might occur due to trial participation.

 <p>Analyze</p>	<p>2. Research teams analyze</p> <ol style="list-style-type: none"> <li>a. Characteristics of the trial population and community that may increase susceptibility to trial-related stigma and social harms;</li> <li>b. Any relevant findings from the formative research activities that pertain to possible social harms and management strategies, including available services;</li> <li>c. Operational guidance from sponsors on the reporting and management of trial-related harms.</li> </ol>
 <p>Prepare</p>	<p>3. Research teams prepare an engagement approach with clearly communicated objectives and two-way feedback processes as well as methods and materials aligned to stakeholders' needs.</p>
 <p>Engage</p>	<ol style="list-style-type: none"> <li>4. Research teams and relevant stakeholders discuss and document feedback on             <ol style="list-style-type: none"> <li>a. Strategies to prevent or reduce the risk of trial-related harms;</li> <li>b. Procedures for reporting of social harms;</li> <li>c. Procedures to investigate events that have been reported indirectly, such as through a third party, taking confidentiality issues into account;</li> <li>d. Procedures for reporting to sponsors, ethics committees, and/or regulatory bodies, even if not specifically required by them;</li> <li>e. Available and appropriate service provision for participants who experience harms, with clear roles and responsibilities and referral procedures;</li> <li>f. Applicable compensation policies.</li> </ol> </li> <li>5. Research teams and stakeholders jointly implement the plan, with clear procedures for two-way feedback.</li> </ol>
 <p>Evaluate</p>	<p>6. Research teams and relevant stakeholders monitor and evaluate the number of trial participants who report trial-related social harms, and the outcomes of referral and other management strategies.</p>





## Key questions for implementers

- Have community representatives been consulted about social harms that might affect trial participants, especially for populations who may be more vulnerable, marginalized or stigmatized due to their gender, sexual orientation, age, socio-economic background or health status?
- Have community stakeholders been consulted about ways to minimize social harms for participants, including strategies for ensuring confidentiality and safety of participants?



## 3.11 Trial accrual, follow-up and exit

### 3.11.A Definition

**Trial accrual** refers to the process of recruiting, screening and enrolling volunteers into a TB vaccine trial.

**Trial follow-up** includes strategies that support participants' retention and adherence to visits stipulated in the trial protocol.

**Trial exit** refers to the end of the follow-up period (also known as trial closure) and often involves transferring participants to ongoing care, treatment or other supportive services.

### 3.11.B Relevance

Community stakeholders can provide the best information on how to design socially and culturally acceptable strategies for recruitment, screening, enrollment, follow-up and exit of trial participants. Inclusion of community stakeholders in the process of developing these strategies can also mitigate trial-related stigma.

### 3.11.C Special considerations

1. TB vaccine trials may include healthy participants who are not yet infected with TB, those with latent TB infection or those who have active TB disease. Community stakeholders can help researchers understand and address potential barriers to accrual and follow-up for different trial populations, such as uncertainty about vaccine efficacy, mistrust of research, low perceived TB risk and fear of vaccine-induced infection.
2. National vaccination campaigns can affect trial accrual where administration of other vaccines is an exclusion criterion. Early engagement of health services at all levels can maximize engagement and enrollment of all eligible individuals in a TB vaccine trial.



### 3.11.D GPP for TB VACC: Trial accrual, follow-up and exit

 <p>Identify</p>	<p>1. Research teams identify relevant community stakeholders that can provide advice about how to improve accrual, follow-up and exit procedures and processes for the target trial population.</p>
 <p>Analyze</p>	<p>2. Research teams analyze what factors and issues could positively or negatively influence accrual, follow-up and exit of the trial participants.</p>
 <p>Prepare</p>	<p>3. Research teams prepare an engagement approach with clearly communicated objectives and two-way feedback processes as well as methods and materials aligned to stakeholders' needs.</p>
 <p>Engage</p>	<p>4. Research teams and stakeholders discuss and document feedback on key trial procedures, including</p> <ol style="list-style-type: none"> <li>a. <b>Trial accrual:</b> recruitment, screening and enrollment strategies and materials that are socially and culturally appropriate, that meet the needs of specific stakeholders in terms of language and literacy and draw on a range of communication modalities, including written, oral and visual;</li> <li>b. <b>Trial follow-up:</b> strategies to ensure the confidentiality of participants during trial visits, while following up with participants outside of the trial clinic and after trial exit;</li> <li>c. <b>Trial exit:</b> procedures for transfer of care at the end of the follow-up period and during trial closure, such as providing participants with referrals to TB-related or other supportive services.</li> </ol>
 <p>Evaluate</p>	<p>5. Research teams maintain written records of discussions regarding trial procedures, including any questions and concerns from community members.</p>



## Key questions for implementers

- Has the research team consulted stakeholders to discuss accrual and follow-up practices that encourage participation and reduce or minimize stigma?
- Have health care providers been consulted about strategies for supporting and linking participants to any needed clinical services at trial exit?
- Have advocates and other researchers been engaged for advice about messaging and strategies to keep participants meaningfully engaged after they have exited the trial?



## 3.12 Trial closure and results dissemination

### 3.12.A Definition

**Trial closure** occurs when all participants have exited from the trial and all trial procedures have been completed.

**Results dissemination** is the process for communication of trial outcomes to participants, community stakeholders and the public at large and includes the unblinding of participants.

### 3.12.B Relevance

1. Involving stakeholders in the analysis and dissemination of trial results enhances the validity of the research, builds research literacy in the community and guides priorities for future TB vaccine research. See *Figure 9: Examples of engagement during trial results dissemination, on page 71.*
2. In the event that a trial is stopped early or unexpectedly, timely and transparent communication about the outcome to stakeholders, initiated by the research team, can minimize the risk of misinformation and prevent negative perceptions of TB vaccine trials in the local community.

### 3.12.C Special considerations

1. In multicountry and/or multisite trials, the follow-up period may conclude at different times. Even if some sites are closed for participant follow-up, research teams at other locations may continue to see participants. Stakeholder engagement activities should continue during this period of staggered site closure.
2. TB vaccine researchers can draw on examples from the HIV research field that illustrate the importance of providing comprehensive and transparent information about outcomes of previous vaccine trials to communities, populations at risk of infection and potential participants in subsequent trials.
3. Ownership of data and issues of publication and release of trial results vary by trial and may be strictly delineated by sponsors or product manufacturers.

## 3.12.D GPP for TB VACC: Trial closure and results dissemination

 <p>Identify</p>	<ol style="list-style-type: none"> <li>1. Research teams identify stakeholders that can contribute to strategies for trial closure and results dissemination, especially for affected communities.</li> </ol>
 <p>Analyze</p>	<ol style="list-style-type: none"> <li>2. Research teams analyze             <ol style="list-style-type: none"> <li>a. Information needs of key stakeholders at multiple levels;</li> <li>b. Existing mechanisms that can be used to broadly disseminate results and for different target audiences;</li> <li>c. Available human and financial resources to support multiple dissemination activities in the community.</li> </ol> </li> </ol>
 <p>Prepare</p>	<ol style="list-style-type: none"> <li>3. Research teams, sponsors and funders prepare a preliminary plan (with timelines) that addresses the following scenarios:             <ol style="list-style-type: none"> <li>a. Closure of one or more sites, as scheduled per protocol;</li> <li>b. Early closure due to evidence of harm, futility or clear protective benefit in interim analyses of trial data;</li> <li>c. Early closure because of evidence of harm or of clear protective benefit from a different trial evaluating the same product;</li> <li>d. Early closure due to unforeseen circumstances such as administrative or financial reasons, stakeholder objection or sudden social unrest.</li> </ol> </li> <li>4. Research teams prepare an appropriate engagement approach, with clearly communicated objectives and two-way feedback processes, as well as methods and materials aligned to stakeholders' needs.</li> </ol>
 <p>Engage</p>	<ol style="list-style-type: none"> <li>5. Research teams engage stakeholders early in the trial planning stage to discuss and document feedback on             <ol style="list-style-type: none"> <li>a. Strategies to ensure that trial participants are provided opportunities to learn and understand the trial results before they are announced publicly;</li> <li>b. How results will be disseminated to community stakeholders and to the public for each closure scenario, using various mechanisms and ensuring the active involvement of community stakeholders when feasible;</li> </ol> </li> </ol>





- c. Key messages and communication methods to be used for each key audience;
  - d. Roles and responsibilities of community stakeholders and research teams in the dissemination activities, including provision of any support;
  - e. How and when participants will be informed of their trial group assignment, if applicable;
  - f. Issues around ownership of the data, data access and publications.
6. Research teams and stakeholders jointly implement the plan, with clear procedures for two-way feedback about questions, concerns and any emerging issues related to results dissemination.
- 
7. Research teams maintain written records of discussions regarding trial closure and dissemination messages, including any questions and concerns from community members about the results.



Evaluate



## Key questions for implementers

- Have strategies for results dissemination been discussed with trial participants and community stakeholders early in the research process?
- Does the dissemination plan provide multiple opportunities for community members to ask questions and for the research team to share information and address misunderstandings?
- Are community stakeholders involved in the analysis and dissemination of research findings to the greatest extent possible (for instance, by designing interactive approaches for the community, working as part of a writing team or helping to develop a conference presentation)?
- Has the timing of media releases been considered when planning for results dissemination, including how to reduce the likelihood of or manage situations in which participants inadvertently learn about results via the media?

## 3.13 Post-trial access to TB vaccine candidates

### 3.13.A Definition

**Post-trial access to TB vaccine candidates** refers to making a TB vaccine that has been tested in an efficacy trial, available to trial participants and local community stakeholders (1) should the new vaccine be scientifically validated or approved by relevant authorities, or (2) in the form of other trials or studies before product licensure or approval, if there are positive findings with the new TB vaccine candidate.

### 3.13.B Relevance

1. Research ethics call for maximizing benefits to stakeholders who participate in research. Therefore, community stakeholders are to be among the first to gain access to products, should they be found to be safe and effective. An equitable, effective access plan must be informed by the local perspectives and realities of the communities most affected by TB.
2. Expectations and discussions about potential product access are likely to have a significant influence on communities' perceptions of and support for the research. Community stakeholders can help researchers to manage expectations, answer questions and respond to any emerging issues or divergent viewpoints.

### 3.13.C Special considerations

1. National regulatory approval processes and timelines will differ by product and by country. These differences should be considered when developing plans for multisite trials.
2. Sponsors can participate in global research platforms and communicate early with funders, vaccine manufacturers and normative agencies to learn about early access programs and advocate for resources.
3. Global community advisory groups and international advocacy organizations, representing TB- and HIV-affected communities, can provide advice about strategies for early access and regulatory approval and could be well positioned to advocate for more equitable pricing and appropriate changes in licensing policies.



### 3.13.D GPP for TB VACC: Post-trial access to TB vaccine candidates

 <p>Identify</p>	<p>1. Sponsors and research teams identify key stakeholders at each level who are influential in the design of and support for the post-trial access strategy.</p>
 <p>Analyze</p>	<p>2. Research teams, sponsors and stakeholders analyze and prioritize targeted populations for early access to the product and any considerations for planning, based on characteristics of the population.</p> <p>3. Research teams, sponsors and key stakeholders analyze issues that could affect future availability of a new TB vaccine, including</p> <ol style="list-style-type: none"> <li>Licensure requirements;</li> <li>Production rights;</li> <li>Manufacturing requirements;</li> <li>Need for additional marketing and distribution research;</li> <li>National health systems and capabilities to roll out a new vaccine.</li> </ol>
 <p>Prepare</p>	<p>4. Trial funders, sponsors and research teams prepare a potential plan to make the new TB vaccine available to participants and/or key affected groups rapidly, affordably and sustainably, should the vaccine be shown to be safe and effective.</p>
 <p>Engage</p>	<p>5. Trial funders, sponsors and research teams engage community stakeholders and ensure ongoing two-way dialogue about their expectations, concerns and questions about product access.</p> <p>6. Trial sponsors involve other relevant stakeholders in planning and decision making about licensure and access issues early in the research process, should the TB vaccine candidate be shown to be safe and effective.</p>
 <p>Evaluate</p>	<p>7. Research teams maintain clear written records of discussions, agreements and actions for outstanding issues and provide feedback to stakeholders.</p>

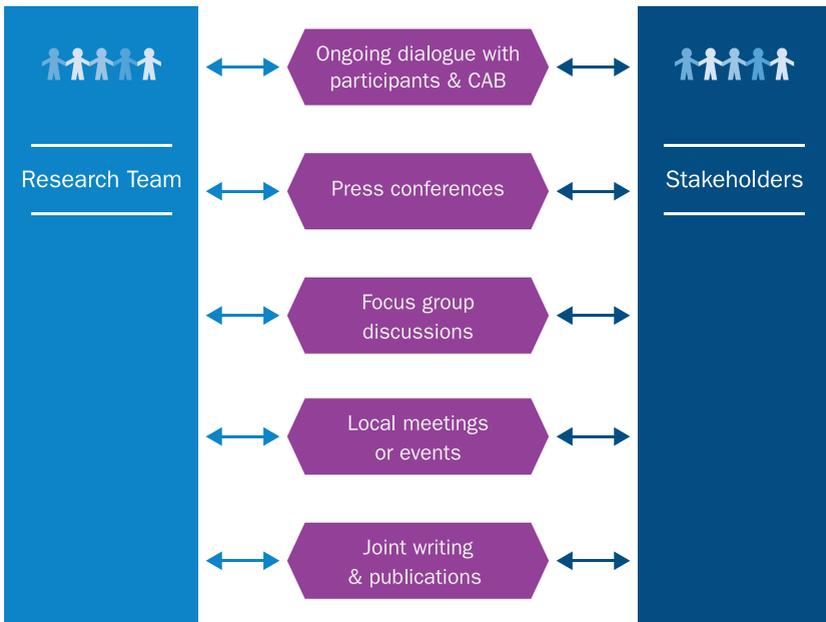


## Key questions for implementers

- Does the national regulatory authority allow expanded access and accelerated approval?
- Have access issues been transparently discussed with advocates and community stakeholders before the trial begins, even if the trial does not address effectiveness or efficacy?

Figure 9: Examples of engagement during trial results dissemination.

Media platforms, scientific conferences, community forums and joint publication efforts can be used by research teams to engage stakeholders in the analysis and discussion of trial results and keep former participants and stakeholders informed about any follow-up.



# Appendices

## Appendix 1: Acronyms

**AIDS** – Acquired immune deficiency syndrome

**BCG** – Bacillus Calmette-Guerin

**CAB** – Community advisory board

**CBO** – Community-based organization

**CIOMS** – Council for International Organizations of Medical Science

**CPTR** – Critical Path to TB Drug Regimens

**GCLP** – Good clinical laboratory practice

**GCP** – Good clinical practice

**GMP** – Good manufacturing practice

**GPP** – Good participatory practice

**HIV** – Human immunodeficiency virus

**ICF** – Informed consent form

**ICH** – International Conference on Harmonisation

**IEC** – Independent ethics committee

**LTBI** – Latent tuberculosis infection

**MDR-TB** – Multi-drug-resistant tuberculosis

**Mtb** – *Mycobacterium tuberculosis*

**NCD** – Noncommunicable disease

**NGO** – Nongovernmental organization

**NTP** – National TB Control Program

**PrEP** – Pre-exposure prophylaxis

**R&D** – Research and development

**TB** – Tuberculosis

**UNAIDS** – The Joint United Nations Program on HIV/AIDS

**WHO** – World Health Organization

**XDR-TB** – Extensively drug-resistant tuberculosis



## Appendix 2: Glossary

**Accrual.** The process of recruiting participants into a clinical trial.

**Acquired immune deficiency syndrome (AIDS).** The most severe manifestation of infection with human immunodeficiency virus (HIV), characterized by deterioration of the immune system and susceptibility to opportunistic infections and cancers. See [Human immunodeficiency virus](#).

**Active TB disease.** An infectious disease in which *Mycobacterium tuberculosis* multiplies in different parts of the body (most often the lungs) and causes illness.

**Activist.** A person or group who acts on behalf of a cause in order to bring about change.

**Advocate.** A person or group who acts on the behalf of individuals, groups or a specific cause.

**Aeras.** A nonprofit research and development organization advancing the development of new tuberculosis vaccines in partnership with other biotech, pharmaceutical and academic organizations.

**AVAC.** A nonprofit organization that uses education, policy analysis, advocacy and community mobilization to accelerate the ethical development and eventual global delivery of AIDS vaccines and other new HIV prevention options as part of a comprehensive response to the pandemic.

**Bacillus Calmette-Guerin (BCG).** A TB vaccine used in many countries where there is a high prevalence of TB. The vaccine provides some protection against severe forms of pediatric TB but has variable protection against the disease in infants and does not protect against adult [pulmonary TB](#) or [latent TB infection](#).

**Biomarker.** A distinctive measurable biological molecule, gene or chemical that serves as an indicator of a biological phenomenon of interest.

**Biomedical HIV prevention trial.** A clinical trial that aims to discover safe and effective products or procedures to prevent HIV transmission.

**Blinded trial or masked trial.** A clinical trial designed to prevent the participants, research teams or both from knowing which participants are in the experimental arm and which are in the control arm of the trial, in order to reduce bias.



**Clinical trial.** A research study that uses human volunteers to answer specific questions about the safety, efficacy, effectiveness and other effects of biomedical or behavioral interventions (including drugs, treatments, devices or new ways of using known drugs, treatments, or devices).

**Community advisory board (CAB).** A group of individuals that acts as an independent advisory voice and facilitates community stakeholder participation in the research process. A CAB meets regularly with research team representatives, informs community stakeholders about proposed and ongoing research and provides feedback to research teams about local norms, beliefs, views and concerns that may impact the research.

**Community groups.** Groups of individuals who come together to act on behalf of common interests, goals and values but whose organization does not require formal designation or registration.

**Community stakeholders.** Individuals and groups who are ultimately representing the interests of people who would be recruited to or participate in a clinical trial, and others locally affected by a trial. Examples (for TB vaccine research) include: the population to be recruited, trial participants, people living in the area where the research is conducted, people living with TB in the area, local TB groups or networks, people in the area affected by the TB epidemic, local nongovernmental organizations, community groups and community-based organizations. See [Stakeholders](#).

**Confidentiality.** The principle that protects the rights of trial participants regarding prevention of unauthorized disclosure of personal information to third parties during data collection, storage, transfer and use.

**Control arm.** The group of participants in a clinical trial who receive the placebo or control product or procedure. See [Placebo](#).

**Efficacy.** The ability to produce a desired effect under clinical trial conditions. For vaccines, efficacy typically refers to protection from infection or disease.

**Experimental arm.** The group of participants in a clinical trial who receive the procedure, product or drug being studied.

**Extensively drug-resistant tuberculosis (XDR-TB).** A form of tuberculosis that is resistant to at least four of the core anti-TB drugs or drug families: isoniazid, rifampicin, at least one of the fluoroquinolone drugs (such as levofloxacin or moxifloxacin) and at least one of the three injectable second-line drugs (amikacin, capreomycin or kanamycin). See [Tuberculosis](#) and [Multiple drug-resistant tuberculosis](#).

**Extrapulmonary TB.** An infection of any tissue in the body, other than the lungs, caused by *Mycobacterium tuberculosis*. The most common sites of extrapulmonary TB are lymph nodes, pleura, abdomen, bones and joints, the spinal cord and the brain and its coverings. See [Pulmonary TB, Mycobacterium tuberculosis and Latent tuberculosis infection](#).

**Formative research activities.** Activities that enable research teams to gain an informed understanding of local populations, sociocultural norms and practices, local power dynamics, local perceptions, channels of communication and of decision-making and local history of research, as well as the needs and priorities of people locally affected by or able to influence a clinical trial. Formative research activities usually constitute the initial phase of stakeholder outreach and engagement.

**Futility.** The inability of a clinical trial to achieve its objectives. This determination may be suggested, for example, during an interim analysis of a trial by a data safety monitoring board.

**Good clinical laboratory practice (GCLP).** Guidelines that set a standard for compliance by laboratories involved in the analysis of samples from clinical trials, to ensure that trial laboratory data are reliable, repeatable, auditable and easily reconstructed in a research setting.

**Good clinical practice (GCP).** Internationally recognized guidelines for designing, conducting, recording and reporting clinical trials in which humans participate. GCP provides guidance to ensure that trial data are credible and to protect the rights, safety and well-being of trial participants. The guidelines were issued by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use.

**Good manufacturing practice (GMP).** Quality assurance practices that ensure that products for clinical trials are consistently produced and controlled to meet appropriate standards, aligned to their intended use and marketing authorization requirements.

**Good participatory practice (GPP).** A participatory and principles-based engagement process to ensure the meaningful and sustained participation of stakeholders in all stages of the research process.

**Human immunodeficiency virus (HIV).** A virus that weakens the immune system and may ultimately lead to acquired immune deficiency syndrome. See [Acquired immune deficiency syndrome](#).

**Implementers.** Synonym for [Trial implementers](#).

**Independent ethics committee (IEC).** Synonym for [Research ethics committee](#).



**Informed consent.** A process by which a competent individual voluntarily confirms his or her willingness to participate in a clinical trial, after being informed about all relevant aspects of the trial and demonstrating comprehension of this information to the research team. Informed consent is an ongoing process that provides information that can be best understood by each participant, based on his or her level of scientific literacy. More detail can be found in *ICH GCP section 4.8: Informed Consent of Trial Subjects*.

**Joint United Nations Program on HIV/AIDS (UNAIDS).** A joint venture of 10 UN organizations in the global AIDS response to help prevent new HIV infections, care for people living with HIV and mitigate the impact of the epidemic.

**Latent tuberculosis infection (LTBI).** A persistent immune response to the *Mycobacterium tuberculosis* bacterium, without evidence of clinically active TB disease. People with LTBI cannot transmit active TB disease to others. However, they may develop TB disease in the future, a process often called “TB reactivation.” See [Tuberculosis, Pulmonary TB, Extrapulmonary TB and Mycobacterium tuberculosis](#).

**Multiple drug-resistant tuberculosis (MDR-TB).** A form of tuberculosis caused by bacteria that do not respond to isoniazid or rifampicin, the two most powerful first-line anti-TB medicines. Individuals with MDR-TB require treatment with second-line treatment regimens, which are more complex than those used to treat patients with ordinary (drug-susceptible) TB. MDR-TB may develop in a person with active TB when the TB treatment is managed improperly or not adhered to. MDR-TB can be transmitted person-to-person. See [Tuberculosis](#) and [Extensively drug-resistant tuberculosis](#).

***Mycobacterium tuberculosis* (Mtb).** The bacterium that causes tuberculosis. The progression of TB disease can have several outcomes, determined largely by the response of the individual’s immune system. See [Tuberculosis](#) and [Latent tuberculosis infection](#).

**Network.** A collaboration of research institutions or centers conducting clinical trials under a common research agenda.

**Nongovernmental organization (NGO).** A not-for-profit, registered entity or group that is organized on local, regional, national or international levels but is not an agency of local or national governments.

**Placebo.** An inactive substance that is designed to appear like an experimental product being studied in all aspects except that it does not contain the active ingredient under study. In clinical trials, the safety and effectiveness of an experimental product are assessed by comparing data from the experimental arm to those from the control arm.

**Pre-exposure prophylaxis (PrEP).** Antiretroviral drugs used by a person who does not have HIV infection, to be taken before possible exposure to HIV in order to reduce the risk of HIV infection.

**Product assignment.** The designation of a trial participant as being in either the **Control arm** or the **Experimental arm**.

**Protocol.** A document that details the rationale, goals, design, methodology, statistical considerations and organization of a study or clinical trial. A protocol describes a scientific study designed to answer specific research questions and describes how the health of the trial participants will be safeguarded.

**Pulmonary TB.** TB disease that affects the lungs. The symptoms of active pulmonary TB disease include cough, weakness, weight loss, fever, loss of appetite and night sweats. A person with active pulmonary TB disease may be infectious and spread TB to others. See **Active TB Disease, Extrapulmonary TB, Latent Tuberculosis Infection** and *Mycobacterium tuberculosis*.

**Randomization.** The use of chance alone to determine which trial participants are assigned to a trial arm. Randomization ensures that the only intended difference between trial arms is which product or procedure a participant is exposed to during the trial.

**Regulatory authorities.** Government agencies charged with carrying out the intent of legislation that constrains the actions of private individuals, businesses, organizations, institutions or government bodies. In most countries, at least one regulatory agency is responsible for ensuring the safety and effectiveness of health products and the correct conduct of clinical trials.

**Research ethics committee (REC).** An independent body made up of medical, scientific and non-scientific members whose responsibility is to protect the rights and safety of human participants in a clinical trial. RECs review and approve the initial protocol and materials used in recruitment and the informed consent process and provide continuing review of a trial protocol and any amendments. The term “institutional review board” is common in the US, whereas other countries commonly use the terms “research ethics committee” or “independent ethics committee.”

**Research life cycle.** The entire research process, starting with the development of the initial concept and the trial protocol and continuing through the implementation of the trial, exiting of participants and dissemination of trial results.

**Research network.** Synonym for **Network**.



**Research process.** A recognized, systematic way to form and test hypotheses by designing controlled experiments to collect data, analyze results and draw conclusions in order to acquire new knowledge or to correct, refine and integrate previous knowledge. See [Research team](#).

**Research team.** A group of investigators and interdisciplinary team members who are directly responsible for the implementation of a clinical trial. The composition of a research team may vary across settings and may also include trial sponsors and staff at coordinating centers, institutions or agencies who work closely with the trial site. See [Research process](#).

**Stakeholders.** Individuals, groups, organizations, governments or other entities that are affected by the outcome of a clinical trial and can potentially influence the research process through their input and actions. See [Community stakeholders](#).

**Stigma (trial-related).** A pattern of prejudice, discounting, discrediting and discrimination directed at trial participants, as well as their significant others, close associates, social groups and communities. Stigma can influence the willingness of an individual to receive appropriate care and treatment and thus can affect disease outcomes.

**Trial arm.** A group of participants who have been assigned a particular product or procedure during the trial. The [trial arms](#) consist of the [Control arm](#) and the [Experimental arm](#).

**Trial arm assignment.** Synonym for [Product assignment](#).

**Trial funder.** An individual or entity responsible for financing the cost of a trial.

**Trial group.** Synonym for [Trial arm](#).

**Trial implementers.** Investigators, research staff and all others specifically responsible for executing clinical trials. Implementers may be employed by governments, government-sponsored networks, nongovernmental organizations, academic institutions, the pharmaceutical industry or other companies, foundations or public–private partnerships.

**Trial participant.** A competent individual who voluntarily provides informed consent to participate in a clinical trial.

**Trial sponsor.** An entity that is ultimately responsible for a trial's initiation and oversight but does not implement research activities at the site(s). A trial sponsor may be a pharmaceutical company, governmental agency, academic institution or private organization.

**Tuberculosis (TB).** A disease caused by the bacterium, *Mycobacterium tuberculosis*, that most often affects the lungs (pulmonary TB) but can also affect other organs such as the brain, kidneys or spine (extrapulmonary TB). TB is spread when an infected person propels the TB germs into the air through coughing, sneezing, spitting or talking. See [Active TB Disease](#), [Extrapulmonary TB](#), [Latent tuberculosis infection](#), [Mycobacterium tuberculosis](#) and [Pulmonary TB](#).

**UNAIDS.** Acronym for [Joint United Nations Program on HIV/AIDS](#).

**Unblinding.** The process of informing trial participants about which product they were assigned to during the trial.

**Vaccine.** A compound that stimulates the body's immune response in order to prevent or control an infection or disease. A vaccine is typically made up of parts of a bacterium or virus, possibly inactivated or weakened.

**Vulnerable population.** A group who is not well integrated into a health care system, due to cultural or gender norms, geographic location or other forms of discrimination and marginalization. The safety and rights of vulnerable populations should be given special consideration by research teams and research ethics committees.



## Appendix 3: Additional Guidance

### International reference guidelines

#### **The Belmont Report, 1979**

This report was written by the US National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, which was established after the US public learned about the Tuskegee Syphilis Study. The Belmont Report established the foundational ethical principles of respect for persons and of beneficence and justice for research involving human volunteers.

##### **Citation:**

National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. (1979). *The Belmont Report: Ethical principles and guidelines for the protection of human subjects of research*. Washington: US Department of Health, Education and Welfare.

#### **Declaration of Helsinki, 1964**

This declaration of the World Medical Association (WMA) is often considered the first document to set world standards for research involving human volunteers.

##### **Citation:**

World Medical Association. (1964). *World Medical Association Declaration of Helsinki: Ethical principles for medical research Involving human subjects*. Helsinki: World Medical Association General Assembly; most recent amendments at the 59th WMA General Assembly, Seoul, 2008.

#### **Ethical Considerations in Biomedical HIV Prevention Trials, 2007**

This ethical guidance document, issued by UNAIDS and WHO for biomedical HIV prevention research, is a revision of UNAIDS *Ethical Considerations in HIV Preventive Vaccine Research*. The original GPP Guidelines were developed to enable trial funders, sponsors, and implementers to comply with Guidance Point 2 of *Ethical Considerations*.

##### **Citation:**

UNAIDS and World Health Organization. (2007). *Ethical considerations in biomedical HIV prevention trials*. UNAIDS guidance document. Geneva: UNAIDS, World Health Organization.

## **The Good Participatory Practice Guidelines for Biomedical HIV Prevention Trials, 2nd edition, 2011**

These guidelines were originally developed by AVAC and UNAIDS in 2007 as the first normative framework for effective engagement of stakeholders in the design, conduct and outcomes of biomedical HIV prevention research.

### **Citation:**

UNAIDS, AVAC. (2011). *The good participatory practice guidelines for biomedical HIV prevention trials, 2nd ed.* Geneva: UNAIDS.

Available:

<http://www.avac.org/ht/a/GetDocumentAction/i/35219>

## **Guideline for Good Clinical Practice, 2016**

This guidance document, issued by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, outlines an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve human volunteers.

### **Citation:**

ICH harmonised tripartite guideline. (2016). *Guideline for good clinical practice. ICH harmonised tripartite guideline.* Geneva: International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use.

## **International Ethical Guidelines for Biomedical Research Involving Human Subjects, 2002**

These guidelines, published by the Council for International Organizations of Medical Sciences (CIOMS), provided guidance around conducting research in developing countries. The 2002 version supersedes the 1982 and 1993 editions.

### **Citation:**

Council for International Organizations of Medical Sciences. (2002). *International ethical guidelines for biomedical research involving human subjects.* Geneva: CIOMS.



## Nuffield Council on Bioethics, 2002

The 2002 Nuffield Council on Bioethics report on the ethics of research, related to health care in developing countries, provides an ethical framework for designing and conducting externally sponsored research in the developing world. The 2004 follow-up report, cohosted with the Medical Research Council of South Africa, discusses how the guidelines can be applied in practice, particularly in light of conflicting ethical advice.

### Citation:

Nuffield Council on Bioethics. (2002). *The ethics of research related to healthcare in developing countries*. London: Nuffield Council on Bioethics; *The ethics of healthcare related research in developing countries: A follow-up discussion paper*. (2005). London: Nuffield Council on Bioethics.

## Nuremberg Code, 1949

This code of research ethics was developed from the rulings of the International Military Tribunal that prosecuted Nazi war criminals after World War II.

### Citation:

US Government Printing Office. (1949). *Trials of war criminals before the nuremberg military tribunals under control council Law No. 10*. Washington DC: US Government Printing Office.

## Other references

### **Communications Handbook for Clinical Trials: Strategies, Tips, and Tools to Manage Controversy, Convey Your Message, and Disseminate Results, 2014**

First published in 2010, this document was created for site-level research teams, communicators, advocates and others working on HIV prevention trials in developing countries. It provides practical guidance on how to anticipate and respond to the special communications challenges posed by the conduct of clinical research.

### Citation:

Robinson, E. T. et al. (2010). *Communications handbook for clinical trials: strategies, tips, and tools to manage controversy, convey your message, and disseminate results*. Microbicides Media Communications Initiative and FHI 360.

### Available:

<https://www.fhi360.org/resource/communications-handbook-clinical-trials-strategies-tips-and-tools-manage-controversy-convey>

## **Ethics Guidance for the Implementation of the End TB Strategy, 2017**

This guidance aims to help ensure that countries implementing the End TB Strategy adhere to sound ethical standards to protect the rights of all those affected.

### **Citation:**

World Health Organization. (2017). *Ethics guidance for the implementation of the end TB strategy*. Geneva: World Health Organization.

## **Ethical and Policy Issues in International Research: Clinical Trials in Developing Countries, 2001**

The report provides recommendations of the US National Bioethics Advisory Commission for US policy regarding conducting clinical trials in developing countries.

### **Citation:**

US National Bioethics Advisory Commission. (2001). *Ethical and policy issues in international research: Clinical trials in developing countries. Volume I: Report and Recommendations of the National Bioethics Advisory Commission*. Washington D.C.:US Government Printing Office.

## **The Global Plan to End TB: The Paradigm Shift (2016–2020)**

The Global Plan is a five-year investment plan that represents the road map for accelerating impact on the TB epidemic and reaching the targets of the WHO End TB Strategy.

### **Citation:**

World Health Organization. (2016). *The global plan to end TB: The paradigm shift (2016-2020)*. Geneva: World Health Organization.

### **Available:**

<https://www.stoptb.org/global/plan/plan2/annexes.asp>

## **The Good Participatory Practice Guidelines for TB Drug Trials, 2012**

These guidelines provide trial funders, sponsors and research team members who are involved in TB drug trials, with a principle-based framework on how to effectively engage stakeholders.

### **Citation:**

Critical Path to TB Drug Regimens. (2012). *The good participatory practice guidelines for TB drug trials*. CPTR Initiative.

### **Available:**

<http://www.cptrinitiative.org/resources/gpp-tb-resource-document/>



## **National Health Research Ethics Council (NHREC) Guidelines for Community Advisory Groups, 2012**

This document provides guidance to clinical researchers, participating communities and ethics committees in Africa about the development, maintenance and evaluation of a community advisory board in a biomedical research context.

### **Citation:**

National Health Research Ethics Council. (2012). *Guidelines for community advisory groups*. South Africa: NHREC.

### **Available:**

[www.nhrec.org.za/docs/DocumentsNHRECGuidelinesCommunity.pdf](http://www.nhrec.org.za/docs/DocumentsNHRECGuidelinesCommunity.pdf)

## **Recommendation for Community Involvement in National Institute of Allergy and Infectious Diseases, HIV/AIDS Clinical Trials Research, 2009**

The National Institute of Allergy and Infectious Diseases (NIAID), Division of AIDS (DAIDS) and community partners developed these recommendations as a tool for research teams and community representatives to further expand and deepen the involvement of community members in HIV prevention research.

### **Citation:**

Recommendation for Community Involvement in National Institute of Allergy and Infectious Diseases, HIV/AIDS Clinical Trials Research. (2009). Community Recommendations Working Group of Community Partners, a global group of community representatives affiliated with the National Institute of Allergy and Infectious Diseases (NIAID) HIV/AIDS clinical trials networks.

## **Stakeholder Engagement Toolkit for HIV Prevention Trials, 2012**

Based on best practices and the experience of clinical trial experts and community-based advocates, this unique resource helps research teams deepen their relationships with allies, measure stakeholder engagement and address community concerns. The toolkit includes short case studies from Tanzania, Uganda and the United States and offers concrete tools to guide and chart stakeholder engagement throughout the progress of a trial. The associated *Toolkit Quick Guide* (2014) helps navigate the *Stakeholder Engagement Toolkit for HIV Prevention Trials*.

### **Citation:**

MacQueen, K. M., Harlan, V. S., West Slevin, K., Hannah, S., Bass, E., Moffett, J. (2012). *Stakeholder engagement toolkit for HIV prevention trials*. FHI 360.

### **Available:**

[www.fhi360.org/resource/stakeholder-engagement-toolkit-hiv-prevention-trials](http://www.fhi360.org/resource/stakeholder-engagement-toolkit-hiv-prevention-trials)



## Endnotes

<sup>1</sup> Ngongo et al. (2012). An assessment of Good Participatory Practice Guidelines at HIV prevention research clinical centers in Eastern and Southern Africa. *Retrovirology*, 9 (S2): O25.

<sup>2</sup> Broder, Gail B., Maynard, James P., Karuna, Shelly T., Anude, Chuka, Sobieszczyk, Magda E., Hammer, Scott M., HVTN 505 Protocol Team of the NIAID-funded HIV Vaccine Trials Network. (2014). Implementing good participatory practice (GPP) in HVTN505 – The HIV Vaccine Trials Network (HVTN). *AIDS Research and Human Retroviruses*, 30(S1): A105-A106.

<sup>3</sup> Thai Treatment Action Group. (2012). *Stakeholder input and recommendations for good participatory practices in biomedical HIV prevention trials in Thailand*. Bangkok, Thailand.

<sup>4</sup> Allman, D., Ditmore, M. H., Kaplan, K. (2014). Improving ethical and participatory practice for marginalized populations in biomedical HIV prevention trials: lessons from Thailand. *PLoS ONE*, 9(6): e100058.

<sup>5</sup> Critical Path to TB Drug Regimens. (2012). *Good participatory practice guidelines for TB drug trials*.

<sup>6</sup> Schito, M., Migliori, G. B. et al. (2015). Perspectives on advances in tuberculosis diagnostics, drugs, and vaccines. *Clinical Infectious Diseases*, 61: S102.

<sup>7</sup> Newman, P. A., Rubincam, C., Slack, C., Essack, Z., Chakrapani, V., Chuang, D. M., Lindegger, G. (2015). Towards a science of community stakeholder engagement in biomedical HIV prevention trials: An embedded four-country case study. *PLoS ONE*, 10(8): e0135937.

<sup>8</sup> MacQueen, Kathleen M., Eley, Natalie T., Frick, Mike, Ruiz Mingote, Laia, Chou, Alicia, Seidel, Stephanie S., Hannah, Stacey, Hamilton, Carol. (2016). Developing a framework for evaluating ethical outcomes of good participatory practices in TB clinical drug trials. *Journal of Empirical Research on Human Research Ethics*, 11(3): 203–213.

<sup>9</sup> ICH Harmonised Tripartite Guideline. (2016). *E6 Guideline for good clinical practice*. Geneva: International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use.

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