# Good participatory practice

## Guidelines for biomedical HIV prevention trials 2011

UNAIDS
JOINT UNITED NATIONS PROGRAMME ON HIV/AIDS
UNHCR UNICEF WFP UNDP UNFPA UNODC ILO UNESCO WHO WORLD BANK

AVAC
Global Advocacy for HIV Prevention

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# Introduction

## Objective of the good participatory practice (GPP) guidelines

The good participatory practice (GPP) guidelines provide trial funders, sponsors, and implementers with systematic guidance on how to effectively engage with stakeholders in the design and conduct of biomedical HIV prevention trials.

In the GPP guidelines, "design and conduct of biomedical HIV prevention trials" refers to activities required for the development, planning, implementation, and conclusion of a trial, including dissemination of trial results.

## Intended audience of the GPP guidelines

The GPP guidelines are primarily written for trial funders, trial sponsors, and trial implementers. Trial funders, sponsors, and implementers include investigators, research staff, and all others involved in designing, financing, and executing biomedical HIV prevention trials. They can include governments, government-sponsored research networks, non-governmental organisations, academic institutions, foundations, public–private partnerships, and pharmaceutical or other companies.

Stakeholders not directly involved in funding, sponsoring, or implementing trials can use the guidelines to better understand the objectives, expectations, and methods of stakeholder engagement and to better evaluate such efforts.

## Scope of the GPP guidelines

The GPP guidelines provide a framework for development of effective stakeholder engagement programmes. The goal of effective stakeholder engagement programmes is to build mutually beneficial, sustained relationships between trial funders, sponsors, and implementers and other stakeholders that are transparent and respectful, that address interests of community stakeholders, and that support the conduct of scientifically rigorous and ethical biomedical HIV prevention trials.

This GPP guidelines publication is a companion document to the UNAIDS/WHO *Ethical considerations in biomedical HIV prevention trials,*[1] which contains explicit guidance on community participation, capacity building, monitoring, informed consent, standard of prevention, and other key ethical issues. The GPP guidelines were developed to enable trial funders, sponsors, and implementers to adhere to Guidance Point 2 of *Ethical considerations*, "Community Participation", which states: "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".

The GPP guidelines provide comprehensive guidance on the participatory conduct of biomedical HIV prevention trials and are not intended to provide guidance on all scientific and ethical aspects of these trials. Multiple guidance documents already exist that address overall scientific and ethical trial conduct, such as *Good Clinical Practice*,[2, 3] *Good Clinical Laboratory Practice*,[4] the *Declaration of Helsinki*,[5] *The Belmont Report*,[6] *Guidelines of the Council for International Organizations of Medical Sciences (CIOMS),*[7] the *Nuffield Council Guidance on ethics of research related to health care in developing countries*,[8,9] *the UNAIDS/WHO Ethical considerations in biomedical HIV prevention trials*,[1] and various national guidelines.

GPP is unique, as it is the only global guidance document to provide guidance about the relationship between a trial's funders, sponsors, and implementers, and other stakeholders in the context of biomedical HIV prevention trials. *Good Clinical Practice* (GCP), in contrast, provides ethical guidance specifically for the relationship between investigators and trial participants and for ensuring the integrity of trial data.

The principles of GPP in Section 2 apply to all biomedical HIV prevention trials, as they outline expectations and the foundations for building meaningful partnerships among stakeholders in biomedical HIV prevention research.

The good participatory practices outlined in the 16 topic areas of Section 3 of these guidelines are applicable to all large-scale effectiveness and efficacy trials.

The complete GPP guidelines are most relevant for trials that are larger and have substantial impacts on individuals and areas where trials are conducted. However, the GPP guidelines can also serve as a guide for other types of trials and studies. Examples of these can include smaller safety studies, follow-on studies, behavioural studies, HIV treatment trials, and studies of other diseases.

## Development of the GPP guidelines

The GPP guidelines were born out of a recommendation from the UNAIDS Creating Effective Partnerships in Research process in 2005[10] that was a response to the controversies and debates of pre-exposure prophylaxis (PrEP) trials in Cambodia and Cameroon.[11, 12, 13]

Development of the original guidelines, led by an international working group, involved exploration and analysis of different viewpoints and the creation of objective measures of community stakeholder engagement in the design and conduct of biomedical HIV prevention trials. Feedback on the draft set of guidelines was provided via interviews, e-mail requests, and listserv postings and represented a diverse range of perspectives, geography, and expertise including advocates, trial site staff, researchers, clinical trial investigators, community liaison officers, members of community advisory boards, policy-makers, industry representatives, research funders, and sponsors.

The GPP guidelines were published in 2007, applied in different settings, and were the subject of formal consultations with stakeholder groups in Africa, the Americas, Asia, and Europe. These AVAC-supported consultations validated the importance of the adoption of the GPP guidelines by trial sponsors and of their implementation at trial sites around the world. Recommendations from the consultations have been incorporated in this second edition of the GPP guidelines.

The GPP guidelines are dynamic and will change over time. Recommendations for modifications and refinements based on experience and reflection can be sent to gpp@unaids.org or avac@avac.org. They will be gratefully received and considered in future updates of the guidelines.

Figure 1. GPP Timeline

**Timeline of GPP and Ethical Considerations**

| *GPP Guidelines* | | *Ethical Considerations* |
|---|---|---|
| | 2000 | ***February:*** UNAIDS regional consultations on ethical considerations in international HIV vaccine trials[14]<br><br>***May:*** *Ethical considerations in HIV preventive vaccine research* UNAIDS guidance document published[15] |
| ***July:*** Cambodia government decides not to support PrEP trial[16] | 2004 | |
| ***February:*** Cameroon stops PrEP trial in progress[16]<br><br>***March:*** Nigerian PrEP trial is discontinued[16]<br><br>***May:*** IAS global PrEP consultation with trial sponsors, researchers, and advocates[17]<br><br>***April & June:*** UNAIDS 'Creating Effective Partnerships' regional consultations[10]<br><br>***June:*** UNAIDS 'Creating Effective Partnerships' international consultation[10] | 2005 | |
| ***September:*** UNAIDS/AVAC working group starts drafting *GPP guidelines for biomedical HIV prevention trials* | 2006 | |
| ***May – June:*** Multiple global stakeholders review draft of *GPP guidelines*<br><br>***July:*** Pre-publication draft of *GPP guidelines* released for comments<br><br>***November:*** UNAIDS/AVAC *GPP guidelines*, 1st Edition published[18] | 2007 | ***May:*** UNAIDS/WHO establish working group to revise *Ethical considerations*<br><br>***July:*** UNAIDS/WHO Expert Committee Meeting to revise *Ethical considerations*<br><br>***July:*** Pre-publication draft of *Ethical considerations* released for comments<br><br>***November:*** UNAIDS/WHO *Ethical considerations in biomedical HIV prevention trials* published[1] |
| ***August 2008 – May 2009:*** Global GPP consultations sponsored by AVAC with multiple stakeholder groups | 2008 | |
| ***May:*** AVAC report-back meeting from global consultations | 2009 | |
| ***May 2009 – May 2010:*** Synthesis of recommendations from global consultations; revision of *GPP guidelines*<br><br>***March:*** AVAC/UNAIDS GPP Revision Working Group Meeting<br><br>***July:*** Draft version of *GPP guidelines*, 2nd Edition released for public comment | 2010 | ***June:*** UNAIDS/WHO Eastern Europe-Central Asia expert consultation on the ethical engagement of people who inject drugs in HIV prevention trials<br><br>***December:*** UNAIDS/WHO Asia region expert consultation on the ethical engagement of people who inject drugs in HIV prevention trials |
| *GPP guidelines*, 2nd Edition published | 2011 | ***April:*** UNAIDS/WHO Latin America-Caribbean expert consultation on the ethical engagement of people who inject drugs in HIV prevention trials<br><br>Guidance Point 20: People who inject drugs |

This timeline shows the development of the UNAIDS/AVAC *Good Participatory Practice guidelines for biomedical HIV prevention trials* and the UNAIDS/WHO *Ethical considerations for biomedical HIV prevention trials.* The GPP guidelines document was developed after a series of regional consultations in 2005 that focused on defining the key elements needed for creating effective partnerships for HIV prevention trials. The first GPP guidelines document was published in 2007. It was developed as a companion to the UNAIDS/WHO guidance document *Ethical considerations* that addresses key ethical issues in a set of guidance points with commentaries.

## Organisation and how to use the GPP guidelines

The GPP guidelines are presented in three main sections that are colour-coded to enable users to easily navigate the document:

**Section 1: The importance of good participatory practice** defines the key terms used in the document and describes the realities and the underlying determinants of the HIV epidemic, the context of conducting biomedical HIV prevention trials, and why a participatory approach is necessary to effectively conduct trials.

**Section 2: Guiding principles of GPP in biomedical HIV prevention trials** outlines the set of principles that serve as the foundation of the relationships among trial funders, sponsors, and implementers and other stakeholders. These principles include respect, mutual understanding, integrity, transparency, accountability, and community stakeholder autonomy.

**Section 3: Good participatory practices in biomedical HIV prevention trials** describes optimal practices to follow when designing and conducting biomedical HIV prevention trials. Under 16 topic areas, this section outlines expected stakeholder engagement activities that take place at each stage of the research life-cycle. The topic areas are:

1. Formative research activities
2. Stakeholder advisory mechanisms
3. Stakeholder engagement plan
4. Stakeholder education plan
5. Communications plan
6. Issues management plan
7. Site selection
8. Protocol development
9. Informed consent process
10. Standard of HIV prevention
11. Access to HIV care and treatment
12. Non HIV-related care
13. Policies on trial-related harms
14. Trial accrual, follow-up, and exit
15. Trial closure and results dissemination
16. Post-trial access to trial products or procedures

Topic areas in the good participatory practices section are divided into the following subsections:

A. Definition.
B. Relevance to good participatory practice.
C. Special considerations.
D. Good participatory practices.
E. Additional guidance.

After the Conclusion (pages 66-67), the reader will find three useful annexes:

**Annex 1** presents the acronyms and abbreviations used in this document.

**Annex 2** is a glossary of the essential terms used throughout the GPP guidelines.

**Annex 3** introduces other international reference guidelines and key documents, for further reading.

**Section 1:**
The Importance of Good Participatory Practice

**The Importance of Good Participatory Practice** defines the key terms used in the document and describes the realities and the underlying determinants of the HIV epidemic, the context of conducting biomedical HIV prevention trials, and why a participatory approach is necessary to effectively conduct trials.

**Section 2:**
Guiding Principles of GPP in Biomedical HIV Prevention Trials

**Guiding Principles of GPP in Biomedical HIV Prevention Trials** outlines the set of principles that serve as the foundation of the relationships among trial funders, sponsors, and implementers and other stakeholders.

**Section 3:**
Good Participatory Practices in Biomedical HIV Prevention Trials

**Good Participatory Practices in Biomedical HIV Prevention Trials** describes optimal practices for trial funders, sponsors, and implementers to follow when designing, conducting, and concluding biomedical HIV prevention trials. Under 16 topic areas, this section outlines expected stakeholder engagement activities that take place at each stage of the research life-cycle.

**Section 1:**
The Importance of Good Participatory Practice

Use this section to understand the meaning of stakeholder engagement, the context of biomedical HIV prevention trials, and why a participatory approach is necessary to effectively conduct trials

- Who are Stakeholders?
- What is Stakeholder Engagement?
- The Wider Context of HIV
- The Dynamics of Biomedical HIV Prevention Trials
- Rationale for GPP Guidelines
- Applying GPP

**Section 2:**
Guiding Principles of GPP in Biomedical HIV Prevention Trials

Use this section to understand the principles that guide the foundation of the relationships among biomedical HIV prevention stakeholders

- Respect
- Mutual Understanding
- Integrity
- Transparency
- Accountability
- Community Stakeholder Autonomy

**Section 3:**
Good Participatory Practices in Biomedical HIV Prevention Trials

Use this section and its optimal practices to guide specific stakeholder engagement activities when conducting biomedical HIV prevention trials

- Formative Research Activities
- Stakeholder Advisory Mechanisms
- Stakeholder Engagement Plan
- Stakeholder Education Plan
- Communications Plan
- Issues Management Plan
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# 1. The importance of good participatory practice

## 1.1 Who are stakeholders?

The starting point of good participatory practice is the identification of key stakeholders in the conduct of a biomedical HIV prevention trial. **Stakeholders** are individuals, groups, organisations, government bodies, or any other individuals or collections of individuals who can influence or are affected by the conduct or outcome of a biomedical HIV prevention trial. In this guidance document, the term "stakeholders" is all-encompassing. It describes any individual or collection of individuals who have a stake in a biomedical HIV prevention trial.

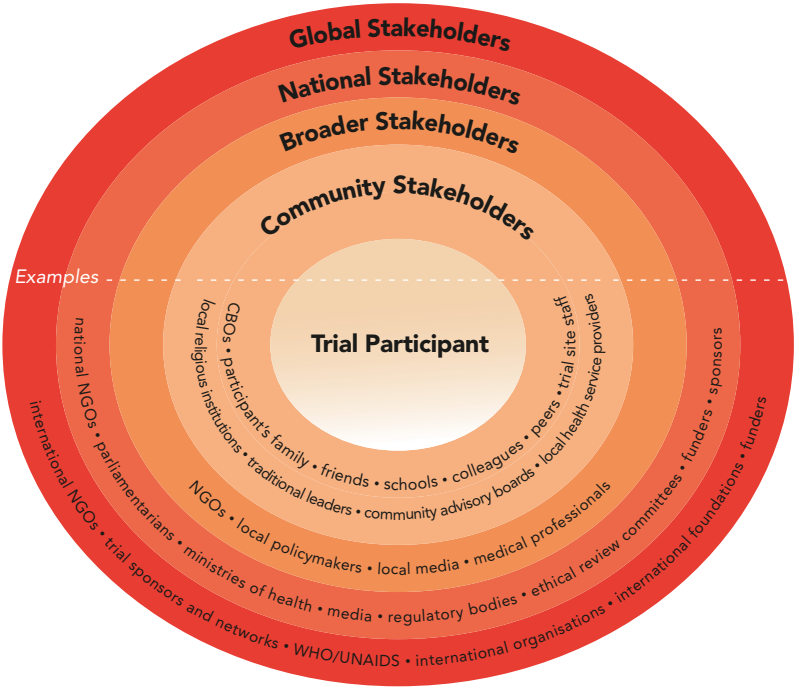
Examples of stakeholders are illustrated in Figure 2 and can include trial participants, families of trial participants, prospective trial participants, individuals resident within, or surrounding, the area where research is conducted, people living with HIV or affected by HIV, prevention and treatment advocates and activists, non-governmental organisations (NGOs), community-based organisations (CBOs), community groups, religious leaders, opinion leaders, media, government bodies, national and local health-care authorities, service providers, trial funders, trial sponsors, and trial implementers.

The definition of "community" is more complicated, as it is a dynamic term that has different meanings to different people.[19] This term is often used to refer to a group of people who have a common set of interests, share a common set of characteristics, or live in a common area. Individuals can be a part of multiple "communities" at the same time. The term "community" is also used to refer to the public at large or to a physical location.

In the GPP guidelines, the preferred term is **"community stakeholders"**, rather than "community", and refers to both individuals and groups that are ultimately representing the interests of people who would be recruited to or participate in a trial, and others locally

affected by a trial. Examples of "community stakeholders" are the population to be recruited, trial participants, people living in the area where the research is conducted, people living with HIV in the area, local HIV-positive groups or networks, people in the area who are affected by the HIV epidemic, local non-governmental organisations, community groups, and community-based organisations. Trial funders, sponsors, and implementers, as well as government bodies or representatives of high-level authority structures, are explicitly excluded from the term "community stakeholders" but are clearly considered trial stakeholders.

Figure 2. Layers of Biomedical HIV Prevention Trial Stakeholders




Various stakeholders may influence or be affected by a biomedical HIV prevention trial. Stakeholders include trial participants and other community stakeholders as well as a broader range of national and international stakeholders.

## 1.2 What is stakeholder engagement?

Of key importance in good participatory practice is sustained, collaborative partnering with stakeholders. In the GPP guidelines, the term "stakeholder engagement" refers to processes through which trial funders, sponsors, and implementers build transparent, meaningful, collaborative, and mutually beneficial relationships with interested or affected individuals, groups of individuals, or organisations, with the ultimate goal of shaping research collectively.

Successful stakeholder engagement requires a broad, inclusive, and multifaceted understanding of the context in which a biomedical HIV prevention trial is conducted. It begins with an inclusive perspective for identification of potential stakeholders. Stakeholder identification is a dynamic process, as stakeholders, interests, priorities, perspectives, and aspects of culture may change over time. Research teams are responsible for identifying stakeholders, a process which begins by determining the trial population to be recruited, considering those who are affected by the trial in the local area, consulting with already known stakeholders, and building on that expertise to develop a richer understanding of potential and known stakeholders.

Different stakeholders will have different perspectives. Some stakeholders will have competing interests or power imbalances within groups, as well as differences in social organisation, hierarchies, gender issues, and relative social and economic status that may then create division and disagreement during the course of a trial. If there is opposition or disagreement among stakeholders, then those issues must be addressed in a way that is honest, transparent, and respectful to all parties.

Stakeholders in biomedical HIV prevention research can learn from other fields that have successfully adopted participatory research approaches, which seek to engage community stakeholders as equal members who share control over all aspects of the research process.[20, 21, 22, 23, 24]

## 1.3 The wider context of HIV

There is an urgent need to develop additional strategies to address the HIV pandemic. Along with necessary behavioural and structural changes, a broad range of biomedical HIV prevention and treatment options is required to meet the diverse needs of individuals and populations. There are many inherent complexities in conducting biomedical HIV prevention trials. By acknowledging and understanding these challenges and complexities, trial funders, sponsors, and implementers can more appropriately and effectively facilitate a mutually beneficial participatory approach to conducting biomedical HIV prevention trials.

Biomedical HIV prevention research cannot succeed without meaningful stakeholder engagement, particularly given the need to involve large numbers of healthy, HIV-negative volunteers as trial participants. It is optimal that experimental HIV prevention options are tested for safety and effectiveness in populations who need these interventions the most and are likely to use them should they prove effective. However, the very factors that increase HIV risk in such populations may contribute to increased vulnerability to exploitation. This underscores the importance of meaningful partnerships with community stakeholders.

A wide range of factors creates, enhances, and perpetuates the risk of HIV infection. Structural determinants can increase vulnerability to HIV at an individual or population level by undermining ability to avoid HIV exposure. Underlying determinants of the HIV epidemic can be entrenched in the social, cultural, legal, institutional, or economic fabric of society. Examples of these determinants include gender and other power inequalities, gender-based violence, economic instability including poverty, migration, human rights violations, homophobia, discriminatory practices, HIV-related stigma, social marginalisation, and criminalisation of HIV transmission. Recognition of these factors is the first step in developing practices

that avoid inadvertently replicating or reinforcing them in the design and conduct of biomedical HIV prevention trials. While stakeholder engagement helps empower and equip community stakeholders to engage in the research process in a meaningful fashion, it also harnesses the expertise that community stakeholders can contribute to the design and conduct of research.

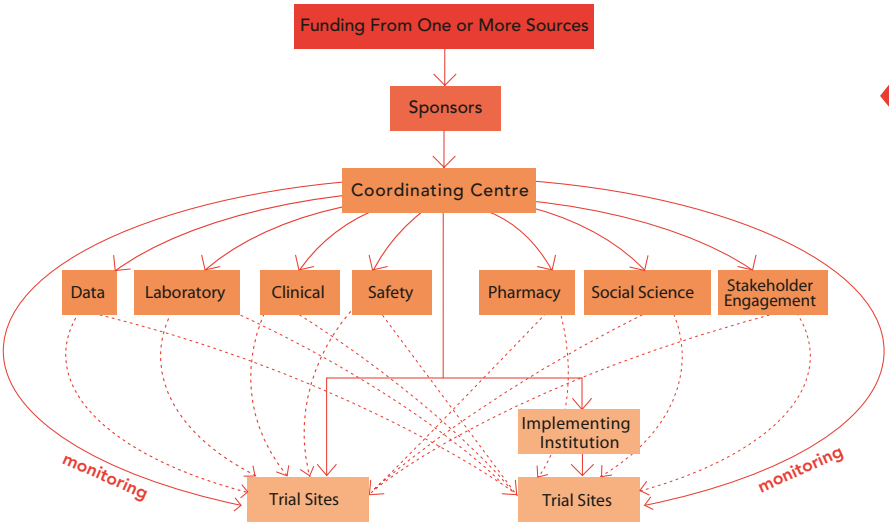
## 1.4 The dynamics of biomedical HIV prevention trials

Power inequalities always exist between funders and funding recipients with respect to a range of issues, such as decision-making processes, priority setting, control of resources, and equitable recognition of input. Biomedical HIV prevention trials are often funded by institutions in developed countries and conducted with multiple partner institutions worldwide, including those in developing countries. Disparities among these institutions and partners can introduce or reinforce power inequalities between and among trial implementers and the funders or sponsors of trials. This can then translate into inequalities between trial implementers and other stakeholders.

The fact that many biomedical HIV prevention trials are conducted in multiple settings and countries introduces another level of complexity. Variation in cultures, physical environments, infrastructure, research experience, health policies, and national laws can introduce inequalities among research teams and between research teams and site-level community stakeholders. Power inequalities between research teams and community stakeholders can include imbalances in literacy, education, and economic resources, as well as those inherent in patient–provider relationships. National, racial, ethnic, and linguistic differences between members of research teams and community stakeholders can also exacerbate inequalities.

In order to achieve meaningful community stakeholder participation and partnership, it is essential to recognise these various power inequalities and address them.

Figure 3. Example of a Trial Network




Basic structure of a typical biomedical HIV prevention trial network. Funding from one or more sources is distributed through a network coordinating centre directly to trial sites or to implementing institutions such as universities that then send funds to trial sites. Trial networks may have several centres responsible for different aspects of trial conduct: data management, laboratory, pharmacy, clinical, safety, social science, and stakeholder engagement. Monitoring of trial conduct may be executed through the coordinating centre or outsourced to an independent monitoring organisation.

## 1.5 Rationale for GPP guidelines

Constructive long-term stakeholder engagement helps ensure the ethical and scientific quality of research as well as its relevance to community stakeholders.[1,25] Stakeholders, in particular community stakeholders, have unique expertise to contribute to the research process. They possess critical knowledge and understandings of local cultures and perspectives, languages, dynamics of the local HIV epidemic, concerns of vulnerable or marginalised populations, and local priorities that trial funders, sponsors, and implementers may lack.

Stakeholder collaboration can help ensure that research questions and procedures are culturally sensitive and appropriate, thus improving recruitment, retention, adherence, and other trial outcomes. It can help avoid reinforcing existing inequalities and increase sensitivity to the needs of vulnerable populations. An essential component of stakeholder engagement is improving stakeholder knowledge and understanding of the research process, building research literacy and competencies. This, in turn, enables stakeholders to contribute more effectively to the process of guiding research and helps to address the power imbalance between research teams and community stakeholders.

Strengthening meaningful collaboration among stakeholders fosters greater trust and respect between trial funders, sponsors, and implementers, and other stakeholders. Stakeholder engagement that is transparent and mutually respectful can minimise misunderstandings and reduce the chances of unnecessary conflict or controversy. Following good participatory practices through the entire research life-cycle helps facilitate local ownership of research, enables more equitable relationships, and increases the likelihood of successful research conduct, trial completion, and application of research results.

## 1.6 Applying GPP

The GPP guidelines broadly describe systematic ways to establish and maintain effective stakeholder engagement that can be applied in diverse locations globally. The specificity of the content of the GPP guidelines enables monitoring of stakeholder engagement activities.

The most effective way for the GPP guidelines to be implemented is for trial sponsors to adopt them as a requirement in trial conduct and to monitor their implementation and evaluate their effectiveness. As an essential element of successful trial implementation, effective

stakeholder engagement requires that trial sponsors provide ample time allocation, adequate human resources, and sufficient funds in site budgets for implementation of Section 3 of the GPP guidelines.

Other stakeholders, such as national authorities, institutions, ethics committees, institutional review boards, and community stakeholders can also require that the GPP guidelines be followed when research is conducted in their country, institution, or area.

Monitoring stakeholder engagement is a complex process. To measure whether the GPP guidelines are being followed, stakeholders can first consult the list of optimal practices in each topic area of Section 3 and determine if the various activities have been executed. Because stakeholder engagement is based on relationships, it may be perceived differently by different stakeholders and may be difficult to measure. Comprehensive monitoring of GPP compliance includes documenting and analysing how well practices have been followed as well as to what extent stakeholders feel the practices have been followed. Comprehensive evaluation of stakeholder engagement requires determining how stakeholders feel regarding the impact of those participatory practices on research and stakeholder relationships. This information can be gained through site records, meeting minutes, monitoring report forms, surveys, interviews, focus group discussions, and other methods.

A variety of other resources and tools may help stakeholders understand, implement, and monitor GPP. Users can refer to AVAC's website for new or revised materials. UNAIDS and AVAC welcome requests for additional tools as well as submissions of materials that are already in use.

# 2. Guiding principles of GPP in biomedical HIV prevention trials

The guiding principles of good participatory practice described below reflect a set of values that constitute the foundation for positive, collaborative, and mutually beneficial relationships that trial funders, sponsors, and implementers can foster with all other stakeholders. These principles are fundamental to sustaining partnerships and ensuring that collectively identified goals are achieved. They also serve to strengthen the foundation for conducting research that contributes to the identification of additional HIV prevention options. The GPP guidelines have been developed within the framework of these principles.

## 2.1 Respect

Respect among stakeholders is key to communicating effectively, fostering trust, and developing partnerships to achieve collective goals. Respect is demonstrated when stakeholders communicate and act in ways that value and honour each other's perspectives and realities.

Ethical research requires fundamental respect for human rights and for confidentiality of trial participants. It also requires respect for local values, cultures, and perspectives as well as respect for the scientific process.

## 2.2 Mutual understanding

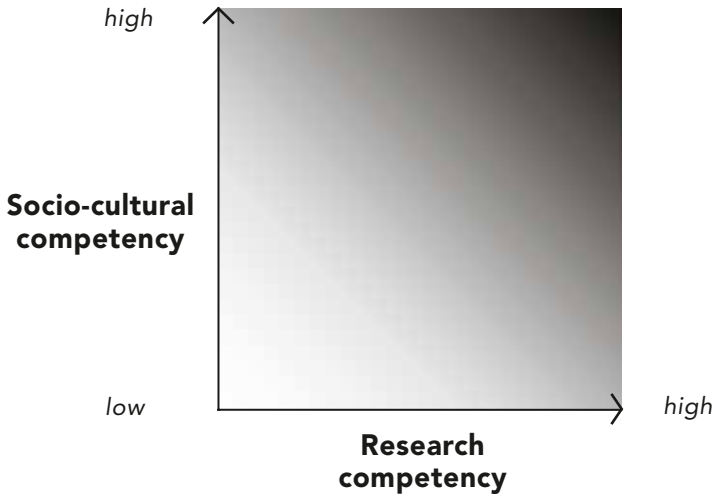
A common understanding about objectives and how to achieve them is essential to effective partnerships among stakeholders. This requires stakeholders to develop competency in both socio-cultural issues and research processes. The initial competency level of different stakeholders will depend on their prior exposure to specific socio-cultural environments and to biomedical HIV prevention trials.

**Socio-cultural competency** includes understanding the norms, practices, and beliefs of relevant local cultures, and local social circum-

stances, as well as diverse community stakeholder perspectives, priorities, and research needs. Building socio-cultural competency enables collaboration among stakeholders with diverse priorities and informs the development of appropriate trial designs and procedures.

**Research competency** includes understanding the scientific process of defining research questions, developing appropriate trial designs, and collecting, analysing, and disseminating data to ensure valid results. Building research competency enables and empowers stakeholders to provide meaningful input into the research process and enhances understanding of the concepts, purposes, practices, limitations, and results of biomedical HIV prevention trials.

Figure 4. Trial Competency Range




Socio-cultural and research competency are shown as gradients along two axes. Individual stakeholders start their involvement at a particular position on the graph, based on their socio-cultural competency and their research competency. A principal investigator new to a particular location may have high research competency but low socio-cultural competency at the start of the design phase of a trial. A community stakeholder new to biomedical HIV prevention research may have high socio-cultural competency but low research competency when their involvement with a trial begins. All stakeholders share ongoing responsibility to review and strengthen both socio-cultural and research competencies in order to improve mutual understanding.

## 2.3 Integrity

Maintaining the highest standards of scientific and ethical integrity is fundamental to achieving the scientific goals of a biomedical HIV prevention trial, maximising benefits for community stakeholders, and advancing global HIV prevention science.

**Scientific integrity** requires adherence to scientific processes in order to ensure that trials meet the highest scientific standards and achieve valid results.

**Ethical integrity** requires consideration of broader societal and ethical issues as well as adherence to universal ethical principles that include respect for persons, beneficence, and justice.[6]

## 2.4 Transparency

Open, honest, timely, and clear communication enables transparency and fosters collaborative, trusting, and constructive relationships. Transparency is relevant to the research process as well as to the roles of stakeholders.

Transparency about research includes ensuring that stakeholders receive open, honest, and understandable information about the objectives and processes of a trial. Transparency means ensuring that feedback from a broad range of stakeholders is acknowledged and addressed.

Transparency about the role of stakeholders includes ensuring that stakeholders are clear on their respective roles and responsibilities; the constituents, if any, they each represent; and the extent to which their input may influence trial-related decisions. Adherence to the principle of transparency means that stakeholders communicate about circumstances that may affect previously agreed levels of consultation, involvement, collaboration, and decision-making.

## 2.5 Accountability

Accountability is fundamental to sustaining relationships built on trust and mutual respect.

Trial funders, sponsors, and implementers are accountable to the society at large for conducting scientifically valid and ethical research. They are accountable to all research stakeholders for the use of participatory practices and for responding to input from relevant stakeholders as mutually agreed. They are also accountable for ensuring that funding is adequate to enable optimal engagement between research teams and other stakeholders.

Community stakeholders and other relevant stakeholders are accountable for ensuring that their input into the research process is fair and constructive, respects the scientific process, and is in the best self-identified interests of community stakeholders. Where stakeholders accept the responsibility to act as liaisons or representatives between research teams and other stakeholders, they are accountable for representing the interests of those they represent, sharing information about planned or ongoing trials with them, and expressing their needs and concerns to research teams.

## 2.6 Community stakeholder autonomy

Community stakeholder autonomy describes the community stakeholders' right to support or refuse proposals to conduct research in a particular area, depending on the community stakeholders' self-identified interests and desires. Different stakeholder groups may well have different perspectives on the relevance or appropriateness of a specific trial, adding complexity to the situation.

Good participatory practice strives to maximise the opportunity for stakeholders to understand the local, national, and global benefits of a specific trial and to make informed decisions regarding the appropriateness of a proposed trial.

While 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 ultimately determine whether or not a trial is conducted in a particular area.

# 3. Good participatory practices in biomedical HIV prevention trials

## Introduction to good participatory practices

The design, planning, and implementation of biomedical HIV prevention trials are guided by a range of standards such as *Good Clinical Practice*,[2,3] *Good Clinical Laboratory Practice*,[4] and *Good Manufacturing Practice*.[26] This section describes a systematic framework that trial funders, sponsors, and implementers can use to develop meaningful and sustained partnerships with relevant stakeholders in the planning and conduct of biomedical HIV prevention trials. The good participatory practices are intended to be adopted by trial sponsors, implemented at trial sites globally, and monitored.

Appropriate and meaningful stakeholder engagement occurs at all stages of the research life-cycle—from trial design to results dissemination—and is not limited to the specific topic areas highlighted in this section. While this section describes stakeholder engagement processes in the general sequence in which they may occur, these processes are not necessarily sequential or time-limited; they can take place as parallel, overlapping, or ongoing activities.

The 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 programmes and activities.

The good participatory practices section is divided into 16 topic areas covering the course of the research life-cycle. Topic areas in section 3 are divided into the following subsections:

A. Definition.
B. Relevance to good participatory practice.
C. Special considerations.
D. Good participatory practices.
E. Additional guidance.

## 3.1 Formative research activities

### 3.1.A. Definition

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

### 3.1.B. Relevance to good participatory practice

Collaborating with community stakeholders to devise questions, gather information, and analyse results related to formative research activities ensures that stakeholders' expertise and understanding of local perceptions, cultures, and traditions inform trial design and conduct. Collaborating with community stakeholders on formative research activities builds trust and lays the foundation for meaningful engagement.

### 3.1.C. Special considerations

1. Formative research activities can be conducted informally to gather information about local populations and research areas or formally as a part of approved, funded protocols.
2. Different sites will have specific needs regarding formative research activities. Whereas new trial sites may require extensive formative research activities, experienced trial sites may require more focused activities. Studying an experimental option new to the area, recruiting from a new location or population, gathering stakeholder feedback regarding previous trials, and the changing nature of cultures are all reasons why experienced trial sites may benefit from formative research activities.

### 3.1.D. Good participatory practices for formative research activities

1. Research teams identify key informants and relevant stakeholders that can assist in planning, implementing, and reviewing the process and results of formative research activities (see also Section 1.2).
2. Research teams designate trial site staff responsible for managing formative research activities.
3. Research teams and relevant stakeholders develop a formative research activity plan that describes:
    a. Key information and questions that need to be gathered and answered in order to support effective planning and implementation of the trial.
    b. The most appropriate methods to collect the required information.
    c. Research team members and community stakeholders best suited to collect the required information.
    d. Approval or notification processes that are required for specific activities.
    e. Implementation plans, including timelines and required resources.
4. Research teams and relevant stakeholders discuss the findings and their implications for trial design, conduct, and development of meaningful stakeholder engagement.
5. Research teams document formative research activities and findings, including techniques used, information collected, areas where clarification or attention is needed, and how findings will inform the trial planning and implementation process.
6. Trial sponsors ensure sufficient funding and research teams create a budget and allocate funds and staff time to conduct formative research activities.

## 3.2 Stakeholder advisory mechanisms

### 3.2.A. Definition

The term "stakeholder advisory mechanisms" refers to strategies or approaches that facilitate meaningful dialogue among research teams and relevant stakeholders about planned or ongoing clinical trials. Stakeholder advisory mechanisms provide research teams with information about relevant stakeholders' perspectives on the design, planning, and implementation of a specific clinical trial and facilitate open communication about research goals, processes, and results. These mechanisms also provide relevant stakeholders with the opportunity to engage with research teams during the life-cycle of a trial.

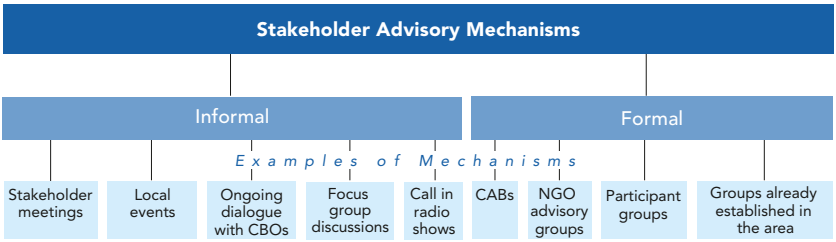
Stakeholder advisory mechanisms may be informal or formal. They can be built and sustained by the trial site or may already exist in the area.

1. Informal stakeholder advisory mechanisms may be events or less formal means by which research teams seek relevant stakeholders' views on proposed or ongoing research. Examples include stakeholder meetings, local events, focus group discussions, interviews, consultations, and suggestion boxes. They may involve individuals, existing organisations, local employer associations, local government or traditional committees, or other advocacy, charitable, cultural, political, religious, or social groups.
2. Formal stakeholder advisory mechanisms typically involve established groups that develop an ongoing relationship with the research team at a particular trial site. Examples are trial participant groups (former or current participants), professional groups (local scientists, service providers, media, or experts on local socio-cultural issues), non-governmental organisation advisory groups (with representatives from different non-governmental organisations or community-based organisations), and community advisory boards (see definition below).
3. Community advisory boards (CABs), also referred to as community advisory groups (CAGs), are a common example of a formal stakeholder advisory mechanism. They are composed of individuals or stakeholder representatives

and provide an independent advisory voice. They facilitate community stakeholder participation and involvement in the research process. They meet regularly with research team representatives, inform community stakeholders about proposed and ongoing research, and provide feedback to research teams about local norms and beliefs, as well as local views and concerns that arise during specific trials.

The composition of community advisory boards or groups varies from site to site but is intended to reflect the diversity of community stakeholder interests and needs. They may include members or representatives of the surrounding area, individuals in the population from which participants will be recruited, people living with or affected by HIV, current or former trial participants, religious or opinion leaders, and representatives of other sections of society as determined by the trial's location and eligibility criteria.

Figure 5. Examples of Stakeholder Advisory Mechanisms




Stakeholder advisory mechanisms can include informal and formal stakeholder advisory mechanisms (see definition 3.2.A). All of these mechanisms, as well as others, may be used to facilitate important dialogue between research teams and other stakeholders. While community advisory boards (CABs) are one example of a stakeholder advisory mechanism, there are many other ways that research teams can effectively engage with stakeholders.

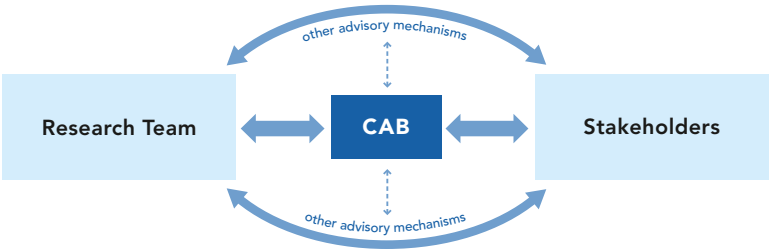
## 3.2.B. Relevance to good participatory practice

Establishment, maintenance, and engagement of stakeholder advisory mechanisms throughout the research process are key to establishing meaningful partnerships with community stakeholders and to ensuring continuous dialogue about biomedical HIV prevention research and specific trials.

## 3.2.C. Special considerations

1. Community advisory boards or groups were first developed in the context of HIV research in the United States of America and Europe. Over the past two decades, they have become a standard element of HIV research worldwide. Nonetheless, the establishment of a community advisory board or group may not always translate as best practice in all locations globally. In many settings, they are necessary but not sufficient for gaining adequate and appropriate community stakeholder input. Careful consideration needs to be given to the range of stakeholder advisory mechanisms that are required to best support effective participatory practices.
2. The need to identify and establish new stakeholder advisory mechanisms may vary from site to site and within a single site, over time. Stakeholder identification and inclusion considers the dynamic stakeholder landscape, as well as whether a trial is conducted in a research-naïve area or at a well-established research facility.
3. Formative research activities (see Section 3.1) help research teams to comprehensively identify which groups or individuals are relevant stakeholders and why.
4. While community advisory boards or groups can assist research teams in thinking about best strategies for trial recruitment, individual members of community advisory boards or groups are not research staff and do not participate in implementing actual trial procedures such as recruitment of prospective participants.
5. While community advisory boards or groups are often funded by research networks or trial sites, they are intended to be an independent advisory voice that is free to express concerns about proposed or ongoing research.

Figure 6. The Role of Community Advisory Boards




Community advisory boards (CABs) can play an important role in translating information between research teams and stakeholders. While community advisory boards are a key mechanism by which research teams inform stakeholders and receive their feedback, research teams are responsible for using other advisory mechanisms in addition to CABs to reach a broader range of stakeholders.

Figure 7. Examples of How Research Teams can Engage with Stakeholders


Examples of advisory mechanisms that research teams may use to engage with stakeholders to facilitate ongoing communication and collaboration.

## 3.2.D. Good participatory practices for stakeholder advisory mechanisms

1. Research teams comprehensively identify and map local stakeholders in order to determine which are relevant to trial implementation and key to sustained stakeholder engagement (see Section 1.2).
2. Research teams designate trial site staff responsible for managing activities and relationships involving stakeholder advisory mechanisms.
3. Research teams ensure that the development or identification of stakeholder advisory mechanisms is transparent to community stakeholders.
4. Research teams and relevant stakeholders identify stakeholder advisory mechanisms needed to ensure greater and more inclusive involvement of relevant stakeholders, in addition to community advisory boards or groups.
5. Research teams ensure that representation of stakeholders is comprehensive, including representatives of populations that will be recruited into trials, and that interactions with stakeholders are meaningful and responsive for all parties.
6. Research teams and relevant stakeholders identify the training needs of members of advisory mechanisms and build their capacity to understand concepts, purposes, practices, and limitations of clinical trials, increasing their ability to provide meaningful input to the research process.
7. Research teams review on an ongoing basis the composition of existing mechanisms and the need for new advisory mechanisms to ensure that relevant stakeholders continue to be represented during the course of a trial.
8. Research teams describe in their stakeholder engagement plans (see Section 3.3) strategies for the identification, establishment, and maintenance of stakeholder advisory mechanisms.
9. Research teams maintain clear written records of discussions and agreements with relevant stakeholders, including requests, concerns, recommendations, actions taken by the research team, and any unresolved issues that require follow-up.

10. Trial sponsors ensure sufficient funding and research teams create a budget and allocate funds and staff time to support establishment, ongoing capacity-building, maintenance, and activities of stakeholder advisory mechanisms.
11. For formal stakeholder advisory mechanisms, research teams and relevant stakeholders determine:
    a. The purpose of each stakeholder advisory mechanism, which may result in establishing terms of reference or by-laws.
    b. The scope of responsibilities of each stakeholder advisory mechanism, such as the responsibility to develop, review, discuss, and provide input on relevant trial documents and procedures.
    c. The structure of each stakeholder advisory mechanism, which may result in establishing guidelines to elect a chairperson and define the duration of service for members.
    d. The frequency of meetings, the frequency with which principal investigators or other key trial staff members attend meetings, and the ways in which members can communicate with research teams between meetings.
    e. Reimbursement policies, if appropriate.
    f. Mechanisms by which individuals or groups can raise concerns with research teams and with off-site trial sponsors in the event that a conflict or concern related to the site emerges.

## 3.2.E. Additional guidance

See *Recommendations for Community Involvement in National Institute of Allergy and Infectious Diseases HIV/AIDS Clinical Trials Research*.[27]

## 3.3 Stakeholder engagement plan[a]

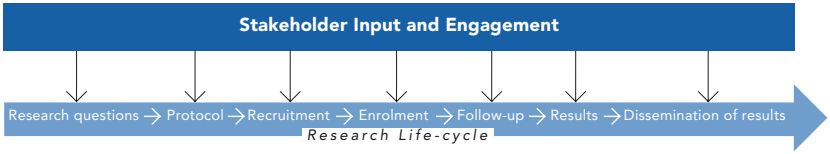
### 3.3.A. Definition

The stakeholder engagement plan describes strategies and mechanisms for building relationships and constructively engaging with a broad range of local, national, and international stakeholders.

### 3.3.B. Relevance to good participatory practice

A comprehensive stakeholder engagement plan enables research teams to collaborate with stakeholders and facilitate a more participatory approach to biomedical HIV prevention research. An effective stakeholder engagement plan will help research teams design and implement research that is effective and locally acceptable, and also lays the foundation for a supportive environment for research that extends beyond the lifespan of a specific biomedical HIV prevention trial.

Figure 8. Stakeholder Engagement through the Research Life-cycle




Robust stakeholder engagement occurs at all stages of the research life-cycle, including during trial design, recruitment, implementation, trial closure, results dissemination, negotiations of next steps, and development of future research questions.

a Stakeholder engagement, education, communications, and issues management (see Sections 3.3, 3.4, 3.5, and 3.6) are four different areas of planning to be addressed during the trial planning phase. Research teams may decide to create separate plans for each of these topic areas, or may decide to combine some or all of these plans as needed. The plans are described separately in the GPP guidelines so that the unique objectives and activities of each plan are clear.

### 3.3.C. Special considerations

Being familiar with and appreciating the relationship dynamics among different stakeholders increases the research team's ability to effectively and constructively engage with a broad range of relevant stakeholders, deepens understanding of local context, and will inform the development of the stakeholder engagement plan.

### 3.3.D. Good participatory practices for stakeholder engagement planning

1. Research teams comprehensively identify relevant stakeholders (see Section 1.2 and Section 3.1) within and surrounding the research area as well as regionally, nationally, and internationally.
2. Research teams designate trial site staff responsible for managing activities and relationships involving stakeholder engagement planning.
3. Research teams and relevant stakeholders discuss and negotiate a stakeholder engagement plan to cover the lifecycle of the trial. The plan defines the following:
    a. The range of different stakeholders to be engaged, specifically ensuring inclusion of relevant non-governmental organisations and community-based organisations and groups.
    b. The type of engagement that is appropriate for each stakeholder, such as being informed, consulted, collaborated with, or empowered to make decisions.
    c. The frequency and type of engagement methods to be used, such as public meetings, workshops, joint decision-making models, or delegated decision-making.
    d. The process by which new relevant stakeholders will be identified and engaged.
    e. The frequency with which the engagement plan will be reviewed.
    f. The criteria by which to review the success of the engagement plan.

4. Research teams implement the plan and maintain clear written records of discussions and agreements, as well as stakeholder engagement activities. This includes stakeholder recommendations, actions taken by the research team, and any unresolved issues that require follow-up.
5. Trial sponsors ensure sufficient funding and research teams create a budget and allocate funds and staff time to manage activities and relationships involved in stakeholder engagement plans.

## 3.4 Stakeholder education plan[b]

### 3.4.A. Definition

The stakeholder education plan describes strategies and mechanisms for providing relevant education about a specific planned trial—and about biomedical HIV prevention research in general—in order to enhance research literacy.

### 3.4.B. Relevance to good participatory practice

Effective stakeholder education is key to building research literacy and, ultimately, empowering community stakeholders as decision-making agents. Building research literacy lays the foundation for a supportive environment for research that extends beyond the lifespan of a specific biomedical HIV prevention trial.

### 3.4.C. Special considerations

1. While it is important that all relevant stakeholders improve their knowledge of research processes, enhancing research literacy for community stakeholders will foster more equitable relationships.
2. The goals and outcomes of stakeholder education are different from those of recruitment activities. While stakeholder

b Stakeholder engagement, education, communications, and issues management (see Sections 3.3, 3.4, 3.5, and 3.6) are four different areas of planning to be addressed during the trial planning phase. Research teams may decide to create separate plans for each of these topic areas, or may decide to combine some or all of these plans as needed. The plans are described separately in the GPP guidelines so that the unique objectives and activities of each plan are clear.

education can positively influence trial recruitment activities, a stakeholder education plan can help clarify the differences between participant recruitment and stakeholder education.

### 3.4.D. Good participatory practices for stakeholder education planning

1. Research teams, with input from relevant stakeholders, determine what education is needed in order to enhance stakeholder understanding of, and engagement with, a specific planned trial and biomedical HIV prevention research more generally.
2. Research teams and relevant stakeholders discuss and negotiate a stakeholder education plan to cover the life-cycle of the trial. The plan defines the following:
    a. The range of different stakeholders that could benefit from specific education about HIV, HIV prevention options, and general research literacy.
    b. The level of knowledge that is optimal and desired by stakeholders to support effective engagement. This will be influenced by the type of engagement defined for each stakeholder in the stakeholder engagement plan (see Section 3.3).
    c. The methods and frequency of educational activities.
    d. The stakeholders who could also deliver or facilitate the delivery of activities in the stakeholder education plan.
    e. The frequency with which the stakeholder education plan will be reviewed.
    f. The criteria by which to review the success of the stakeholder education plan.
3. Research teams implement the plan and document stakeholder education activities, including questions that arise, topics that cause confusion, and suggestions for future educational activities.
4. Trial sponsors ensure sufficient funding and research teams create a budget and allocate funds and staff time to support activities outlined in the stakeholder education plan.

## 3.5 Communications plan[c]

### 3.5.A. Definition

The communications plan describes policies and strategies that will increase broad awareness of the trial, facilitate dissemination and understanding of correct information about trial design, conduct, and results, and coordinate communication between the research team and relevant stakeholders.

### 3.5.B. Relevance to good participatory practice

Ongoing, transparent, and accurate communication with relevant stakeholders about proposed and ongoing research is essential for respectful, transparent relationships and builds trust among stakeholders. Additionally, consultation with relevant stakeholders will help research teams design communications strategies that are effective and help create a supportive and conducive environment for trial initiation and implementation.

### 3.5.C. Special considerations

The communications plan exclusively addresses external communication. However, effective internal communication, especially across multidisciplinary teams, is a prerequisite to attaining effective external communications.

### 3.5.D. Good participatory practices for communications planning

1. Research teams and relevant stakeholders comprehensively identify potential audiences within and surrounding the research area as well as regionally, nationally, and internationally.
2. Research teams and relevant stakeholders discuss and negotiate a communications plan to support open channels

c Stakeholder engagement, education, communications, and issues management (see Sections 3.3, 3.4, 3.5, and 3.6) are four different areas of planning to be addressed during the trial planning phase. Research teams may decide to create separate plans for each of these topic areas, or may decide to combine some or all of these plans as needed. The plans are described separately in the GPP guidelines so that the unique objectives and activities of each plan are clear.

of communication about the trial throughout its life-cycle. The plan describes the following:

a. The information needs of the different stakeholders at various stages of the research life-cycle, from early phases of stakeholder engagement to recruitment, enrolment, trial closure, and results dissemination.

b. The key messages to be communicated about the trial, such as the purpose, risks, benefits, ongoing progress, closure, and results dissemination.

c. The various communication methods that will be used for specific stakeholders, taking into account literacy levels and language needs.

d. Local stakeholders who could deliver or facilitate communications activities.

e. Specific training needs necessary to effectively deliver messages.

f. Procedures and timelines for disseminating information and procedures for actively addressing inquiries about the trial or HIV prevention research.

g. The frequency with which the communications plan will be reviewed.

h. The criteria by which to review the success of the communications plan.

3. Research teams develop communication materials in understandable language and translate them as needed, seeking input from relevant stakeholders.

4. Research teams implement the plan and maintain clear written records of discussions, agreements, and communication activities. This includes relevant stakeholder recommendations, actions taken by the research team, and any unresolved issues that require further follow-up.

5. Trial sponsors ensure sufficient funding and research teams create a budget and allocate funds and staff time to support activities outlined in the communications plan.

### 3.5.E. Additional guidance

See *Communications Handbook for Clinical Trials: Strategies, tips, and tools to manage controversy, convey your message, and disseminate results*.[28]

## 3.6 Issues management plan[d]

### 3.6.A. Definition

The issues management plan describes how research teams intend to manage issues of concern or any unexpected developments that may emerge before, during, or after the trial, including those that could limit the support for, or success of, the specific trial or future biomedical HIV prevention trials.

Examples of the types of issues that may emerge are negative media coverage, rumours about the trial, socio-cultural taboos around certain trial procedures, developments in other HIV prevention trials, premature closure of a trial for reasons of harm, futility, or proven efficacy in interim analyses, recruitment challenges, or protocol issues.

### 3.6.B. Relevance to good participatory practice

The risk that unexpected developments will negatively affect a trial can be mitigated if research teams work closely with relevant stakeholders to identify and plan for such risks and if relevant stakeholders provide advice and direction on how to resolve issues when they do arise. By developing an issues management plan prior to trial implementation, research teams are better equipped to deal with issues or risks as they arise and are more likely to avert a crisis.

d Stakeholder engagement, education, communications, and issues management (see Sections 3.3, 3.4, 3.5, and 3.6) are four different areas of planning to be addressed during the trial planning phase. Research teams may decide to create separate plans for each of these topic areas, or may decide to combine some or all of these plans as needed. The plans are described separately in the GPP guidelines so that the unique objectives and activities of each plan are clear.

### 3.6.C. Special considerations

Research teams may find it helpful to participate in communications networks of biomedical HIV prevention trials to share and discuss emerging issues and their potential management.

### 3.6.D. Good participatory practices for issues management planning

1. Research teams identify and list all known issues that could emerge and undermine the success of the trial before, during, or after trial completion.
2. Research teams and relevant stakeholders discuss and negotiate an issues management plan to cover the life-cycle of the trial. The plan defines the following:
    a. A site-level strategy to manage unexpected developments and emerging concerns.
    b. Key trial site staff who are responsible for addressing emerging issues.
    c. A chain of communication within the research team and with relevant stakeholders for emerging issues.
    d. Relevant stakeholders who can act as advisers and help implement steps of the issues management plan.
    e. Key messages created to address anticipated concerns.
    f. Clear processes by which media reports and media requests will be addressed.
3. Research teams implement the plan and maintain clear written records of issues that emerge, how they are responded to, and their outcome.
4. Trial sponsors ensure sufficient funding and research teams create a budget and allocate funds and staff time to support activities outlined in the issues management plan.

### 3.6.E. Additional guidance

See *Communications Handbook for Clinical Trials: Strategies, tips, and tools to manage controversy, convey your message, and disseminate results*.[28]

## 3.7 Site selection

### 3.7.A. Definition

Site selection is the process by which trial funders, sponsors, or networks evaluate sites for funding for a trial protocol, inclusion in a multisite trial, or inclusion in a trial network.

### 3.7.B. Relevance to good participatory practice

Site assessment of stakeholder engagement programmes or plans for their development is critical to anticipating a site's ability to conduct a trial according to good participatory practice.

### 3.7.C. Special considerations

New sites may not have the full range of stakeholder engagement plans and advisory mechanisms in place. Optimal sites for selection already have established stakeholder engagement processes and programmes or, in the case of new sites, have demonstrated commitment to establishing such processes.

### 3.7.D. Good participatory practices for site selection

1. Trial funders, sponsors, or network representatives assess sites with respect to stakeholder engagement programmes, taking into account the following issues:
    a. Evidence of or plans for development and maintenance of meaningful relationships with relevant stakeholders.
    b. Evidence of previous stakeholder engagement activities for sites that have conducted research.
    c. Findings from formative research activities or a workplan for completing formative research activities.
    d. Previous development of multiple stakeholder advisory mechanisms or a workplan to develop them.
    e. Demonstrated awareness and consideration of human rights issues that may be raised by the trial, particularly as they relate to vulnerable, marginalised, or criminalised groups.

2. Trial funders, sponsors, or network representatives continue to monitor site progress towards developing appropriate plans, resolving identified issues, and following good participatory practices during the site development phase of the trial.

## 3.8 Protocol development

### 3.8.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 organisation of a trial.

### 3.8.B. Relevance to good participatory practice

A range of stakeholders can provide meaningful input into many aspects of trial protocol development. In particular, community stakeholders bring expertise that can assist research teams in ensuring that protocol designs and procedures are locally appropriate, are acceptable to the trial population, and optimise successful implementation of the trial.

### 3.8.C. Special considerations

1. Opportunities for protocol review and input by local research teams and relevant stakeholders vary by trial. In some circumstances, particularly multicountry or multisite trials, protocol development may be largely centralised. It is good practice in the protocol development process to incorporate mechanisms to facilitate stakeholder input early in the process.
2. Research teams can consider documenting community stakeholder input into protocol development and sharing these recommendations with protocol review bodies, even when not explicitly required by such bodies.

### 3.8.D. Good participatory practices for protocol development

1. Trial sponsors and network leadership provide opportunities and time for local research teams to contribute to trial protocol development.

2. Trial sponsors, network leadership, and local research teams provide opportunities and time for local stakeholders, in particular community stakeholders, to contribute to trial design issues and procedures such as products to be tested, trial objectives, recruitment strategies, informed consent materials and procedures, reimbursement policies, counselling approaches, follow-up procedures, and post-trial access to trial products or procedures.
3. Research teams maintain clear and transparent communication about the protocol development process with relevant stakeholders, in particular, formal stakeholder advisory mechanisms.
4. Research teams provide relevant stakeholders with draft versions of the protocol and make technical information as accessible as possible by providing protocol summaries and translated materials, or by facilitating workshops, as necessary.
5. Research teams inform relevant stakeholders of protocol reviews and approval processes and provide regular updates.
6. Trial sponsors or implementers make full, final protocols of trials available and easily accessible to stakeholders.
7. Research teams maintain clear written records of discussions and agreements. This includes relevant stakeholders' recommendations, actions taken by the research team, and any unresolved issues that require follow-up.
8. Trial sponsors ensure sufficient funding and research teams allocate resources and time to support stakeholder engagement in the protocol development process.

## 3.9 Informed consent process

### 3.9.A. Definition

Informed consent is a process by which a competent individual is provided with enough information about a trial to make an independent decision whether or not to participate in the trial. In this process, research staff members educate the prospective participant about the trial, including about the potential risks and benefits, trial procedures, and what is expected of the participant.

When an individual provides consent, this is documented on the informed consent form. Informed consent is an ongoing process. Participants may decide to drop out of the trial at any point, even after providing consent to enrol in the trial.

### 3.9.B. Relevance to good participatory practice

The informed consent process is relevant to good participatory practice because a wide range of stakeholders can help research teams develop locally acceptable and effective informed consent procedures and materials.

### 3.9.C. Special considerations

Community stakeholders can provide research teams with invaluable advice to improve the informed consent process and materials. However, the actual implementation of the informed consent process between an individual and the research staff is confidential. Only designated research staff members have access to confidential information about the identity of trial participants. The informed consent process itself is conducted in accordance with *Good Clinical Practice*.[2]

### 3.9.D. Good participatory practices for the informed consent process

1. Research teams discuss the following topics with community stakeholders during development of the informed consent materials and procedures:
    a. Who needs to be consulted locally to enable research teams to invite individuals to join the trial.
    b. What local cultural practices may affect individual decision-making ability, and how working within these structures can be facilitated while ensuring protection of individual autonomy to provide informed consent.
    c. The general literacy level of the population to be recruited and how to assess the literacy level of prospective participants.

d. Considerations and requirements for illiterate participants, including discussion of possibilities of who may serve appropriately as a witness to the informed consent process.

e. The prevalence of different languages in the area and which languages are required for obtaining informed consent from individuals.

f. Local and legal forms of identity (name and age) verification and local practices around the use of names.

g. The legal, local, and trial sponsor definitions of a "minor" and consideration of legal and local determinations of who can serve as a minor's guardian.

h. Locally appropriate reimbursement and compensation.

i. Appropriate strategies to ensure participant rights are protected, including voluntariness of participation, ensuring undue inducement is avoided, and mitigating the influence of social desirability in influencing individual agreement to enrol.

j. Strategies to ensure comprehension of informed consent materials and critical trial-related terms and concepts, including the use of visual or audio formats, flipcharts, props, analogies, and other supportive materials and methods.

k. Techniques to assess comprehension of trial participation and the frequency with which they are to be used.

l. Explanation of potential trial-related harms and how such harms will be addressed (see Section 3.13).

m. Strategies to ensure that follow-up of participants after missed visits respects agreements between the participant and research team about how to contact the participant.

n. Consideration of the length of informed consent forms and the estimated time required to complete the informed consent process.

o. Preferred ways for participants to contact research teams and stakeholders independent from the research team to ask questions or express concerns about trial participation.

p. Ways to pilot informed consent materials.

2. Research teams maintain clear written records of discussions and agreements. This includes community stakeholder recommendations, actions taken by the research team, and any unresolved issues that require follow-up.
3. Trial sponsors ensure sufficient funding and research teams create a budget and allocate funds and staff time to allow informed consent materials to be properly developed, piloted, translated, and implemented, including materials to assess participants' ongoing consent.

### 3.9.E. Additional guidance

1. Informed consent is the cornerstone of ethically conducted research and is explicitly discussed in guidance documents that address the overall ethical conduct of research, such as the *Declaration of Helsinki*,[5] *CIOMS* guidelines,[7] *The Belmont Report*,[6] *Good Clinical Practice*,[2] the World Health Organization *Handbook for Good Clinical Research Practice*,[3] the *Nuremberg Code*,[29] the *Nuffield Council Guidance on health research in developing countries*,[8, 9] and UNAIDS/WHO *Ethical considerations in biomedical HIV prevention trials,*[10] and in relevant national guidelines.
2. There are extensive literature and other resources on the development of informed consent processes in multiple contexts, including a range of innovative approaches to measure and assess participant understanding, to address literacy issues, and to accommodate the desire of participants to consult with families and friends. [30, 31, 32, 33, 34]

## 3.10 Standard of HIV prevention

### 3.10.A. Definition

The term "standard of HIV prevention" refers to the package of comprehensive counselling and state-of-the-art HIV risk reduction methods provided or made available to participants in biomedical HIV prevention trials.

## 3.10.B. Relevance to good participatory practice

Helping trial participants reduce their risk of acquiring HIV is a key ethical obligation of research teams. Determining the components of the HIV prevention package is a joint effort between research teams and relevant stakeholders. Trial sponsors and implementers must work with relevant stakeholders in establishing the type, scope, and process by which participants are provided with, or referred to, services to access the full HIV prevention package. How trial sites help participants prevent HIV acquisition is often at the forefront of community stakeholder concerns. Therefore, successful negotiation with stakeholders about the prevention package to be provided to trial participants is likely to have a significant influence on community stakeholder perceptions of a trial.

## 3.10.C. Special considerations

1. Deviations from expected standard HIV prevention packages at a trial site or among trial sites in multisite studies may be caused by national legal restrictions.
2. When funding-body restrictions limit which prevention methods can be paid for by trial funds, research teams have the responsibility to find other ways to provide these methods, such as through alternative funding streams or linkages with non-governmental organisations or community-based organisations.
3. Research teams may need to review the HIV prevention package regularly, taking into consideration new HIV counselling models and risk reduction methods that are scientifically validated and, when appropriate, approved by national bodies for use.
4. To improve relevant stakeholder understanding of the prevention package offered and the clinical trial process, research teams can describe the trial as comparing the study product plus the HIV prevention package, with the placebo (or comparator arm) plus the HIV prevention package.

## 3.10.D. Good participatory practices for standard of HIV prevention

1. Research teams and relevant stakeholders negotiate the HIV prevention package during the protocol development phase of the trial.
2. Research teams determine which stakeholders already provide HIV prevention services, what types of services they provide, and their capacity to provide adequate services. This will enable research teams to provide optimal referrals and make linkages when necessary.
3. Research teams and relevant stakeholders discuss and negotiate the comprehensive HIV prevention package and consult local HIV prevention service providers when appropriate. All scientifically validated methods are discussed, and their appropriateness for the trial design and population assessed, including:
    a. Risk assessment and risk-reduction counselling—including partner and couple counselling.
    b. Male and female condoms—with appropriate instructions and demonstrations.
    c. Testing for and treatment of sexually transmitted infections.
    d. Sterile injecting equipment and drug substitution treatment.
    e. Medical male circumcision.
    f. Post-exposure prophylaxis.
    g. Other novel HIV risk-reduction strategies as they become available.
4. Research teams and relevant stakeholders discuss and negotiate the comprehensive HIV prevention package, taking account of the following:
    a. The HIV prevention package required as a minimum for the trial protocol.
    b. Current HIV prevention standards and services available nationally and locally.

c. Current national laws on HIV prevention strategies and services, as well as national ethical guidance on research.

d. The trial's funding source, any implications this may have for the prevention package, and how these will be addressed to ensure participants are offered a comprehensive package.

e. The HIV prevention services and options that will be offered through referral mechanisms.

f. The HIV prevention services that will be available to partners of trial participants.

g. The impact that any services offered by the trial, as well as those to which participants will be referred by the trial, could have on local services.

5. Research teams and relevant stakeholders discuss how the HIV prevention package will be implemented and monitored, including uptake and standards of referral services.

6. Research teams maintain clear written records of discussions and agreements. This includes recommendations, actions taken by the research team, and any unresolved issues that require follow-up.

7. Trial sponsors ensure sufficient funding and research teams create a budget and allocate funds and staff time to ensure provision of the comprehensive HIV prevention package.

## 3.10.E. Additional guidance

1. *Ethical considerations in biomedical HIV prevention trials* (Guidance Point 13, page 45, Standard of HIV Prevention).[1]
2. *Ethical considerations in biomedical HIV prevention trials* (page 13, selected circumstances in which biomedical HIV prevention trials should not be conducted).[1]
3. *Mapping the Standards of Care at Microbicide Clinical Trial Sites*.[35]
4. *The challenge of defining standards of prevention in HIV prevention trials*.[36]

## 3.11 Access to HIV care and treatment

### 3.11.A. Definition

Access to comprehensive HIV care and treatment refers to care and treatment services made available to individuals who are identified as HIV-positive during the screening process and to trial participants who acquire HIV infection during the trial. Comprehensive HIV care includes all preventive, psychosocial, psychological, and clinical components of HIV care. HIV treatment refers to antiretroviral therapy regimens internationally recognised as optimal for the management of HIV.

### 3.11.B. Relevance to good participatory practice

Trial sponsors and implementers are ethically obligated to ensure that participants who acquire HIV during trial participation have access to clinical evaluation, and stage-appropriate HIV care and treatment. This issue is often at the forefront of community stakeholder concerns. Therefore, how access to HIV care and treatment is negotiated with relevant stakeholders and how it is provided to trial participants are likely to have a significant influence on community stakeholder perceptions of a trial.

### 3.11.C. Special considerations

1. HIV care and treatment guidelines vary by country.
2. Treatment options may improve over time and research teams may need to modify their HIV care and treatment access plans in line with updated national guidelines.
3. Mechanisms to provide HIV care and treatment require long-term logistics planning as people living with HIV require lifelong care and treatment, and, for some participants, HIV treatment may begin after trial exit or completion.

### 3.11.D. Good participatory practices for access to HIV care and treatment

1. Research teams identify local HIV care and treatment services, local HIV non-governmental organisations or community-based organisations, and HIV support groups, determine

their capacities, and seek their views and perspectives. This enables research teams to design optimal referral mechanisms in consultation with service providers.

2. During protocol development, research teams and relevant stakeholders discuss access to HIV care and treatment for the following:
   a. Individuals who are identified as HIV-positive during the screening process.
   b. Individuals who become HIV-positive during the trial.
   c. Women who are identified as HIV-positive during the screening process or who acquire HIV during the trial, and when appropriate HIV-positive men, for provision of information about the risk of mother-to-child HIV transmission and the benefits of vertical transmission prevention services.
3. Research teams and relevant stakeholders discuss the HIV care and treatment package, taking account of the following:
   a. The HIV care and treatment package required as a minimum for the trial protocol.
   b. Current national HIV care and treatment guidelines and policies and local provision of HIV care and treatment services.
   c. Anticipated numbers of people likely to be found HIV-positive during screening and the anticipated numbers of participants likely to seroconvert during the trial.
   d. Current national laws that could affect a person's right or ability to access HIV care and treatment.
   e. HIV care and treatment services that will be offered through referral mechanisms.
   f. The possibility of negotiating provisions for priority access to national care and treatment programmes, at the time needed, for individuals who become HIV-positive during a trial.

g. Treatment regimens that will be available if the technology under study has the potential to give rise to antiretroviral resistance.

h. Local health institution responsibilities and proposed trial sponsor and implementer commitments regarding:

- Who will finance and who will deliver specific HIV care and treatment services.
- The duration of HIV care and treatment services being provided by each partnering stakeholder.

i. The impact that any services offered by the trial, or to which participants will be referred, could have on local services.

4. Research teams include a description of the HIV care and treatment package in informed consent forms for screening and enrolment.
5. Research teams and relevant stakeholders discuss optimal referral procedures and the most appropriate way to ensure that all individuals screened and enrolled are aware of how to access the HIV care and treatment services.
6. Research teams and relevant stakeholders discuss how to monitor access to HIV care and treatment services. They consider how to gather and analyse information on numbers of seroconverters who access HIV care, barriers to accessing HIV care and treatment programmes and other issues that may arise.
7. Research teams maintain clear written records of discussions and agreements. This includes relevant stakeholder recommendations, actions taken by the research team, aspects of HIV care and treatment that will not be offered and why, and any unresolved issues that require follow-up.
8. Trial sponsors ensure sufficient funding and research teams create a budget and allocate funds and staff time to ensure that the locally agreed HIV care and treatment package can be effectively delivered.

### 3.11.E. Additional guidance

1. *The Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects*.[5]
2. *Ethical considerations in biomedical HIV prevention trials* (Guidance Point 14, page 48, Care and Treatment).[1]
3. *Ethical considerations in biomedical HIV prevention trials* (page 13, selected circumstances in which biomedical HIV prevention trials should not be conducted).[1]
4. *Mapping the Standards of Care at Microbicide Clinical Trial Sites*.[35]

## 3.12 Non HIV-related care

### 3.12.A. Definition

Non HIV-related care refers to health and social care services provided or made available to trial participants that are not directly related to HIV prevention, HIV care and treatment, or trial-related harm. The non HIV-related care services appropriate for trial participants will depend on the trial population and local health priorities. Examples could include provision of female or male sexual and reproductive health care, management of infectious diseases, nutritional health, psychiatric care, and psychosocial services.

### 3.12.B. Relevance to good participatory practice

Access to non HIV-related care can provide benefits for participants, contribute to their welfare, and improve clinical trial outcomes. Negotiating the range of non HIV-related services available to participants at the trial site or via referral will assist in ensuring that relevant stakeholders clearly understand the breadth of services available and reasons for inclusion and exclusion of certain services.

### 3.12.C. Special considerations

Non HIV-related care packages may vary from site to site, depending on local health priorities and local standards of care.

## 3.12.D. Good participatory practices for non HIV-related care

1. Research teams identify the existence and capacity of local social care and primary health-care services and of secondary and tertiary diagnostic and treatment services. This enables the provision of appropriate referrals and linkages, should the need arise.
2. Research teams and relevant stakeholders discuss access to non HIV-related care services during the trial's protocol development phase.
3. Research teams and relevant stakeholders discuss non HIV-related care services to be offered to participants and consult with local social and health-care service providers when appropriate. Discussions take account of the following:
   a. Non HIV-related care services required by the trial protocol.
   b. Additional non HIV-related care services that community stakeholders would like to see the trial site offer to participants.
   c. Services that will be offered through referral.
   d. Whether any non HIV-related services will be available to partners of trial participants.
   e. The impact on local service delivery of any services offered or referred to by the trial.
4. Research teams maintain clear written records of discussions and agreements. This includes relevant stakeholder recommendations, actions taken by the research team, and any unresolved issues.
5. Trial sponsors ensure sufficient funding and research teams create a budget and allocate funds to ensure provision of the locally discussed, non HIV-related care package.

## 3.12.E. Additional guidance

See *Mapping the Standards of Care at Microbicide Clinical Trial Sites*.[35]

## 3.13 Policies on trial-related harms

### 3.13.A. Definition

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

### 3.13.B. Relevance to good participatory practice

A key ethical obligation of research teams is to maximise benefits and minimise harms for trial participants. Relevant stakeholders can provide valuable input about possible social harms of trial participation. These are of particular concern for individuals or groups who may be vulnerable, marginalised, stigmatised, or who have less power in society. Relevant stakeholders can also provide advice about local expectations of research team obligations to address trial-related physical and social harms. Discussing with stakeholders before a trial starts and clearly explaining how trial-related harms will be addressed and mitigated can significantly influence community stakeholder perceptions of the trial and of how well community stakeholder concerns will be addressed.

### 3.13.C. Special considerations

Sponsors typically give specific and binding guidance to research teams on how to determine and report physical harms as adverse events. It is good practice to define similarly stringent procedures for the determination, documentation, reporting, and management of social harms that trial participants may experience. Examples of social harms due to trial participation include stigma, discrimination, and verbal, emotional, physical, or sexual abuse.

### 3.13.D. Good participatory practices for policies on trial-related harms

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

2. Research teams and relevant stakeholders discuss and develop policies on trial-related physical and social harms, considering the following issues:
    a. Strategies to prevent or reduce the risk of trial-related harms.
    b. Procedures to encourage and facilitate reporting of social harms.
    c. Procedures to investigate events that have been reported indirectly, such as through a third party, taking confidentiality issues into account.
    d. Procedures for reporting social harms and whether these are to be reported to sponsors, ethics committees, and regulatory bodies, even if not specifically required by them.
    e. Procedures for ensuring optimal referrals to appropriate services for trial-related harms.
    f. Strategies to inform trial participants of the potential risks of engaging with media.
    g. Compensation or insurance policies, when applicable, for specific trial-related harms, coverage provided by the policies, how claims are made, and how participants are informed of their rights in relation to the policies.
3. Research teams and relevant stakeholders review follow-up strategies to reduce trial-related physical and social harms over the course of the trial.
4. Research teams maintain clear written records of discussions and agreements. This includes recommendations, actions taken by the research team, and any unresolved issues that require follow-up.
5. Trial sponsors ensure sufficient funding and research teams create a budget and allocate funds and staff time to ensure the effective management of physical and social harms related to participation in a trial.

## 3.13.E. Additional guidance

1. *Ethical considerations in biomedical HIV prevention trials* (Guidance Point 11, page 40, Potential Harms).[1]

2. *International Ethical Guidelines for Biomedical Research Involving Human Subjects* (Guideline 19, page 78 right of injured subjects to treatment and compensation).[7]

## 3.14 Trial accrual, follow-up, and exit

### 3.14.A. Definition

Trial accrual, follow-up, and exit activities include the recruitment, screening, enrolment, follow-up, and exit of trial participants in biomedical HIV prevention trials.

### 3.14.B. Relevance to good participatory practice

Community stakeholders can provide the best information on how to design socially and culturally acceptable strategies for recruitment, screening, enrolment, follow-up, and exit. Community stakeholders included in the process of developing these strategies can play an important role in identifying and mitigating trial-related stigma, misconceptions, or miscommunication.

### 3.14.C. Special considerations

1. Follow-up of participants after missed visits must respect agreements between the participant and research team about how to contact the participant.
2. Exiting a trial may present changes in what participants have become accustomed to with regard to clinical care and the impact of the trial on their social relationships. Anticipation and discussion of these issues between research teams and community stakeholders will help in the development of appropriate strategies to support participants upon trial exit.

### 3.14.D. Good participatory practices for trial accrual, follow-up, and exit

1. Research teams consult with relevant stakeholders about accrual, follow-up, and exit processes, taking account of the following:

a. Strategies and messages that are socially and culturally appropriate, meet the needs of specific stakeholders in terms of language and literacy, and draw on a range of communication modes, including written, oral, and visual.

b. Procedures to anticipate, monitor, and mitigate trial-related stigma resulting from ineligibility to enrol or from enrolment itself.

c. Procedures for training and supervising trial site staff on creating respectful relationships with participants and fostering an environment that is nonjudgmental and welcoming.

d. Strategies to ensure the confidentiality of participants during trial visits, while following up participants outside of the trial clinic, and after trial exit.

e. Procedures for informing participants about trial results and trial product assignment, when available.

f. Procedures for transfer of care at the end of follow-up or trial closure, such as providing participants with referrals to HIV counselling and testing and to other supportive services.

2. Research teams provide relevant stakeholders with ongoing updates on trial accrual, follow-up, and trial exit.

3. Research teams seek advice from relevant stakeholders on how to improve accrual, follow-up and exit processes, and messages.

4. Research teams maintain clear written records of discussions and agreements, as well as ongoing discussions about ways to modify strategies.

5. Trial sponsors ensure sufficient funding and research teams create a budget and allocate funds and staff time to support stakeholder engagement in the development of locally acceptable trial procedures.

## 3.15 Trial closure and results dissemination

### 3.15.A. Definition

Trial closure occurs when all participants have exited from the trial and all trial procedures are completed. Results dissemination

involves dissemination of trial results to participants, community stakeholders, and the public at large, as well as the unblinding of participants to trial group or arm assignment.

## 3.15.B. Relevance to good participatory practice

Effectively engaging relevant stakeholders about trial closure and results dissemination in a transparent process is essential for building trust and lays a positive foundation for future research. In the event that a trial is stopped early or unexpectedly, research team-initiated dialogue with relevant stakeholders will minimise the risk of misinformation.

## 3.15.C. Special considerations

1. Trials may run to completion per protocol or may be stopped early. Reasons for stopping early may be evidence of a clear protective effect, evidence of harm, or evidence of futility. Trials may also stop early due to other unforeseen circumstances, such as administrative or financial reasons, local objection, or sudden social unrest.
2. In multicountry or multisite trials, sites may complete participant follow-up at different times. Thus, while some sites might be closed for participant follow-up, research teams at other locations may continue to see participants.
3. Where trial product manufacturers are publicly traded companies, there may be legal requirements that affect the timing and methods for public announcement of a trial closure.
4. Ownership of data, issues of publication, and release of trial results vary by trial and may be strictly delineated in non-negotiable terms by sponsors or product manufacturers.

## 3.15.D. Good participatory practices for trial closure and results dissemination

1. Research teams consult with relevant stakeholders early in the research life-cycle to develop a trial closure plan. The plan addresses a range of possible closure scenarios, including:
   a. Trial closure as scheduled per protocol.

b. Early closure due to evidence of harm, futility, or clear protective benefit in interim analyses of trial data.

c. Early closure because of evidence of harm or of clear protective benefit from a different trial evaluating the same product.

d. Early closure due to unforeseen circumstances, such as administrative or financial reasons, stakeholder objection, or sudden social unrest.

2. Research teams ensure that trial participants are provided opportunities to learn trial results before they are announced publicly.

3. Research teams consult with relevant stakeholders to develop a results dissemination plan, detailing the following issues:

a. Strategies to manage expectations about trial results, including by preparing participants and relevant stakeholders for all possible outcomes.

b. Planned timelines for trial closure at the site and at other sites, completion of data analyses, and availability of results.

c. Procedures and timelines for those who will be informed of trial results in confidence prior to public release and how results will be disseminated publicly.

d. Development and piloting of key messages, how the messages will be finalised when the results are known, and the range of communication methods to be used.

e. How the messages will explain implications of the results for the area where the trial was conducted, limitations of the trial, and its ability to generalise findings for specific aspects, such as by sex, behaviours, or location.

f. How best to disseminate trial results that may be of a sensitive nature or that may put certain individuals or groups at risk of harm or stigmatisation.

g. Procedures for contacting and informing trial participants of research results before they are announced publicly.

h. Whether and how to disseminate additional findings that are not related to the primary trial question but may be of interest to some stakeholders, such as reported patterns

of sexual networks, rates of various infections, or demographic data.

i. How and when participants will be informed of their trial group assignment.

j. How community stakeholder responses to the results will be systematically collected and documented. Although community stakeholder agreement may not be a prerequisite for publishing or sharing research in a scientific forum, it is important that community stakeholder interpretations be noted, particularly if they differ from predominant scientific analyses.

k. Issues around ownership of the data, data access, and publication, including how the research team will facilitate community stakeholder access to published results of the trial.

4. Research teams maintain clear written records of discussions regarding trial closure and dissemination messages, as well as documentation of responses to the results.

5. Trial sponsors ensure sufficient funding and research teams create a budget and allocate funds and staff time to ensure comprehensive dissemination of results for participants, community stakeholders and other relevant stakeholders.

## 3.16 Post-trial access to trial products or procedures

### 3.16.A. Definition

The term "post-trial access to trial products or procedures" refers to making the prevention product or procedure tested in the trial available to trial participants and local community stakeholders (1) should the new product or procedure be scientifically validated or approved by relevant authorities, and (2) in the form of follow-on, open label, or other such studies before product licensure or approval, should an efficacy or effectiveness trial have a compelling positive finding, with no safety concerns.

### 3.16.B. Relevance to good participatory practice

Research ethics call for maximising benefits to stakeholders who participate in research. Thus, local community stakeholders are to be among the first to gain access to new prevention products should they be found safe and effective. How trial sites communicate and interact with community stakeholders about issues of access to the prevention product or procedure studied is likely to have a significant influence on community stakeholder perceptions of a trial.

### 3.16.C. Special considerations

1. Availability of newly identified products or procedures to trial participants and other community stakeholders will depend on the biomedical HIV prevention strategy being tested.
2. After a trial is completed, other trials may be needed to corroborate findings.
3. After results from relevant trials are available, it may take time for normative agencies and appropriate regulatory authorities, including national governments, to approve the new product or procedure. Approval processes and timelines will differ by product or procedure and by country.
4. National regulatory authorities make the ultimate decision about whether a new product or procedure will be approved for use within a particular country.
5. Availability and pricing of new products or procedures may be affected by product-manufacturer parameters as well as by agreements with trial sponsors.

### 3.16.D. Good participatory practice practices for post-trial access to trial products or procedures

1. Research teams discuss with relevant stakeholders, early in the trial process, issues affecting future product or procedure availability, including the need for corroborated biomedical evidence, pursuit of licensure, production rights, and additional marketing and distribution research.

2. Trial funders, sponsors, and research teams conducting efficacy or effectiveness trials discuss with relevant stakeholders, early in the trial life-cycle, expectations about possible pre-licensure access, plans for follow-on, open label, or other such studies, and how such pre-licensure access will be funded, in the event that a compelling positive result, with no safety concerns, is observed.
3. Trial sponsors and research teams discuss, negotiate, and agree on responsibilities and funding requirements with national governments concerning licensure requirements and access issues, should the HIV prevention product or option under investigation be shown to be safe and effective.
4. Trial sponsors and research teams develop a clear strategy and funding mechanisms for how the HIV prevention product or procedure will be made available to participants (at a minimum) rapidly, affordably, and sustainably, should the HIV prevention product or procedure be shown to be safe and effective. Sponsors and research teams can collaborate with multiple stakeholders, such as UN organisations, development partners, local governments, and non-governmental organisations to design and support the overall access strategy.
5. Research teams inform community stakeholders of their rights, the access plan, and the factors that could postpone or prevent their gaining access to the new prevention product or procedure, such as the need to secure regulatory approvals or parameters related to the product manufacturer. Research teams give community stakeholders updates as they are available.

## 3.16.E. Additional guidance

1. *Ethical considerations in biomedical HIV prevention trials* (Guidance Point 19, page 60, Availability of Outcomes).[1]
2. *Rethinking the Ethical Roadmap for Clinical Testing of Microbicides: Report on an International Consultation* (Chapter 10, After the trial: continued access and post-approval studies).[37]
3. *Ethical and Policy Issues in International Research: Clinical Trials in Developing Countries* (Recommendation 4.1).[38]

## Conclusion

Well-conducted biomedical HIV prevention trials are essential to discovering additional options to reduce new HIV infections. The GPP guidelines set global standard practices for stakeholder engagement. When applied during the entire life-cycle of a biomedical HIV prevention trial, they enhance both the quality and outcomes of research. While there is much guidance in the field on how to conduct trials, the GPP guidelines are the only set of global guidelines that directly address how to engage stakeholders in the design, conduct, and outcome of biomedical HIV prevention trials.

Adherence to good participatory practices is an investment that benefits the research process. These practices facilitate the engagement of relevant stakeholders to achieve mutual gains in local capacity building for biomedical HIV prevention research. Significant power imbalances exist between trial funders, sponsors, and implementers and community stakeholders—the GPP guidelines are a critical resource to help address and mitigate these disparities. A core aim of the guidelines is to enhance the skills of individuals and groups who are most vulnerable to both HIV and to exploitation. The GPP guidelines help build community stakeholder capacity for more robust engagement in the research process and improved decision-making abilities.

Effective stakeholder engagement can exist only when appropriate funds and resources are made available to research teams so they may adhere to good participatory practice. Sponsors of biomedical HIV prevention trials are responsible for enabling GPP by ensuring ample budget allocations and staff time to facilitate participatory approaches.

Investment in establishing mutually respectful relationships and building capacity of community stakeholders is a long-term process that extends throughout and beyond the life-cycle of any single clinical trial. Although it is highly beneficial to maintain and support key staff at trial sites and

sustain relationships that have been developed with local partners during the course of a trial, sponsors of biomedical HIV prevention trials often only support implementation of specific clinical trials. Investing in collaborative long-term, sustained relationships between research teams and relevant stakeholders, such as academic institutions, ministries of health, and non-governmental organisations, can improve research literacy, enhance the success of stakeholder engagement, and provide the foundation for future trials.

The GPP guidelines are intended to provide trial funders, sponsors, and implementers with systematic guidance on how to effectively engage with relevant stakeholders in the design and conduct of biomedical HIV prevention trials. Developing participatory processes that balance the opinions of all stakeholders while achieving the scientific goals of a trial can ensure that the needs of both community stakeholders and the broader HIV prevention field are met.

In a forward-looking approach, it is important to gather and analyse stakeholders' experiences with the implementation of the GPP guidelines. Recommendations for modifications and refinements based on experience and reflection can be sent to gpp@unaids.org or avac@avac.org, where they will be gratefully received and considered in future updates of these guidelines.

# Annex 1. Acronyms and abbreviations

**AE** – Adverse event
**AIDS** – Acquired Immunodeficiency Syndrome
**ARV** – Antiretroviral drug
**CAB** – Community Advisory Board
**CAG** – Community Advisory Group
**CBO** – Community-Based Organisation
**CIOMS** – Council for International Organizations of Medical Science
**EC** – Ethics committee
**DSMB** – Data safety monitoring board
**DSMC** – Data safety monitoring committee
**GCLP**– Good Clinical Laboratory Practice
**GCP** – Good Clinical Practice
**GMP** – Good Manufacturing Practice
**GPP** – Good Participatory Practice
**HIV** – Human Immunodeficiency Virus
**IDMC** – Independent data monitoring committee
**IDU** – Injecting drug use
**IRB** – Institutional review board
**MSM** – Men who have sex with men
**NGO** – Non-governmental organisation
**PEP** – Post-exposure prophylaxis
**PMTCT** – Prevention of mother-to-child transmission
**PrEP** – Pre-exposure prophylaxis
**REC** – Research ethics committee
**SOP** – Standard operating procedure
**STI** – Sexually transmitted infection
**UNAIDS** – Joint United Nations Programme on HIV/AIDS
**WHO** – World Health Organization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# Annex 2. Glossary

**Accrual.** The process of recruiting participants into a clinical trial in order to reach target participant numbers.

**Acquired immunodeficiency syndrome (AIDS).** The most severe manifestation of infection with human immunodeficiency virus (HIV), characterised by deterioration of the immune system and susceptibility to a range of opportunistic infections and cancers. (See **human immunodeficiency virus**.)

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

**Adverse event (AE).** An unwanted effect experienced by a participant in a clinical trial. This may or may not be related to the product or procedure being studied.

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

**Antiretroviral (ARV) drug.** A drug or medication that acts against or suppresses a retrovirus such as HIV.

**AVAC.** An international, non-profit organisation that uses education, policy analysis, advocacy, and community mobilisation 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.

**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 or group and which are in the control arm or group of a trial, in order to reduce bias.

**Clinical trial.** A research study that uses human volunteers to answer specific questions about the safety, efficacy or effectiveness, and medical effects of a specific procedure, medication, product, or treatment. A clinical trial process may include Phases I, II, IIb, III, and IV (post-marketing evaluation).

**Community advisory boards (CABs)** or **community advisory groups (CAGs).** Boards or groups composed of individuals or stakeholder representatives that act as an independent advisory voice and facilitate community stakeholder participation and involvement in the research process. They meet regularly with research team representatives, inform community stakeholders about proposed and ongoing research, and provide feedback to research teams about local norms and beliefs, as well as local views and concerns that arise in specific trials.

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

**Community stakeholders** (per the GPP guidelines). 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 of "community stakeholders" are the population to be recruited, trial participants, people living in the area where the research is conducted, people living with HIV in the area, local HIV-positive groups or networks, people in the area affected by the HIV epidemic, local non-governmental organisations, community groups, and community-based organisations. (See **stakeholders**.)

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

**Condom.** A sheath or pouch that is worn either over the penis (male condom) or inside the vagina (female condom) during sexual intercourse, for the purpose of protecting against sexually transmitted infections (including HIV) or preventing pregnancy. (See **female condom** or **male condom**.)

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

**Data and safety monitoring board (DSMB) or independent data monitoring committee (IDMC).** An independent committee established by a trial sponsor to assess, at intervals, the progress of a clinical trial, safety data, and critical efficacy or effectiveness endpoints. A data and safety monitoring board may recommend to the sponsor that a

trial be stopped or modified if there are safety concerns, if trial objectives have been achieved, or if assessment of trial progress reveals that continuing the trial would be futile since it will no longer be possible to answer the research question that the trial is addressing.

**Ethics committee.** See **research ethics committee.**

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

**Female condom.** A pouch that when inserted in the vagina before vaginal intercourse, provides protection against most sexually transmitted infections, including HIV, and pregnancy. During anal sex, the female condom, when placed on the penis after removing the inner ring, provides protection against most sexually transmitted infections, including HIV. Currently made of polyurethane (female condom 1) or a synthetic latex (female condom 2), it is stronger than the natural latex used in male condoms, odourless, non-allergenic, and usable with oil-based and water-based lubricants. For vaginal intercourse, it can be inserted vaginally prior to intercourse, is not dependent on male erection, and does not require immediate withdrawal after ejaculation. (See also **male condom**.)

**Formative research activities.** Activities that enable research teams to gain an informed understanding of local populations, socio-cultural norms and practices, local power dynamics, local perceptions, channels of communication and 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 one or more of 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. These guidelines provide guidance to ensure that trial laboratory data are reliable, repeatable, auditable, and easily reconstructed in a research setting.

**Good Clinical Practice (GCP).** Internationally recognised 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 are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorisation. Good manufacturing practices are aimed primarily at diminishing the risks inherent in any pharmaceutical or medical device production.

**Good Participatory Practice (GPP).** Guidelines that provide trial funders, sponsors, and implementers with systematic guidance on how to effectively engage with stakeholders in the design and conduct of biomedical HIV prevention trials.

**HIV vaccine (or AIDS vaccine).** A vaccine designed to prevent HIV infection. (See **vaccine**.)

**Human immunodeficiency virus (HIV).** The virus that weakens the immune system, ultimately leading to acquired immunodeficiency syndrome (AIDS).

**Implementer.** See **trial implementer**.

**Informed consent.** A process by which a competent individual voluntarily confirms his or her willingness to participate in a particular clinical trial after having been informed of all aspects of the trial that are relevant to the individual's decision to participate. Informed consent is an ongoing process throughout the course of a clinical trial.

**Institutional review board (IRB).** See **ethics committee**.

**Male condom.** A sheath designed to be worn over the penis during vaginal, anal, or oral intercourse as a means of preventing sexually transmitted infections, including HIV, or preventing pregnancy in the case of vaginal intercourse. (See also **female condom**.)

**Medical male circumcision.** The surgical removal of the entire foreskin of the penis. Three clinical trials conducted in sub-Saharan Africa have shown that medically performed male circumcision is safe and can reduce men's risk of HIV infection during vaginal sex by about 60%. Prevalence of male circumcision varies by geography, religion, and cultural practices.

**Men who have sex with men (MSM).** Men who have sexual contact with other men, regardless of whether or not they also have sex with women or have a personal or social gay or bisexual identity. This concept also includes men who self-identify as heterosexual but have sex with other men.

**Microbicides.** A range of products that could be used vaginally or rectally (such as a gel, cream, ring, film, suppository or sponge) that are being tested to determine if they reduce or prevent the transmission of HIV and other disease-causing organisms during vaginal and anal intercourse.

**Network** or **research network.** A cooperative of research institutions or centres conducting clinical trials under a common research agenda.

**Non-governmental organisation (NGO).** A not-for-profit, registered entity or group that is organised on local, 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 for the absence of the active ingredient under study. In clinical trials, the safety and effectiveness of an experimental product are assessed by comparing data from the experimental product trial arm to those from the placebo arm.

**Post-exposure prophylaxis (PEP).** Antiretroviral medicines prescribed and taken after exposure or possible exposure to HIV, to reduce the risk of acquiring HIV. The exposure may be occupational, as in a needle stick injury, or non-occupational, as in the case of rape.

**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 acquiring HIV infection.

**Product or trial arm assignment.** The specific study product or procedure, such as the experimental or 'active' arm or the placebo arm,

to which a participant is assigned for the designated follow-up period. (See **placebo** and **experimental arm**.)

**Protocol.** A document that details the rationale, goals, design, methodology, statistical considerations, and organisation 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.

**Randomisation.** A method based on chance alone by which trial participants are assigned to a trial arm or group. Randomisation ensures that the only intended difference between trial arms or groups is which product or procedure a trial participant is exposed to during the trial.

**Randomised trial.** A clinical trial in which participants are assigned by chance to one of the trial arms or groups. (See **randomisation**.)

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

**Research ethics committee (REC) or institutional review board (IRB).** An independent body made up of medical, scientific, and non-scientific members whose responsibility is to protect the rights, safety, and well-being of human participants involved in a clinical trial. Research ethics committees review and approve the initial protocol, review materials to be used in recruiting and consenting trial participants, and provide continuing review of a trial protocol and any amendments. The term "institutional review board" is common in the United States of America, whereas other countries commonly use the term "research ethics committee" or "independent ethics committee".

**Research network.** See **network**.

**Research team.** A group of investigators and staff involved in implementing biomedical HIV prevention trials. Research teams can include investigators and staff at a specific trial site as well as investigators and staff working at coordinating centres, institutions, or agencies.

**Scientific process.** A recognised systematic way to form and test hypotheses by designing controlled experiments to collect data, analyse results, and draw conclusions in order to acquire new knowledge or to correct, refine, and integrate previous knowledge.

**Seroconversion.** The process by which a newly infected person develops antibodies that can be detected by an HIV antibody test. Development of antibodies may occur anywhere from weeks or months following HIV infection.

**Sexually transmitted infections (STIs).** Infections caused by microorganisms that are transmitted from one person to another during sexual or intimate contact.

**Stakeholders or trial stakeholders.** Individuals, groups, organisations, governments, or other entities that are affected by the outcome of a biomedical HIV prevention trial or that can influence proposed research through their input and actions. (See **community stakeholders**.)

**Standard operating procedure (SOP).** A document that gives step-by-step instructions for how to conduct a procedure, in order to ensure that each staff member can perform the procedure in the same way.

**Stigma.** AIDS-related stigma refers to a pattern of prejudice, discounting, discrediting, and discrimination directed at people perceived to have HIV or AIDS, their significant others and close associates or their social groups.

**Therapeutic HIV vaccine.** A compound designed to stimulate the immune response to HIV in a person already infected with the virus, in order to control the infection. Also referred to as an immunotherapeutic vaccine. (See **vaccine** and **HIV vaccine**.)

**Trial arm or group.** A group within a clinical trial formed of participants who have been assigned a particular product or procedure during a trial. (See **control arm or group**, **experimental arm or group**.)

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

**Trial implementer.** Investigators, research staff, and all others specifically responsible for executing biomedical HIV prevention trials. Implementers may be employed by governments, government-spon-

sored networks, non-governmental organisations, academic institutions, the pharmaceutical industry or other companies, foundations, or public–private partnerships.

**Trial life-cycle.** The entire process of a trial, starting from developing the initial concept and writing the protocol and continuing through to the implementation and conduct of the trial to completion, exiting of participants, and dissemination and reporting of results.

**Trial participant.** A competent individual who voluntarily provides informed consent to participate in a clinical trial. Trial participants are assigned to a particular trial arm or group, in which they receive a particular product or procedure.

**Trial sponsor.** An entity that is responsible for a trial but that does not actually conduct it. The sponsor may be a pharmaceutical company, governmental agency, academic institution, or private or other organisation.

**UNAIDS (Joint United Nations Programme on HIV/AIDS).** UNAIDS brings together the resources of the UNAIDS Secretariat and 10 UN system organisations to lead and inspire the world in achieving universal access to HIV prevention, treatment, care, and support.

**Unblinding or unmasking.** The process of revealing trial participants' product or procedure assignments. Unblinding involves informing 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. A vaccine is typically made up of parts of a bacterium or virus that cannot itself cause an infection. (See **HIV vaccine**.)

# Annex 3. Additional guidance

## International reference guidelines

### *The Belmont Report*, 1979

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

**Citation:** National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*. Washington, DC, Department of Health, Education and Welfare, 1979.

### *Declaration of Helsinki*, 1964

This Declaration of the World Medical Association is often considered to be the first document to set world standards for research involving human volunteers.

**Citation:** World Medical Association General Assembly. *World Medical Association Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects*. Helsinki, World Medical Association, 2008.

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

This is an ethical guidance document, issued by UNAIDS and WHO, for biomedical HIV prevention trials. This document is a revision of *Ethical Considerations in HIV Preventive Vaccine Research: UNAIDS Guidance Document*. Geneva, UNAIDS, 2000.

**Citation:** UNAIDS and WHO. *Ethical Considerations in Biomedical HIV Prevention Trials*. Geneva, UNAIDS, 2007.

### *Guideline for Good Clinical Practice*, 1996

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

**Citation:** *Guideline for Good Clinical Practice: ICH Harmonised Tripartite Guideline*. Geneva, International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, 2006.

### *International Ethical Guidelines for Biomedical Research Involving Human Subjects*, 1993

These guidelines, published by the Council for International Organizations of Medical Sciences (CIOMS), added guidance on conducting research in developing countries to the body of ethical guidelines. The 2002 version supersedes the 1982 and 1993 guidelines.

**Citation:** *International Ethical Guidelines for Biomedical Research Involving Human Subjects*. Geneva, Council for International Organizations of Medical Sciences, 2002.

### Nuffield Council on Bioethics, 2002

The 2002 Nuffield Council on Bioethics report on The Ethics of Research Related to Healthcare in Developing Countries provides an ethical framework for designing or conducting externally sponsored research in the developing world. The 2004 follow-up report, co-hosted with the Medical Research Council of South Africa, discusses how the guidelines could be applied in practice, particularly in light of conflicting ethical advice.

**Citation:** *The Ethics of Research Related to Healthcare in Developing Countries*. London, Nuffield Council on Bioethics, 2002; and *The Ethics of Healthcare Related Research in Developing Countries: A Follow-up Discussion Paper*. London, Nuffield Council on Bioethics, 2005.

***Nuremberg Code*, 1949**

This code of research ethics came out of the ruling of the International Military Tribunal that prosecuted Nazi war criminals at the end of the Second World War.

**Citation:** *Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10.* Vol. 2. Washington, DC, United States Government Printing Office, 1949:181–182.

## Other references

***Communications Handbook for Clinical Trials: Strategies, Tips, and Tools to Manage Controversy, Convey Your Message, and Disseminate Results*, 2010**

The *Communications Handbook for Clinical Trials* is a practical guide developed for site-level research teams, communicators, advocates, and others working on HIV prevention trials. It provides guidance on how to anticipate and respond to the special communication challenges posed by the conduct of clinical research.

**Citation:** Robinson ET et al. *Communications Handbook for Clinical Trials: Strategies, Tips, and Tools to Manage Controversy, Convey Your Message, and Disseminate Results*. Washington, DC, Microbicides Media Communications Initiative and Research Triangle Park, NC, FHI, 2010.

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

This is a report and set of recommendations published by the United States National Bioethics Advisory Commission for United States policy on conducting clinical trials in developing countries.

**Citation:** *Ethical and Policy Issues in International Research: Clinical Trials in Developing Countries.* Vol. I. *Report and Recommendations of the National Bioethics Advisory Commission*. Washington, DC, United States National Bioethics Advisory Commission, 2001.

### *Mapping the Standards of Care at Microbicide Clinical Trial Sites*, 2008

The Global Campaign for Microbicides mapped the standard of care being provided across various microbicide clinical trial sites. The report resulted in a set of recommendations relating to the standard of care that is appropriate to provide to participants in microbicide clinical trials.

**Citation:** Heise L, Shapiro K, West Slevin K. *Mapping the Standards of Care at Microbicide Clinical Trial Sites*. Washington, DC, Global Campaign for Microbicides, 2008.

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

The Division of AIDS of the United States National Institute of Allergy and Infectious Diseases and Community Partners (a global group of community representatives affiliated with the National Institute of Allergy and Infectious Diseases HIV/AIDS clinical trials networks) developed these recommendations as a tool for research teams and community representatives to further expand and deepen community involvement in HIV clinical trials research.

**Citation:** Community Recommendations Working Group, Community Partners. *Recommendations for Community Involvement in National Institute of Allergy and Infectious Diseases HIV/AIDS Clinical Trials Research*. Bethesda, MD, 2009.

### *Rethinking the Ethical Roadmap for Clinical Testing of Microbicides: Report on an International Consultation*, 2005

In 2003, the Global Campaign for Microbicides held a consultation to rethink the issues and ethical dilemmas facing the field of microbicide development. The report addresses ethical issues such as informed consent, standards of care, and post-trial access.

**Citation:** *Rethinking the Ethical Roadmap for Clinical Testing of Microbicides: Report on an International Consultation*. Washington, DC, Global Campaign for Microbicides, 2005.

### *Standards of Prevention in HIV Prevention Trials*, 2010

In March 2009, the Global Campaign for Microbicides, UNAIDS, and the United States Centers for Disease Control and Prevention jointly convened a consultation on the standards of prevention in HIV prevention trials in Kampala, Uganda. The resultant report summarises points of agreement and proposes a range of recommendations for standards of prevention in future HIV prevention clinical trials.

**Citation:** *Standards of Prevention at HIV Prevention Trials: Consultation Report and Recommendations*. Seattle, Global Campaign for Microbicides, PATH, 2010; and Philpott S et al. The Challenge of Defining Standards of Prevention in HIV Prevention Trials. *Journal of Medical Ethics*, 2011, 37:244–248.

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3 *Handbook for Good Clinical Research Practice (GCP): Guidance for Implementation*. Geneva, World Health Organization, 2002.

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The Joint United Nations Programme on HIV/AIDS (UNAIDS) brings together ten UN agencies in a common effort to fight the epidemic: the Office of the United Nations High Commissioner for Refugees (UNHCR), the United Nations Children's Fund (UNICEF), the World Food Programme (WFP), the United Nations Development Programme (UNDP), the United Nations Population Fund (UNFPA), the United Nations Office on Drugs and Crime (UNODC), the International Labour Organization (ILO), the United Nations Educational, Scientific and Cultural Organization (UNESCO), the World Health Organization (WHO), and the World Bank.

Leveraging the AIDS response, UNAIDS works to build political action and to promote the rights of all people for better results for global health and development. Globally, it sets policy and is the source of HIV-related data. In countries, UNAIDS brings together the resources of the UNAIDS Secretariat and 10 UN system organizations for coordinated and accountable efforts to unite the world against AIDS.


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