



**Good Participatory Practice Tools**

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## **GPP Summary Sheets**

February 2014

## Introduction

### What are the GPP Summary Sheets?

The GPP Summary Sheets serve as an at-a-glance reference to the UNAIDS/AVAC [Good Participatory Practice: Guidelines for biomedical HIV prevention trials, second edition](#), offering quick, accessible guidance and support to research teams and other trial stakeholders working to apply the GPP guidelines in a clinical trial setting.

### How are the GPP Summary Sheets structured?

The summary sheets are organized into three parts, each representing a stage of the research life cycle: **Trial Planning and Preparation**, **Trial Execution**, and **Trial Follow-Up**. Each part consists of two pages, highlighting points from the GPP topic areas that are most relevant to the trial stage at hand. Each two-page summary features the following sections:

**Keep in Mind:** a distillation of best practices from select GPP topic areas

**GPP Topic Areas:** a comprehensive definition derived from select GPP topic areas

**For More Information:** a hyperlinked list of resources for additional GPP-related information\*

**Considerations for Specific Stakeholders:** GPP guidance targeted to four types of stakeholders: research teams, funders, civil society, and media

\*The References page at the end of the document lists the resources from all three sections.

### How can the GPP Summary Sheets be used?

The summary sheets can be used to supplement training materials or as a job aid, keeping research team members and stakeholders aware of key GPP principles throughout the course of a trial. It's important, however, to note that while the summary sheets peg GPP topic areas to particular trial stages, the practices associated with them are not necessarily meant to be performed sequentially or solely in relation to a particular trial stage. The three trial stages are simply an organizing principle for the material. Planning and preparation for all stages should be done well before a trial begins, and GPP should be applied throughout the trial life cycle, as circumstances dictate.

**Note:** *The summary sheets are part of a suite of tools and resources being developed by AVAC, in collaboration with other trial stakeholders, to support and promote effective implementation of the GPP guidelines at trial sites where biomedical HIV research is conducted. Users can customize the summary sheets and other related materials to suit their needs. Users can share their adaptations and send feedback about the GPP tools to [gpp@avac.org](mailto:gpp@avac.org).*

## KEEP IN MIND

- » **Each trial site** is unique and should have a **stakeholder engagement plan** that's driven by input from community stakeholders and supported by national and international stakeholders.
- » Even **experienced trial sites** should develop a robust stakeholder engagement plan for each new trial.
- » **CABs** provide an **independent advisory voice** but should not be the sole body that represents, engages, and solicits input from community stakeholders.
- » Research teams should use a **variety of advisory mechanisms** to ensure broad representation of community members and other stakeholders.
- » Trial sites should have a **plan for addressing criticism** from groups representing potential participants and other influential community groups.
- » **Adequate funding and staff time** should be arranged and committed to in advance to support site-level engagement efforts.

## FOR MORE INFORMATION

- » [Recommendations for Community Involvement in National Institute of Allergy and Infectious Diseases HIV/AIDS Clinical Trials Research](#)
- » [Communication Handbook for Clinical Trials: Strategies, tips, and tools to manage controversy, convey your message, and disseminate results](#)

## GPP TOPIC AREAS

- » **Formative research activities**  
Initial research activities lay a foundation for stakeholder engagement, establishing relationships and building trust between community stakeholders and research teams. These activities help researchers identify key stakeholders, define trial-relevant populations, and learn about the needs, interests, and backgrounds of local leaders and citizens, ultimately gaining an understanding of how community is defined in the local context. They can provide insight into potential objections, allowing researchers to refine the trial protocol and objectives, creating programs that are feasible, acceptable, and relevant to local needs and priorities. Involving community stakeholders in formative research activities can also help broaden the scope of the research, build research literacy, and ensure that participants' rights are protected.
- » **Site selection**  
The ideal trial site will have a variety of foundational tools for stakeholder engagement and a completed work plan for engagement activities *before* selection by funders, sponsors, or networks. Short of that, a work plan should be in progress and a site should be able to demonstrate its commitment to establishing meaningful and ongoing participatory practices.
- » **Stakeholder engagement plan**  
A site-specific plan for engaging stakeholders throughout the course of a trial and during intervals between trials should not only cover engagement activities but also stakeholder education, communication strategies, and issues management (all of which are topic areas in the *GPP Guidelines*). While focusing on any one topic area, researchers (with input from a diverse range of stakeholders) can address issues in multiple stages of the trial life cycle—for instance, when working on communications, they might simultaneously develop messaging for recruitment, potential adverse events, and results dissemination.
- » **Protocol development**  
Involving stakeholders in trial planning demonstrates a commitment to GPP, increases their sense of ownership of the trial, and can have a favorable impact on trial conduct and outcomes. Providing select stakeholders with protocol drafts and summaries in an accessible (e.g., translated) form encourages meaningful input. When protocol development is centralized for multisite or multicountry trials, it is essential to take each trial site's formative research findings into account.





### RESEARCH TEAMS

- » Develop a set of policies and procedures for soliciting and incorporating input from stakeholders and community members on an ongoing basis.
- » Consult a variety of stakeholders when developing the trial protocol.
- » Initiate formative research activities early, and be sure to engage a broad range of decision makers, not only those on the CAB.
- » Confer with stakeholders to gain an understanding of how community is defined in the local region.



### FUNDERS

- » Provide funding streams that allow for comprehensive stakeholder engagement activities and adequate staff time to support these initiatives.
- » Ensure that the stakeholder engagement budget is controlled (allocated to specific activities) at site level.
- » Cultivate and support a culture among trial site staff that frames compliance to GPP as a long-term investment.
- » Require researchers to show metrics demonstrating their commitment to GPP principles as a prerequisite for funding.



### CIVIL SOCIETY

- » Help ensure diverse representation of community members on the CAB.
- » Identify potential questions about and objections to the trial.
- » Help researchers strategize to improve communications (for instance, by consulting with research staff at the outset of planning, explaining procedures in non-technical terms, and establishing clear channels for participant feedback) so that they can implement GPP more effectively.



### MEDIA

- » Act as a partner to the trial site, helping research teams deal with controversy and disseminating key messages and updates about the trial.
- » Collaborate with research teams early in the planning process to address the questions and concerns of potential trial participants.



## KEEP IN MIND

- » **Both national standards of care, which may vary from country to country**, as well as international guidelines for clinical trials impact prevention and treatment policies for participants.
- » **The CAB should be structured** in a way that optimizes its **ability to inform the research**.
- » **HIV prevention packages** should be reviewed during the course of a trial and revised if necessary to reflect the population's needs, the availability of services, and current research findings.
- » **Procedures for addressing trial-related social harms** should be as stringent as those for addressing physical harms.
- » Site plans and activities should be **systematically documented and regularly evaluated** to determine whether they're effectively helping the site meet objectives.

## FOR MORE INFORMATION

- » [The challenge of defining standards of prevention in HIV prevention trials](#)
- » [Declaration of Helsinki](#)
- » [CIOMS Guidelines](#)
- » [The Belmont Report](#)
- » [Nuffield Council on Bioethics guidance on health research in developing countries](#)
- » [UNAIDS/WHO Ethical considerations in biomedical HIV prevention trials](#)
- » [Mapping the Standards of Care at Microbicide Clinical Trial Sites](#)

## GPP TOPIC AREAS

- » **Stakeholder advisory mechanisms**  
A full range of mechanisms—from informal local events to more formal NGO advisory meetings—should be used to facilitate meaningful dialogue between research teams and a variety of stakeholders. Mechanisms that are not trial-specific can continue beyond the trial life cycle, increasing opportunities for open communication and paving the way for unimpeded trial conduct.
- » **Informed consent process**  
Stakeholder input is critical to developing best practices for obtaining consent. It should also inform strategies for assessing participant comprehension throughout the trial, discussing potential trial-related harms, and settling on reimbursement and compensation policies. All documents related to these efforts should be pilot tested before use.
- » **Access to HIV care and treatment**  
Plans and procedures linking participants to providers should be developed with stakeholder input. Plans must be flexible enough to accommodate changes in standards of care, which may occur during the course of a trial (though not necessarily for every trial site).
- » **Standard of HIV prevention**  
In developing the HIV prevention package for trial participants (and their families and partners, when possible) all available options should be considered, including newly approved strategies. Input should be sought from a broad range of stakeholders, especially when there are discrepancies between national policies and available options. The impact on local prevention services as well as post-trial access must also be taken into account.
- » **Non-HIV-related care**  
Community stakeholder input as well as protocol design will inform which services the site will provide or make available, such as reproductive health care, family planning, infectious disease management, nutritional health, and psychiatric and psychosocial services.
- » **Trial accrual, follow-up, and exit**  
Messages and strategies to recruit, screen, and enroll participants should be socially and culturally appropriate, drawing from stakeholder input. Trial site staff should be trained to cultivate a non-judgmental environment in which trial stigma is minimal.
- » **Policies on trial-related harms**  
Potential social and physical harms should be delineated at the outset of the trial, and procedures—as well as a budget—to manage them should be developed with community input.





RESEARCH  
TEAMS

- » Design and test informed consent documents, as well as comprehension assessments, incorporating feedback from community stakeholders.
- » Work with civil society to design recruitment and retention practices that encourage participation and reduce or minimize stigma.
- » Incorporate community stakeholder input into policies and procedures to minimize and manage trial-related physical, social, and psychosocial harms.



FUNDERS

- » Ensure that operational policies at all sites include procedures for managing potential physical, social, and psychosocial harms.
- » Advocate for stakeholder involvement in negotiating a comprehensive package of care for participants (as it can improve local access to health services and serve as an incentive for participation in the trial).



CIVIL  
SOCIETY

- » Participate in the development of culturally and socially relevant informed consent procedures and materials.
- » Assist with pilot testing of the informed consent draft and any companion tools to gauge comprehension.
- » Advocate in support of the research agenda by meeting with local ministries of health and other key decision makers.
- » Assist with the development of recruitment and retention strategies.



MEDIA

- » Provide communications support to research teams, and help publicize trial successes.
- » Help strengthen communications between research teams and participants.
- » Share insights about how social, print, and broadcast media are influencing community perceptions of and responses to the trial.



## KEEP IN MIND

- » When and why a trial will end can't always be predicted, so **trial closure and post-trial procedures** should be **developed for a variety of scenarios**.
- » Stakeholders should play a central role in developing **messaging around results dissemination**.
- » Community stakeholders should be actively involved in **planning and implementing the results dissemination strategy**.
- » In **multisite trials**, dissemination strategies and plans for continued engagement should take staggered site closure into account.
- » Post-trial plans for multisite trials should account for the fact that approval processes and timelines for **post-trial access will vary** by product, procedure, and country.
- » **Funding for post-trial access** to products and procedures, as well as mechanisms for access, should be **negotiated in advance of trial enrollment**.

## FOR MORE INFORMATION

- » [UNAIDS/WHO Ethical considerations in biomedical HIV prevention trials](#)
- » [Ethical and Policy Issues in International Research: Clinical Trials in Developing Countries](#)
- » [The Belmont Report](#)
- » [Nuffield Council on Bioethics guidance on health research in developing countries](#)
- » [Rethinking the Ethical Roadmap for Clinical Testing of Microbicides: Report on an International Consultation](#)

## GPP TOPIC AREAS

- » **Trial accrual, follow-up, and exit**  
Exiting a trial can leave participants without access to the quality of care they have become accustomed to, which may have physical, emotional, and social repercussions that should be planned for. Policies and procedures should be developed to link participants who become HIV-positive to care and treatment. Participant confidentiality and privacy should be maintained around follow-up procedures, and the preferred method of contact along with other terms agreed to upon enrollment should be honored.
- » **Trial closure and results dissemination**  
A clear trial closure and results dissemination strategy should be developed in close consultation with stakeholders—and should include timelines and processes for reaching various groups (starting with participants) as well as key messages for each stakeholder group. When appropriate, the strategy should include post-dissemination debriefing events, where community members can ask questions and the research team can share information and address any rumors or misunderstandings. Ideally, community stakeholders will be involved in results analysis and dissemination, as well—for instance, by working as part of a writing team or helping to develop presentations.
- » **Post-trial access to trial products or procedures**  
Community stakeholder support is vital to future introduction and acceptance of any product or procedure. Stakeholders can play a key role in helping to devise socially and culturally acceptable approaches to reducing trial-related stigma. Deliberations and decisions around possible preclosure access and plans for open-label, follow-on, or other types of studies should be based on the trial's scientific end points and made in close consultation with a variety of stakeholders. Stakeholders can help craft messages to manage expectations. A clear plan and funding strategy for making the option available to participants affordably, quickly, and sustainably should be finalized before the trial enrolls its first participant.





RESEARCH  
TEAMS

- » Develop a post-trial plan that includes a full range of scenarios for trial closure.
- » Keep participants meaningfully engaged, even after they have exited the trial.
- » Ensure that the results dissemination plan prioritizes participants and involves communication to external audiences, such as journalists and media.



FUNDERS

- » Ensure that funding for stakeholder engagement activities continues after the trial ends—particularly, in the case of multisite trials, during the period of staggered site closure before results are disseminated.
- » Prior to enrollment, discuss funding for post-trial access to the study product or procedure with key stakeholders; consider helping to underwrite it.
- » Involve stakeholders, such as local leaders and ministries, in the presentation and dissemination of results.



CIVIL  
SOCIETY

- » Assist in the creation and implementation of dissemination strategies.
- » Help shape messaging and strategies to enhance post-trial engagement.
- » Work with research teams to develop strategies for linking participants with post-trial services in a variety of scenarios, such as efficacy trials, demonstration projects, and open-label extension studies.



MEDIA

- » Help trial sites manage community expectations and prepare stakeholders for different trial closure scenarios.
- » Work with research teams to address questions related to post-trial access, and keep former participants informed of any long-term, follow-up plans.





## References

### Stage 1: Trial planning and preparation

- » Recommendations for Community Involvement in National Institute of Allergy and Infectious Diseases HIV/AIDS Clinical Trials Research
  - [http://www.hvtn.org/community/CAB\\_Recommendations\\_Certified.pdf](http://www.hvtn.org/community/CAB_Recommendations_Certified.pdf)
- » Communication Handbook for Clinical Trials: Strategies, tips, and tools to manage controversy, convey your message, and disseminate results
  - <http://www.fhi360.org/resource/communications-handbook-clinical-trials-strategies-tips-and-tools-manage-controversy-convey>

### Stage 2: Trial conduct

- » The challenge of defining standards of prevention in HIV prevention trials
  - <http://www.ncbi.nlm.nih.gov/pubmed/21186207>
- » Declaration of Helsinki
  - <http://history.nih.gov/research/downloads/helsinki.pdf>
- » CIOMS guidelines
  - [http://www.cioms.ch/publications/layout\\_guide2002.pdf](http://www.cioms.ch/publications/layout_guide2002.pdf)
- » The Belmont Report
  - <http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html#ncil>
- » Nuffield Council on Bioethics guidance on health research in developing countries
  - <http://www.nuffieldbioethics.org/sites/default/files/files/Clinical%20research%20in%20developing%20countries%20Discussion%20Paper.pdf>
- » UNAIDS/WHO Ethical considerations in biomedical HIV prevention trials
  - [http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2012/jc1399\\_ethical\\_considerations\\_en.pdf](http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2012/jc1399_ethical_considerations_en.pdf)
- » Mapping the Standards of Care at Microbicide Clinical Trial Sites
  - <http://www.global-campaign.org/clientfiles/SOC-ES.pdf>

### Stage 3: Post-trial issues

- » UNAIDS/WHO Ethical considerations in biomedical HIV prevention trials
  - [http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2012/jc1399\\_ethical\\_considerations\\_en.pdf](http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2012/jc1399_ethical_considerations_en.pdf)
- » Ethical and Policy Issues in International Research: Clinical Trials in Developing Countries
  - <http://bioethics.georgetown.edu/nbac/clinical/execsum.html>
- » The Belmont Report
  - <http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html#ncil>
- » Nuffield Council on Bioethics guidance on health research in developing countries
  - <http://www.nuffieldbioethics.org/sites/default/files/files/Clinical%20research%20in%20developing%20countries%20Discussion%20Paper.pdf>
- » Rethinking the Ethical Roadmap for Clinical Testing of Microbicides: Report on an International Consultation
  - [http://www.path.org/publications/files/GCM\\_rethink\\_ethical\\_roadmap\\_rpt.pdf](http://www.path.org/publications/files/GCM_rethink_ethical_roadmap_rpt.pdf)