

The
AIDS VACCINE ADVOCACY COALITION'S

FACILITATOR'S GUIDE

to

GOOD PARTICIPATORY PRACTICE (GPP) GUIDELINES

for

BIOMEDICAL HIV PREVENTION TRIALS

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BACKGROUND ON THE GOOD PARTICIPATORY PRACTICE GUIDELINES

What does Good Participatory Practice mean?

The phrase *Good Participatory Practice* was created to describe the wide range of activities that trial sponsors, research sites, and communities can use to work towards more equitable partnerships and a shared understanding of and commitment to the process of biomedical HIV prevention research. The term Good Participatory Practice (GPP), is also meant to link this document to other international guidance documents related to research involving human volunteers. For example, Good Clinical Practice (GCP), is an internationally accepted guidance document for establishing ethical and scientific quality standards on how to design, conduct, analyse, and report on clinical trials involving human participants. The working group of civil society groups, UNAIDS representatives and members of clinical research teams that drafted the Good Participatory Practice guidelines chose the word “participatory” because it emphasizes the importance of active community participation in every aspect of the research process including the planning, community education, recruitment, implementation, follow-up, and monitoring of the study. The term “participatory” is meant to emphasize active collaboration, while recognizing the many social and economic factors that make it difficult to establish equal partnerships.

What do the GPP guidelines cover and who are they for?

The GPP guidelines were developed in response to many stakeholders’ observation that it could be helpful to have a tool that allowed researchers, communities, advocates, and other stakeholders to both plan and evaluate community engagements in biomedical HIV prevention trials. The aim was to create a guidance document that would help establish ways to develop and objectively measure how trial sponsors and implementers are communicating and partnering with communities in the process of conducting HIV prevention trials. The GPP guidelines are primarily written for an audience of trial sponsors, researchers, and trial site staff. It is divided into three main sections: Core Principles, Essential Issues and Activities, and Good Participatory Practice and the Research Life Cycle:

- The ***Core Principles*** section outlines a set of aspirational principles that serve as the foundation for all stakeholder relationships and how biomedical HIV prevention trials should be conducted with respect to involving communities.
- The ***Essential Issues and Activities*** section addresses major, overarching issues that cut across all stages of the research process and do not correlate with a specific time point within the conduct of a trial.
- The ***Good Participatory Practice and the Research Life Cycle*** section follows step-by-step the stages of preparing for, conducting, and concluding a biomedical HIV prevention trial and discusses the community engagement activities that should take place at each stage.

Why is GPP needed?

Tasks like “establishing trust,” “building relationships,” or “ensuring community support” are easy to label, but hard to describe in detail, and even harder to measure and monitor. Many sponsors of biomedical prevention research emphasize the importance of accomplishing these and other tasks before, during, and after any trial. But as strong as the commitment to building trust and partnership may be among both researchers and community groups, there can still be areas where expectations are not met and where misunderstandings arise. The GPP guidelines aim to provide clinical trial teams and

communities with a common starting point for what is expected of clinical trial teams throughout the process of planning for, conducting, and concluding a trial. The GPP guidelines will not prevent or resolve all conflicts, and they do not provide exhaustive instructions, but as a whole, they aim to offer a foundation for discussions and for evaluation of the critical, but hard-to-measure task of building trusting, mutually respectful relationships between communities and clinical trial teams.

How do the GPP guidelines relate to existing published guidance documents?

The Declaration of Helsinki, the Council for International Organizations of Medical Sciences (CIOMS) guidelines, and other international guidance documents on ethics of research in human participants focus on the human rights of the research participants. This is known as a *rights-based approach* and includes rights such as:

- The right to freely participate in research only after being fully informed about the trial in a process that is known as *informed consent*
- The right to confidentiality, or privacy, about one's participation in the trial
- The right to know the study results when the trial is over
- The right to have access to interventions that prove effective

The GPP guidelines do not replace these ethical guidance documents. It is assumed that trial sponsors are adhering to the principles outlined in these documents. The GPP guidelines build on the rights-based approach with a focus on how research sponsors and implementers should work to establish relationships with communities with the goal of:

- Ensuring that communities have an informed voice and are able to contribute to all aspects and stages of research
- Ensuring that the proposed research is relevant, acceptable, understood, and culturally sensitive to target communities
- Ensuring that the trial design addresses community priorities and concerns

At the same time that UNAIDS and AVAC were developing the GPP guidelines, UNAIDS and WHO were developing *Ethical considerations in biomedical HIV prevention trials* (http://data.unaids.org/pub/Report/2007/jc1399-ethicalconsiderations_en.pdf). This document serves as a useful companion piece to the GPP guidelines and this Facilitator's Guide.

INTRODUCTION TO THE FACILITATOR'S GUIDE

What is the Facilitator's Guide to the Good Participatory Practice (GPP) Guidelines?

This guide serves as a companion to the UNAIDS/AVAC publication *Good Participatory Practice: guidelines for biomedical HIV prevention trials* (http://www.avac.org/gpp/gpp_en.pdf). Published in 2007, these guidelines provide guidance to trial sites and communities on how to engage with one another in the process of planning for, conducting, and explaining the results of biomedical HIV prevention trials. This Facilitator's Guide is a simplified, user-friendly summary that walks the reader through each section of the full-length guidelines. The Facilitator's Guide provides a starting point for working with the full GPP guidelines, and is not intended as a replacement but meant to be read together with the GPP guidelines.

Why was the Facilitator's Guide written and how can it be used?

- The Facilitator's Guide was written to help make the full GPP guidelines easier to understand and more accessible to a wider range of stakeholders. Although the Facilitator's Guide can be used by anyone, its target audience is civil society stakeholders, and thus it is designed to help facilitators and participants with discussions about the GPP guidelines.
- The Facilitator's Guide, like the full GPP guidelines, was written to help stakeholders begin to pilot and implement the actual Good Participatory Practice guidelines discussed in the document.
- The GPP guidelines were published in 2007, and there is an ongoing need for feedback on how useful and how feasible a tool it is in the field. This Facilitator's Guide was designed to help civil society groups explore and give feedback on the GPP guidelines. Each section of the Facilitator's Guide includes discussion questions on specific topic areas. In addition to these specific questions, there are some overarching considerations to keep in mind as you read through this guide and the GPP guidelines:
 - What important points, perspectives, or recommendations are missing from the GPP guidelines?
 - Do the GPP guidelines offer appropriate and sufficient direction to help communities and researchers effectively address the issues they face when implementing HIV prevention trials?
 - If these guidelines were implemented, would conflict among stakeholders be avoided?
 - What are the barriers to implementing the GPP guidelines in your setting?

How is the Facilitator's Guide organized?

The organization of the facilitator's guide mirrors that of the GPP guidelines document. This guide includes a description and discussion of the main sections of the document: Core Principles, Essential Issues and Activities, and Good Participatory Practice and the Research Life Cycle. Within each main section, you will find the following elements:

- **Summaries:** These contain a brief overview of the content of the section or subsection from the GPP guidelines.
- **“What the GPP Guidelines Say”:** In some sections specific quotes from the guidelines are excerpted to highlight essential points.

- **“Discussion Tools”**: This section includes specific questions designed to encourage discussion and critical consideration of the text of the GPP guidance document.

At the end of the Facilitator’s Guide, you will find case studies that are based on experiences in biomedical HIV prevention trials. These case studies can be used as the basis for discussion and consideration of the GPP guidelines.

The GPP Guidelines and Facilitator’s Guide are both *living* documents that will change over time based on your comments and experience

In the coming months and years, it is expected that these Good Participatory Practice guidelines for biomedical HIV prevention trials will be applied, validated, and revised as they are used in the context of biomedical HIV prevention trials and considered by communities that are affected by and involved in HIV prevention research.

AVAC and its partners have a number of activities that are being implemented to help ensure that community input into the guidelines is obtained and incorporated into future versions.

We welcome your suggestions and comments on both the *Good Participatory Practice guidelines for biomedical HIV prevention trials* and the companion *Facilitator’s Guide to the GPP guidelines*. Please e-mail us at gpp@avac.org.

Founded in 1995, the non-profit AIDS Vaccine Advocacy Coalition (AVAC) seeks to create a favorable policy and social environment for accelerated ethical research and eventual global delivery of AIDS vaccines and other HIV prevention options as part of a comprehensive response to the pandemic.

GPP GUIDELINES: PROLOGUE AND INTRODUCTION

Prologue Summary

The *Prologue* section describes the events that led to the drafting of the Good Participatory Practice guidelines. These include a series of UNAIDS-sponsored meetings in different parts of the world, where stakeholders discussed the relationships among communities, trial sites, and sponsors. These meetings, which took place in 2005, led to a recommendation for standard guidelines on community engagement in biomedical HIV prevention research. UNAIDS worked with AVAC and several other partners to draft these guidelines, which came to be called *Good Participatory Practice guidelines for biomedical HIV prevention trials* or “GPP.” The GPP guidelines were drafted in 2006-2007 and are now available for communities and trial sites to use. They are available at www.avac.org/gpp.htm.

Introduction Summary

The *Introduction* discusses how the GPP guidelines relate to existing important ethical guidance documents and other guidelines for the conduct of biomedical research. As it explains, the GPP guidelines recognize the central importance of documents such as the Declaration of Helsinki and the Council for International Organizations of Medical Sciences (CIOMS) *International Ethical Guidelines for Biomedical Research Involving Human Subjects* guidelines. Another important tool is the 2007 UNAIDS/WHO document *Ethical considerations in biomedical HIV preventive trials*, which emphasizes the importance of community involvement. All of these internationally recognized guidelines state the ethical principles that protect the rights of human participants in research. These guidelines do not, however, provide specific guidance on building working relationships between trial sponsors and communities involved with research. The GPP guidelines aim to meet this need. They do not address every potential problem or dictate exactly how communities and researchers should relate. Instead, the guidelines have been developed as a starting point for planning, discussion, and conflict resolution and thus aim to be an important tool for both researchers and communities.

What the GPP Guidelines say

“Great strides have been made in reaching communities affected by biomedical HIV prevention trials with information, discussion fora and skills-building that effectively empower them to work as partners with researchers in critical aspects of trial design and conduct. However, there is no existing, standard and internationally recognized guidance that primarily addresses ‘*Good participatory practice*’ and community engagement in biomedical HIV prevention trials.”(GPP page 9)

“Questions and concerns arise about how to protect the rights of trial participants and their surrounding communities in light of the tremendous differences in power, wealth, education and literacy which often exist between individuals proposing to conduct research and those who are hardest hit by the HIV epidemic. Such concerns in placebo-controlled and other randomised controlled trials play out under the close scrutiny of ethicists, advocates, and activists. Planned trials may be cancelled while trials underway may be closed prematurely when it is perceived that affected communities have not been adequately involved in trial design and conduct.” (GPP page 10)

Discussion tools

- Are you familiar with ethical guidance documents such as the Declaration of Helsinki? What other ethical guidelines have you heard about?
- Why might there be a need for the GPP guidelines?

GPP GUIDELINES: CORE PRINCIPLES

Summary

The *Core Principles* section outlines ten fundamental principles that form the basis for all of the recommendations throughout the GPP guidelines. These principles are the foundation for designing specific activities and approaches. Each principle and its full description are reprinted below.

What the GPP Guidelines say

“Ten fundamental principles for Good Participatory Practice underpin this guidance for researchers, trial sponsors, and research site staff on how to work toward achieving adequate standards of community engagement, participation and input throughout the life-cycle of a biomedical HIV prevention trial. These core principles, referenced throughout the document, form a foundation for evaluating existing community engagement efforts and creating new approaches.” (GPP page 13)

1. Scientific and ethical integrity
2. Respect
3. Clarity in roles and responsibilities
4. Towards shared responsibility
5. Participatory management
6. Autonomy
7. More transparency
8. Standard of prevention
9. Access to care
10. Building research literacy

1. Scientific and ethical integrity

“Maintaining the highest standards of scientific and ethical integrity, including adherence to the universal ethical principles of respect for persons, beneficence and justice, is fundamental to achieve the scientific goals of a biomedical HIV prevention trial, maximise the benefits for the trial community, and advance science in the interests of global HIV prevention.” (GPP page 13)

2. Respect

“Mutual respect among all stakeholders is key to effectively communicating, fostering trust, and developing partnerships to achieve mutual goals. Respect for communities includes respect for communal values; protecting and empowering social institutions; and, where applicable, abiding by the decisions of legitimate communal authority. Respect for research includes respect for the scientific method and for the importance of maintaining scientific and ethical integrity in order to achieve valid trial results.” (GPP page 14)

3. Clarity in roles and responsibilities

“Articulating expectations and negotiating to achieve a clear understanding of the diverse roles and responsibilities of all biomedical HIV prevention trial stakeholders is the first step in creating an effective framework for community engagement.” (GPP page 14)

4. Towards shared responsibility

“Researchers, trial funders, research site staff, local authorities (including health authorities), and the community of people affected by a trial (including trial participants, family members, community leaders, and related advocacy groups) should work jointly to develop and conduct ethical biomedical HIV prevention trials whose goals, risks, and benefits are clearly understood and supported by all stakeholders. Shared responsibility commits all stakeholders to work in partnership...from initial outreach to dissemination of research results.” (GPP page 14)

5. Participatory management

“Communities of people affected by research should play an active, informed role, working throughout trial conduct with site research staff and the principal investigator who is responsible for all aspects of a trial, including efforts to enhance community participation. Acknowledging structural power imbalances and striving to overcome these is an overarching concern for all parties.” (GPP page 15)

6. Autonomy

“The principle of autonomy highlights the importance of the independence of established community advisory mechanisms. Researchers and trial site staff must pay close attention to possible conflicts of interest that may inhibit collective critical input of participating community members and strive to create conditions to minimise these.” (GPP page 15)

7. More transparency

“Open and honest communication is fundamental to Good Participatory Practices. The principal investigator and research staff should provide clear, comprehensible, and timely access to trial-related information for communities affected by research. Protocols, communications plans, community education materials, and deliberations related to a trial that are public knowledge should be made readily available for community partners in appropriate formats, summarized and translated when appropriate.” (GPP page 15)

8. Standard of prevention

“Researchers, research site staff, and trial sponsors have an ethical responsibility to ensure that appropriate risk-reduction counselling and access to proven HIV prevention methods are provided to all biomedical HIV prevention trial participants throughout the duration of the trial as an integral component of the research protocol.” (GPP page 16)

9. Access to care

“This principle reinforces core tenets of the Declaration of Helsinki and CIOMS guidelines stating that trial participants have the right to access medical care for trial-related injuries and harm, and to the experimental product under investigation should it prove effective. In the specific context of biomedical

HIV prevention trials, participants who acquire HIV infection during the conduct of the trial have the right to access a comprehensive package of care, including eventual antiretroviral treatment, which is negotiated before trial conduct and defined in terms of components and timeframe.” (GPP page 16)

10. Building research literacy

“Researchers, trial sponsors, research site staff, and community representatives have a responsibility to contribute to strengthening community research literacy, not only in the interest of improved study conduct but as a broader contribution to development.” (GPP page 16)

Discussion tools

The core principles are one way to give researchers and communities a common language for discussing activities related to research. But the reality of research that takes place in resource poor and/or marginalized communities is that inequalities in power, resources and education can make it hard to realize principles like “shared responsibility” or “participatory management.” These principles are fundamental, but they are also aspirational. This means that they represent goals to strive for, but which may not be fully attained in every setting, every time. Many community groups that reviewed the GPP guidelines suggested that recognizing the fundamental inequalities and power imbalances surrounding many research projects is a critical first step.

Communities looking at the GPP Guidelines might want to discuss:

- What relationship is there between each guiding principle and what happens in practice?
- How can these core principles frame and guide concrete practices and policies that are implemented in trials?
- Which of these core guiding principles do you think are most important? Why?
- What are the guiding principles you think may be most difficult to achieve in practice? Why? What could be done to make these more achievable?

Respect: This principle speaks to the fundamental need for all stakeholders involved in research to speak and act in ways that value and honour each other’s perspectives and realities. Respect can mean different things in different cultures and contexts. How can communities and research teams develop common definitions of respect? What are concrete ways to develop and build this genuine respect between parties? Where there are power imbalances or inequities that may fuel conflict, what are concrete ways that parties in research can express respect for one another?

Towards shared responsibility: This principle suggests that communities and researchers should be jointly invested in and accountable for the conduct of a research study. What are some of the ways that a community can and should be responsible for the research process? What are some of the challenges to truly “sharing” responsibility for a clinical trial? How might the sharing of responsibility vary at different stages of a clinical trial, and what might be learned from this? How can researchers be held accountable for sharing responsibility?

Participatory management: This principle suggests that communities be actively involved in trial-related decisions throughout the duration of the study—including helping to make decisions and guide actions

and responses to unanticipated situations. What would you or your community group require to equitably fill this role? What are the barriers to joint management? What are the ways that this principle could be used to guide activities that address inequalities in your community?

Autonomy: Definitions of the word autonomy include “independence,” “self-sufficiency,” or “self-rule.” The goal at the heart of this principle is that community bodies and individuals are assured an independent voice in the research process—and that this voice is heard and respected by clinical trial teams. In resource-poor settings, clinical trial teams may establish and support a variety of community advisory mechanisms. These are essential and valuable. Community advisory mechanisms supported by the clinical trial team may naturally be allied with the site and its project. There is nothing wrong with this. However, it is also important for communities where research takes place to have channels for expressing their views that are independent of the trial-supported mechanisms. The principle of autonomy stresses that community groups including CABs, participants, and other key stakeholder groups have the right to formulate their views, and that site teams have the responsibility to engage with these groups, even if they are not officially linked to the trial. Given that many sites provide important support to community advisory mechanisms, including education and transport allowances, how can autonomy be ensured? What other mechanisms can be used to give communities an independent voice? What mechanisms can be used to help ensure that research implementers working with marginalized populations respect and act on suggestions from community members—particularly those whose views may be different from those expressed by CAB or community advisory mechanisms members?

More transparency: This principle stresses the need for open and timely communication among the trial sponsors, trial site staff, and communities. What does “timely communication” mean in this context? Can timely communication mean different things for communities, researchers, and sponsors? If so, how? Are there dangers or other challenges to transparency? If so, what might these be and how might they be addressed? What are some of the critical pieces of information communities need to know? What are strategies for dealing with local conditions—distance, lack of telephone or electricity—that make it difficult to communicate? How should the principle of transparency be balanced against that of the need to keep sensitive trial information confidential?

Standard of prevention: This principle explains that research trials must ensure access to a high quality package of prevention services. In trials designed to reduce the risk of sexual transmission of HIV, this includes HIV testing and risk reduction counselling, provision of male and female condoms, and screening and treatment for sexually transmitted infections (STIs). What activities can help ensure that trial sites and communities have a shared definition of the standard of prevention?

Access to care: This principle underscores the guidance from the Declaration of Helsinki and other ethical guidance documents that participants have the right to access medical care for trial-related injuries. It also stresses that, for HIV prevention trials, the standard of care for HIV treatment, including eventual antiretroviral treatment in participants who seroconvert, has to be discussed and fully endorsed by communities before the trial starts. What are some of the needs and priorities in your community? What are concerns with trial-related access to care?

Building research literacy: This principle describes the need for trial sponsors to invest in and provide overall education and outreach that builds community-wide understanding of how research happens outside the context of a specific trial. What kinds of activities would be most useful to make this principle a reality in your community? What are the challenges or barriers to making this principle a reality in your community?

GPP GUIDELINES PART I: ESSENTIAL ISSUES AND ACTIVITIES

Summary

The *Essential Issues and Activities* section describes the *minimum activities* that trial sponsors should undertake related to community participation in some of the most important aspects of any trial. These include discussions such as how informed consent will be obtained and evaluated over time, standards of prevention and care for trial participants and their communities, community advisory mechanisms, communications plans, and other activities. This section has lists of the “minimum elements of good practice” for several of these essential components. These lists of minimum elements can be excerpted from the text and used to guide focused community discussions on various topics.

What makes an activity essential?

Two main parts of the GPP guidelines are *Essential Issues and Activities* and *The Research Life Cycle* (see the section that begins on page 26). All of the content is important, and there are overlapping areas in both sections. An essential activity is, in general, one that has to be addressed before a trial even starts and which is frequently revisited throughout the research process. It is also an activity where community input and understanding are essential. For example, while a trial site may make a decision about what kind of HIV test kit to order without consulting community organizations, it should not make a decision about how to deliver key trial-related messages without talking to communities about how these messages are likely to be heard and understood. Developing a communications plan is one of the essential activities discussed in this section. Other areas where community input is essential include informed consent, formative research (to learn about and better define the community prior to launching a trial), standards of prevention and care, communications strategies, and outreach plans.

Formative research

Summary

Formative research is the term used for the work that clinical trial teams do with communities to form definitions of and gather key information about the communities where research is planned—who is included, local geography, key opinion leaders, etc. During this period of information gathering, community members can share their priorities and concerns to the trial team. The GPP guidelines identify some specific elements of good practice at this stage.

From the GPP guidelines: key steps for clinical trial teams

- A plan that says how the formative research will be done and provides a list of local groups that will be partners in the work.
- Funding and staff time for the work.
- A report on the results that describes questions, issues, concerns, and next steps.
- Meetings with local partners to discuss the results.

To read the specific language of the GPP guidelines see GPP page 20

Discussion tools

- Make a list of the best ways that researchers can work with and learn from communities before a research study starts. Make a list of the steps that should be taken to make sure that communities are involved in the planning of a trial. Do the GPP guidelines encourage researchers to take all these steps? What's missing? If researchers follow the GPP guidelines, will that be enough for problems and controversies between communities and research sites to be minimized or avoided altogether?
- How would you define your community? Would your neighbor or a member of your mosque or church define it the same way? What types of groups exist in your area? How many communities do you belong to?
- What if researchers do their best to work with the “community,” but other members of the “community” don't feel they have been included in the discussions? What can be done to avoid this? Do the GPP guidelines adequately address this issue?
- If the relevant community is a population that may be marginalized or criminalized, such as sex workers, drug users, men who have sex with men (MSM), or transgender people, how can true participation be ensured when more typical forms of inclusion may put those community members at risk? An additional challenge is that other community members, trial site staff, CAB or IRB members may hold negative feelings about these groups. Do the GPP guidelines adequately address this issue?
- Can you suggest other ideas that should be included in this section of the GPP guidelines?

Protocol development

Summary

The protocol is a comprehensive document describing what the trial will do and how it will do it. A protocol may go through a number of revisions before it is finalized and approved. The GPP guidelines discuss the timing of community input into protocol development, and identify some important activities that can be helpful in the process.

From the GPP guidelines: key steps for clinical trial teams

- Communicate to communities the timeline of protocol development and the parts of the protocol the community can comment on and when.
- Provide a simple summary and translation, if needed, of the protocol for community advisory boards (CABs) or community advisory mechanisms.
- Allow opportunities for community advisory mechanisms to comment on aspects of the trial.
- Consider creating other community advisory mechanisms if there is not already a community advisory board.
- Include a way or plan for communities and trial sites to resolve disagreements.

To read the specific language of the GPP guidelines see GPP page 23

Discussion tools

- A protocol involves the whole range of activities included in a clinical trial—from the laboratory tests that are conducted, to the informed consent process, to the number of study visits, and an array of other information. The protocol can be lengthy and technical, and yet it also contains essential details of what the trial will involve and how will it be run. What are some of the key areas of a protocol that might be most critical for communities to review?
- What are some of the challenges communities and researchers might face when working together on research protocols? If the research is taking place in a location where there is low literacy, what suggestions do you have for how researchers and communities can work together?
- Make a list of ways that researchers and community members could work together to review and understand a proposed protocol. As the GPP guidelines explain, there are some instances where the communities will have the chance to review the protocol before it is approved by regulatory bodies. In other cases, communities may be asked to comment on an approved protocol. What are the important steps that should happen in either, or both, of these scenarios? Compare your list to the GPP guidelines. Are there parts of your list that are not covered in the GPP guidelines?
- Can you suggest other ideas that should be included in this section of the GPP guidelines?

Institutional review boards (IRBs), ethics committees, and other regulatory mechanisms

Summary

Every trial protocol is reviewed by a range of independent committees that regulate clinical trials research. These regulatory bodies are intended to help ensure that trials are scientifically well-designed and ethical, and that participants' rights are fully protected. Examples of bodies that review, evaluate, and decide whether to approve biomedical HIV prevention trial protocols are institutional review boards, ethics committees, drug regulatory agencies, and national research regulatory bodies. The GPP guidelines stress that these approval processes should be transparent to community representatives and describe ways for this to happen.

From the GPP guidelines: key steps for clinical trial teams

- Inform community partners about the various committees that must approve the study.
- Let community partners know how the committees are set up and how they work.
- Tell community partners about the decisions the review committees have made and concerns that were raised.

To read the specific language of the GPP guidelines see GPP page 24

Discussion tools

- Are you familiar with the different kinds of review committees in place for approving research in your community? Where do they sit? Do you know anyone who is a non-scientist or a community representative sitting on such a committee? Would it be helpful for you to have more information about how these committees work? Make a list of suggestions for how researchers can explain this information to community members.
- Would you or someone you know like to participate in a review committee? What would the process be of joining, for example, an ethics committee?
- What might deter researchers from following suggestions about sharing results from review committees with communities? What recommendations do you have for encouraging researchers to share such results?
- Are there scenarios you can think of in which community members are supportive of the research, but review boards are not? Are there scenarios in which review boards are supportive of the research but communities may not be? How might these differences be resolved?
- What mechanisms can be put in place to help ensure that decisions of review committee members are not inappropriately influenced by their personal views of marginalized populations?
- Can you suggest other ideas that should be included in this section of the GPP guidelines?

Informed consent

Summary

Informed consent is the process through which an individual agrees to participate in a clinical trial. It is a voluntary agreement that the participant makes after a full explanation of the trial question, the risks and benefits of participation, and other aspects of the trial. The elements of informed consent are reviewed throughout the trial, and participants are free to leave the trial at any time. The GPP guidelines lay out some of the critical elements of informed consent that community members should help to shape, evaluate, and monitor.

From the GPP guidelines: key steps for clinical trial teams

- Site staff should spend time with community partners to clearly explain both the research process and the informed consent process.
- Site staff should discuss the content of the informed consent forms in detail with community partners.
- Site staff should document discussions with the community representatives regarding recommendations, actions taken, and any issues where there is disagreement.
- Site staff should ensure plans and funds exist to review trial participants' understanding of the study and their rights over time.
- Site staff should report results of these reviews with community partners and advisors.

To read the specific language of the GPP guidelines see GPP page 24

Discussion tools

- Developing an informed consent process can be one of the most challenging aspects of research. Make a list of ways that researchers and community members can work together to create an informed consent process that meets the needs of researchers in terms of assuring and documenting that participants understand the trial requirements and their rights, and that also incorporates community views and expertise on this essential issue. Do the GPP guidelines offer enough guidance to help communities and researchers address these issues?
- How can communities and research staff work together to develop informed consent forms when community members may have low levels of education and limited time?
- What is the best way to manage obtaining an individual's informed consent when in many communities, a woman, for example, may not have full ability to agree to a study without permission from other members of her family or community?
- How can study staff work to ensure that participants truly and fully understand the informed consent forms and their participation in the study?

- What are strategies to help minimize the degree to which people choose to participate in trials—in spite of concerns they might have about the study—in order to access study benefits like financial compensation or improved health care?
- Can you suggest other ideas that should be included in this section of the GPP guidelines?

Standard of prevention and access to care

Summary

Standard of prevention refers to the package of services and interventions that a volunteer in a biomedical HIV prevention trial receives. For trials that aim to prevent sexual transmission of HIV, this includes provision of condoms, treatment for sexually transmitted infections, and risk reduction counselling, among other strategies. Trials involving injection drug users should offer clean syringes and harm reduction strategies. Level of care refers to the health care participants receive, including the treatment that is available to them should they acquire HIV during the study. The GPP guidelines review the minimum elements of prevention and care packages for HIV prevention trials and discuss the key areas where community input is essential.

From the GPP guidelines: key steps for clinical trial teams

- Trial sites should build capacity of community members to understand HIV prevention research, how it works, and key issues of trial study design.
- Before the trial begins, trial sites should hold discussions with community representatives and stakeholders about the kinds of services that are available in the local setting as well as what expectations the community representatives have about the type of care and services the trial should offer.
- Site staff should document these discussions with the community representatives, including recommendations, actions taken, and any issues where there is disagreement.
- Site staff should assess how well other organizations and services in the community can help with providing prevention and care services to trial participants.
- Plans should be written and funded to build capacity of local services, where needed.
- Sites should have a plan for how to collect information about how trial participants were able to access various services and what problems or barriers they may have encountered.
- Information about the ways in which participants had access to prevention and care services should be included in the results of the study that is shared with the community.

To read the specific language of the GPP guidelines see GPP page 28

Discussion tools

- As more research is conducted, new discoveries are being made about ways to prevent HIV infection. In the future, research may indicate that microbicides, a vaccine, pre-exposure prophylaxis (PrEP), or other strategies might be effective in preventing HIV infection. Recent clinical trials have shown that medical male circumcision reduces the risk of men becoming infected with HIV. Given that research results about effective HIV prevention strategies are changing quickly, how should researchers and communities manage issues around standards of prevention when planning trials? How should the latest discoveries be incorporated into the prevention package for trial participants?
- Now that antiretroviral medications (ARVs) are increasingly available, there is no longer an ethical debate about whether trial sites should provide ARVs to participants who become HIV-positive

during the study. Guidance documents such as UNAID's *Ethical Considerations in Biomedical HIV Prevention Trials* make clear that trial sites are responsible for providing access to HIV treatment for such participants. The current challenge is how to implement these policies. For example, trials will often end years before participants will need such medications. What kind of local, regional, and national mechanisms could be developed to ensure ARV access to trial participants years after the end of the trial? Can you think of other challenges to providing ARV access to trial participants? Make a list of commitments and strategies would you like trial sites to put in place to ensure ARV access for HIV-positive trial participants? Do the GPP guidelines provide guidance that will be helpful to communities and researchers in addressing these issues?

- Can you suggest other ideas that should be included in this section of the GPP guidelines?

Policy on coverage for research-related harm

Summary

Every trial must have specific plans for how volunteers will be treated for injuries or illness that are caused by participation in the trial. These policies must be expressed in simple, comprehensible language. The GPP guidelines specify the need for community involvement in these policies.

To read the specific language of the GPP guidelines see GPP page 31

Discussion tools

- What are the possible physical harms or negative effects someone might experience by participating in an HIV prevention trial?
- What do you think should be included in a policy about research-related harm? Make a list of those items. Compare your list to that section in the GPP guidelines. Do the GPP guidelines address the content of your list?
- In addition to injuries or illness that might be caused by participation in a trial, HIV prevention trials can also be challenging because of possible social harms. The term “social harm” refers to any problem that trial participants might encounter because they are participating in the trial, but not because of the study product (vaccine, drug, etc.) that is being studied. For example, some trial participants might face stigma or discrimination because people in their community may assume that trial participants are HIV-positive. Women participants may be exposed to domestic violence if their partners do not approve of their participation in the study.

What should a policy on social harms include? What recommendations do you have for communities and researchers to work together to help prevent such events? What recommendations do you have for communities and researchers to work together to design a policy on how to manage these problems if they happen?

- Can you suggest other ideas that should be included in this section of the GPP guidelines?

Community engagement/involvement/education plan

Summary

Community outreach and education is a critical component of the clinical trial process. Educating communities about the purpose and goals of the trial is an important first step and should happen before the recruitment and screening process begins. The GPP guidelines describe the core elements of planning, budgeting, and implementing community engagement, and provide a roadmap for both communities and trial teams to evaluate and adjust outreach and education activities.

From the GPP guidelines: key steps for clinical trial teams

- There should be at least one staff member on the research team who is responsible for leading community activities.
- Funds must be available to conduct activities in the community engagement/education plan.
- Key community partners should help in creating the outreach and education plan, including ideas about what the messages will be and how they will be shared with the community.
- Both the CAB chairperson and principal investigator of the study should sign the community education plan to show they are in agreement.
- If there are other ways, not directly related to the implementation of the specific trial, that sites can help build research literacy within community, they should offer their help.
- The community engagement/education plan should cover the entire period of the trial and should be reviewed periodically by study participants and study staff.

To read the specific language of the GPP guidelines see GPP page 31

Discussion tools

- What activities do you think a research team should include in its community education plan before the trial? While it is going on? After it is completed? Make a brief list. Who should be involved? What are some of the ways that community education should take place—meetings, radio messages, etc.? Look at the GPP document—does it guide research teams to take most or all of these activities?
- Can you suggest other ideas that should be included in this section of the GPP guidelines?

Communications plan

Summary

A communications plan identifies the strategies that will be used for providing information to different stakeholders involved in a biomedical HIV prevention trial. The GPP guidelines identify key topics that this plan should address, from early phases of outreach, recruitment, and enrolment to trial closure and dissemination of results.

From the GPP guidelines: key steps for clinical trial teams

- Trial sites should write a communications plan with input from community partners. The plan should outline how communications about the trial will take place among the trial site staff and other stakeholders such as participants, the public, and the media.
- Trial sites should have at least one staff member who will be responsible for carrying out the plan.
- Trial sites should have a way of evaluating how well the plan is being implemented well and whether it addresses all communication needs.

To read the specific language of the GPP guidelines see GPP page 33

Discussion tools

- If there is an important announcement from a trial, what would be the best way to share this news with the trial community? If an announcement comes at an unexpected time and the research team needs to reach trial volunteers quickly, what would be most effective means of doing this in your community? Make a short list for each, then look back at the GPP guidelines. Does it guide researchers to take these steps?
- Can you suggest other ideas that should be included in this section of the GPP guidelines?

Monitoring and issues management plan

Summary

The GPP guidelines discuss the strategies that trial teams should use to monitor community engagement and partnership. The starting point for this work is a plan that identifies how the trial team will evaluate community engagement, and engage with or respond to issues such as rumours, specific concerns, and reactions to other trials.

Discussion tools

- Sometimes rumors or concerns about a research project can circulate in communities, and it is important that research teams are aware of these sooner rather than later. What would be the best way for a research team to stay aware of these concerns in your community? What would you suggest the research team do if it does learn of a rumor?
- Can you suggest other ideas that should be included in this section of the GPP guidelines?

Community advisory mechanisms

Summary

The term “community advisory mechanisms” refers to a range of structures that are used to support dialogue between community members and trial teams before, during, and after a trial is completed. One of the most familiar types of community advisory mechanism is the “CAB” or community advisory board. As the GPP document discusses, CABs are often necessary, but often not sufficient, for gaining community input. The guidelines suggest strategies that trial teams can use to gain input from many community stakeholders and vice versa.

From the GPP guidelines: key steps for clinical trial teams

- Trial sites must either partner with or create a CAB, which has a number of very important characteristics.
- Funds must be available to teach CAB members and maintain their understanding of how HIV prevention research is conducted.
- CABs should have written by-laws or other written guiding documents that help define the roles and responsibilities of the CAB.
- Funds must be available to have regular documented meetings.
- If it is not possible to use a CAB, then investigators should create other community advisory mechanisms such as town hall meetings, door-to-door campaigns, or call-in radio shows.

To read the specific language of the GPP guidelines see GPP page 36

Discussion tools

- In many instances, a new trial site will have to establish its own CAB. In other cases, the new site may work with an existing CAB that was started for another research project. For those sites that are establishing a CAB, this will involve identifying members, training them on biomedical prevention research and the specific project, and introducing them to their roles and responsibilities. What are some of the specific activities that a clinical trial team should undertake as it goes through these initial steps?
- Make a list of CAB roles and responsibilities, and of the roles and responsibilities that a trial site should have towards a CAB. How does your list compare to the suggestions in the GPP guidelines? If investigators follow the GPP guidelines, will it be likely that the CAB will represent the community? Do the guidelines describe steps that will lead the CAB to gain the skills to comment on and inform the research process?
- CABs are generally attached to a specific research study or institution. Would it make sense for CABs to be organized in a different way, such as by topic area like vaccines or microbicides, or by study population such as MSM, adolescents, or sex workers?
- How can the independence of CABs be enhanced and ensured? Who should be responsible for funding research literacy for CABs? How can communication between CABs and the communities that they represent be established and sustained?

- Are CABs always the best way to help researchers engage with the community? What are some of the difficulties in working with CABs?
- What are additional options for community advisory mechanisms? What are the pros and cons of using other community advisory mechanisms versus the pros and cons of using CABs?
- Can you suggest other ideas that should be included in this section of the GPP guidelines?

GPP GUIDELINES PART II: GOOD PARTICIPATORY PRACTICE AND THE RESEARCH LIFE CYCLE

Summary

The *Good Participatory Practice and the Research Life Cycle* section goes through the stages of the clinical research process, from beginning to end. It identifies key elements of good participatory practice at every stage. Key stages include site selection, site development, study initiation, study conduct, and study closure. The roles of different stakeholders should be clearly defined and documented at the beginning and throughout each stage. Important activities include developing plans around communication, community outreach and education, setting up community review mechanisms, building relationships, data analysis, publication, and dissemination of research results. It also includes planning for what happens after the research is finished, including future access to HIV prevention research and services.

What the GPP guidelines say

Site selection: “For the purposes of this guidance document, site selection refers to the earliest stages of identifying a site to conduct clinical research... At the outset of the research process, sites...will not in every instance have the full complement of community advisory mechanisms and processes in place. However, research teams should be able to demonstrate that the basic elements for an effective community programme exist or are being actively developed through participatory processes.” (GPP pages 41-42)

Site development: “Includes critical work on strengthening and deepening the relationship between the site and the surrounding community prior to the launch of the study protocol. Relevant activities include formative research, communications and education plans, and establishment of community advisory mechanisms, all described in Part I.” (GPP page 44)

Study initiation: “This section addresses activities which take place during trial recruitment including the launch of pre-screening, screening, and enrolment—all of which may continue for the first year(s) of the study. By the time these activities are set to begin, partnerships between the site and the communities affected by the research will already be in place, guided by the essential activities described in Part I...” (GPP pages 45-46)

Study conduct: “During this phase of study visits and follow-up of trial participants, mechanisms for ongoing information-sharing, monitoring, evaluation, adjustments and trouble-shooting are essential.” (GPP page 50) “A range of issues not anticipated during preparatory activities may emerge during trial conduct... Communications plans and crisis management tools described in Part I are indispensable for addressing these issues.” (GPP page 52)

Study closure: “Trials run until their scheduled completion dates, may be prolonged or may be stopped early. The latter may be due to findings of clear protective effect, evidence of harm or recognition of

futility (the study will not be able to prove or disprove the trial hypotheses in a reasonable amount of time)... Regardless of the scenario – early closure, scheduled closure, etc. – the following are elements of good practice:

- dissemination of regularly updated trial timelines to key audiences including study participants, community partners and stakeholders;
- creation and documentation of an activity plan, with staffing and budget, for results dissemination in the community;
- Clear communications plans addressing trial participants, communities, and other stakeholders as the trial comes to a close.”(GPP pages 52-53)

Data analysis, validation, dissemination, and publication: “The roles of sponsors, principal investigators, and site level researchers should be clearly defined and documented at the outset of the process. It is important for research staff, trial participants, and community partners to understand their involvement in data analysis, validation, and dissemination of results... Dissemination meetings which present the findings to various stakeholders in country, including trial participants, surrounding communities, medical professionals, policy makers, and others must also be conducted, both as an obligation and as an opportunity to validate the findings and explore their potential implications.” (GPP pages 55-56)

Site maintenance between trials: “Site maintenance between individual trials refers to core activities which continue in between trials... From the perspective of community engagement, it is highly beneficial for the trial site to sustain the relationships that have been developed with community partners and networks during the research process, maintain and support key staff at the trial site, and engage in ongoing activities to develop and expand the local research agenda. This provides a strong base for future activities and may lead to greater efficiency in the launch of future studies.” (GPP page 58)

Future access to HIV prevention technologies: “When a biomedical prevention is being tested, trial sponsors should have a clear strategy... in place for ensuring rapid, affordable, and sustainable access to the intervention for trial participants at a minimum...” (GPP page 59)

Discussion tools

- The GPP guidelines are written with an audience of trial sponsors and staff in mind. The level of language and detail may be more technical than is useful for community readers. The “research lifecycle” section refers to the stages of the research process, which may be unfamiliar to many groups, or may not be the way that the process is described when an actual trial is being conducted. There are a number of ways that community groups and individuals can orient themselves to the process, including background documents and questions posed to site staff, like:
 - When do you plan to start enrolling participants?
 - What are the steps that you have already taken to launch this study?
 - How long will your planned activities (e.g., education and outreach, follow-up) take?

- Are there are certain stages when community input is often left out or forgotten? Does this usually happen at the same stage in different studies, or does it vary? What steps can community groups take to ensure or advocate for communication during the various steps?

FACILITATOR'S GUIDE CASE STUDIES

Case Study 1: Results dissemination in the context of an unexpected trial result

Background

In September 2007, a scheduled data safety monitoring board (DSMB) review of the data from the STEP trial of the Merck AIDS vaccine candidate resulted in the recommendation that immunizations be stopped. During the time between the DSMB recommendation and the public announcement of the decision to stop immunizations, sites implemented various strategies to communicate the results to participants, with every effort made to ensure that participants learned results from the trial site and not from the media. Communication methods were decided locally by each site and included SMS text messages, phone calls, letters, information sessions at the study clinic as participants came in for scheduled study visits, and flyers and signs posted in places the participants frequented, asking them to come in for updates.

Outcomes

- Many participants received the news about the result before the public learned about it from the media. Site staff, CABs, and participants reported generally positive feelings about the effort made by the sites to deliver the initial update and subsequent information.
- Prior to the DSMB meeting, there had been little preparation of a communications strategy for a negative result. Therefore, the strategy was designed after the negative results came out, in reaction to the event.
- Some participants did not learn about the result before the public knew about it
- There were more communications later on (about unblinding, cessation of Phambili—the South African trial of the same vaccine candidate—and around the finding that some participants may have been at increased risk of infection). In some cases, these updates required Ethics Committee approval before they could go to participants, which caused delays in disseminating that information to trial participants. Some sites and participants also reported challenges with waves of updates on various developments, and talked about the need to strike a balance between keeping participants up to date and not overwhelming them with information.

Discussion tools

- Find the section(s) in the GPP guidelines that you think apply most directly to this scenario. Which principles are at work here?
- Make a short list of the lessons learned from this scenario, including both positive and negative outcomes. Do the GPP guidelines contain guidance that if followed by trial sites would ensure similar positive outcomes? Do the GPP guidelines contain guidance that if followed might prevent some of the negative outcomes?
- Are there changes, additions, or clarifications that you would make to the GPP guidelines in order to replicate the strengths and address the lessons suggested by this scenario? If so, what are they?

Case Study 2: Unresolved community concerns during protocol development/pre-study activities

Background

In 2004, a trial of pre-exposure prophylaxis (PrEP) was scheduled to enroll sex workers in Cambodia, a country that did not, at that time, have a national ARV program that made the drugs available. Also of relevance, US restrictions around funding commercial sex workers (CSWs) had recently been put into place, causing US funds for CSWs and their organizations to be pulled from Cambodia. During that time, the trial team undertook a range of outreach activities to explain the protocol and its goals to various groups representing CSWs. Some of the specific concerns raised by these groups included the standard of prevention that would be supplied to volunteers, and the provisions that would be made to ensure access to treatment and care, including ARVs, should participants become HIV-positive during the trial. Some CSW groups did not feel that their concerns were adequately addressed by the trial team. International allies in civil society also joined in voicing key concerns and in raising additional suggestions that the trial was setting out to deliberately encourage participants to take risks and get infected. The concern and controversy increased, with direct action against the industry partner in the trial at the 2004 International AIDS Conference. The Cambodian government ultimately announced that the trial would not take place.

Outcomes

- In-country civil society groups were able to raise concerns about a specific protocol, engage with international partners, and make the relevant issues widely known.
- The research team implemented a pre-determined plan of formative research and community engagement. Although this plan did not lead to a successful trial, it was in place and implemented as a demonstrable attempt at community engagement.
- Heated controversies including strong community concerns can result in trials being shut down.
- Communities and research teams can have very different ideas about whether sufficient community engagement has taken place.
- Language can be a significant barrier to problem solving and conflict resolution. As the concerns moved from Khmer to French to English, for example, the concern about long-term access to treatment for seroconverters became, in many accounts, a demand for health insurance for life.
- There are major challenges to conducting prevention research in countries lacking national AIDS treatment plans and protections for human rights of marginalized groups.

Discussion tools

- Find the section(s) in the GPP guidelines that you think apply most directly to this scenario. Which principles are at work here?
- Make a short list of the lessons learned from this scenario, including both positive and negative outcomes. Do the GPP guidelines contain guidance that if followed by trial sites would ensure similar positive outcomes? Do the GPP guidelines contain guidance that if followed might prevent some of the negative outcomes?
- Are there changes, additions, or clarifications that you would make to the document in order to replicate the strengths and address the lessons suggested by this scenario? If so, what are they?

Case Study 3: Double enrollment in microbicide studies

Background

In 2008, in South Africa, it was discovered that some women had enrolled in two different microbicide studies at the same time. Microbicide studies cannot enroll women into a trial if they are already enrolled in another microbicide trial. When a woman is being screened for possible enrolment in a microbicide trial, she is asked whether she is participating in any other microbicide studies. This is an important question, since microbicides are experimental products and how they interact with other experimental microbicides is not known. Women who enrolled in both microbicide studies concealed their participation in one study from the trial team of the other study. This is of concern for a number of reasons. The use of two different experimental microbicides could raise safety concerns for study participants. If side effects do emerge, the site staff cannot provide the best possible care and follow-up as it could be harder to find the cause of the problem if they do not know that the woman has been exposed to two experimental products. Finally, when women are using two different microbicides at the same time, it is not possible to interpret the data from the trial—whether positive or negative—since the effects of each of the products cannot be analyzed separately. This is also known as undermining the “validity” of the data generated by the trial.

Outcomes

- Once trial sites of the two different studies suspected a problem, they investigated and determined which women had enrolled in both studies.
- Participants who were enrolled in both studies were contacted, counseled about the risks and complications of double enrollment, and were assigned to continue follow-up in a single study.
- The trial sponsors acted immediately to provide clear and accurate information both to the trial participants and to the broader community of microbicide and HIV prevention advocates about what had happened and what steps were taken to address the situation.
- This specific instance of double enrollment has led to a broader discussion of ways for trials to coordinate and design enrollment procedures so that this is less likely to happen in the future.

Discussion tools

- Why do you think women may have wanted to enroll in two microbicide studies at the same time? How could this have been avoided? What issues should communities, trial sites, trial sponsors, and regulatory bodies be examining in this scenario?
- List the sections in the GPP guidelines that you think apply most directly to this scenario.
- Do the GPP guidelines contain guidance that if followed would help prevent a situation like this? Are there changes, additions, or clarifications that you would make to the guidelines in order to address the lessons learned by this scenario? If so, what are they?

We welcome your suggestions and comments on both the *Good Participatory Practice guidelines for biomedical HIV prevention trials* and the companion *Facilitator's Guide to the GPP guidelines*. Please e-mail us at gpp@avac.org.



About AVAC

Founded in 1995, the non-profit AIDS Vaccine Advocacy Coalition (AVAC) seeks to create a favorable policy and social environment for accelerated ethical research and eventual global delivery of AIDS vaccines and other HIV prevention options as part of a comprehensive response to the pandemic.

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