

FACT sheet

Background on The Good Participatory Practice Guidelines

What does Good Participatory Practice mean?

The term Good Participatory Practice (GPP) 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 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, analyze, and report on clinical trials involving human participants. The working group composed 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. The document 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 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; and
- 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; and
- ensuring that the trial design addresses community priorities and concerns.

This document serves as a useful companion piece to the GPP guidelines and this Facilitator’s Guide.