

Ensuring & expanding community participation

An update on the development of Good Participatory Practice guidelines in HIV prevention trials

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Objective

- To establish clear, global standards for community participation and input in HIV prevention trials and to publish guidance on Good Participatory Practice Guidelines for Biomedical HIV Prevention Trials

Process

- Follow-up to recommendations of the 2005 UNAIDS global consultation *Creating Effective Partnerships for HIV Prevention Trials*:
 - An interdisciplinary, international working group was convened.
 - Guidelines were drafted to provide minimum standards, common principles to guide HIV prevention trials, and systematic ways of evaluating engagement of community before, during, and after trials are completed.
 - The draft was systematically reviewed based on input from researchers, trial sponsors, community members, advocates, and the public, through e-mail comments, interviews, and listserve postings for a wide range of stakeholders.

Result

- Outlines ten core principles, describes essential issues and activities and illustrates these throughout the research life-cycle.
- Provides guidance to researchers, funders, and communities on the conduct of prevention trials.
- Defines minimum standards and common principles to enhance existing research programmes and assist in the development of new HIV prevention trials globally.
- Describes systematic ways of evaluating engagement of the community before, during, and after a trial is completed.
- Lays a foundation for locally-driven processes which could address critical questions and issues.

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Good participatory practice guidelines for biomedical HIV prevention trials



Pre-publication









Core Principles

1. Scientific and Ethical Integrity

Maintain the highest standards, including the universal ethical principles of respect for persons, beneficence, and justice.

2. Respect

Respect communal values, communal authority, and social institutions, key to fostering trust in developing partnerships.

3. Clarity in Roles and Responsibilities

Clearly articulate the expectations of all trial stakeholders.

4. Shared Responsibility

Work collaboratively together: researchers, funders, staff, and the community.

5. Participatory Management

Ensure communities continue to play an active role once a trial has started.

Core Principles

6. Autonomy

Establish independence of community advisory mechanisms.

7. Transparency

Provide clear, comprehensible, and accessible trial-related information to communities in a timely manner.

8. Standard of Prevention

Provide risk-reduction counselling and proven HIV prevention methods to trial participants.

9. Access to Care

Uphold trial participants' right to access medical care for trial-related injuries, illness, or harm, and the right to access the experimental product, should it prove effective.

10. Building Research Literacy

Contribute to strengthening community research literacy.

Essential issues and activities

- Formative research with the community
- Protocol development and review
- Institutional review boards, ethics committees, and other regulatory mechanisms
- Informed consent
- Standard of prevention and access to care
- Policy on coverage for research-related harm
- Community engagement/Involvement/Education plan
- Communications plan
- Monitoring and issues management plan
- Community advisory mechanisms

GPP & the research life-cycle

- Site Selection
- Site Development
- Study Initiation
 - Messaging
 - Materials and outreach
 - Monitoring and evaluation of recruitment and enrolment efforts
 - Pre-screening
 - Screening
 - Enrolment
- Study conduct
 - Study visits and follow-up of volunteers
 - Monitoring scientific conduct
 - Responding to emerging issues

GPP & the research life-cycle

- Study closure
 - Scenario: Planned trial closure
 - Scenario: Unexpected trial closure
 - Termination of study participants from the study
- Data analysis, validation, dissemination, and publication
 - Discussion of follow-up research
- Site maintenance between trials
- Future access to HIV prevention technologies
 - Future access policies
 - Access in the interval prior to approval
 - New product interactions

Conclusions and next steps

- Good Participatory Guidelines for Biomedical HIV Prevention Trials
 - provide guidance on the roles and responsibilities of entities funding and conducting trials towards participants and their communities
 - provide a foundation of minimum standards and common principles to enhance existing research programmes and assist in the global design and conduct of new biomedical HIV prevention trials
- Revise the document before final printing and distribution after input from further individual interviews, small focus groups, community-based consultations, and public general comments.
- Please review the document at www.unaids.org/en/GetStarted/Researchers.asp, put the principles into use, and send us your feedback and suggestions for changes to gpp@unaids.org.