

Updated Ethics Guidance for HIV Prevention Research

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HIV Prevention Trials Network



Issues

Much has changed in HIV prevention science since the HIV Prevention Trials Network (HPTN) issued its 2003 Ethics Guidance Document for Research (EGD). Over the ensuing years there have been published results from important trials, challenges with community engagement in pre-exposure prophylaxis studies, increased availability of anti-retroviral treatment, critical attention in the professional literature to related ethical issues, and the promulgation of prominent guidance documents. These changes prompted the HPTN to revise the EGD.

Description

The revision process began with an empirical project which assessed the actual ethical issues encountered in HPTN research as well as a comprehensive literature review. The EGD was then revised to reflect this information and the current HIV prevention landscape. The HPTN Ethics Working Group and other experts met to debate and to revise the document. Subsequent versions of the document were circulated within and beyond the network for feedback and approval.

Lessons Learned

- 15 guidance points span the continuum of research
- Unlike other guidance documents, some of the points are morally required, while others are aspirational, reflecting the realities and constraints inherent to practice
- Each point identifies those accountable for it

Before Research

Guidance point 1: Ensuring high-quality scientific and ethical research

HPTN is committed to developing and maintaining procedures designed to ensure high-quality scientific research and the incorporation of ethical considerations throughout the various stages of HPTN research.

Guidance point 2: Setting research objectives and priorities

Research questions pursued by HPTN should respond to a public health priority in places where the research is being conducted.

Guidance point 3: Engaging communities

In order to ensure that HPTN research is appropriate as well as scientifically and ethically sound, relevant communities will be engaged in a meaningful process that will help guide the research from protocol development to dissemination of results.

Guidance point 4: Building local capacity and partnerships

The conduct of HPTN research should be accompanied, to the greatest extent reasonably possible, with the development of local capacity, such as transferring skills and knowledge and contributing to material infrastructure. Capacity-building efforts should be conducted in close collaboration with local partners.

Guidance point 5: Ethical issues in study design

HPTN investigators will design HIV prevention research capable of answering important research questions or producing valuable information while minimizing risks and maximizing benefits to study participants and their communities.

Guidance point 6: Consent, assent, permission and re-consent

Each HPTN site involved in a research project will develop, document and implement meaningful informed consent and assent processes. These processes should include assessments of the decision-making capacity of potential participants to give consent, comprehension of relevant information, and re-consent of participants when appropriate.

Guidance point 7: Addressing vulnerabilities

HPTN investigators should be aware of the social, cultural and other factors that may place research participants at heightened risk, and develop procedures and safeguards that appropriately monitor, assess and respond to these factors within the context of research.

Guidance point 8: Ethical review of research

HPTN research protocols will be reviewed by independent ethics review boards in the host country. HPTN should encourage capacity-building of host country ethics review where appropriate.

During Research

Guidance point 9: Standard of prevention

In partnership with key stakeholders, HPTN should establish a package of effective, comprehensive and locally sustainable prevention services to be offered to participants in each HPTN study.

Guidance point 10: Standards of care and treatment

In designing the care and treatment package to be provided to study participants, HPTN will meet and strive to exceed local standards of medical services, while taking into account the implications of those standards for research participants, and the potential impact that research-associated care may have on local communities.

Guidance point 11: Independent data safety and monitoring

Particularly in late-stage clinical trials, HPTN should ensure that an independent data monitoring committee is in place in order to help ensure study validity and safety, and assess whether it would be in the interest of study participants to modify or terminate a study. Reliable mechanisms should be established to communicate the results of this independent review to key stakeholders.

After Research

Guidance point 12: Disseminating research results

HPTN will plan for the timely communication and dissemination of HIV prevention research results to participants, local communities and other audiences in a manner that promotes comprehension and trust.

Guidance point 13: Sustaining capacity-building and infrastructure into the future

HPTN will work to increase the likelihood that the investments made in capacity-building and infrastructure will continue to provide benefits and opportunities for local communities after the research is over.

Guidance point 14: Continuing care for research participants

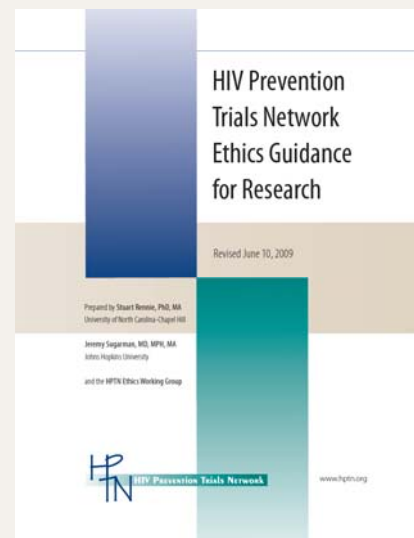
HPTN research projects will seek to ensure continuity of care after the termination of research, where appropriate, for participants who have received (and continue to need) medical care and treatment during their involvement in HPTN research.

Guidance point 15: Provision of successful research interventions

HPTN research seeking to establish the efficacy of an intervention must have a preliminary plan regarding the provision of successful interventions to research participants and communities.

Next Steps

The revised EGD is well-positioned to help address the ethical challenges being faced in HIV prevention research. Energy will now be focused on operationalizing the guidance.



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