

Strengthening Structures for HIV Prevention Research: National Policy Guidelines for Research Oversight and Administration

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“Kenya is responding positively to the epidemic and has heavily invested in HIV prevention and treatment”

-President Mwai Kibaki, 2010

“The current clearance and control mechanism is weak with many loopholes, which have been exploited in the past in this country by people who do not want to do sound scientific and ethically acceptable research.”

-Guidelines for Ethical Conduct of Biomedical Research Involving Human Subjects in Kenya, 2004

Objective

- With HIV prevention research priorities often governed by outdated policy frameworks, this project seeks to create a landscape analysis of the clinical research review process in Kenya – outlining the laws, regulations, and stakeholders governing HIV prevention research and analyzing gaps in this regulatory framework.

Introduction

- Unprecedented HIV prevention research in sub-Saharan Africa has highlighted the need to strengthen longstanding national institutions to oversee and administer research as a means to provide national coordination, secure technical expertise, and enforce ethical conduct.
- With foreign-sponsored prevention research posing novel dilemmas in nurturing sustainable research capacity and enrolling vulnerable at-risk populations, an imperative has arisen to develop national policy frameworks commensurate with these changing clinical research realities.

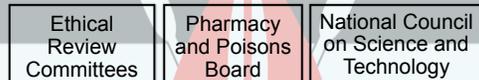
Methods

- The researchers reviewed current structures for approving and conducting HIV prevention research in Kenya.
- Key informant interviews:
 - Identification of stakeholders based upon their documented participation in clinical research.
 - Semi-structured interviews explore:
 - Role of the informant in the research review process;
 - Challenges to conducting research;
 - Gaps in research policy.
- Policy landscape analysis:
 - Narrative description of the research review process examines the role of organizations and regulations governing HIV prevention research.
 - The process of identifying themes highlights ethical considerations relevant to research policy.

Results

- Through landscape analysis of the clinical research review process, this project has examined the role of organizations and pertinent regulations governing HIV prevention research:

- Research approval institutions



- Ethical considerations relevant to prevention research
- Strategies to strengthen research policy
 - Governance Transparency
 - Ethical Review Harmonization
 - Capacity Building
 - Clinical Research Documentation

Conclusions

- Although government ministries set the broad agenda for HIV/AIDS programming, there is lack of documentation and clarity regarding the specific processes of ethical review in Kenya.
- Decentralization of research approval processes leads to ambiguity in the respective roles of various stakeholders and their relationships with each other.

Policy Implications

- To secure the benefits of research while protecting the human rights of research subjects, there is a need to develop clear, simple, and transparent documentation of research oversight.
- This project serves to inform stakeholders of the ways in which the regulation of research approval can be used to frame the review of HIV prevention research:
 - Informing the research approval process;
 - Promoting safeguards for ethical oversight of clinical trials;
 - Supporting sustainable national health research systems;
 - Setting a valuable precedent for future national policy revisions throughout sub-Saharan Africa.



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