Kigali Manifesto on the Inclusion of People Living with HIV in Clinical Research

Preamble

People living with HIV (PLHIV) are living longer lives. With the advent of modern HIV treatment, PLHIV have nearly the same life expectancy as HIV-uninfected persons. Despite these advances, outdated procedural exclusions routinely prohibit PLHIV from participation in clinical research.[1–3] These exclusions are not evidence-based and they undermine the human rights and dignity of PLHIV.[4–5]

Research institutions and regulatory bodies bear a responsibility to ensure that the design and conduct of clinical research is aligned with ethical principles, scientific integrity, and public trust.

This document proposes a best practices framework rooted in human rights and modern science to promote equitable engagement of PLHIV in clinical research. It outlines ten foundational principles designed to guide policy formation, institutional review, and operational standards across the global clinical research enterprise.

Respect the Personhood and Rights of PLHIV and Key Populations

Clinical research must affirm the full personhood and legal rights of PLHIV. Participants must be regarded not as passive subjects, but as individuals with the right to equal treatment under scientific and ethical standards.[4]

Unless a Scientific or Medical Rationale Exists for Exclusion, Research Protocols Should Include PLHIV

Research protocols for non-HIV indications should include PLHIV unless a valid scientific or medical rationale exists for their exclusion. Any exclusion based on HIV status must be accompanied by a specific, scientifically validated rationale.[6] When feasible, protocol inclusion criteria should affirm the participation of PLHIV.

Inclusion of Individuals Using HIV Prevention Therapies

Clinical research must recognize that individuals using HIV prevention therapies, such as pre-exposure prophylaxis (PrEP), are part of real-world populations. Their routine exclusion from research lacks scientific basis and undermines diversity and validity. Unless a compelling and evidence-based reason exists, PrEP use must not be a barrier to participation.

Discontinue Reliance on Template-Based Exclusions

Protocol language and eligibility criteria should not rely on inherited text from legacy studies. Each study must be constructed in reference to current clinical evidence and reviewed for appropriateness on a case-specific basis.

Use Language Grounded in Science and Subject to Ongoing Review

Language in research protocols must reflect current scientific understanding and avoid terminology that reinforces stigma, bias, or outdated assumptions.[7] It should be accurate and inclusive of the populations research intends to serve. To uphold this, protocols must undergo regular review to ensure that eligibility criteria and standard language are aligned with contemporary evidence and community-informed standards. Institutional templates and boilerplate language should not be carried forward unexamined; they must be revised routinely to prevent the perpetuation of exclusionary norms.

Ensure Representation and Accountability

Members of affected communities must be included in protocol development, ethics review, and study oversight to ensure fair representation and strengthen study design. Institutions should also publish exclusion rationales and document community engagement to promote transparency, public trust, and accountability.[8]

Facilitate Equitable Participation Across Therapeutic Areas

PLHIV must be eligible for participation in all therapeutic areas where medical relevance exists. PLHIV's exclusion from non-HIV clinical research represents a failure of equity and reduces the generalizability of findings.

Mandate Professional Education on Inclusive Research Design

Institutions and sponsors must provide mandatory, ongoing training on health equity, eligibility design, and ethical frameworks for inclusive research participation. Training must include guidance on equitable engagement of PLHIV and other key populations, and be built into compliance and oversight mechanisms.

Support Global Harmonization of Participation Standards

International sponsors, agencies, and research institutions should collaborate to develop harmonized standards that ensure consistent application of equitable eligibility and engagement criteria to facilitate inclusion of PLHIV in clinical research.

Procedural Imperative

This framework is offered as a working model for institutions seeking to implement equitable and rigorous standards in the design and conduct of clinical research. It is intended to inform internal governance, external partnerships, and regulatory compliance.

Equity in research is not aspirational. It is operational. Where PLHIV are excluded without clear justification, research findings may lack generalizability and public confidence. The correction of this imbalance is necessary for both scientific excellence and ethical legitimacy.

Footnotes

1. Vora KB, Ricciuti B, Awad MM. Exclusion of patients living with HIV from cancer immune checkpoint inhibitor trials. Sci Rep. 2021 Mar 23;11(1):6637.
2. Venturelli S, Dalla Pria A, Stegmann K, Smith P, Bower M. The exclusion of people living with HIV from clinical trials in lymphoma. Br J Cancer. 2015;113(6):861–3.
3. Singh JA et al. The ethics of exclusion: why pregnant and lactating women must be front and centre of HIV research. J Int AIDS Soc. 2022;25(Suppl 2):e25926.
4. The Denver Principles (1983)
5. Global Consensus Statement on HIV, U=U, and Stigma (2021)
6. U.S. FDA Guidance on Inclusion of HIV-Positive Participants in Clinical Trials (2020)
7. Yogyakarta Principles Plus 10 (2017)
8. Declaration of Amsterdam on Patient and Public Involvement in Research (2016)