

Informed Consent Language and Structural Inequity in African Clinical Trial Governance: A Cross-Sectional Audit

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Methods Note · Volume 2

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Background

Informed consent is intended to protect participants, yet evidence shows persistent comprehension gaps in sub-Saharan Africa, particularly regarding randomization, risks, and distinctions between research and care. Language barriers, complex documentation, and constrained healthcare access may compromise voluntariness. African countries also remain underrepresented in global trials, raising concerns about structural influences on consent

Methods

We analyzed interventional trials registered on ClinicalTrials.gov to April 2026, comparing African countries ($n = 3,515$) with the United States ($n = 159,433$). Shannon entropy assessed distribution across African settings; sponsorship and reporting practices were also examined. Results: The United States registered ~45 times more trials.

Within Africa, trials were highly concentrated. Prior studies indicate limited participant understanding and context-driven enrollment, while researchers report challenges adapting externally designed protocols

Interpretation

Concentration and external funding shape consent processes, often privileging standardized templates over local realities, potentially undermining meaningful consent. Limitations and Conclusions: Registry data limit insight into consent quality. Structural inequities highlight the need for locally grounded, context-sensitive research governance

Interactive dashboard figures

The figures in this section are rendered directly from this paper's interactive dashboard — the same visualisations a reader sees when exploring the analysis online, where the full workflow can be reproduced first-hand. **Interactive dashboard:** <https://mahmood726-cyber.github.io/africa-e156-students/governance-justice/dashboards/informed-consent-language.html>



Figure 1. Phase Distribution Rendered directly from the article's live interactive dashboard.

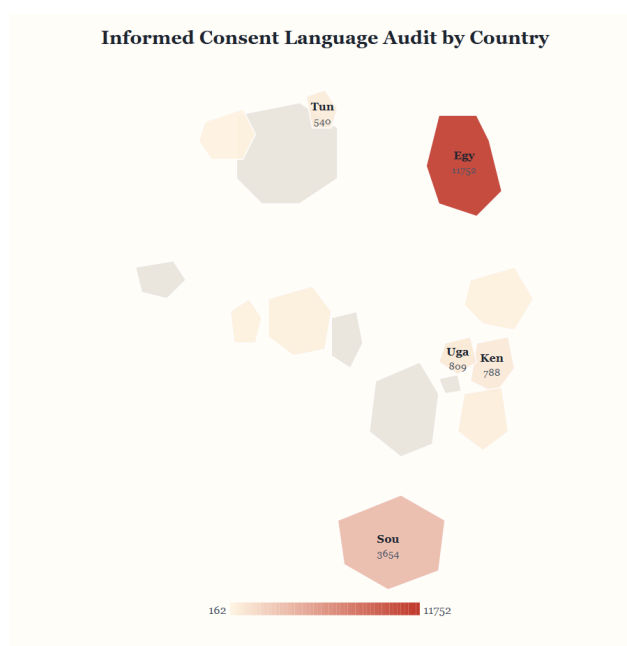


Figure 2. Informed Consent Language Audit by Country Rendered directly from the article's live interactive dashboard.

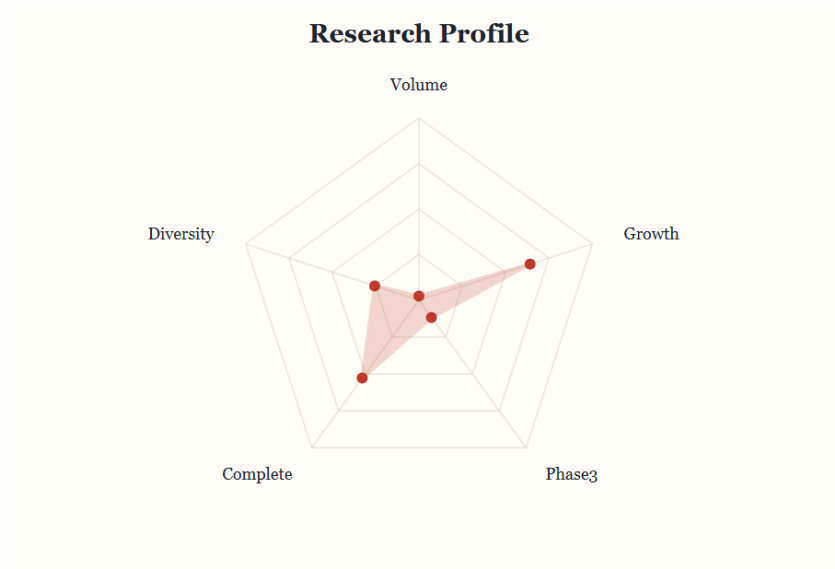


Figure 3. Research Profile Rendered directly from the article's live interactive dashboard.

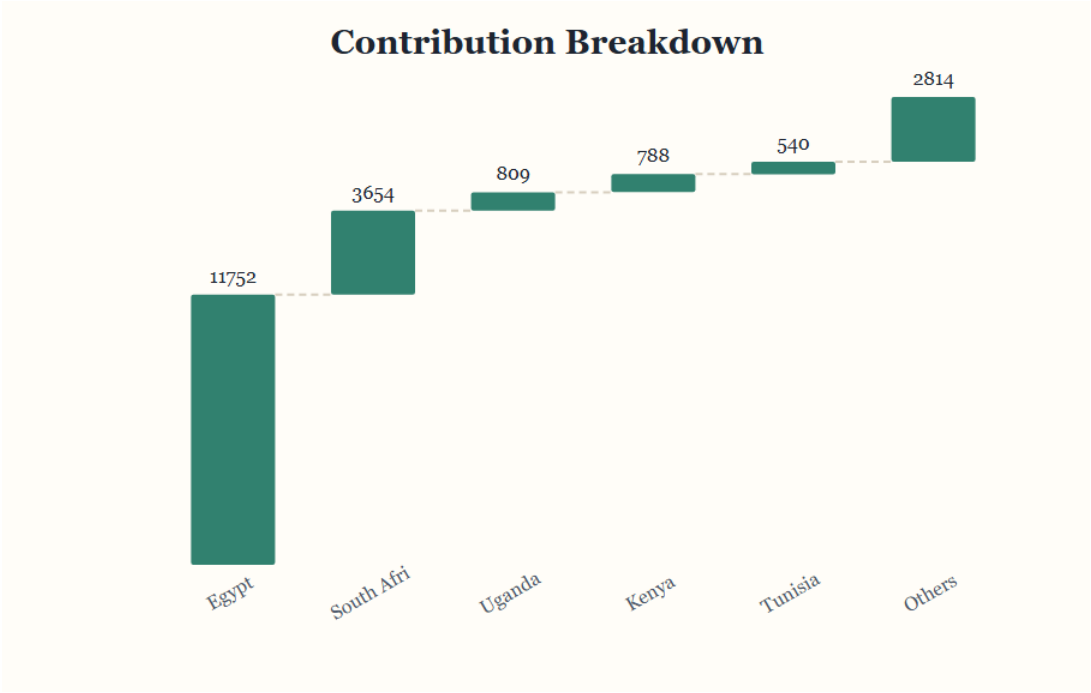


Figure 4. Contribution Breakdown Rendered directly from the article's live interactive dashboard.

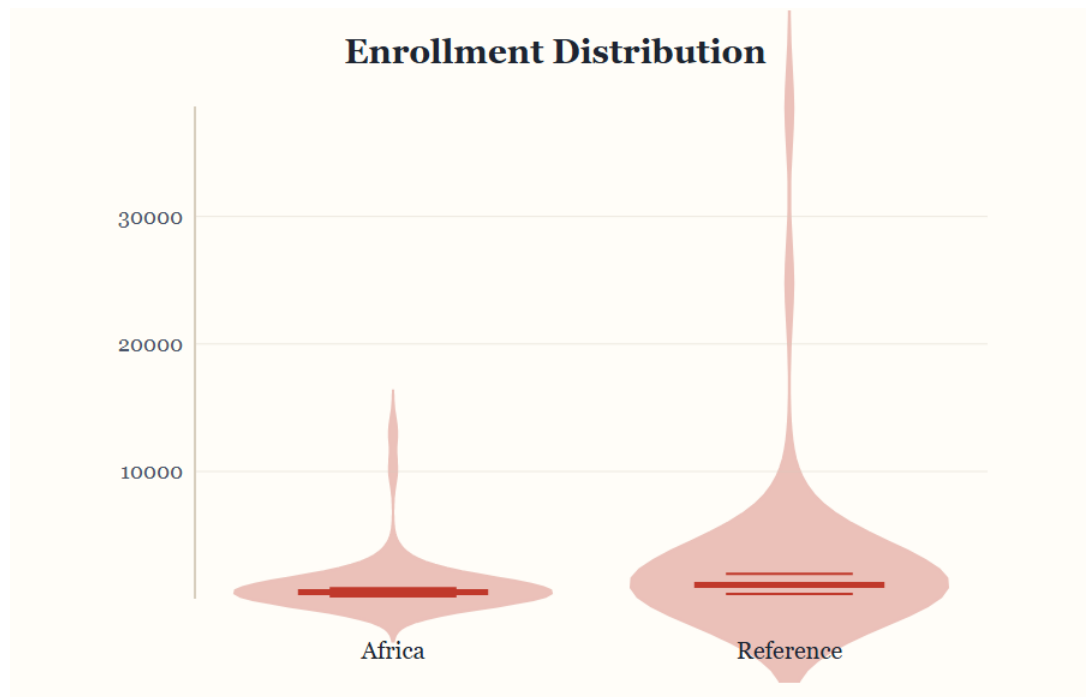


Figure 5. Enrollment Distribution Rendered directly from the article's live interactive dashboard.

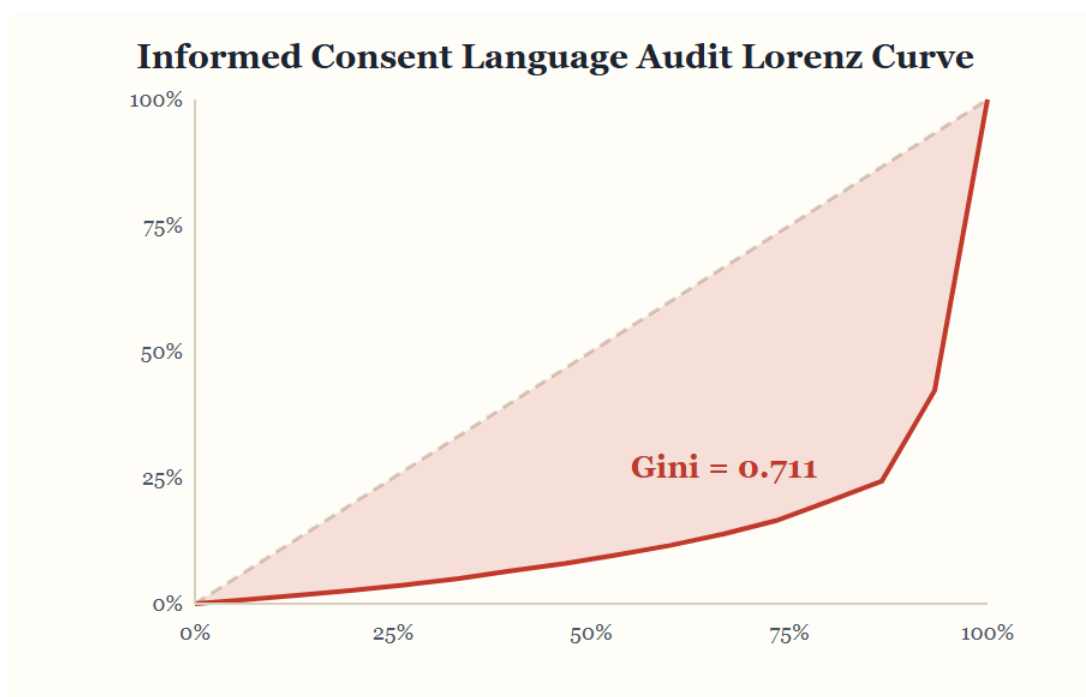


Figure 6. Informed Consent Language Audit Lorenz Curve Rendered directly from the article's live interactive dashboard.

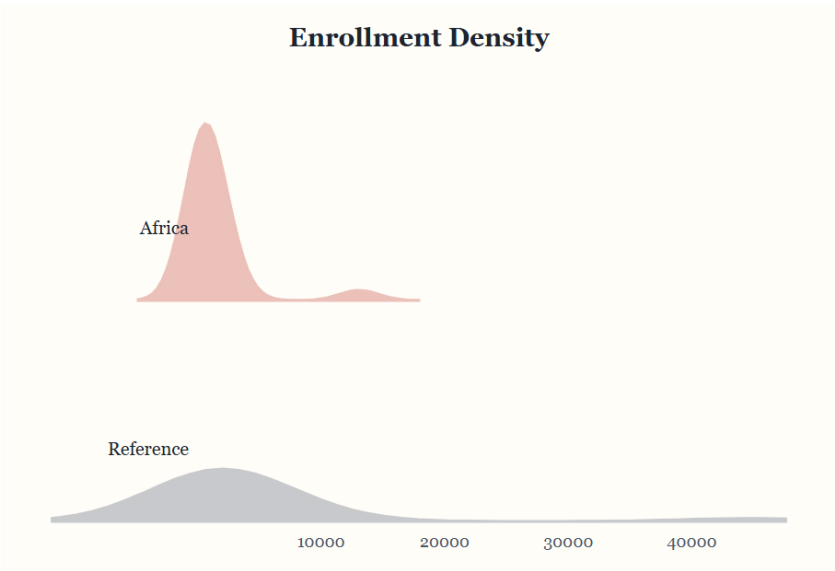


Figure 7. Enrollment Density Rendered directly from the article's live interactive dashboard.

HOW TO CITE

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