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National Commission for Science, Technology and Innovation

ADVISORY TO THE KEMRI SCIENTIFIC AND ETHICS REVIEW UNIT (SERU)

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Subject: Strengthening Ethical and Scientific Oversight to Enhance Kenya's Clinical Trials Ecosystem

The Strengthening Clinical Trials Ecosystem in Kenya policy brief underscores the critical role of the KEMRI Scientific and Ethics Review Unit (SERU) in safeguarding research participants, ensuring scientific validity, and promoting ethical conduct of clinical trials in Kenya. As one of the country's leading ethics review bodies, SERU is strategically positioned to strengthen ethical oversight while supporting efficient and responsive clinical research review processes.

The policy brief notes that increasing complexity in clinical research, including genomics, digital health technologies, artificial intelligence applications, adaptive trial designs, and advanced therapeutics, presents new ethical and scientific review challenges. SERU is therefore advised to strengthen its capacity to evaluate emerging and innovative research methodologies through specialized reviewer training, continuous professional development programmes, and establishment of multidisciplinary expert review panels. Such investments will enhance the quality, consistency, and responsiveness of ethical review processes.

To improve efficiency within the clinical trials ecosystem, SERU should explore mechanisms for greater collaboration and harmonization with the Pharmacy and Poisons Board (PPB), National Commission for Science, Technology and Innovation (NACOSTI), and other accredited ethics review committees. Adoption of reliance models, harmonized review frameworks, common application templates, and coordinated review processes would reduce duplication, shorten approval timelines, and improve consistency in review outcomes, particularly for multicentre and multinational studies.

The policy brief further highlights the importance of adopting risk-proportionate ethics review approaches. SERU should develop clear frameworks for categorizing studies according to risk and implement differentiated review pathways for low-risk, minimal-risk, and high-risk studies. Such an approach would allow the committee to focus resources on studies with greater potential risks to participants while improving overall review efficiency.

Strengthening post-approval oversight should be a strategic priority. While ethics review at the approval stage remains important, participant protection requires continuous monitoring throughout the lifecycle of a study. SERU is advised to enhance post-approval monitoring systems through routine progress report reviews, targeted monitoring visits, review of protocol deviations, oversight of informed consent processes, and follow-up on participant complaints and adverse events. Robust post-approval monitoring will ensure continued compliance with approved protocols and ethical standards.

The policy brief also identifies community trust and public engagement as key determinants of successful clinical research. SERU should strengthen requirements for meaningful community engagement, participant involvement, and stakeholder consultation throughout the research process. Particular emphasis should be placed on culturally appropriate informed consent processes, protection of vulnerable populations, transparency in participant communication, and mechanisms for reporting concerns and grievances.

In recognition of growing international collaborations, SERU is advised to promote ethical standards that support equitable partnerships between Kenyan and international research institutions. Ethics review processes should encourage fair benefit sharing, meaningful involvement of local investigators,

capacity strengthening, technology transfer, responsible data sharing, and access to research benefits for participating communities. Such measures will ensure that international clinical trials contribute to sustainable national research capacity.

The policy brief further recommends strengthening governance of health data and biological samples. Given increasing use of genomic research, biobanking, and cross-border data sharing, SERU should continue to develop guidance on secondary use of samples, broad consent, data protection, data ownership, privacy, and benefit-sharing arrangements in line with national legislation and international ethical best practice.

Key Recommendations for SERU

1. Strengthen reviewer capacity in emerging research areas, including genomics, digital health, artificial intelligence, adaptive trial designs, and advanced therapeutics.
2. Collaborate with NACOSTI, PPB, and accredited ethics committees to establish harmonized and coordinated review mechanisms.
3. Implement risk-based ethics review and oversight frameworks that align review intensity with participant risk levels.
4. Enhance post-approval monitoring through systematic review of progress reports, site monitoring visits, protocol deviation oversight, and participant safety monitoring.
5. Strengthen guidance on informed consent, participant protection, community engagement, and inclusion of vulnerable populations.
6. Promote equitable international research partnerships that support local leadership, technology transfer, and sustainable capacity development.
7. Support digitization of ethics review and post-approval monitoring processes to improve efficiency, transparency, and accountability.

Conclusion

The KEMRI Scientific and Ethics Review Unit remains a cornerstone of Kenya's clinical research governance framework. By strengthening risk-based ethical oversight, enhancing post-approval monitoring, building capacity to review emerging technologies, and promoting harmonization across the research ecosystem, SERU can further improve participant protection, maintain public trust in research, and help position Kenya as a leading destination for ethical, high-quality clinical trials in Africa.