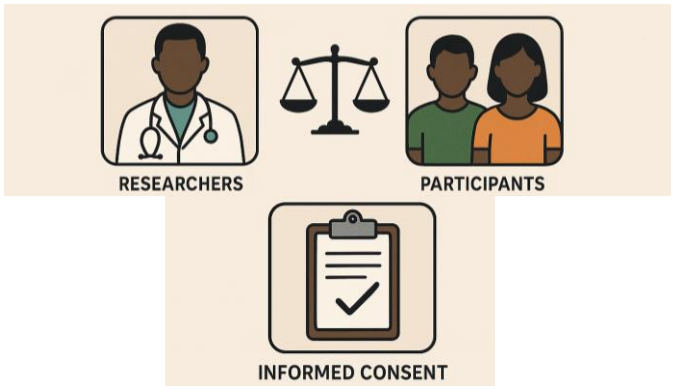
MRCZ ANNUAL

NEWSLETTER

2025

Ethics First: Protecting People, Advancing Health



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NOTE FROM THE EDITOR

Dr. Nyaradzo M. Mgodi - MRCZ Newsletter Editor

As we reflect on the evolving landscape of health research ethics, it is clear that 2025 has been a year of significant transformation. The global discourse on legislative reforms and ethical standards continues to gain momentum, and Zimbabwe is actively engaging in these conversations to ensure our frameworks remain responsive, inclusive, and aligned with international best practices.

This edition of the MRCZ Newsletter brings together critical insights from thought leaders and practitioners who are shaping the future of ethical research in Zimbabwe. The recent revision of the **Declaration of Helsinki (2024)** and the **ICH-GCP E6(R3)** guidelines mark a pivotal shift in how we approach participant protection, community engagement, and scientific integrity. As highlighted by Natasha Tsandukwa Rusike and Anesu Gumbo, these updates emphasise inclusivity, respect, and shared responsibility across the research ecosystem. The move from exclusion to evidence-based inclusion—particularly for historically marginalised groups such as pregnant women—signals a progressive step toward equity in research participation.

Dr E. Shana's comprehensive article on **Informed Consent** reinforces the principle of autonomy and the ethical obligation to ensure participants are fully informed throughout the research process. His emphasis on clarity, voluntariness, and cultural sensitivity is a timely reminder that informed consent is not a formality, but a continuous dialogue rooted in respect and trust.

Equally important is the call for **meaningful community involvement**, as explored in the issue. Community engagement must go beyond tokenism. It should be embedded throughout the research process—from protocol development to post-trial access. This approach not only enhances research relevance and integrity but also fosters mutual understanding and trust between researchers and the communities they serve.

As Zimbabwe continues to review and align its national ethics guidelines with these global standards, the Medical Research Council of Zimbabwe remains committed to promoting ethical excellence, public trust, and participant empowerment. We encourage all stakeholders—researchers, institutions, and community representatives—to actively participate in shaping a research environment that is ethical, inclusive, and impactful.

Let us continue to uphold the values that define responsible research: respect, justice, integrity, and partnership.

FEATURE: BUILDING ETHICAL, INCLUSIVE HEALTH RESEARCH IN ZIMBABWE

BY PROFESSOR TENDAYI A. KUREYA

It is with great pride and a deep sense of responsibility that I present this year's edition of the *Medical Research Council of Zimbabwe (MRCZ) Newsletter*. As the Executive Secretary of MRCZ, I have had the privilege of witnessing firsthand the resilience, innovation, and dedication of our research community, even in the face of significant systemic challenges.
This year marks a turning point in Zimbabwe's health research journey.

The national consultations and the comprehensive baseline assessment conducted under the Trial Regulation and Clinical Ethics Optimisation (TRACE) initiative have laid bare the urgent need for reform. They have also illuminated a path forward, one that is inclusive, forward-looking, and grounded in both global best practices and our national context.

This lead article in this issue, which I have authored, reflects on the key challenges facing researchers in Zimbabwe today and outlines the bold steps being taken to address them through the proposed Health Research Bill. This legislative reform is not merely a bureaucratic exercise; it is a foundational shift toward a more enabling, ethical, and efficient research environment.

(Continued on the next page)

As one participant aptly noted during the consultations, "The current framework does not empower us to act decisively when researchers breach ethical standards. We need a legal backbone that protects participants

and upholds the integrity of our research." This sentiment captures the urgency and importance of the reforms we are undertaking.
I invite all our stakeholders—researchers, policymakers, funders, and community partners—to engage with the insights shared in this edition. Let us continue to work together to build a research ecosystem that not only meets the highest standards of scientific and ethical integrity but also delivers tangible benefits to the people of Zimbabwe.
Together, we can ensure that health research becomes a cornerstone of national development and a beacon of hope for generations to come.

Understanding the need to strengthen health research governance in Zimbabwe

Zimbabwe's health research regulatory framework, established in 1974, is outdated and misaligned with modern scientific, ethical, and governance standards. The TRACE Baseline Assessment (June-August 2025) identified critical gaps: lack of digitalisation, weak coordination, limited ethics capacity, and absence of monitoring and evaluation systems.

Why Reform is Needed

Health research has grown in complexity, encompassing clinical trials, genomics, data science, and traditional medicine. The current framework does not adequately address data protection, biobank regulation, or emerging technologies such as AI.

Key Improvements required

- Establishment of a health research authority in Zimbabwe (HRAZ) for national coordination and oversight.
- Creation of a National Health Research Ethics Committee (NHREC) and accreditation of Institutional Research Ethics Committees (IRECs).
- Digital governance: mandatory e-submission, e-review, and monitoring platforms for ethics and research oversight.
- National Clinical Trials Centre to streamline trial coordination and maintain a public registry.
- Regulation of biological materials, biobanks, and data governance aligned with international standards.
- Dedicated principles on capacity development, monitoring & evaluation, and community engagement with benefit sharing.
- Health Research Fund for sustainable financing, including performance-based grants.
- Emergency research pathways and ethical governance for AI and emerging technologies.

In parallel with legislative reforms, the TRACE Zimbabwe initiative is spearheading the development of a digital ethics review system to streamline clinical trial approvals. The proposed platform, built on Microsoft Azure architecture, will integrate workflows between MRCZ and the Medicines Control Authority of Zimbabwe (MCAZ) to replace fragmented, manual processes. Key features include:

- End-to-end review tracking for clinical trials.
- Reduced reliance on proprietary code and costly external consultants.
- Enhanced transparency through governance and cost-sharing models.

Expected Impact

The revised Health Research Bill, when enacted into law, will modernise Zimbabwe's health research ecosystem, enhance ethical oversight, promote transparency, and align with WHO and AU standards. These reforms will strengthen public trust, attract investment, and accelerate innovation for better health outcomes. Stakeholder engagement will continue to ensure alignment with global best practices and Zimbabwe's national priorities. To sum it all up, modernising our systems and legal frameworks is not just a compliance issue—it's about enabling ethical, efficient, and innovative research that benefits our communities.

Looking Ahead: Shaping the Future of Ethical Health Research in Zimbabwe

As we turn the page to 2026, MRCZ stands at a defining moment in its journey to strengthen the nation's health research ecosystem. The progress made in 2025—through legislative consultations, digital transformation initiatives, and renewed emphasis on inclusivity—has laid a solid foundation. Now, our focus shifts to implementation and impact. Our Strategic Priorities for 2026 include:

- Legislative Reform: Finalise and operationalise the Health Research Bill, establishing the Health Research Authority of Zimbabwe (HRAZ) and embedding principles of accountability, transparency, and innovation.
- Digital Transformation: Roll out the TRACE-powered ethics review platform to streamline submissions, reduce delays, and enhance oversight through integrated, secure digital systems.
- Capacity Building: Strengthen Institutional Review Boards (IRBs) nationwide through training, accreditation, and harmonisation with global best practices.

- Community Partnership: Deepen engagement with communities to ensure research reflects local priorities, respects cultural contexts, and delivers equitable benefits.
- Ethics in Emerging Technologies: Develop guidance for responsible use of AI, genomics, and biobanking, safeguarding participant rights while enabling scientific progress.
- Sustainable Financing: Expand partnerships and secure funding streams to support ethical oversight, research innovation, and capacity development.

Our Vision for 2026 and Beyond We envision a research environment where ethics and excellence go hand in hand—where Zimbabwe is recognised regionally and globally as a leader in responsible, inclusive, and innovative health research. This is not just about compliance; it is about building trust, fostering collaboration, and ensuring that every study conducted under our watch contributes meaningfully to the health and well-being of our people.
Together, with our stakeholders—researchers, policymakers, funders, and communities—we will continue to uphold the values that define ethical research: respect, justice, integrity, and partnership. The future of health research in Zimbabwe is bright, and 2026 will be the year we turn vision into reality.

CHARTING A NEW COURSE FOR HEALTH RESEARCH IN ZIMBABWE

By Professor Charles Nhachi, Chairman of the Board, Medical Research Council of Zimbabwe (MRCZ)

As we reflect on the past year, Zimbabwe stands at a pivotal moment in the evolution of its health research landscape. The Medical Research Council of Zimbabwe (MRCZ), established in 1974 under Government Notice 225 of that year, has served the nation with distinction. However, the world of health research has changed dramatically over the past five decades. The emergence of complex health challenges—ranging from HIV and TB to COVID-19 and non-communicable diseases—has underscored the urgent need for a modern, responsive, and ethically grounded research governance framework.

In 2025, the MRCZ, in collaboration with the Ministry of Health and Child Care, initiated a comprehensive reform process to develop a new Health Research Bill. This process was informed by a rigorous baseline assessment and enriched by robust national consultations held in Harare and Bulawayo. The consultations brought together researchers, academics, legal experts, and institutional representatives to deliberate on the future of health research regulation in Zimbabwe.
What emerged from these engagements was a clear consensus: the current legislative framework is no longer fit for purpose. Researchers face a host of challenges that hinder innovation, delay ethical approvals, and limit the country's ability to attract and manage high-quality research.

Among the most pressing issues raised were:

- Outdated Legislation: The existing legal framework does not reflect the realities of modern research, including digital health, genomics, artificial intelligence, and biobanking.
- Fragmented Oversight: The lack of coordination between institutional and national ethics committees has led to duplication, inefficiencies, and delays in protocol reviews.
- Limited Enforcement Powers: The absence of legal provisions to address researcher misconduct—such as conducting studies without approval or failing to obtain informed consent—has weakened accountability.
- Inadequate Support for Innovation: Researchers highlighted the need for a system that not only regulates but also promotes innovation, commercialisation, and the protection of intellectual property.
- Insufficient Capacity and Infrastructure: Many Institutional Review Boards (IRBs) lack the resources and training to function effectively, placing undue pressure on the national ethics committee.
- Lack of Digital Systems: The absence of an integrated digital platform for submissions, tracking, and monitoring has made the research approval process cumbersome and opaque.
- Community Engagement and Benefit Sharing: There is a growing demand for inclusive research practices that respect indigenous knowledge systems and ensure equitable benefit sharing.

The proposed Health Research Bill seeks to address these challenges head-on. It envisions the establishment of the Health Research Authority of Zimbabwe (HRAZ)—a modern, independent regulatory body with the mandate to coordinate, regulate, and promote health research in the country. The Bill also provides for the creation of a National Health Research Ethics Committee (NHREC), the accreditation of Institutional Research Ethics Committees (IRECs), and the development of a National Clinical Trials Centre to streamline and strengthen clinical research oversight. Notably, the Bill embeds principles of digital transformation, capacity development, gender equity, and community participation. It aligns with international best practices while remaining grounded in Zimbabwe's unique legal, cultural, and health systems context.

As we move forward, the MRCZ remains committed to supporting this legislative transition and ensuring that Zimbabwe's research ecosystem is not only compliant but also competitive, ethical, and inclusive. We extend our gratitude to all stakeholders who contributed to the consultations and look forward to continued collaboration as we build a future-ready health research system.

Let us seize this moment to reimagine and reinvigorate health research in Zimbabwe—for the benefit of our people, our institutions, and future generations.

GLOBAL ETHICS UPDATE:

KEY UPDATES TO THE DECLARATION OF HELSINKI (2024) AND ICH-GCP E6 (R3) GUIDELINES

Natasha Tsandukwa Rusike and Anesu M. Gumbo MRCZ.

First adopted in 1964, the Declaration of Helsinki remains the World Medical Association's most influential statement on the ethics of medical research involving human participants. Over six decades and seven amendments later, its latest revision, endorsed at the October 2024 General Assembly, marks a pivotal moment in global research ethics. This updated version responds to the dynamic realities of modern clinical research, addressing emerging ethical challenges while reaffirming the principles of respect, integrity, justice, and participant protection that underpin ethical research.

Key Revisions in the 2024 Declaration

Significant changes have been made to the Declaration of Helsinki, and this article discusses the key revisions likely to influence research practices in Zimbabwe and beyond. One of the most notable updates is the deliberate shift in language throughout the document. The terminology is now person-centred, emphasising respect, inclusion, and the protection of participants' dignity. The 2024 revision replaces language referring to human subjects with that of study participants throughout the document, reflecting a modern, respectful view that recognises individuals as active partners in research rather than passive objects of study. The pronoun 'they' is also now used for inclusivity instead of gendered language, such as 'he' or 'she'. While semantics may seem trivial, they play a crucial role in shaping how we perceive and engage with research participants. (Corpus, 2023).

The updates also focus on enhanced protection for vulnerable individuals. Specific guidance has been provided calling for engagement with communities throughout the research process, particularly when working with groups facing historic exclusion or marginalisation, like pregnant women and children. Authentic and meaningful community engagement, not just a tick-box exercise, is advocated. The theme is to move from exclusion to inclusion for protection, respecting these populations' unique health needs and priorities as a key aspect of respect for marginalised groups (Zhang, 2024). For Zimbabwe, this means that the previous practice of automatically categorising pregnant women as a vulnerable population requiring exclusion from research is no longer appropriate. Instead, reviewers and researchers are now encouraged to apply nuanced, evidence-based considerations that prioritise inclusion where scientifically and ethically justified. With proper safeguards in place, pregnant women and other groups of marginalised populations should be enabled to participate in research that addresses their specific health needs, ensuring both protection and equitable access to the potential benefits of scientific advancement.

The revised Declaration reinforces the principles of equity, distributive justice, and global justice by calling for a fair and balanced distribution of research benefits, risks, and burdens across all populations. It places renewed emphasis on inclusive participation and the prevention of exploitation, particularly in international and cross-border research. Notably, for the first time, scientific integrity and a zero-tolerance stance on research misconduct have been codified as core ethical requirements. For Zimbabwe, this sets a strengthened expectation of integrity and research quality. Investigators are required to ensure that study designs are scientifically sound and that results are shared publicly and promptly, promoting accountability in all research activities.

The modernisation of informed consent processes, including the use of electronic consent documentation to reflect the growing reliance on digital platforms in research, is also acknowledged. Furthermore, the revised Declaration provides clarity on post-trial access to beneficial interventions. New provisions also address consent for the future use of participant data, biological materials, and samples, with attention to the emerging ethical challenges posed by artificial intelligence and digital data systems.
Ethical accountability now extends beyond physicians to encompass all individuals involved in research. This underscores the principle of shared responsibility for ethical compliance and scientific integrity across the entire research ecosystem. The document further enhances coherence and alignment with other internationally recognised ethical frameworks, promoting harmonisation of global standards and consistency in ethical review practices.

Overall, the 2024 revision represents a significant milestone in the evolution of research ethics. Researchers must now align their protocols and standard operating procedures with these strengthened provisions. As always, the Medical Research Council of Zimbabwe (MRCZ) remains steadfast in upholding these international standards to ensure that research conducted under its purview reflects the highest ethical and scientific integrity.

Updates to the Good Clinical Practice (GCP) guidelines – ICH E6(R3)
GCP is an international scientific, ethical, and quality standard for the conduct of clinical trials involving human volunteers, ensuring that the rights, safety, and well-being of participants are safeguarded and that the results generated are reliable. GCP ensures that the conduct of a trial is consistent with the ethical principles set out in the World Medical Association (WMA) Declaration of Helsinki. It's worth noting that although ICH-GCP is primarily intended for interventional trials, its core principles are also relevant to other forms of research involving human volunteers, especially in areas such as ethical standards, safeguarding participant welfare, and ensuring the accuracy and integrity of data. The guideline remains relevant to Zimbabwe and beyond, and prior training and certification in ICH-GCP remain a prerequisite for investigators conducting health research in the country.

Similar to updates to the Declaration of Helsinki, the latest iteration of the guidance came in response to a rapidly evolving research environment, particularly the clinical trials ecosystem. Prior versions of the guideline did not make adequate provisions for this. Concerns about the lack of proportionality and a "one-size-fits-all" approach to clinical trials are among some of the shortcomings highlighted in the preceding R2 guideline (ICH, 2017). Adopted on January 6, 2025, the updated guideline came into effect on July 23, 2025, to improve its applicability in a more modern clinical trial ecosystem. It encourages a risk-based proportionate approach to the conduct of clinical trials.

ICH-E6 (R3) builds on key concepts outlined in ICH E8(R1) guidance for clinical studies. It is grounded in the foundational principle of Quality by Design (QbD), which encourages thoughtful design and conduct by integrating quality into the scientific and operational design of a clinical trial across its stages. QbD focuses on critical-to-quality factors in the trial to maximise the likelihood that the study meets its objectives. These factors should be identified prospectively, as they are fundamental to protecting research participants, ensuring the reliability and interpretability of results, and informing the decision-making and use of those results. (ICH, 2025)

Protocol optimisation is emphasised through the use of fit-for-purpose approaches. Principle 7 states that clinical trial processes should be proportionate to the importance of the data being collected, the risks to participants, and the reliability of the results, to avoid an unnecessary burden not only on participants but also on investigators (ICH). These risks include those to the rights, safety, and welfare of participants, as well as risks to the reliability of trial results. The risks to the critical-to-quality factors must be continuously monitored, and the necessary adjustments must be made throughout the trial. The guidance under this principle encourages the feasibility of trials by circumventing unnecessary complexity, procedures, and data collection. This, again, potentially helps lessen participant burden and improves accrual and

retention. It is important to remember that a well-designed protocol is fundamental to protecting research participants.
The guideline provides for the exploration of technology use in clinical trials. The principles are intended to support efficient approaches to design and conduct, for example, by encouraging the use of innovative technologies such as wearable devices and sensors. This increases the variety of sources through which data can be obtained in a clinical trial setting.

The use of innovative trial designs and technologies may enable the inclusion of a broader, more diverse population of participants, thereby increasing the applicability of trial outcomes. Decentralised clinical trials and point-of-care designs, conducted in everyday clinical settings rather than specialised, controlled environments, can address key questions in real-world clinical care. This not only facilitates participation by improving accessibility but also reduces participation attrition.

A new section on data governance was introduced in the current iteration of the guideline on the management of data integrity to facilitate accurate reporting, verification and interpretation of trial-related information. The section, directed to investigators and sponsors, defines key processes to be addressed throughout the data lifecycle. The approach to management of computerised systems should be proportionate to the importance of participant safety and the reliability of trial results.
E6 R3 recognises the evolution in approaches to obtaining informed consent. Various formats for presenting information to participants, such as text, images, and videos, have been considered. The guidance also stresses the importance of community engagement and inclusivity to enrich the research approach, ensuring that it responds to their specific needs and priorities. Similar provisions have been made in the revisions to the Declaration of Helsinki. Other minor modifications to the guidance and glossary of terms have been made to improve readability and clarify the scope.

The updated guideline seeks to accommodate innovations in clinical trial design and conduct, while proffering guidance to ensure participant safety and production of reliable data. The MRCZ, through the National Health Research and Development Committee (NHRDC), will update the ethics guidelines for health research involving human participants to align with revisions to global ethics frameworks. The research fraternity is encouraged to familiarise themselves with and apply these guidelines to ensure compliance with local regulatory requirements and to adhere to ethical standards that protect communities, promote public trust, and uphold research integrity.

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PRACTICAL ETHICS AND OVERSIGHT

INFORMED CONSENT IN A CHANGING WORLD

By Dr Emmanuel Shana

Research ethics committees, researchers, research institutions, and sponsors have an ethical obligation to ensure that all participants in health-related studies have voluntarily given informed consent, unless an ethics committee has granted a waiver. Informed consent is based on the ethical principle of respect for persons or autonomy, which protects individuals' rights to make independent decisions based on the information provided. Any modifications, waivers, or amendments to informed consent documents must be implemented only after approval from the research ethics committee. Both researchers and participants in health-related research share responsibility for protecting the integrity of the collected data and the safety and welfare of study participants. This commitment must be reflected in the informed consent document.

Researchers must ensure that no unjustified deception, undue influence, or coercion is applied to participants during the informed consent process. In fact, informed consent is an ongoing process that begins with initial contact with potential study participants and continues throughout the study. Therefore, researchers need to obtain informed consent from each participant again if there is a significant change to the study protocol or if new information becomes available that may affect the original conditions under which participants enrolled. In long-term studies, it is also essential to confirm participants' ongoing willingness to continue in the research.

The Medical Research Council of Zimbabwe (MRCZ) has made available a template of guidelines on its website (mrcz.org) outlining the information that should be included in informed consent forms. Researchers conducting studies in Zimbabwe are encouraged to familiarise themselves with these guidelines to prevent inconsistencies and facilitate a smoother, more efficient review of submitted protocols. The essential elements of informed consent include:
Competence: Participants must possess the capacity to provide informed consent.
Disclosure of Information: Researchers must offer adequate, relevant, and appropriate information to participants.

Comprehension and Understanding: Information must be presented clearly and simply to each participant, taking into account their age and level of education. Researchers should avoid technical jargon and lengthy explanations. The use of audiovisual aids, pictorials, and quizzes can enhance participants' understanding of complex bioscientific subjects.

Confidentiality: Robust measures should be implemented to protect participants' privacy and confidentiality.

Voluntariness: Participants must be assured that they can engage in the study freely, without any undue pressure or coercion, and they should retain the right to withdraw from the study at any time without jeopardising any benefits that would otherwise be available to them.

Types and forms of consent

Written informed consent must be obtained from all study participants unless the ethics committee has granted a waiver. Verbal consent, an alternative to written permission, is rarely granted under MRCZ and ICH/GCP guidelines. An ethics committee may need to determine whether verbal consent is appropriate based on the specific circumstances. If the primary participant cannot read or write, an impartial witness may sign the consent form.

Additionally, a legally authorised representative may sign on behalf of an incompetent or compromised participant. In both cases, the ethics committee must approve the content and circumstances surrounding the consent process. An unqualified person may need to sign the informed consent document once they regain competency.

Informed consent can take several forms:

- Individual Consent: For individuals capable of giving informed consent.
- Parental Consent: For those under the legal age of maturity or adolescents.

- Assent: Required when conducting research with minors, which necessitates parental or guardian consent as well.

Informed Consent Requirements in Health Research
Community authorisation from leaders cannot substitute for individual informed consent, which is necessary for research participation. Participants must provide consent for the storage of their biological specimens, the use of their materials in future studies, and the shipment of samples abroad. They should be informed about the storage duration, how to withdraw consent, and the processes for retrieving or destroying their materials if desired.

A research ethics committee may approve waivers or modifications of informed consent under certain conditions, such as when the research is impractical without them, holds significant social value, or poses minimal risk to participants. Examples of such scenarios include anonymous surveys or studies involving illegal behaviours.

An informed consent form must clearly explain that the study is research, identify the researcher and institution, describe participant selection, outline the study duration and procedures, and state any benefits and risks involved. It must also indicate that participation is voluntary and that alternatives exist. Special populations, including pregnant women, children, and prisoners, require additional protections, with specific consent guidelines to follow.

Several factors may hinder genuine consent, including dependent relationships, poverty, educational levels, cultural traditions, and religious beliefs. Other regulatory aspects include provisions for oral consent when participants cannot comprehend written forms, and waivers of signature requirements for confidentiality concerns. Overall, an ethics committee can waive informed consent requirements if the study poses minimal risk, would be impractical without a waiver, or poses a confidentiality threat.

Summary

Informed consent is a process that begins when a participant is approached and continues until the study results are shared. Participants must receive all necessary information to make an informed decision about participation, which is documented in clear, non-technical language suitable for their age and cultural background. Participants must voluntarily give consent, which is documented in informed consent documents approved by an ethics committee before the study's commencement. For minors, consent is provided by parents or guardians, with the child offering assent. Legally appointed representatives can sign on behalf of participants who are unable to do so themselves, with ethics committee approval. It's crucial that participants sign consent forms without coercion, and that all recruitment materials be ethically reviewed. Non-compliance with informed consent regulations may lead to study suspension and sanctions from regulatory bodies.

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THE CRISIS OF ETHICAL PEER REVIEWING

By Mr Tinashe Mudzviti

Peer review is the bedrock underpinning the foundation for acceptance of evidence. Given that medicine is an evidence-based practice, peer review is of utmost importance and should always be held in high regard. For the avoidance of doubt, I will define peer review as the process in which scientists from the same field (usually the more 'experienced' scientists) of the authors evaluate a submission for quality and priority. Whether we are discussing peer review of a manuscript for consideration by a journal or the review of an application for ethical soundness by an institutional review board, the underlying principle remains the same: The reviewer's choices and actions have direct consequences!

The last 20 years have raised significant concerns about the efficiency of the peer-review process in journal publishing. Consider the following metric: in 2005, approximately 4,844 journals were listed in PUBMED/MEDLINE. This number has grown to approximately 5,600 and 30,000 journals in 2015 and 2025, respectively. Over the last 10 years, the number of journals has grown by more than 5 times. To maintain an effective and robust peer-review process, there needs to be a commensurate increase in the number of 'experienced' scientists available to review all submitted material however, because it takes time to develop critical masses of 'experience' we now find a prevailing scenario where the number of reviews that need to be done outweighs the 'experience' needed to conduct them.

We would not have done justice to this discussion if we had not mentioned the 'elephant in the room': the financial aspects of the peer review process. The peer review process is often one that offers no monetary reward to 'experienced' reviewers, which can pose challenges. With the widespread use of digital technologies, academic editors can now use metrics to identify 'fast reviewers' who can handle a high volume of reviews while submitting them on time. What academic editors will not quickly see is the quality to which these 'fast reviewers' are producing. With an explosion in materials requiring peer review and with turnaround time (manuscript submission to publication) given high priority, this process risks prioritising rapid reviews over time-consuming ones. Coming back to the money, 'experienced' reviewers will likely have other commitments competing for their time. Therefore, sacrificing paid time to fulfil competing commitments to review unpaid time might not be a priority.

If peer review is the bedrock of evidence acceptance, we cannot have our most experienced scientists view peer review as a 'sacrifice' or a missed opportunity for remuneration. The debate over whether reviewers should be remunerated may need to be revisited, especially in an age when many journals charge article processing charges (APCs). One of the ethical principles speaks to justice. Is justice being upheld by journals that charge APCs whilst they do not provide remuneration for reviewers? How do we maintain the integrity of the process while keeping 'experienced' scientists engaged in the review process?

The peer review process will need to evolve and adapt to the explosion in volume of submissions being generated by the vast number of journals coming into existence. The ratio of reviewers to submissions must be maintained to ensure the integrity of the peer review process. The use of digital technologies and artificial intelligence (AI) as review aids may need to be adopted and further explored to improve the overall peer review process. Whilst we did not expand on the use of AI in the review process, the inevitable explosion in submissions will require AI support. Peer review is the foundation of evidence, and its integrity needs to be jealously guarded.

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IMPROVING THE VALIDITY AND RELIABILITY OF PARTICIPANT RESPONSES THROUGH ACCURATE TRANSLATIONS

By Professor Webster Mavhu

This piece stems from my experience translating scientific studies over the last two decades, as well as from reviewing other researchers' translations.

What is Translation? Translation is often viewed as simply a replacement of textual material in one language by equivalent textual material in another, that is, an easy exercise that people can do with a basic grounding in a language other than their own – mere bilinguals. Translation has always been perceived as a secondary activity, a mechanical rather than a creative process. Discussions on translation have analysed only the product and the results of the translation process, not the process itself. However, translation is both a process and a product, and most importantly, it involves more than just a working acquaintance with two or more languages. The art of translation itself is not simple. It can be viewed as follows: Text (A) => Theory => Text (B). In this illustration, Text (A) is the source language (SL) text, whilst Text (B) is the target language (TL) text. A translator practically applies theory to an SL text to produce a TL text. The application of some theory is a process that leads to a product, the TL text. Translation is challenging because a translator must produce a TL text identical to the SL text. A translator must also be faithful to both the producer of the SL text and the recipients of the TL text.

Translations and the informed consent process. In research, translations need to support the informed consent process, ensuring that participants participate only when they have fully understood what the research is about. Specialised terminology particularly presents challenges. A study, for example, may be focusing on: *Exploring the prevalence of male genital schistosomiasis in semen collected from fishermen*. Strategies to achieve an accurate translation of male genital schistosomiasis may include using a term that is commonly used and therefore familiar, e.g., *bhirihaziya rinowanikwa muvanhurume* [in Shona]. Rendering "semen" into indigenous languages will also need to be done carefully. Graphic descriptions can compromise a study's overall acceptability, particularly in conservative communities.

On the other hand, even some indigenous terms may be too deep or unrelatable to especially younger or urban participants. Therefore, indigenous terms, e.g., dutavanhu (bus), shushururu (beans), mukoti (nurse), may need to be used alongside their borrowed, albeit familiar, terms, e.g., *bhazi, bhinzi, nesi*.

Pretesting questions are essential. Pretesting study questions with a sample of intended participants is crucial. One strategy is cognitive interviewing–a technique that focuses on the thought processes respondents use when answering survey questions. It aims to identify potential sources of response error by exploring how individuals comprehend, retrieve and respond to questions. Collectively, translation, pretesting, and iterative refinement help improve the validity and reliability of research participants' responses.

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Community Engagement

THE IMPORTANCE OF MEANINGFUL COMMUNITY ENGAGEMENT IN CLINICAL TRIALS: INSIGHTS FROM HIV PREVENTION RESEARCH INVOLVING WOMEN

By Dr N.M. Mgodi *– HVTN 2025 Service Award Recipient (Outstanding Community Engagement – AMP Studies) and* ***Mr Stanford Chimutimunzeve*** *– Community Advisory Board Member, UZ-CTRC*

Introduction

Community engagement has become a critical component of ethical and practical clinical research. As Owusu-Ansah (2013) notes, scientific inquiry cannot be separated from the cultural and historical contexts of the communities it serves. In HIV prevention research—particularly studies involving women—meaningful engagement ensures that scientific objectives remain aligned with community needs, expectations, and lived experiences. Participatory approaches guided by Good Participatory Practice (GPP) principles are therefore essential to producing research that is trusted, relevant, and impactful.

Understanding Community Engagement in Clinical Research

In clinical research, the "community" refers to individuals linked by geography, shared experiences, social identity, or common health concerns. GPP guidelines emphasise the importance of integrating community perspectives throughout the research lifecycle—beginning with protocol development and extending to implementation, results dissemination, and post-trial access.

Meaningful community engagement goes beyond consultation and requires sustained partnership. Activities such as focus group discussions, stakeholder meetings, and key informant interviews help ensure that research activities are culturally appropriate and ethically grounded. The establishment and active functioning of Community Advisory Boards (CABs) remain central to these efforts.

Role and Composition of a Community Advisory Board (CAB)

The CAB at UZ-CTRC comprises representatives of diverse stakeholder groups, including community leaders, civil society, youth and women's organisations, key populations, local healthcare providers, and former study participants.

The CAB serves as a liaison between researchers and the community, contributing to:

- Review of informed consent materials
- Guidance on recruitment and retention strategies
- Community sensitisation and education
- Ensuring cultural appropriateness of study procedures
- Feedback on dissemination strategies

Meetings are held quarterly, with additional sessions when study needs arise. **Community Engagement Activities in PrEP Studies Involving Pregnant and Breastfeeding Women. Inclusion** of PBFPs in HIV PrEP research – Community engagement is an essential ethical and scientific requirement for HIV PrEP studies involving pregnant and breastfeeding women in Zimbabwe. Previously excluded as a vulnerable group, this population makes health decisions within family, cultural, and community structures. Early engagement with community leaders, partners, health workers, and Community Advisory Boards helps ensure that the study is contextually appropriate, culturally sensitive, and responsive to concerns about PrEP use in pregnancy and breastfeeding. It enables clear communication of risks and benefits, addresses misconceptions, and builds trust in the research process. Community input also strengthens recruitment strategies, consent language, and study procedures, improving feasibility, participant protection, and retention. Meaningful engagement enhances ethical conduct, fosters community

ownership, and increases the study's acceptability, oversight, and scientific validity.

Robust community consultations were integral to the **DELIVER** and **B-PROTECTED** studies evaluating the dapivirine vaginal ring and oral PrEP in pregnant and breastfeeding women. Stakeholders included representatives from the MoHCC, regulatory bodies, civil society organisations, former study participants, CAB members, MTN leadership, and UZ-CTRC investigators. NGOs such as I-TECH, Katswe Sistahood, JF Kapneck Trust, ZACH, and Musasa enriched discussions with community-level insights.

These engagements informed strategies for acceptability, consent, and integration of HIV prevention into maternal and child health services, ensuring that implementation approaches aligned with the realities of reproductive health care in Zimbabwe.

Reflections from MATRIX Stakeholder Consultations

The MATRIX Regulatory and Product Development Consultation (1 September 2023, Johannesburg) brought together 36 stakeholders from Kenya, South Africa, and Zimbabwe, representing regulatory authorities, ethics bodies, ministries of health, and regional organisations.

Key objectives were to:

1. Identify preferred mechanisms for researcher-regulator engagement throughout the product development lifecycle.
2. Understand national and regional priorities around HIV prevention technologies for women.

Stakeholders emphasised alignment with country priorities and integration with existing service delivery models.

"The quality of partnership with ministries will determine the pace and value of research implementation." – **Prof. T. Kureya, Executive Secretary, MRCZ.**

"Zimbabwe has demonstrated success in integrating family planning, contraception, and HIV services–an approach that supports holistic care and improves uptake." – **Mr M. Ngwenya, WHO Zimbabwe.**

These insights underscore the principle that research must be locally grounded and shaped by those it aims to serve–echoing the widely embraced ethic, *"Nothing for us, without us."*

Benefits of Meaningful Community Engagement

Effective community engagement enhances:

1. **Ownership** – fostering empowerment and shared responsibility.
2. **Relevance** – ensuring research questions reflect community priorities.
3. **Trust and participation** – improving enrolment and retention.
4. **Mutual understanding** – promoting transparency in research goals.
5. **Cultural appropriateness** – supporting correct interpretation of findings.
6. **Myth reduction** – improving research literacy and correcting misconceptions.
7. **Efficient approvals** – reducing protocol amendments and delays.
8. **Sustainability** – anchoring interventions in real community needs.

Together, these benefits contribute to stronger ethical practice and more effective clinical research outcomes.

Conclusion

Community engagement is not simply an ethical requirement–it is an essential driver of scientific excellence. Experiences from Zimbabwe's HIV prevention research highlight how structured dialogue, CAB participation, and respect for local knowledge strengthen research implementation and enrich study outcomes. When communities are treated as partners, research becomes more credible, acceptable, and impactful–ultimately advancing both scientific progress and public health.

MRCZ MANDATE AND ACTIVITIES

By Professor CFB Nhachi, MRCZ Board Chairman

Introduction and Background

The Medical Research Council of Zimbabwe (MRCZ) comprises members from various health-sector stakeholders, including the Ministry of Health and Child Care, medical aid societies, and academic institutions. Members are appointed by the Minister of Health and Child Care for a three-year term, based on Government Notice Number 225 of 1974.

To enhance efficiency, the MRCZ operates through the Executive Committee and three Technical Committees: the National Health Research Development Committee (NHRDC), the Traditional, Alternative, and Complementary Medicines Research Committee (TCAMRC), and the Research Funding Committee. The MRCZ Chairperson leads the council and appoints committee members.

The MRCZ is a specialised body of the Research Council of Zimbabwe (RCZ), established in 1974 to oversee health research across Zimbabwe. It supervises, coordinates, and promotes research to address national health needs, as detailed in the council's Terms of Reference (TORs).

Terms of Reference

The responsibilities include promoting ethical health research that influences health policy in Zimbabwe and raising funds for such research. It is essential to review medical research to ensure it meets the country's needs and to foster coordination among those involved in health research.

The organisation also commissions health research, establishes national health research priorities, and guides matters presented by the Ministry of Health and Child Care and other stakeholders. Promoting awareness of national health research expectations and developing relevant policies are key focuses.

Additionally, it facilitates the strengthening of research oversight and coordination structures within institutions, monitors their functionality, and serves as an appeals body for researchers facing unfavourable decisions from the National Health Research Development Committee. This paper provides an overview of how these responsibilities have been implemented.

Activities of the Technical Committees

The MRCZ oversees medical research, focusing on ethics in health research through its technical committees, including the National Health Research Development Committee (NHRDC) and the Traditional Complementary and Alternative Medicine (TCAM) Committee. The NHRDC meets monthly to review new research protocols, progress reports, annual reports, renewal applications, and requests for extensions, evaluating approximately 6 to 10 new protocols each month.

The TCAM committee reviews protocols as needed to ensure that traditional medicine use is scientifically justified. During 2025, two significant studies are being conducted: (1) “Antimalarial Activity and Safety of Pterocarpus Angolensis and Afzelin Herbal Extracts” and (2) “Preclinical Evaluation of the Safety and Efficacy of Makomo Herbal Ointment.” The results will contribute valuable scientific documentation on traditional medicine.

Institutional Review Boards (IRBs)

All health research institutions in the country must have an Institutional Ethics Review Committee (IRB) to review research protocols before submission to the MRCZ for approval. The MRCZ promotes scientific and ethical aspects of medical research by creating and training IRBs at research and educational institutions involved in health research in Zimbabwe. These boards work in coordination with the MRCZ to review protocols. Several IRBs, including JREC, MSU, GZU, NUST, AUREC, BRTI, the Chitungwiza Hospital Ethics Committee, and the City of Harare Ethics Committee, are currently operational, with more under development.

Inspections and Monitoring of Approved Research Projects

The MRCZ is responsible for on-site inspections of human research approved by Technical Committees. These routine inspections serve to confirm adherence to approved procedures, investigate reported Adverse Events, and address protocol breaches. Inspections follow prescribed Standard Operating Procedures (SOPs) and are

divided into four phases: before, during, and after the visit, and the presentation of findings to the Council/Board for recommendations. These inspections are essential to the MRCZ's responsibilities, with several successfully conducted in 2025.

Continuous Health Ethics Education Training

The MRCZ conducts periodic Training workshops for Continuous Health Ethics Education, inviting specialists to facilitate. At the most recent workshop, experts in AI Ethics and Genetic Ethics highlighted the importance of aligning AI systems with societal values and of addressing the ethical considerations surrounding genetic testing. Ethical use of genetic data is crucial to prevent misuse and discrimination. The MRCZ will continue these enlightening workshops at your convenience.

Promotion and Funding of Health Research

The MRCZ plays a crucial role in promoting health research, despite limited resources. One key initiative is the annual funding of prizes for the Annual Medical Research Day (AMRD), coordinated by the Faculty of Medicine and Health Sciences at the University of Zimbabwe. The MRCZ sponsors awards for categories such as best clinical paper, best biomedical paper, best undergraduate paper, best provincial paper, best postgraduate paper, and best overall paper. We hope these prizes encourage greater involvement in health research.

Fundraising

Raising funds for baseline capacity building and upgrading online facilities to promote health research in Zimbabwe is a crucial function of the Medical Research Council of Zimbabwe (MRCZ). In 2025, the MRCZ received a grant from the Gates Foundation, in partnership with the Medicines Control Authority of Zimbabwe (MCAZ), to support strengthening ethics oversight and enhancing clinical trial capacities.

The activities mentioned above are among the functions the MRCZ has performed over the 2025 period in an endeavour to fulfil its responsibilities.

About the Medical Research Council of Zimbabwe (MRCZ)

The Medical Research Council of Zimbabwe is the national authority mandated to promote, coordinate, and oversee health-related research in Zimbabwe. Our mission is to ensure that all medical and scientific research conducted in the country meets the highest ethical standards and contributes to improving public health.

What We Do

- Ethical Review & Approval of research proposals.
- Monitoring & Compliance for ongoing studies.
- Capacity Building for researchers and institutions.
- Community Engagement to protect participants' rights.

Why It Matters

Research saves lives. By safeguarding ethics and integrity, MRCZ ensures that innovations in medicine and public health benefit Zimbabweans while respecting human dignity.

Get Involved

- Are you a researcher? Submit your protocol for ethical review.
- Are you a participant? Know your rights and responsibilities.
-

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MRCZ – Protecting People, Promoting Science.

Medical Research Council of Zimbabwe