The National Health Research Ethics Council 2024 Guidelines – suspended in part, legally precarious in whole

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The National Health Research Ethics Council (NHREC), established under section 72 of the National Health Act 61 of 2003 (NHA), is responsible for setting ethical standards for health research in South Africa (SA). Its Ethics in Health Research: Principles, Processes and Structures (the Guidelines),[1] published in May 2024, aim to regulate research involving human participants and animals. However, three appeals lodged in mid-2024 challenge critical aspects of the Guidelines – namely, the Guidelines' denial of ownership in human biological material (HBM) and data; the failure to differentiate between lawful and unlawful benefit sharing; and the purported guidance issued in relation to the Protection of Personal Information Act 4 of 2013 (POPIA). These critical issues are compounded by a serious procedural irregularity concerning the NHREC's appointment, as analysed by Bellengère and Bellengère[2] in this issue of the *South African Journal of Bioethics and Law*. This editorial examines these concerns and proposes corrective measures.

Ownership of human biological material and data

The Guidelines assert that neither HBM nor data can be privately owned under SA law. I respectfully dissent from this interpretation. My colleagues and I have developed comprehensive legal reasoning in support of the position that both HBM (as corporeal objects once separated from the human body) and recorded instances of personal information (as digital objects) are indeed susceptible to private ownership in SA law.[3-7]

The notion of owning health data is not novel in SA bioethics. The Health Professions Council of South Africa (HPCSA) affirms, in paragraph 8.1 of its Guidelines for Good Practice in the Healthcare Professions: Guidelines on the Keeping of Patient Health Records:[8] 'A patient health record is owned by the health practitioner or the entity generating such a patient health record.'

A patient health record – whether in digital or physical form – is clearly treated as an object of ownership. The same reasoning applies to other forms of health data and, by extension, to research data. This raises an important question: was the NHREC aware of the HPCSA's position? And if so, did it fully consider the implications of issuing guidance that is in direct conflict with it?

Furthermore, many of SA's leading universities assert ownership over the data they generate and the HBM they collect.[9] The NHREC's categorical denial of such ownership places it in conflict not only with the HPCSA but also with these universities' internal governance frameworks. This, in turn, creates an untenable situation for university-based health research ethics committees, which must choose between complying with institutional policy and adhering to national guidelines. More broadly, the NHREC's position may inadvertently expose SA research institutions to neo-colonial exploitation by foreign collaborators. Institutional ownership of HBM and data is not only a matter of prudent policy but also a necessary legal safeguard to protect local research assets.[6,9] By denying the legal possibility of ownership in these objects, the NHREC therefore risks weakening this protection and inviting forms of appropriation that SA law should guard against.

In response to these concerns, I sent two formal letters to the NHREC, urgently requesting the removal of the erroneous statement on ownership from the Guidelines via corrigendum. When both letters went unanswered, I felt compelled to lodge a formal appeal with the Minister of Health as a last resort.

Alas, the denial of ownership is not the only issue of concern in the Guidelines. I now turn, briefly, to the other two.

Benefit sharing

The Guidelines' endorsement of benefit sharing fails to distinguish between practices that are lawful and those that are not. In terms of section 60(4) of the NHA, financial or other rewards for the donation of blood, tissue, etc. are prohibited, except for the reimbursement of reasonable expenses incurred. This provision reflects a deliberate legislative choice to reject reciprocity-based ethical arguments that research participants should receive something in return for their contribution. Instead, the law adopts a strict altruistic cost-recovery model. Violations of section 60(4) attract criminal liability under section 60(5).

While this model neither prohibits benefits that are inherent to health research – such as access to medicines developed through that research – nor precludes benefit sharing by research institutions, certain forms of benefit sharing, such as the provision of infrastructure to research participant communities, would constitute a clear and flagrant violation of the law. Such practices amount to rewarding research participants for their participation, and if such participation entails the donation of blood or tissue, it would fall squarely within the scope of the statutory prohibition.[10,11]

The omission in the Guidelines of any discussion of this legal constraint risks misleading researchers into engaging in unlawful conduct. It could also undermine SA's standing as a jurisdiction committed to ethically and legally sound health research. In light of this concern, a colleague of mine lodged a separate appeal with the Minister of Health, also in mid-2024, contesting the Guidelines' unqualified endorsement of benefit sharing.

Is the present altruistic cost-recovery model for research participation as per the NHA the best or most suitable model for SA?

This is an important question that deserves academic engagement. However, the point of the appeal is that the law as it stands should be acknowledged.

Application of POPIA

The Guidelines address health data governance, ostensibly to assist researchers in handling personal information in compliance with POPIA. However, the approach adopted is flawed in several respects. First, the Guidelines deviate from POPIA's established statutory terminology by introducing an alternative lexicon – redefining key terms such as 'de-identified'. This departure from the statutory language risks generating confusion among researchers, who rely on POPIA's precise definitions to ensure legal compliance.

Second, the Guidelines exceed the NHREC's statutory mandate under section 72(6) of the NHA, which empowers the NHREC to determine norms and standards for health research ethics – not to interpret or provide legal guidance on POPIA compliance. POPIA itself vests this interpretive authority in the Information Regulator. This overreach raises a critical procedural question: did the NHREC consult the Information Regulator in the drafting of these POPIA-related sections of the Guidelines?

To clarify this issue, a request was submitted under the Promotion of Access to Information Act 2 of 2000 to the Department of Health, as the department responsible for administering the NHREC. Based on the Department's response, the answer appears to be in the negative: the NHREC made no attempt to consult the Information Regulator.

In light of these substantive and procedural deficiencies, a colleague of mine lodged an appeal with the Minister of Health, challenging the Guidelines' treatment of health data governance. The appeal argues that the Guidelines, as drafted, risk undermining the coherence and legal authority of POPIA's framework in the context of health research.

Suspension of the impugned aspects of the Guidelines

Under SA administrative law, where a decision is appealed, and the enabling legislation does not provide that the decision remains in force pending the outcome of the appeal, the decision is *automatically suspended*.[12,13] Neither the NHA nor the NHREC Regulations – under which the current appeals were lodged – contain any provision preserving the effect of a decision during the pendency of an appeal. Accordingly, all the provisions of the Guidelines currently under appeal – the denial of data and HBM ownership, the endorsement of benefit sharing, and the attempt to govern health data under POPIA – have been suspended since the appeals were filed in mid-2024. In other words, these provisions have not been in force for approximately a year.

It is deeply concerning that the NHREC has taken no steps to communicate this suspension of significant portions of its Guidelines to the research community. I suggest that the NHREC bears both a legal and an ethical obligation to do so – in the interests of transparency, institutional trust, and ensuring compliance with binding legal instruments. Its contrasting approach to another controversial issue, heritable human genome editing, is noteworthy. In that case, the NHREC acted with apparent agility by withdrawing the relevant section of the Guidelines and replacing it with a placeholder noting the need for further dialogue. Yet, more than a year after the three appeals were lodged, the NHREC has issued no communication acknowledging the suspension of the impugned provisions. This continued silence risks misleading researchers and health research ethics committees into applying provisions that currently have no legal force – an outcome that may expose them to legal liability.

Irregular appointment of the NHREC

The grave matters discussed above are further compounded by the irregular appointment of the NHREC. As Bellengère and Bellengère[2] compellingly demonstrate in this issue of the *South African Journal of Bioethics and Law*, the appointment of NHREC members did not comply with the NHA's legal requirements. In particular, the NHA mandates a public call for nominations published in the *Government Gazette*. No such call appears to have been issued.

The implications are serious. As Bellengère and Bellengère highlight, decisions made by a body that is improperly constituted are susceptible to invalidation by the court. The principle of legality in SA administrative law is well established and operates independently of the merits of a decision. Therefore, beyond the provisions already suspended due to the appeals, the Guidelines as a whole stand on uncertain legal footing.

Conclusion

What, then, is the current position with regard to ethics guidance in health research? Importantly, pending the outcome of the appeals, all impugned provisions of the NHREC Guidelines – the denial of data and HBM ownership, the endorsement of benefit sharing, and the attempts to govern health data – are suspended. Research institutions that affirm ownership of HBM and data in their internal policies may continue to assert and exercise these property rights, consistent with existing legal frameworks.

With regard to benefit sharing, researchers and health research ethics committees should take care to distinguish between different models of benefit sharing, ensuring compliance with the NHA's altruistic cost-recovery model for research participation. On health data governance, I suggest that the voluntary POPIA Compliance Framework for Researchers and Research Institutions[14] developed by the Academy of Science of South Africa offers a more appropriate and legally coherent guide to POPIA compliance: it adopts POPIA's terminology, offers accurate interpretations, and is tailored specifically for the research environment.

Finally, and fundamentally, I call on the Minister of Health to urgently resolve the issue of the NHREC's irregular appointment by initiating a new, legally compliant appointment process. This process must be conducted with transparency, inclusivity, and genuine public participation. Only then can the NHREC regain the authority and legitimacy required to fulfil its vital role in SA's health research ecosystem.

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