Reminding ourselves of the ethico-regulatory framework for health research

Before any health research activity involving humans commences, independent ethics review and approval are necessary. Articles submitted to the *SAMJ* must include the ethics approval number and the name of the health research ethics committee (HREC) that reviewed the protocol. From time to time, an abstract is submitted without reference to ethics review and approval. Upon follow-up, the author has usually forgotten to add on this requirement. Occasionally, the researcher has not applied for ethics approval, by and large because of a lack of understanding of the need for this prerequisite. Ethics review and approval of health research are both international[1-3] and local obligations, and a condition for publication by reputable peer-reviewed journals.

In South Africa (SA), the constitutional[4] protection and promotion of human rights, including dignity, equality, privacy, and bodily and psychological integrity, are clearly defined. These protections safeguard against research abuse. In particular, section 12(2) provides that no-one is to be subjected to scientific or medical experiments without providing informed consent. This emanates from Article 7 of the 1966 United Nations International Covenant on Civil and Political Rights.[1] In the constitutional context, 'experiment' translates to 'research'.[5] Statutory authority for the governance of health research and the necessary regulatory health research infrastructure are provided for by the National Health Act 61 of 2003[6] (NHA), which defines health research as including any research that contributes to the knowledge of:

'a) the biological, clinical, psychological or social processes in human beings,
b) improved methods for the provision of health services,
c) human pathology,
d) the causes of disease,
e) the effects of the environment on the human body,
f) the development or new application of pharmaceuticals, medicines, and related substances, and
g) the development of new applications of health technology'.

As can be seen by the above definition, health research includes a very broad set of activities. Section 72 of the NHA gives authority to the National Health Research Ethics Council (NHREC) to, *inter alia*, set norms and standards for the conduct of research, and to determine guidelines for the functioning of HRECs, which, in addition, must be registered with the NHREC. These guidelines are binding on all health and health-related research involving human participants. In terms of the NHREC's guidelines,[5] all health research requires research ethics approval prior to commencement of the study. HRECS may not grant retrospective ethics approval. While research that utilises data from the public domain does not, as a rule, require ethics review, the NHREC cautions as follows: 'Research that relies exclusively on information that is publicly available and does not require gate keeping, site or platform permission, or that is accessible in terms of legislation or regulation, may need to undergo formal ethics review, depending on ethical considerations relevant to the research.' Regarding quality assurance and quality improvement studies (audits), programme evaluation activities, performance reviews and consumer surveys, these generally do not constitute research, and formal ethics review is usually not necessary. However, the NHREC stipulates that it would be prudent to obtain ethics approval if publication of such studies is planned.

The Protection of Personal Information Act 4 of 2013[7] (POPIA) has added another layer of safeguards in health research. It regulates processing of personal information to protect privacy, and provides guidance on how this information may be processed. The Act classes research activities as a 'legitimate interest', hence, while some flexibility is allowed, the protective measures as provided by the Act must be adhered to. The NHREC urges researchers and HRECs to pay careful attention to protection of privacy and confidentiality interests in line with the POPIA, which stipulates that the right to privacy includes 'protection against unlawful collection, retention, dissemination and use of personal information'.

According to section 73 of the NHA, institutions, health agencies and health establishments at which health research is conducted must establish or have access to a HREC, which is registered with the NHREC. It further mandates the function of HRECs as that of reviewing research proposals and protocols to ensure that research conducted by the relevant institution, agency or establishment will promote health, contribute to the prevention of communicable or non-communicable diseases or disability, or result in cures for communicable or non-communicable diseases. In addition, HRECs are to grant approval for research by the relevant institution, agency or establishment only if the research proposals and protocols meet the ethical standards of that HREC. Of note, the NHREC guidelines set the minimum norms and standards for SA, and using these as a benchmark, most establishments have developed their own contextually relevant guidance documents and policies.

In this editorial I have briefly described SA's ethico-regulatory framework for governance of health research. Authors are urged to familiarise themselves with the relevant documents, in particular the NHREC guidelines, and to ensure that their submissions include the necessary information on HREC approval.

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4. Constitution of the Republic of South Africa, 1996. https://www.gov.za/documents/constitution/constitution-republic-south-africa-04-feb-1997 (accessed 25 February 2026).
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