Section on heritable human genome editing withdrawn from the National Health Research Ethics Council Guidelines

To the Editor: This correspondence is with reference to our editorial titled: 'Heritable human genome editing in South Africa – time for a reality check'[1] and our correspondence titled: 'Response to: In defence of South Africa's National Health Research Ethics Council guidelines on heritable human genome editing'.[2]

Withdrawal of section 4.3.2 from the NHREC Guidelines, 2024

We would like to update the scientific and academic community by bringing to the attention of all concerned that a new version 3.1 of the National Health Research Ethics Council (NHREC) Guidelines has been published,[3] and that the section (4.3.2) on heritable human genome editing (HHGE), which made reference to prospective parents, prospective children and individuals born as a result of HHGE research interventions, has been withdrawn from the guidelines entirely, and replaced with the following placeholder clause:

> '4.3.2 Heritable human genome editing
> Given the ongoing debates on heritable human genome editing research, there is a need for further national stakeholder engagement to guide the update of ethics review in this area of research. These updates will be communicated to RECs accordingly.'[3]

Context

The withdrawal of section 4.3.2 from the NHREC Guidelines is welcomed, and follows an international call for a 10-year moratorium on HHGE,[4] endorsed by the Alliance for Regenerative Medicine (ARM), International Society for Cell & Gene Therapy (ISCT) and the American Society of Gene & Cell Therapy (ASGCT) – three leading global scientific and advocacy organisations focused on bringing the benefits of genetic medicines to patients, healthcare systems and society.

The concerns around the initial wording of section 4.3.2 of the NHREC Guidelines were discussed and debated at an Indaba titled 'Ethical, legal, and social implications of heritable human genome editing: A South African perspective' hosted by the Southern African Society for Human Genetics (SASHG) on 11 December 2024.[5] At this Indaba, the NHREC members present recognised the concerns raised, and initiated a process for amending the section on HHGE in the NHREC Guidelines.

Conclusion

We commend the NHREC for addressing the national and international concern that was expressed following the initial publication of section 4.3.2 – and are grateful to the South African academic community, patients advocacy organisations and others for fostering a robust debate about the ethical acceptability of HHGE in this moment. The withdrawal of this section in the guidelines now paves the way for transparent dialogue on the medical, scientific, ethical, legal and societal concerns that HHGE raises in the context of clinical application. These concerns include, but are not limited to, feasibility and safety; irreversible impact on human evolution and future generations; potential misuse; issues of social justice and equity; and legal uncertainty stemming from the absence of robust regulatory frameworks in many jurisdictions. It is imperative that these complex issues be addressed collectively, rather than in disciplinary or policy silos.

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