

# PRINCIPLES FOR HERITABLE HUMAN GENOME EDITING

## Principle 01

### Human germline editing should be regulated, not banned

Given its potential to improve the lives of the people of SA, human germline editing should be regulated, not banned. Such health research will be regulated by the National Health Act and would include Human Research Ethics Committee oversight who should apply the same substantive criteria as with any other proposed health research, including human participants who provided human biological material. However, considering that modifications made during germline editing will be passed on to future generations, the potential long-term implications of the proposed research must also be considered.

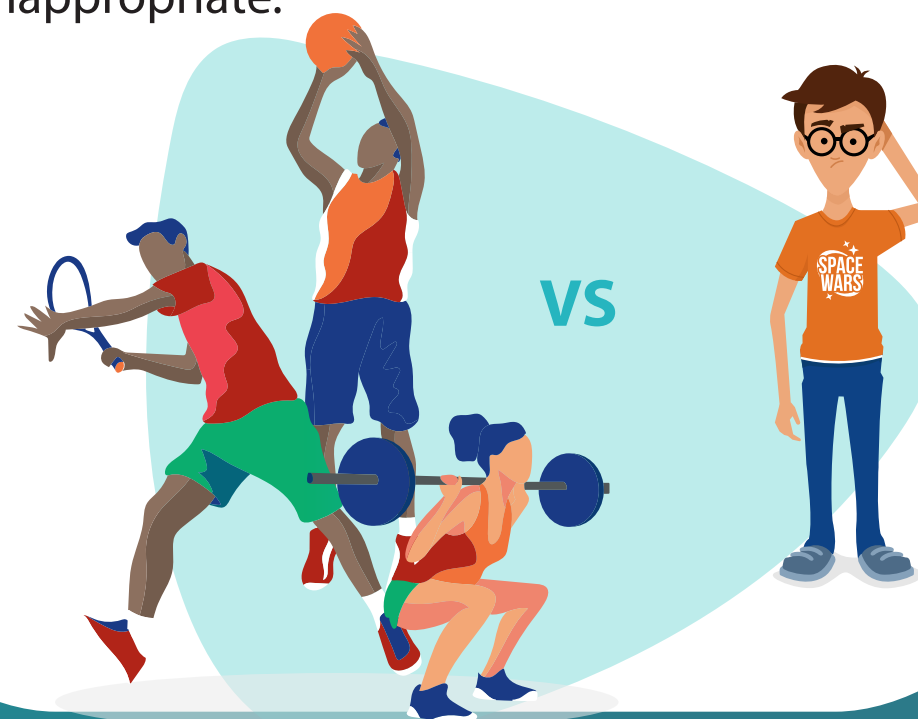


Human germline editing holds much promise for improving people's lives, but at the same time this novel biotechnology raises ethical and legal questions. The South African ethics regulatory environment is problematic, as it prohibits all research on, and the clinical application of, human germline editing. By contrast, the South African legal regulatory environment allows a regulatory path that would, in principle, permit research on human germline editing. However, the legal regulation of the clinical application of human germline editing is uncertain. As such, the current ethical and legal positions in South Africa are in need of reform. We propose these 5 guiding principles – aligned with the values of the Constitution – guide ethical and legal policy reform regarding human germline editing in South Africa.

## Principle 03

### Non-therapeutic uses of germline gene editing may be permissible

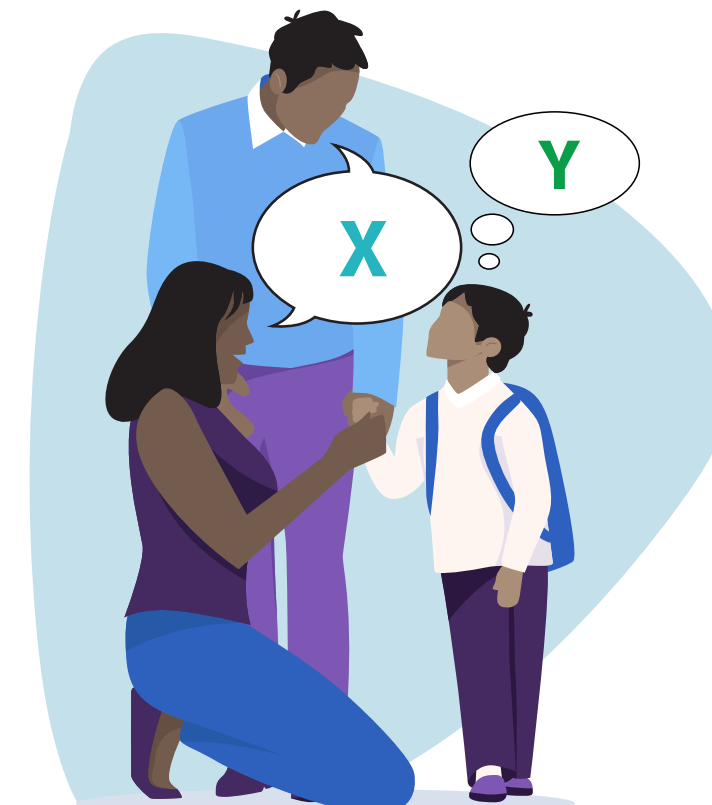
Genetic 'enhancement' is ethically problematic and often viewed as morally reprehensible because it is seen as reminiscent of the state-sponsored eugenics programmes of early 20th Century Britain, America and Nazi Germany. Whereas state-enforced eugenic regimes used coercive means that violated procreative freedom, individual uses of germline editing technologies promote procreative freedom by leaving their application up to individual choice. The Nuffield Council on Bioethics opined that genetic enhancement may sometimes be ethically justifiable and that a blanket prohibition on non-therapeutic applications of germline editing is inappropriate.



## Principle 04

### Respect parents' reproductive autonomy

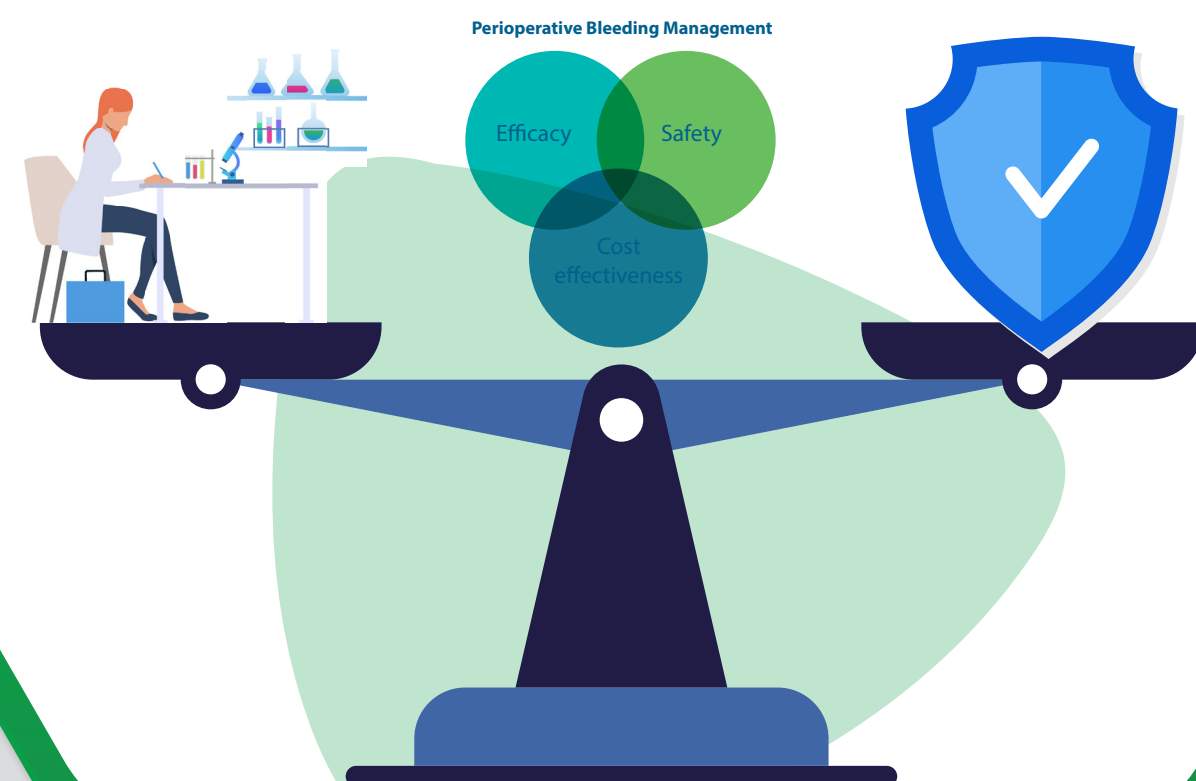
The choice to use safe and effective germline editing should be made by individual prospective parents. The Nuffield Council on Bioethics states that the use of germline editing technology intersects with the high premium modern liberal democracies give to the need to respect the reproductive goals of persons seeking to become parents. The National Academies of Sciences, Engineering, and Medicine reaffirmed (2017) that 'Access to heritable genome editing would be consistent with the broadest legal and cultural interpretations of parental autonomy rights in the United States'.



## Principle 02

### Use the well-established standard of safety and efficacy

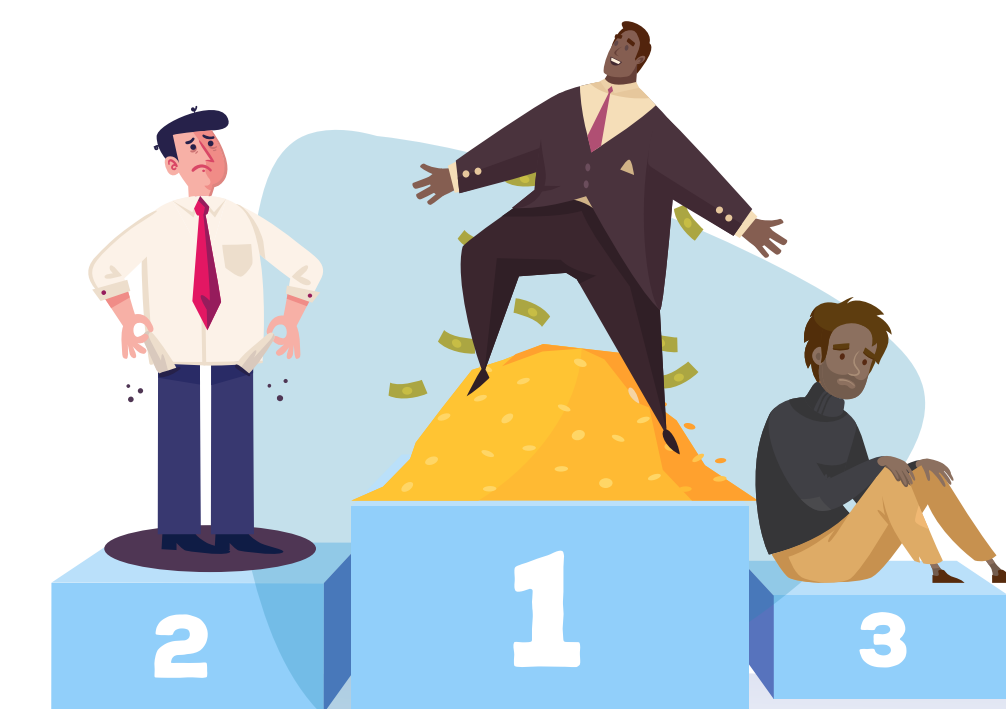
Human germline editing clinical applications should be subjected to clinical trials on humans. Clinical trial protocols must be mindful thereof that germline editing is heritable. The first human trials may have to monitor the trial participants over multiple years, perhaps even over generations. Human germline editing clinical applications should only be made accessible to the public if they are proven to be safe and effective, including the safety and efficacy of germline editing for future generations.



## Principle 05

### Promote the achievement of equality of access

New technology may only be accessible to the rich, exacerbating existing inequalities in society – particularly in societies like SA given the wide gap between the rich and poor, and the lack of access to healthcare for the underprivileged. Although new technologies are initially expensive, eventually it becomes more affordable. However, possible inequality cannot suppress the technology, as that would mean levelling down, rather than by levelling up. A state should rather take measures to make these technologies as widely available as possible, thereby remedying the inequality.



#### References

- Department of Health, Republic of South Africa. Ethics in health research: principles, processes and structures. Pretoria: DoH; 2015.
- Health Professions Council of South Africa [Internet]. Booklet 14: general ethical guidelines for biotechnology research in South Africa. Guidelines for good practice in the health care professions. HPCSA; [updated 2016 September; cited 2019 July 18]. Available from: [https://www.hpcsa.co.za/uploads/editor/Userfiles/downloads/conduct\\_ethics/Booklet%2014.pdf](https://www.hpcsa.co.za/uploads/editor/Userfiles/downloads/conduct_ethics/Booklet%2014.pdf)
- Medical Research Council [Internet]. Guidelines on ethics in reproductive biology and genetic research. MRC; [updated 2002–2004; cited 2019 July 18]. Available from: <http://www.mrc.ac.za/sites/default/files/attachments/2016-06-29/ethicsbook2.pdf>
- National Health Act 61 of 2003.
- The Republic of South Africa. Regulations Relating to Research with Human Participants GN R719/GG 38000 of 19 Sep 2014.
- The Republic of South Africa. Regulations relating to the Use of Human Biological Material GN R177/GG 35099 of 2 Mar 2012.
- Medicines and Related Substances Control Act 101 of 1965.
- AB v Minister of Social Development [2016] ZACC 43, 2017 (3) SA 570 (CC).