
WHO Expert Advisory Committee on
Developing Global Standards for Governance
and Oversight of Human Genome Editing

HUMAN GENOME EDITING:
**A FRAMEWORK FOR
GOVERNANCE**



World Health
Organization

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Foreword

Technological advances hold great opportunities and challenges for global health and society. In order to harness the power of science and innovation, WHO's Science Division was created in 2019 to support Member States in achieving the health-related Sustainable Development Goals (SDGs) and emergency preparedness and response. The Division provides global leadership in translating the latest in science, evidence, innovation, and digital solutions to improve health and health equity for all. This contributes to the WHO's 13th Programme of Work (2019-2023) which stipulates that "...WHO's normative guidance will be informed by developments at the frontier of new scientific disciplines such as genomics, epigenetics, gene editing, artificial intelligence, and big data, all of which pose transformational opportunities but also risks to global health."

Human genome editing has great potential to improve human health and medicine. Human genome editing technologies can be used on somatic cells (non-heritable); germline cells (not for reproduction) and germline cells (for reproduction). Potential benefits of human genome editing include new strategies for diagnosis, treatment and prevention of genetic disorders; new avenues to treat infertility; new ways to promote disease resistance; contribution to vaccine development and enhanced knowledge of human biology. For example, application of somatic human genome editing has already been undertaken, including in vivo editing, to address HIV, sickle-cell disease and transthyretin amyloidosis.¹ Germline human genome editing contributes to deepen our understanding of the role of specific genes and processes in early human development, physiology and diseases. However, there are important areas of ongoing uncertainty as to potential benefits and risks, and gaps in scientific understanding in such key domains as off-target effects and long-term risks.

At the same time, however, somatic, germline and heritable human genome editing raise important and outstanding ethical and social issues. Challenges associated with somatic human genome editing include, for example, rogue clinics, medical travel, as well as the reporting of illegal, unregistered, unethical or unsafe research and other activities including the offer of unproven so-called therapeutic interventions. Heritable human genome editing also gives rise to great concerns as the edit might be passed to subsequent generations. Additional issues include enhancement to improve certain traits, the lack of diversity in collections of human samples and associated data, the need for equity of access to and benefit from human genome editing. There are important differences in the scale of the current challenges posed by somatic, germline and heritable human genome editing.

1 Gillmore JD et al. CRISPR-Cas9 In Vivo Gene Editing for Transthyretin Amyloidosis. NEJM.org. 26 June 2021. DOI: 10.1056/NEJMoa2107454.

In December 2018, WHO established an Expert Advisory Committee on Developing Global Standards for Governance and Oversight of Human Genome Editing. This global multi-disciplinary panel of 18 experts has provided advice and recommendations on appropriate institutional, national, regional and global governance mechanisms for human genome editing, and produced the Governance Framework and Recommendations on Human Genome Editing over a two-year period under the lead of the Health Ethics & Governance Unit in the Science Division.

This work is deliberately future focused. It is situated within wider emerging technologies and makes headway in focusing on addressing systemic issues that will affect the uptake of emerging technologies into public health. The outputs from the Committee are intended to set a footprint for how to harness the power of science and innovation and are already informing the work of WHO in the area of responsible use of the life sciences.

The governance framework intends to provide those responsible for the oversight of genome editing with the tools and guidance they need, putting forward values and principles to inform both how and what decisions are made. The governance framework aims at being scalable, sustainable and appropriate for use at the institutional, national, regional and international levels. Moreover, the Committee produced a series of nine key recommendations on the governance of human genome editing which consider some broader issues associated with the governance of human genome editing. A position paper provides a summary of these two publications.

Finally, I would like to acknowledge and thank all those experts, stakeholders and individuals who have provided inputs throughout the work of the Committee and who contributed to the development of these reports. I hope that these reports will contribute to the safe, effective and ethical uses of human genome editing so all populations can truly benefit from the great potential of these technologies.



Dr Soumya Swaminathan

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