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

HUMAN GENOME EDITING:
RECOMMENDATIONS



World Health
Organization

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

**HUMAN GENOME EDITING:
RECOMMENDATIONS**



**World Health
Organization**

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

ISBN 978-92-4-003038-1 (electronic version)

ISBN 978-92-4-003039-8 (print version)

© World Health Organization 2021

Some rights reserved. This work is available under the Creative Commons Attribution-NonCommercial-ShareAlike 3.0 IGO licence (CC BY-NC-SA 3.0 IGO; <https://creativecommons.org/licenses/by-nc-sa/3.0/igo>).

Under the terms of this licence, you may copy, redistribute and adapt the work for non-commercial purposes, provided the work is appropriately cited, as indicated below. In any use of this work, there should be no suggestion that WHO endorses any specific organization, products or services. The use of the WHO logo is not permitted. If you adapt the work, then you must license your work under the same or equivalent Creative Commons licence. If you create a translation of this work, you should add the following disclaimer along with the suggested citation: “This translation was not created by the World Health Organization (WHO). WHO is not responsible for the content or accuracy of this translation. The original English edition shall be the binding and authentic edition”.

Any mediation relating to disputes arising under the licence shall be conducted in accordance with the mediation rules of the World Intellectual Property Organization (<http://www.wipo.int/amc/en/mediation/rules/>).

Suggested citation. WHO Expert Advisory Committee on Developing Global Standards for Governance and Oversight of Human Genome Editing. Human Genome Editing: recommendations. Geneva: World Health Organization; 2021. Licence: **CC BY-NC-SA 3.0 IGO**.

Cataloguing-in-Publication (CIP) data. CIP data are available at <http://apps.who.int/iris>.

Sales, rights and licensing. To purchase WHO publications, see <http://apps.who.int/bookorders>. To submit requests for commercial use and queries on rights and licensing, see <http://www.who.int/about/licensing>.

Third-party materials. If you wish to reuse material from this work that is attributed to a third party, such as tables, figures or images, it is your responsibility to determine whether permission is needed for that reuse and to obtain permission from the copyright holder. The risk of claims resulting from infringement of any third-party-owned component in the work rests solely with the user.

General disclaimers. The designations employed and the presentation of the material in this publication do not imply the expression of any opinion whatsoever on the part of WHO concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted and dashed lines on maps represent approximate border lines for which there may not yet be full agreement.

The mention of specific companies or of certain manufacturers' products does not imply that they are endorsed or recommended by WHO in preference to others of a similar nature that are not mentioned. Errors and omissions excepted, the names of proprietary products are distinguished by initial capital letters.

All reasonable precautions have been taken by WHO to verify the information contained in this publication. However, the published material is being distributed without warranty of any kind, either expressed or implied. The responsibility for the interpretation and use of the material lies with the reader. In no event shall WHO be liable for damages arising from its use.

This publication contains the collective views of the WHO Expert Advisory Committee on Developing Global Standards for Governance and Oversight of Human Genome Editing and does not necessarily represent the decisions or the policies of WHO

Photo credit - Front cover: © iStock.com/Natali_Mis

Graphic design and layout by Trans.Lieu Company Ltd

Contents

Foreword	iv
Acknowledgements	vi
Executive summary	viii
Part 1. Background	1
Part 2. Recommendations	3
2.1 Leadership by WHO and its Director-General	3
Recommendation	5
2.2 International collaboration for effective governance and oversight	5
Recommendations	7
2.3 Human genome editing registries.....	8
Recommendations	9
2.4 International research and medical travel	10
Recommendations	12
2.5 Illegal, unregistered, unethical or unsafe research and other activities	12
Recommendation	14
2.6 Intellectual property	14
Recommendations	15
2.7 Education, engagement and empowerment.....	16
Recommendations	18
2.8 Ethical values and principles for use by WHO.....	19
Recommendation	20
2.9 Review of the recommendations.....	20
Recommendation	20
Annex Meetings, consultations and webinars: participants	21

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 amyloidosis¹. 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
Chief Scientist



Acknowledgements

The governance framework and the recommendations on human genome editing form a pair of reports that have been developed by the WHO Expert Advisory Committee on Developing Global Standards for Governance and Oversight of Human Genome Editing.

These publications have been developed under the direction and coordination of Ms Katherine Littler (Co-lead, Health Ethics & Governance Unit), under the overall guidance of John Reeder (Director, Research for Health) and Soumya Swaminathan (Chief Scientist).

Dr Piers Millett (consultant, United Kingdom of Great Britain and Northern Ireland) provided support to the project and was the lead writer of the publications as well as the meeting reports of the Committee. Dr Emmanuelle Tuerlings (consultant, Switzerland) also provided support and contributed to the writing of the documents.

WHO wishes to thank the following individuals and organizations for their contributions to the development of these publications.

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

WHO is most grateful to the Co-Chairs, Dr Margaret Hamburg, former Commissioner of the U.S. Food and Drug Administration and former Foreign Secretary, National Academy of Medicine, United States of America and Justice Edwin Cameron, Inspecting Judge of Correctional Services, South Africa, and the members of the Committee for their invaluable guidance, expertise and great support throughout the project and the conceptualization and development of the three publications (by alphabetical order):

预览已结束，完整报告链接和二维码如下：

https://www.yunbaogao.cn/report/index/report?reportId=5_23728

