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

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HUMAN GENOME EDITING:  
**RECOMMENDATIONS**



World Health  
Organization



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

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

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# Foreword

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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<sup>1</sup>. 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.

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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

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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.

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

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All authors and members of the WHO Expert Advisory Committee on Developing Global Standards for Governance and Oversight of Human Genome Editing declared their interests according to WHO standard procedures. None of the interests declared were found to be significant.

To the experts and organizations who participated in the in-person meetings, the online meetings and webinars and provided valuable inputs through sharing their experiences and insights on human genome editing. The Annex of this document lists the participants in meetings, consultations and webinars.

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# Executive summary

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The recent application of tools, such as CRISPR-Cas9 (clustered regularly interspaced short palindromic repeats; Cas9 nuclease), to edit the human genome with the intention of treating or preventing disease and the gaps in our scientific understanding, in addition to some of the proposed applications of human genome editing, raise ethical issues that have highlighted the need for robust oversight in this area. The COVID-19 pandemic has clearly demonstrated the importance of using new tools and methods to combat serious diseases and highlighted the potential benefits of human genome editing research. It also reminds us of the need to develop technology carefully, with robust testing and quality assurance measures in place to maximize benefit and minimize harm. The balance between benefit and harm, safety and speed, and innovation and access is relevant to all of human genome editing.

In December 2018, the World Health Organization (WHO) established a global, multidisciplinary expert advisory committee (the Expert Advisory Committee on Developing Global Standards for Governance and Oversight of Human Genome Editing, hereafter called the Committee) to examine the scientific, ethical, social and legal challenges associated with human genome editing (somatic, germline and heritable). The Committee was tasked to advise and make recommendations on appropriate institutional, national, regional and global governance mechanisms for human genome editing. Its remit did not include a review of matters to do with safety and efficacy. Committee members were drawn from each of the WHO regions – Africa, the Americas, South-East Asia, Europe, Eastern Mediterranean and Western Pacific.

The 18 members of the Committee worked for two years and developed several products and initiatives. The governance framework on human genome editing, along with the recommendations of the Committee, form a set of two publications that provide advice and recommendations on appropriate institutional, national, regional and global governance mechanisms for human genome editing. A position paper on human genome editing provides a summary of these two publications.

During its work, the Committee reviewed the current literature on human genome editing research and its applications, considered existing proposals for governance and relevant ongoing initiatives, and gathered information on a range of topics relating to the different uses of this technology. The Committee consulted widely with individuals and representatives of organizations including, but not limited to, United Nations (UN) and other international agencies; academies of science and medicine as well as other national or professional bodies; patient groups and civil society organizations.

To ensure a participatory process in the course of its work, the Committee consulted widely and solicited information about societal attitudes towards a number of areas of research and clinical use of human genome editing technology. The Committee consulted with international organizations, regional organizations, national health ministries, national regulatory authorities, national research institutes, national boards of technology, patient groups and patient advocates, civil society organizations, indigenous groups, campaign groups, industry associations, private companies, national academies, bioethics

committees, professional societies, universities, medical schools and academic research institutions, as well as other relevant experts and interested parties. Participants from 29 distinct groups contributed to the Committee's meetings. The Committee also held two in-person and 15 online topic-specific meetings drawing on contributions from 71 distinct groups.

Following careful reflection and deliberation, the Committee produced a series of recommendations in nine discrete areas. The Committee noted that its recommendations are subject to the limits of WHO's mandate and resources. In implementing these recommendations, the Committee wished to stress the importance of avoiding unfunded mandates.

## **1. Leadership by WHO and its Director-General**

WHO and its Director-General should demonstrate both scientific and moral leadership, by: (i) being open about the opportunities and challenges inherent to human genome editing; (ii) clearly stating the ethical aspects of human genome editing (including a statement on somatic human genome editing to address equitable access to the benefits of research and priority setting and, for heritable human genome editing, at a minimum, reiteration of the Director-General's statement of July 2019); and (iii) outlining the consequences of failing to address the ethical issues before us if we develop and use technologies without prior careful reflection and intentional collaborative decision-making.

## **2. International collaboration for effective governance and oversight**

WHO should work with others to develop and implement a shared vision for an ongoing international process to: (i) identify and develop points of agreement or convergence; (ii) establish a process for identifying key decision points; (iii) explore opportunities for collaborative engagement, standard-setting, investigation and oversight; and (iv) share information on relevant existing and planned policies (laws, regulations and guidelines).

In the interim, the Director-General should institute a cross-institutional approach, including to: (i) task the regulatory strengthening and capacity building teams within WHO's Department of Essential Medicines and Health Products to begin working on integrating human genome editing into their activities; (ii) convene a meeting of regulators from Member States on the feasibility of international agreements, capacity-building needs and possibilities for harmonization; and (iii) task the Science Division to convene meetings on human genome editing in each of the six WHO regional offices with regulators, medical and scientific leaders, patient groups, civil society organizations and other relevant bodies.

## **3. Human genome editing registries**

WHO should: (i) ensure that clinical trials using somatic human genome editing technologies are reviewed and approved by the appropriate research ethics committee before inclusion in the Registry of human genome editing clinical trials; (ii) request that national and regional clinical trials registries make use of keywords to identify clinical trials using human genome editing technologies; (iii) develop an assessment mechanism to identify clinical trials using human genome editing technologies that may be of concern; (iv) establish a small expert committee to regularly monitor the clinical trials Registry and to develop and review a set of international standards for clinical trials involving human genome editing for the clinical trials Registry; and (v) support members of the scientific community to develop an additional basic and preclinical research registry.

## **4. International research and medical travel**

The Director-General, in consultation with his new Science Council, should make a policy statement that somatic or germline human genome editing research should only take place in jurisdictions with domestic policy and oversight mechanisms. WHO, with guidance from the Science Council, should integrate into all of its relevant activities a focus on fostering responsible international research and medical travel.

## **5. Illegal, unregistered, unethical or unsafe research and other activities**

WHO, with advice from its recently established Science Council, should charge the Science Division to lead an effort to create a multisector collaboration to develop an accessible mechanism for confidential reporting of concerns about possibly illegal, unregistered, unethical and unsafe human genome editing research and other activities.

## **6. Intellectual property**

WHO should: (i) work with others to encourage relevant patent holders to help ensure equitable access to human genome editing interventions; (ii) encourage industry to work with resource constrained countries to build capacity to take advantage of human genome editing inventions; and (iii) convene a meeting of those holding or applying for patents relevant to human genome editing, industry bodies, international organizations, such as the World Intellectual Property Organization and the World Trade Organization, and those involved in establishing or running relevant patent pools to explore the potential for the adoption of appropriate ethical licensing requirements.

## **7. Education, engagement, and empowerment**

The Director-General should: (i) call upon the United Nations Secretary-General to establish a United Nations interagency working group on frontier technologies that facilitates global dialogue and produces a report outlining the implications of innovative technologies, including human genome editing, and the ethical frameworks to guide their application; and (ii) call for an inclusive dialogue on the future of human genome editing, including scientific, ethical and societal aspects.

WHO should: (i) develop models of best practice of inclusive multidirectional, multistakeholder dialogue, and supporting materials, that can be applied to human genome editing; and (ii) explore how best to include in decision-making under-represented groups that are interested in human genome editing.

## **8. Ethical values and principles for use by WHO**

WHO should charge the health ethics and governance unit in the Science Division to lead an effort to create a set of officially endorsed and clearly defined ethical values and principles for use by its expert committees and in WHO deliberations. These values and principles should be built on public health goals and priorities. These should go beyond the WHO workforce, and provide an important road map for progress towards the Organization's goals.

## **9. Review of the recommendations**

In no more than 3 years, WHO's Science Division should initiate an extensive review of these recommendations and the progress made to implement them. This review should not take longer than 18 months and should take into account scientific, technological, and societal changes, adequacy of implementation and assessment of impact, and potential future needs or concerns.



# Part 1.

## Background

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The recent application of tools, such as CRISPR-Cas9 (clustered regularly interspaced short palindromic repeats; Cas9 nuclease), to edit the human genome with the intention of treating or preventing disease and the gaps in our scientific understanding, in addition to some of the proposed applications of human genome editing, raise ethical issues that have highlighted the need for robust oversight in this area. The World Health Organization (WHO) established a global, multidisciplinary expert advisory committee (the Expert Advisory Committee on Developing Global Standards for Governance and Oversight of Human Genome Editing, hereafter called the Committee) to examine the scientific, ethical, social and legal challenges associated with human genome editing (somatic, germline and heritable).<sup>2</sup> Committee members were chosen from each of the WHO regions – Africa, the Americas, South-East Asia, Europe, Eastern Mediterranean and Western Pacific.<sup>3</sup>

The Committee was tasked to advise and make recommendations on appropriate institutional, national, regional and global governance mechanisms for human genome editing. Its remit did not include a review of matters to do with safety and efficacy. This charge was given to the International Commission on the Clinical Use of Human Germline Genome Editing.<sup>4</sup> During the course of its work, the Committee reviewed the current literature on human genome editing, considered existing proposals for governance and relevant ongoing initiatives, and gathered information on societal attitudes towards the different research and clinical uses of this technology.

The Committee consulted widely with individuals and representatives of organizations including, but not limited to, relevant United Nations and other international agencies, academies of science and medicine as well as other national or professional bodies, patient groups and civil society organizations. These consultations explored how best to promote transparent and trustworthy policies and practices and ensure appropriate assessments of relevant work prior to it being undertaken.

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2 Expert Advisory Committee on Developing Global Standards for Governance and Oversight of Human Genome Editing (who.int) (accessed 27 June 2021).

3 Expert Advisory Committee on Developing Global Standards for Governance and Oversight of Human Genome Editing (who.int) (accessed 27 June 2021).

4 National Academy of Medicine, National Academy of Sciences and the Royal Society. Heritable human genome editing. Washington, DC: The National Academies Press; 2020. <https://doi.org/10.17226/25665>



During its work, the Committee was mindful of the fact that the science and technology of genome editing was changing rapidly. To support its understanding of recent advances and developments, the Committee commissioned a report on current capabilities for human genome editing.<sup>5</sup> This report highlights important developments in the understanding of relevant basic science, such as on repairing genetic material (for example, in both non-homologous end joining and homology-directed repair).

The report reviewed tools for human genome editing, such as base editing and prime editing. It discussed different approaches to human genome editing, such as altering the regulation of genes rather than the genetic material, for example, transcriptional modulators and epigenetic editing. The report also explored different ways in which human genome editing might be used, such as for prenatal (in utero) somatic human genome editing. The report addressed different targets of human genome editing, such as precision editing of mitochondrial DNA.

The Committee invited and received a wide range of inputs to their deliberations, including through participation in its meetings, online public consultations,<sup>6</sup> and a series of webinars (Annex). The Committee shared the view of the European Group on Ethics in Science and New Technologies on the importance of “participatory development of a governance framework”.<sup>7</sup> The Committee reflected carefully on all the materials available. This document gives the key recommendations to the WHO Director-General resulting from the Committee’s deliberations. It is intended to complement, and not replace, other outputs from the Committee’s work, which include:

- the global Registry on human genome editing;<sup>8</sup>
- a policy statement by the Director-General, resulting from an interim recommendation by the Committee to clarify that “it would be irresponsible at this time for anyone to proceed with clinical applications of germline human genome editing”;<sup>9</sup>
- a governance framework for human genome editing;<sup>10</sup>
- an accessible glossary of common terms available to the public;<sup>11</sup> and
- Reports of the Committee’s work, including summaries of six meetings and two open-ended public consultations.<sup>12</sup>

5 Expert Advisory Committee on Developing Global Standards for Governance and Oversight of Human Genome Editing (who.int) (accessed 27 June 2021).

6 Expert Advisory Committee on Developing Global Standards for Governance and Oversight of Human Genome Editing (who.int) (accessed 27 June 2021).

7 European Group on Ethics in Science and New Technologies. Ethics of genome editing. Brussels, European Union; 2021:87 (<https://op.europa.eu/en/web/eu-law-and-publications/publication-detail/-/publication/6d9879f7-8c55-11eb-b85c-01aa75ed71a1>, accessed 5 May 2021).

8 WHO launches global registry on human genome editing (accessed 27 June 2021).

9 Statement on governance and oversight of human genome editing (who.int) (accessed 27 June 2021).

10 Expert Advisory Committee on Developing Global Standards for Governance and Oversight of Human Genome Editing (who.int) (accessed 27 June 2021).

11 Expert Advisory Committee on Developing Global Standards for Governance and Oversight of Human Genome Editing (who.int) (accessed 27 June 2021).

12 These documents and more resources developed during the work of the Committee can be found on its webpages: Expert Advisory Committee on Developing Global Standards for Governance and Oversight of Human Genome Editing (who.int) (accessed 27 June 2021).

# Part 2.

## Recommendations

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Following careful reflection and deliberation, the Committee formulated a set of recommendations in nine areas (Box 1).

**Box 1.****Recommendations of the Committee on the governance and oversight of human genome editing**

1. Leadership by the WHO and its Director-General
2. International collaboration for effective governance and oversight
3. Human genome editing registries
4. International research and medical travel
5. Illegal, unregistered, unethical or unsafe research and other activities
6. Intellectual property
7. Education, engagement and empowerment
8. Ethical values and principles for use by WHO
9. Review of the recommendations

The Committee noted that its recommendations were subject to the limits of WHO's mandate and resources. In implementing these recommendations, the Committee wished to stress the importance of avoiding unfunded mandates.

These recommendations complement other deliverables outlined in Part 1.

### 2.1 Leadership by WHO and its Director-General

As an organization dedicated to advocating for and ensuring the health and well-being of all people and all nations, WHO, led by its Director-General, has an essential role to play in helping negotiate and promote norms and regulations that can ensure our most important values will guide the application of genome editing technologies. Indeed, WHO and its Director-General are uniquely positioned to articulate global ethical values and principles, exercise moral authority and thereby lead through moral suasion. WHO and its Director-General are also in the position to offer advice and assistance.

While WHO cannot stipulate global policy, the Organization and its Director-General can and do make policy statements calling attention to both good and bad policies and practices in an effort to encourage those in positions of authority and power to support change and promote global unity. For example, in July 2019, the Director-General issued a statement on governance and oversight of heritable human genome editing calling on “regulatory or ethics authorities to refrain from issuing approvals concerning requests for clinical applications for work that involves human germline genome editing.”<sup>13</sup> That call was heeded. For example, in response to public statements made by a researcher, the Ministry of Health of the Russian Federation clarified that existing policies included contraindications and restrictions on the use of assisted reproductive technologies, and announced that they would not approve the planned research.<sup>14,15</sup>

More recently, in January 2021 with regard to access to the coronavirus disease 2019 (COVID-19) vaccine, the Director-General told WHO’s Executive Board, “I need to be blunt: the world is on the brink of a catastrophic moral failure – and the price of this failure will be paid with lives and livelihoods in the world’s poorest countries.”<sup>16</sup> These remarks were widely reported and had an impact around the world. For example, they seem to have helped increase the speed of vaccine distribution to low- and middle-income countries. They also prompted the heads of other organizations, such as the United Nations Children’s Fund (UNICEF) and the World Trade Organization, to join the call.<sup>17,18</sup> Similar calls to ensure access to the benefits of human genome editing have already been made. For example in March 2021, the European Group on Ethics in Science and New Technologies urged that for somatic human genome editing “access to clinical studies and, once approved, to clinical application in healthcare is granted according to the principle of social justice and without discrimination”.<sup>19</sup>

Being proactive and calling out examples of what should not happen (such as the Director-General’s statement on human genome editing in July 2019), and helping visualize a path towards what should happen (such as the January 2021 statement on COVID-19 vaccine equity and many subsequent statements) is one key aspect of WHO’s leadership that the Committee considers important and appropriate.

Effective governance and oversight of human genome editing will require laws, policies and practices at institutional, national, regional and international levels across the world. While the Committee’s governance framework details a number of approaches and resources that might be helpful, the practical implementation of governance for human genome editing will require working with many different groups, peoples and institutions who will each bring their experiences, strengths and resources to this collective effort. WHO can, and should, play a leadership role in providing technical, legal, ethical and regulatory expertise and helping to sustain efforts to regulate or govern human genome editing in all its Member States.

This broad leadership is particularly important because human genome editing technologies may be used by many different people, in different ways and in pursuit of different goals. Public health is only one aspect of efforts to ensure effective governance and oversight of these and other emerging technologies. Furthermore, genome editing of non-human organisms may also have an impact on public health. To take advantage of shared endeavours, and avoid duplicating efforts and wasting resources, WHO will need to work openly and in partnership with a wide range of groups, people and institutions, within and beyond the global public health community, to maximize potential benefits and minimize potential harms from human genome editing technologies.

13 Statement on governance and oversight of human genome editing (who.int) (accessed 27 June 2021).

14 <https://doi.org/10.1038/d41586-019-03617-x> (accessed 5 May 2021).

15 <https://tass.ru/obschestvo/6968512> (accessed 5 May 2021).

16 <https://www.who.int/director-general/speeches/detail/who-director-general-s-opening-remarks-at-148th-session-of-the-executive-board> (accessed 9 March 2021).

17 <https://www.who.int/news/item/10-02-2021-in-the-covid-19-vaccine-race-we-either-win-together-or-lose-together> (accessed 5 May 2021).

18 [https://www.wto.org/english/news\\_e/news21\\_e/dgno\\_09mar21\\_e.htm](https://www.wto.org/english/news_e/news21_e/dgno_09mar21_e.htm) (accessed 5 May 2021).

19 European Group on Ethics in Science and New Technologies. Ethics of genome editing. Brussels, European Union; 2021:88 (<https://op.europa.eu/en/web/eu-law-and-publications/publication-detail/-/publication/6d9879f7-8c55-11eb-b85c-01aa75ed71a1>, accessed 5 May 2021).

<b>Purpose</b>	The Committee believes that WHO and its Director-General should lead through moral persuasion, encouraging others to welcome and actively support the WHO vision of promoting health equity and reducing human suffering.
<b>Relevant values and principles</b>	All.
<b>Actions</b>	<ol style="list-style-type: none"> <li>1. To promote effective governance and oversight of human genome editing in accordance with sound ethical values and principles.</li> <li>2. To support relevant actions by others in the role of convenor and facilitator.</li> </ol>
<b>Practical considerations</b>	WHO and its Director-General can readily show leadership in the short term. This leadership will need to be sustained in the medium to longer term. Further concrete action will require additional resources (including political capital). Focus and resources on this issue will be limited while the world is suffering or recovering from the COVID-19 pandemic.

## Recommendation

WHO and its Director-General should demonstrate both scientific and moral leadership by:

- a. Being open about the opportunities and challenges inherent in human genome editing and communicating these issues in clear, jargon-free, language that is accessible to us all;
- b. Clearly stating the ethical aspects of human genome editing. This will require statements on both somatic and heritable human genome editing. For somatic human genome editing, a statement should address equitable access to the benefits of research and priority setting (for example, sickle-cell disease as a priority). For heritable human genome editing, at a minimum, a statement should reiterate the earlier statement of July 2019;<sup>20</sup> and
- c. Outlining the consequences of failing to address the ethical issues before us if we develop and use technologies without prior careful reflection and intentional collaborative decision-making.

## 2.2 International collaboration for effective governance and oversight

The Committee believes that no one international body, institution or organization can have sole responsibility for the governance of human genome editing.

The Committee reiterated that it encourages but cannot mandate a coordinated global approach. In the absence of such an approach, the Committee acknowledges that different jurisdictions, with different political systems, and cultural, historical and religious contexts will likely differ in their preferred regulatory approaches. The Committee has attempted through its governance framework to assist regional, national and local efforts through: (i) identification of values and principles to guide policy-making; (ii) attention to the many different and complex ways in which governance mechanisms can be used to provide good-quality oversight; (iii) sample questions to be considered when strengthening and developing governance measures for human genome editing in general, as well as questions specific to a number of special challenges; and (iv) scenarios to explore real-world opportunities and challenges with human genome editing.

20 <https://www.who.int/news/item/26-07-2019-statement-on-governance-and-oversight-of-human-genome-editing> (accessed 5 May 2021).

The Committee discussed the merits of having a new and permanent international body for the governance of human genome editing, and considered different institutional models for bringing together the necessary partners. Approaches adopted by the Intergovernmental Panel on Climate Change, ethics work at the United Nations Educational, Scientific and Cultural Organization (UNESCO), and the Working Party on Biotechnology, Nanotechnology and Converging Technologies of the Organisation for Economic Co-operation and Development (OECD) were considered. The Committee identified strengths and weaknesses with each model. While the resources required for each of these models were different, they were all considerably greater than those currently devoted to the international governance of human genome editing – taking, for example, the resources invested in the International Commission<sup>21</sup> and the Committee as a benchmark.

The Committee maintains that the governance of human genome editing, as with many emerging technologies, cannot be resolved using a single process or meeting. Rather, given the rapidly evolving nature of the underlying technologies and the resulting potential for benefit, harm or other effects, an ongoing process is needed that takes into account relevant technical, societal, economic, legal and ethical developments and adapts governance measures accordingly. As a result, the Committee believes that the need for many of its tasks will not end when it has fulfilled its mandate and, therefore, an ongoing international process is required.

The Committee also considered whether there were opportunities to reduce the potential for duplication of efforts and increase efficiency and effectiveness. The Committee identified the following two aspects of human genome editing to consider for future work that may be broadly or narrowly focused.

1. **The impact.** Human genome editing will have public health implications but will also likely affect human rights, ethics and the Sustainable Development Goals. Should future work be narrowly focused on public health considerations or should it be part of a broader consideration? Even if limited to public health considerations, should the focus be only on direct health impacts, or should it include WHO's broader view of public health and consider issues such as food security, energy security and environmental security?
2. **The technology.** Human genome editing is only one way in which new and future genome editing tools can be used. These tools are already being used, for example, in agriculture, industrial manufacturing, and in the chemical and energy industries. Should future work be narrowly focused on the use of these technologies in humans, or should it be part of a broader consideration of genome editing technologies? Or should future work have an even wider focus, perhaps as part of efforts to consider emerging technologies and their convergence more broadly?

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21 <https://www.nationalacademies.org/our-work/international-commission-on-the-clinical-use-of-human-germline-genome-editing> (accessed 26 May 2021).

<b>Purpose</b>	The Committee believes that it is important to explore collaborative international governance and oversight of human genome editing.
<b>Relevant values and principles</b>	Inclusiveness, caution, social justice, solidarity and global health justice.
<b>Actions</b>	<ol style="list-style-type: none"> <li>1. To bring together the international organizations, institutions, bodies and people interested in the ethics and governance of human genome editing.</li> <li>2. To share information of relevant policies (including laws, regulations and guidelines).</li> <li>3. To identify points of agreement or convergence associated with international governance.</li> <li>4. To explore opportunities for collaborative engagement, standard-setting, investigation and oversight.</li> </ol>
<b>Practical considerations</b>	Given that the implications of human genome editing are closely connected with broader efforts on emerging technologies, human genome editing has consequences not only for public health. At the same time, uses of genome editing, other than human genome editing, could have public health implications. A global process to explore collaborative international governance and oversight of human genome editing is therefore needed. A wide range of organizations, institutions, bodies and peoples will need to be involved in future oversight processes on human genome editing. These bodies may have competing interests or mandates. Substantial resources will be required for sustained international collaboration.

## Recommendations

WHO, including its Science Division and the departments focusing on regulatory strengthening and capacity-building, should collaborate with relevant international bodies, such as the International Bioethics Committee of UNESCO, to develop and implement a shared vision for an ongoing international process, to: (i) identify and develop points of agreement or convergence; (ii) establish a process for identifying key decision points; (iii) explore opportunities for collaborative engagement, standard-setting, investigation and oversight; and (iv) share information on relevant existing and planned policies (laws, regulations and guidelines).

In the interim, the Director-General should institute a cross-institutional approach, including to:

- a. Task the regulatory strengthening and capacity building teams within WHO's Department of Essential Medicines and Health Products to begin working on integrating human genome editing into their activities.
- b. Convene a meeting of regulators from Member States to address: (i) the feasibility of international agreements on regulatory approaches for human genome editing; (ii) capacity-building needs; and (iii) possibilities for harmonization. This meeting may build on past efforts, such as those undertaken by the OECD and Member States.
- c. Task the Science Division to convene meetings on human genome editing in each of the six WHO regional offices with regulators, medical and scientific leaders, patient groups, civil society organizations and other relevant bodies. The outcomes from these regional discussions should be directly included in international consideration of these issues.

## 2.3 Human genome editing registries

Accepting the interim recommendation of the Committee, WHO launched the global human genome editing registry (Registry) in August 2019. This Registry, currently in a pilot phase, compiles existing and incoming data from the WHO International Clinical Trials Registry Platform for the Registry's database. The goal is to make information on clinical trials involving human genome editing publicly accessible. The Registry covers all human genome editing technologies, including base editing, prime editing, editing of mitochondrial DNA and epigenetic editing, and captures any form of genetic manipulation. Existing genetic manipulation tools and future technologies and processes are covered by the Registry. At present, the Registry is focused on clinical trials involving somatic genome editing. If, at some future time, clinical trials involving heritable human genome editing are approved, the Registry should include those data. This parallels a recent call by the European Group on Ethics in Science and New Technologies to "establish a public registry for research on germline genome editing".<sup>22</sup>

In accordance with the values and principles of openness, transparency, honesty and accountability, the Registry is publishing all information received about clinical trials using human genome editing. However, without monitoring this information, problems could arise. In the field of stem cell research, unscrupulous entrepreneurs and clinics have deliberately misused clinical trial registries by registering procedures they plan to undertake as if they were properly sanctioned clinical trials. These procedures have had little or no scientific justification, lacked preclinical data and were ethically flawed. There was little evidence that a trial would ever be conducted. Because these procedures are in a clinical trials registry, they appear legitimate, even though they lack evidence of safety or efficacy, and they attract participants who are desperate for an intervention that they think will treat their illness. Furthermore, not all registries require research ethics approval before registration. The Committee acknowledges that these challenges are not unique to human genome editing and that clinical trials registries in general may need to be improved.

Existing clinical trials registries, including WHO's International Clinical Trials Registry Platform, currently are not set up to include basic or preclinical research. A registry that includes basic and preclinical human genome editing research will help support responsible research practices, prevent unnecessary duplication of research and contribute to the provision of best examples for protocols.

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22 European Group on Ethics in Science and New Technologies. Ethics of genome editing. Brussels, European Union; 2021:87 (<https://op.europa.eu/en/web/eu-law-and-publications/publication-detail/-/publication/6d9879f7-8c55-11eb-b85c-01aa75ed71a1>, accessed 6 May 2021).



<b>Purpose</b>	The Committee believes that better information on current practices associated with and progress on relevant basic, preclinical and clinical human genome editing research is urgently needed.
<b>Relevant values and principles</b>	Openness, transparency, honesty and accountability, responsible regulatory stewardship, responsible stewardship of science and responsible stewardship of research resources.
<b>Actions</b>	<ol style="list-style-type: none"> <li>1. To create and host a Registry for human genome editing clinical trials that will provide structured mechanisms for collecting and curating details of planned and ongoing clinical trials involving human genome editing.</li> <li>2. To ensure that clinical trials included in the Registry of human genome editing clinical trials have proper ethics approval before registration.</li> <li>3. To task a small expert committee to monitor and update the Registry of human genome editing clinical trials, review international standards and develop a review mechanism to identify and alert people to clinical trials using human genome editing technologies that may be of concern.</li> <li>4. To support members of the scientific community to create a registry for basic and preclinical research using human genome editing technologies that will provide structured mechanisms for collecting and curating details of such planned and ongoing research involving human genome editing.</li> <li>5. To identify a host organization for the basic and preclinical registry once it has been developed.</li> <li>6. To encourage effective reporting of illegal, unregistered, unethical or unsafe human genome editing clinical trials.</li> </ol>
<b>Practical considerations</b>	In the short-to-medium term, pre-existing databases will need to be used such as the WHO International Clinical Trials Registry Platform for the clinical trials Registry. WHO should work in partnership with other organizations to: (i) maintain the clinical trials Registry and develop and implement the proposed screening mechanism; and (ii) develop and maintain a registry for basic and preclinical research using human genome editing technologies.

## Recommendations

WHO should ensure that clinical trials using somatic human genome editing technologies are reviewed and approved by the appropriate research ethics committee before inclusion in the Registry of human genome editing clinical trials. National and regional clinical trial registries should require ethics approval information when registrants submit trials using human genome editing technologies. Such information should be available in a format that is easily accessible for translation. If at some future time clinical trials using heritable human genome editing technologies are approved, similar measures should be taken to include relevant data in the clinical trials Registry.

WHO should request that national and regional clinical trial registries make use of keywords to identify clinical trials using human genome editing technologies. A keyword such as “human genome editing” that will capture any of the many variants of human genome editing technologies should be included in the registries. This will help national and regional registries and the Registry of human genome editing clinical trials keep up to date with technological changes. Any clinical trials using human genome editing already available or tools being developed (for example, by the somatic cell genome editing program of the United States National Institutes of Health<sup>23</sup>) should also include “genome editing” as a search term.

23 <https://www.nature.com/articles/s41586-021-03191-1#Sec3> (accessed 6 May 2021).

WHO should develop an assessment mechanism to identify clinical trials using human genome editing technologies that may be of concern. This mechanism should make public that certain clinical trials may raise questions or concerns if they do not fulfill the criteria for inclusion in the clinical trials Registry. These criteria will need to be developed but may start by adapting the *International standards for clinical trial registries* published by WHO<sup>24</sup> for use with human genome editing.

WHO's Science Division should establish a small expert committee to (i) regularly monitor the clinical trials Registry, including reviewing and updating its definitions and algorithms, and (ii) develop and review a set of international standards for clinical trials involving human genome editing for the clinical trials Registry. Any clinical trials of concern should be highlighted. The expert committee should work as a peer-review panel, underlining the importance of undertaking responsible and high-quality research. Careful attention should be paid to issues of conflict of interest. This monitoring process could also serve as a model for other emerging technologies.

WHO should support members of the scientific community to develop an additional basic and preclinical research Registry for research using human genome editing technologies on (i) human embryos and (ii) germline cells or their progenitors when gametes derived from these will be used to create embryos that will not be used to establish a pregnancy.<sup>25</sup> Existing national and regional clinical trial registries do not include basic or preclinical research. Funders, journals and professional organizations should participate in the operationalization of this recommendation. A host organization for this Registry would need to be identified.

## 2.4 International research and medical travel

Scientific research has become increasingly collaborative and international in nature. While this development could extend the potential benefits of scientific innovation to the global population, it also introduces important ethical challenges. Of concern are differences in regulatory standards across the world, and heterogeneity in terms of what is permitted and what is prohibited. This has led to calls for the need “to organise ethics oversight of international research collaboration and prevent ethics dumping”.<sup>26</sup>

Not all countries have committed, or can commit, the resources required to ensure the effective regulation and oversight of research involving humans, including research involving human genome editing (See Table 1 and Table 2 of the governance framework). This situation introduces the risk that research which is prohibited, restricted or considered unethical in countries with robust regulation and oversight will be conducted in countries with no relevant domestic policy (including laws, regulations and guidelines) or with relevant policy but limited oversight. The Committee is particularly concerned about the possibility that somatic or germline human genome editing research might be conducted in countries with limited or no relevant policy and oversight, *for the sole purpose of* avoiding oversight and ethical standards, which, if adhered to, may have financial, logistical or other costs. This is particularly inexcusable if the research and subsequent uses will primarily benefit residents of better regulated countries while the residents of countries where the research was conducted receive little or no benefit.

24 International standards for clinical trial registries – version 3.0. Geneva: World Health Organization; 2018 (<https://www.who.int/clinical-trials-registry-platform/publications>, accessed 7 June 2021).

25 Research on human germline cells, such as anything from embryonic stem, induced pluripotent stem cells, primordial germ cells to spermatogonial stem cells can be carried out without the need for them to be registered. The registry captures all relevant research that might involve a human embryo (whether created in vitro or in vivo).

26 European Group on Ethics in Science and New Technologies. Ethics of genome editing. Brussels, European Union; 2021:88 (<https://op.europa.eu/en/web/eu-law-and-publications/publication-detail/-/publication/6d9879f7-8c55-11eb-b85c-01aa75ed71a1>, accessed 6 May 2021). Explanation of ethics dumping is given later in this section.

The Committee supports all efforts to prevent unethical research where individuals or companies specifically choose to locate their research activities in countries with limited or no domestic policy and oversight. A number of terms are used to describe this practice including so-called regulatory triage, offshore research and helicopter research. A new term that is increasingly applied to this research practice is ethics dumping,<sup>27</sup> which has been used in relation to human genome editing.<sup>28,29</sup>

To better understand and discuss this issue, the Committee held a satellite meeting at the meeting of the Global Forum on Bioethics in Research in Singapore in November 2019 (Annex). The Committee was also briefed on this issue at its third meeting in February 2020 by representatives of the San Council of South Africa and South African regulators and ethics committee members. The Committee learnt about codes of conduct that specifically focus on preventing unethical research in lower-resource settings, such as the San Code of Research Ethics<sup>30</sup> and the Global Code of Conduct for Research in Resource-Poor Settings.<sup>31</sup> The Committee also held webinar discussions with key informants.

The Committee recognises that there are legitimate reasons for research to be conducted in a country other than the country(ies) where the research team is based, for instance if the research involves efforts to address current global health and science inequities. The Committee does not accept that avoiding responsible policy, oversight and ethical standards is a legitimate justification for the international conduct of research.

A similar challenge arises with the offer of premature, so-called therapeutic interventions. This challenge is especially acute when individuals or companies avoid responsible policy, oversight and ethics guidelines by locating their activities in jurisdictions lacking relevant policy, or with relevant policy but limited or no oversight. This is sometimes referred to as medical travel or medical tourism. Medical travel occurs when an individual travels from their home jurisdiction (for example, their country of residence) to another jurisdiction to access therapeutic interventions.

The Committee recognises that there are legitimate reasons for medical travel, for example, where people travel in pursuit of elective or medically necessary procedures that are available in their home jurisdiction, but for which waiting lists are long or the cost is considerably higher than in other jurisdictions. In addition, there can be legitimate medical travel to another jurisdiction where individuals seek an established (safe and effective) therapeutic intervention that is not yet approved where they live, or that is prohibited in their home jurisdiction for religious or other restrictive reasons.

Separate from these reasons is travel to access medical procedures that are unavailable in their home jurisdiction because they have not yet been shown to be safe and effective under any responsible regulatory scheme. In considering recent experience with the sale of unsafe and unproven, so-called stem cell therapies, the Committee is concerned about the possibility that individuals or companies would offer such unsafe and unproven so-called therapies related to human genome editing in jurisdictions with no relevant policy, or with relevant policy but limited or no oversight, in order to avoid responsible policy, oversight and ethics guidelines in other jurisdictions.

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27 Schroeder D, Cook J, Hirsch F, Fenet S, Muthuswamy V, editors *Ethics dumping: case studies from north-south research collaborations*. Basingstoke: Springer Nature; 2018.

28 No dumping, please. *The Economist*. 2 February 2019.

29 Pennisi E. Genomes arising. *Science*. 202;371(6529):556–9. <https://doi.org/10.1126/science.371.6529.556>

30 San code of research ethics. Kimberley: South African San Institute; 2017 (<https://www.globalcodeofconduct.org/affiliated-codes/>, accessed 6 May 2021).

31 <https://www.globalcodeofconduct.org/> (accessed 6 May 2021).

<b>Purpose</b>	The Committee highlights the importance of preventing scientific research and medical travel where individuals or companies locate their activities in countries lacking relevant policy (including laws, regulations and guidelines), or with relevant policy but limited or no oversight for no reason other than to avoid responsible policy, oversight and ethical guidelines.
<b>Relevant values and principles</b>	Caution, fairness, social justice, solidarity, global health justice, responsible regulatory stewardship and the responsible stewardship of science.
<b>Action</b>	To integrate into relevant WHO activities, including those undertaken as a result of other recommendations in this document, a specific focus on preventing instances of scientific research and medical travel where individuals or companies locate their activities in countries lacking relevant policy (including laws, regulations and guidelines), or with relevant policy but limited or no oversight in order to avoid responsible policy, oversight and ethics guidelines.
<b>Practical considerations</b>	Appropriate resourcing to support additional work within WHO to continue strengthening the science regulatory and oversight capacities of Member States across the world. These should not be unfunded mandates.

## Recommendations

The Director-General, in consultation with his new Science Council, should make a policy statement that somatic and germline human genome editing research should only take place in jurisdictions with domestic policy and oversight mechanisms. The absence of policy covering human genome editing should preclude such research from taking place in that country. WHO and other organizations such as UNESCO should assist Member States in developing or adapting domestic policy as needed, including when a country without domestic policy relevant to human genome editing would like to participate in such research.

WHO, with guidance from its Science Council, should integrate into all of its relevant activities a focus on fostering responsible international research and medical travel. For example, this issue could be explicitly included in the mandate of both the meeting of regulators from Member States under the recommendations for international collaboration (section 2.2) and the scoping meeting for reporting illegal, unregistered, unethical or unsafe research and other activities (section 2.5).

### 2.5 Illegal, unregistered, unethical or unsafe research and other activities

Many of the barriers to raising concerns about possible wrongdoing are not unique to the field of human genome editing, nor scientific research more broadly, but are often the result of wider cultural and contextual barriers.

In light of issues surrounding Dr He Jiankui's work and concerns about unauthorized clinics offering unproven stem cell interventions to unsuspecting customers, the Committee recommends changes in policy and practice to support the reporting of possible illegal, unregistered, unethical or unsafe human genome editing research and other interventions. The aim is to prevent similar future occurrences.

The Committee commissioned a report on whistleblowing and consulted with a number of people with particular expertise in whistleblowing. The recommendations in this section are based on this report as well as insights drawn from consultations and discussions.

The Committee believes a cultural change is needed around the reporting of possible illegal, unregistered, unethical or unsafe research and other activities. This requires reinforcing efforts to promote research integrity and best practices. A transparent reporting mechanism is also needed to investigate concerns, which includes support and protection for those reporting possible wrongdoing. Responsibility for the establishment of such a mechanism must lie with a trustworthy network as no single organization is well placed to cover everything. This network should take advantage of existing organizations and relationships. Institutional, national and regional capacity will be needed to form an international network that functions regardless of where the research or other activity takes place, or where the people reporting the research are based.

With the increased focus on research integrity in recent years, the number of relevant national and international statements and codes has grown. There is, however, no evident mechanism for reporting possible illegal, unregistered, unethical or unsafe practices in human genome editing at the global level. The Committee stressed the importance of developing a mechanism for reporting violations of research integrity that goes beyond human genome editing, that is, one focused on emerging technologies more broadly.

While many people are familiar with and use the term whistleblowing, it has both technical limitations and negative connotations. The term whistleblowing was introduced some years ago as “a conscious effort to redescribe people who had previously been called ‘traitors,’ ‘rats,’ or ‘stool pigeons’”.<sup>32</sup> In the intervening years, the term has come to be used pejoratively. Perhaps consideration should be given to alternate language, for example, speaking up. Finding an acceptable term is important as having people identify and report wrongdoing is essential to any well functioning governance system.

<b>Purpose</b>	The Committee believes that it is very important to promote the best possible open science.
<b>Relevant values and principles</b>	Openness, transparency, honesty and accountability, responsible regulatory stewardship, responsible stewardship of science, social justice.
<b>Actions</b>	<ol style="list-style-type: none"> <li>1. To work with both the research community and people with experience in reporting possible wrongdoing to promote a culture of open science.</li> <li>2. To work with both the research community and people with experience in reporting possible wrongdoing to identify mechanisms for the effective reporting of illegal, unregistered, unethical or unsafe research and other activities.</li> </ol>
<b>Practical considerations</b>	Cultural context is important and clearly no one organization can tackle the wider underlying cultural issues. WHO should work with others in the research community to promote a culture where concerns about research misconduct can be raised without fear of retaliation. However, the Committee recognizes that the desire to create new mechanisms (or mechanisms specifically for human genome editing) is low, due in part to lack of resources. It should be possible to build on pre-existing initiatives or regulatory structures and to link the global mechanisms with those at regional and national levels.

32 Elliott C. Why they blow the whistle. The Atlantic. 2 October 2019. (<https://www.theatlantic.com/ideas/archive/2019/10/why-they-blow-whistle/599230/>, accessed 6 May 2021).

## Recommendation

WHO, with advice from its recently established Science Council, should charge the Science Division to lead an effort to create a multisector collaboration to develop an accessible mechanism for confidential reporting of concerns about possibly illegal, unregistered, unethical and unsafe human genome editing research and other activities. The mechanism should include: (i) a clear reporting system; (ii) a transparent process for investigations; and (iii) support and protection for those raising concerns. The collaboration should take advantage of entities and existing mechanisms for investigating and disciplining such experiments, including: national regulatory agencies; relevant government ministries, academies of science and medicine (as well as the InterAcademy Partnership);<sup>33</sup> journals; professional societies; and funders. WHO, at least initially, should be the place to which concerns could be reported, and then shared with the most appropriate investigating and disciplinary body among these global partners.

## 2.6 Intellectual property

During their deliberations, the Committee discussed the potential for intellectual property controls to be used as a governance tool.<sup>34</sup> To explore this idea in more detail, in November 2020 the Committee held a webinar with experts on patents and intellectual property (Annex).

While certain aspects of human genome editing (such as specific human genetic sequences) might not be subject to patents in some parts of the world, the underlying tools developed to edit genes, for example, CRISPR-Cas systems, are eligible for intellectual property controls, such as patents. The owners of these patents then have certain rights over how their intellectual property is used.

The Committee heard of both negative and positive rights associated with patents. Positive rights are where the patent holder grants permission for someone else to use their patent to do something. Negative rights include the potential for the patent holder to explicitly prohibit their patent from being used to do something.

The Committee were interested in the potential use of negative rights to prevent relevant patents being used for unethical purposes. This is often referred to as ethical licensing. For example, the Committee heard that the Broad Institute intended to limit the use of any patents it obtains for genome editing tools, in particular “any human clinical use must be consistent with all laws and regulations, and we do not license the technology for clinical use of human germline editing”.<sup>35</sup>

The Committee also discussed how intellectual property systems might be used or adapted to make key inventions more accessible, including opportunities to reduce patent bottlenecks and through the use of public-private partnerships.

The Committee noted that patents often affected activities associated with commercial development of a technology, rather than the use of certain tools in research. As a result, governance measures based on patent or intellectual property might allow future activities to unlock the potential benefits of human genome editing by enabling further research, while at the same time feasibly controlling its application for commercial purposes.

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33 <https://www.interacademies.org/> (accessed 6 May 2021).

34 Parthasarathy S. Use the patent system to regulate gene editing. *Nature*. 2018;562(7728):486–8. <https://doi.org/10.1038/d41586-018-07108-3>

35 <https://www.broadinstitute.org/partnerships/office-strategic-alliances-and-partnering/information-about-licensing-crispr-genome-edition> (accessed 6 May 2021).

The Committee was concerned that the use of patents could complicate, rather than simplify, the governance and oversight of human genome editing. The Committee noted that the use of patents as a governance tool might place direct control over how, why and for what purposes a patent could be used in the hands of individuals or small groups. The Committee also observed that patents also potentially prevented others from delivering similar capabilities at a cheaper cost.

The Committee noted the territorial nature of patents, as they are confined to specific countries or regions. As a result, in some countries, the use of patented tools, such as those used for genome editing, may be effectively unrestricted. This issue may lead to a situation similar to ethics dumping, where an unscrupulous clinic deliberately locates itself to avoid ethical licensing constraints that would otherwise affect its activities. Consequently, governance measures based on patent or intellectual property alone will be insufficient to strengthen the governance and oversight of human genome editing but might usefully be integrated into a broader governance framework.

<b>Purpose</b>	The Committee believes that governance measures based on patent or intellectual property, when used together with other tools, may help strengthen the governance and oversight of human genome editing. It will be important to avoid using patents in ways that potentially prevent others from delivering similar capabilities at a cheaper cost.
<b>Relevant values and principles</b>	Openness, transparency, honesty and accountability, responsible stewardship of science, caution, fairness, social justice, solidarity and global health justice.
<b>Action</b>	To bring together relevant patents holders (and those with patents pending) and those establishing or running relevant patent pools (often associated with complex technologies that require complementary patents to provide efficient technical solutions) to explore the possible use of intellectual property as a governance measure for human genome editing.
<b>Practical considerations</b>	Relevant patent holders may be unwilling to limit the use of their inventions. Convening the above-mentioned meeting will require resources and logistical support. An unequal geographic distribution of patent holders is likely, given the location of current patent applications relevant to human genome editing.

## Recommendations

In collaboration with other international organizations, such as the World Intellectual Property Organization and the World Trade Organization and its Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS agreement), WHO should encourage relevant patent holders to help ensure equitable access to human genome editing interventions. This may include making licensing costs proportional to the economic situation of a country.

WHO should encourage industry to work with resource-constrained countries to build capacity to take advantage of human genome editing inventions.

WHO should convene a meeting of those holding or applying for patents relevant to human genome editing, industry bodies, international organizations such as the World Intellectual Property Organization and the World Trade Organization, and those involved in establishing or running relevant patent pools to explore the potential for the adoption of appropriate ethical licensing requirements.



## 2.7 Education, engagement and empowerment

Because human genome editing has the potential to affect all of us, developing responsible governance systems to ensure its wise use is everyone's responsibility.

During the course of its work, the Committee consulted widely with individuals and representatives of organizations, institutions, professional bodies, patient advocacy groups and civil society organizations to improve its understanding of possible strategies to educate, engage and empower members of the general public. Of particular concern was how best to reach out to traditionally vulnerable and marginalized people and groups so as to include their contributions to credible and sustainable governance of human genome editing in ways that increase transparency, improve public trust and optimize outcomes that enhance the common good.

A basic understanding of the scientific, ethical and regulatory issues relating to human genome editing will facilitate meaningful public participation in discussions about whether and, if so how, these powerful technologies might be used. Therefore, public education in these areas is essential. A challenge for public education, however, is the frequency with which such efforts are based on false assumptions, such as that members of the public are not well enough informed to contribute to priority setting, that they cannot offer an independent perspective, and that they are not representative of all the public.

While public education is a worthy and necessary goal, education alone is not sufficient to engage the public. Creating opportunities for members of the public to participate in decision-making and inform strategic priorities is also essential to ensure that human genome editing research reflects the views and values of citizens. This parallels the recent call by the European Group on Ethics in Science and New Technologies for policy that is “preceded by careful consideration of the conceptualisation, acceptability and desirability of the technology”.<sup>36</sup> The Committee endorsed a strong commitment to public engagement – a bidirectional activity aimed at facilitating a meaningful exchange of views, values and priorities among all those with an interest in the ethics and governance of human genome editing. Meaningful public engagement that increases the voices of those outside traditional science and policy circles and encourages the circulation of information, views and values is imperative to establish trust and legitimacy in any governance process.

The Committee believes it is essential that all people have an influence in public deliberations about whether, and if so how, human genome editing technologies should be used and to what ends. Public empowerment would strengthen the conditions for autonomy and agency by having members of the public actively involved in discussing and debating the what, whether and why of human genome editing. As such, it would help shape the research and policy agenda so that these reflect public values, perspectives, experiences, interests and priorities.

The Committee agreed with the European Group on Ethics in Science and New Technologies that there is a need for “broad and open public debate on the ethical and social implications” of human genome editing.<sup>37</sup>

The Committee acknowledged that many issues about education, engagement and empowerment are not unique to human genome editing but apply more broadly to a range of public health questions on the science, policy and practice of emerging technologies. To facilitate its work, the Committee established a dedicated working group on education, engagement and empowerment. The Committee met with (i) communities, individual experts and people often under-represented in international science policy processes, and (ii) groups who map public engagement approaches.

<sup>36</sup> European Group on Ethics in Science and New Technologies. Ethics of genome editing. Brussels, European Union; 2021:87 (<https://op.europa.eu/en/web/eu-law-and-publications/publication-detail/-/publication/6d9879f7-8c55-11eb-b85c-01aa75ed71a1>, accessed 6 May 2021).

<sup>37</sup> European Group on Ethics in Science and New Technologies. Ethics of genome editing. Brussels, European Union; 2021:86 (<https://op.europa.eu/en/web/eu-law-and-publications/publication-detail/-/publication/6d9879f7-8c55-11eb-b85c-01aa75ed71a1>, accessed 6 May 2021).

This included targeted invitations to in-person meetings and online consultations, hosting a meeting in Africa to gather context-specific evidence, hosting panels in relevant meetings organized by other groups, active outreach to relevant communities, such as indigenous and patient groups, and dedicated webinars on these issues (Annex). The Committee stressed the importance of having activities that include efforts to learn from both the general public and under-represented groups. These activities paralleled calls by the European Group on Ethics in Science and New Technologies to “widen the basis of expertise and broaden what counts as relevant knowledge at the level of expert committees”.<sup>38</sup>

During these consultations, the Committee heard that while broad societal consensus exists on the need for informed and engaged public debate, consensus on how best to achieve this goal is lacking. Different mechanisms and methods exist for different settings. Some methods, such as the online consultations used by the Committee, are more suitable for situations involving specific policy options, while others, such as citizen assembly consensus and consensus conference methods, are more appropriate for open discussion in the early stages of developing governance mechanisms.

The Committee considered that it would be counter-productive to be too prescriptive on how to pursue education, engagement and empowerment activities. The Committee stressed the fundamental need for robust local, national and global efforts in each of these important areas. In addition, the Committee noted good practices in its governance framework (governance framework Box 4) that provide good models on which future efforts might be built.

The Committee highlighted the challenge language poses for education, engagement and empowerment. As with other issues, much of the debate to date on human genome editing and many of the relevant resources are only available in a few languages and are mainly available through digital platforms. This is a major barrier for many who may want to learn more about, or engage in the governance of, human genome editing. Given the importance of robust, harmonized international governance of human genome editing, it is vital that discussions, debates and decision-making are global and have representation of all regions, with a particular emphasis on the inclusion of vulnerable and marginalized populations.

The Committee also highlighted lessons learned from the COVID-19 pandemic on online efforts at education, engagement and empowerment activities, both in terms of positive examples and new capabilities, and also negative examples of harmful misinformation.

The Committee believes that more research, planning and structures are needed at all levels to ensure that education, engagement and empowerment can best inform governance and decision-making. Best practices for education, engagement and empowerment should be captured and experiences systematically shared.<sup>39</sup> This is an essential component of developing sound regulatory infrastructures for human genome editing in all contexts. To this end, the Committee stressed the importance of working with Member States, other relevant organizations and community groups on these issues.

While much discussion on the issues of education, engagement and empowerment focuses on the general public, the Committee emphasized the importance of parallel efforts for other groups, such as clinicians, policy-makers and genetic counsellors. The Committee also highlighted the importance of covering both science literacy and ethics literacy in these efforts.

38 European Group on Ethics in Science and New Technologies. Ethics of genome editing. Brussels, European Union; 2021:88 (<https://op.europa.eu/en/web/eu-law-and-publications/publication-detail/-/publication/6d9879f7-8c55-11eb-b85c-01aa75ed71a1>, accessed 6 May 2021).

39 The Committee wanted to highlight several relevant initiatives and guidance, including: (1) European Group on Ethics in Science and New Technologies. Ethics of genome editing. Brussels: European Union; 2021 ([https://ec.europa.eu/info/files/ethics-genome-editing\\_en](https://ec.europa.eu/info/files/ethics-genome-editing_en), accessed 6 May 2021); (2) Guide to public debate on human rights and biomedicine. Brussels: Council of Europe; 2020 (<https://rm.coe.int/prems-009521-ex-061320-gbr-2007-guide-on-public-debate-16x24-web/1680a12679>, accessed 6 May 2021); (3) Global Observatory for Genome Editing (<https://global-observatory.org/>, accessed 6 May 2021); (4) Global Citizens' Assembly on Genome Editing (<https://www.globalca.org/>, accessed 6 May 2021); (5) Danish Board of Technology's World Wide Views project (<http://wwwviews.org/>, accessed 6 May 2021); (6) Mitochondria replacement consultation: advice to government. London: Human Fertilisation and Embryology Authority; 2013 ([https://www.hfea.gov.uk/media/2618/mitochondria\\_replacement\\_consultation\\_-\\_advice\\_for\\_government.pdf](https://www.hfea.gov.uk/media/2618/mitochondria_replacement_consultation_-_advice_for_government.pdf), accessed 6 May 2021).

<b>Purpose</b>	The Committee believes that education, engagement and empowerment activities must be embedded as a core feature of the development of responsible governance systems for human genome editing in particular and for emerging public health technologies more broadly.
<b>Relevant values and principles</b>	Inclusiveness, fairness, social justice, equal moral worth and solidarity.
<b>Actions</b>	<ol style="list-style-type: none"> <li>1. To support greater diversity in the information, views and values that are included in discussions about the governance of human genome, particularly by involving under-represented groups.</li> <li>2. To strengthen international institutional support for robust and rigorous education, engagement and empowerment activities associated with the development and introduction of emerging technologies in public health.</li> <li>3. To develop a better model of relevant education, engagement and empowerment activities, and bring together those working in this area.</li> <li>4. To improve the sharing of experiences and best practices associated with education, engagement and empowerment activities.</li> <li>5. To lower barriers to learning about, and becoming active and influential in, the governance of human genome editing.</li> </ol>
<b>Practical considerations</b>	The Committee recognizes that meaningful education, engagement and empowerment is challenging and requires a considerable amount of time and resources. Without these, education, engagement and empowerment activities could be seen as empty public relations or window dressing. While effective education, engagement and empowerment improves the quality, credibility and sustainability of governance systems, their absence almost inevitably leads to a loss of trust from the general public and under-represented groups.

## Recommendations

Human genome editing exists within the context of broader technological change. The Director-General should call upon the United Nations Secretary-General to establish, in the first instance, a United Nations interagency working group on frontier technologies that facilitates global dialogue and produces a report outlining the implications of innovative technologies, including human genome editing, and the ethical frameworks to guide their application. The remit of this group should include a specific mandate to educate, engage and empower the general public and under-represented groups.

The Director-General should call for an inclusive dialogue on the future of human genome editing, including scientific, ethical and societal aspects. In pursuit of this goal, WHO should support ethics and science literacy by establishing an education and dialogue portal on the WHO website or elsewhere providing easily accessible, open and reliable information, and essential dialogue questions to help people join the conversation about human genome editing. This site should draw together existing material such as those developed by UNESCO, and facilitate the creation of new material, to be done in partnership with those already active in this field.

WHO should develop models of best practice of inclusive multidirectional, multistakeholder dialogue, and supporting material, that can be applied to human genome editing. Such material, should include scientific, ethical and societal information in as many languages as possible.

WHO, in partnership with other organizations, should explore how best to include in decision-making under-represented groups that are interested in human genome editing. Approaches may include platforms to foster dialogue, greater inclusion in guidance development, earmarked funds to hold meetings and routes of access to policy-makers.

## 2.8 Ethical values and principles for use by WHO

Ethical values and principles clearly guide the work of WHO. In large part, these values and principles underpin WHO's founding documents, and have been reinforced by many decades of procedure, policy, practice and associated documentation focused on building a better and healthier future for people all over the world.

However, while many WHO guidance documents promote a large number of ethical values and principles, they are not necessarily suitable for the global public health context, nor are they consistently used or applied across WHO guidance documents. To address the absence of a set of WHO principles that can be consistently used in WHO guidance documents, the Committee recommends developing a set of WHO ethical values and principles that can be consistently applied across all WHO activities, including human genome editing. The Committee believes that the procedural and substantive values and principles described in the governance framework would be a good starting point in this process.

The proposed set of WHO ethical values and principles could provide a firm foundation for the work of future expert committees and other applicable units. Future expert committees could identify which of the WHO values and principles are most relevant to their specific mandate and focus on how these values and principles need to be adapted or supplemented for the issues they are exploring.

The proposed set of WHO ethical values and principles is different from the set of WHO values already published.<sup>40</sup> The published WHO values are intended for the workforce of the Organization, adhere to the United Nations values of integrity, professionalism and respect for diversity, and reflect the principles of human rights, universality and equity established in WHO's Constitution as well as the ethical standards of the Organization. The proposed set of WHO ethical values and principles is intended to: (i) be outward facing; (ii) feed into the work of expert committees and other relevant units; (iii) shape how the committees and units work to bring us closer to the vision of a world in which all people attain the highest possible level of health; (iv) keep the world safe; and (v) serve the vulnerable, with measurable impact for people at the country level.

<b>Purpose</b>	The Committee recommends that WHO develops ethical values and principles to inform the future work of the Organization on emerging technologies.
<b>Relevant values and principles</b>	Inclusiveness and fairness.
<b>Action</b>	To develop officially endorsed WHO ethical values and principles to guide the work of WHO.
<b>Practical considerations</b>	In the short-to-medium term, WHO could use the ethical values and principles described in the human genome editing governance framework as a starting point (removing specific reference to human genome editing) and involve WHO health ethics and governance unit, its working groups and collaborating centres and members of committees who have drafted past lists of values and principles for specific expert discussions.

<sup>40</sup> <https://www.who.int/about/who-we-are/our-values> (accessed 6 May 2021).

## **Recommendation**

The WHO Director-General should charge the health ethics and governance unit in the Science Division to lead an effort to create a set of officially endorsed and clearly defined ethical values and principles for use by its expert committees and in WHO deliberations. These values and principles should be built on public health goals and priorities. These should go beyond the WHO workforce and provide an important roadmap for progress towards the Organization's goals.

## **2.9 Review of the recommendations**

### **Recommendation**

In no more than 3 years, WHO's Science Division should initiate an extensive review of these recommendations and the progress made to implement them. This review should not take longer than 18 months and should take into account scientific, technological and societal changes, adequacy of implementation and assessment of impact, and potential future needs or concerns.

# Annex.

## Meetings, consultations and webinars: participants

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The following lists give the participants in the meetings, consultations and webinars held by the Expert Advisory Committee on Developing Global Standards for Governance and Oversight of Human Genome Editing (the Committee).

### Committee meetings

*First committee meeting, 18–19 March 2019, Geneva, Switzerland*

#### Experts

##### **Dr Shakeel Bhatti**

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World Intellectual Property Organization  
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##### **Dr Dafna Feinholz**

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*Second committee meeting, 26–28 August 2019, Geneva, Switzerland*

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*Third committee meeting, 25–26 February 2020, Cape Town, South Africa*

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**Topic-specific meetings**

*Sickle Cell Disease-Genome Editing Consultation Meeting, 24 February 2020, Cape Town, South Africa*

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*Virtual consultations on the human genome editing registry, July 2019–January 2020*

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*Virtual meeting between the European Group on Ethics in Science and New Technologies and the WHO Expert Advisory Committee on Developing Global Standards for Governance and Oversight of Human Genome Editing on the ethics and governance of human genome editing, 2 December 2020<sup>41</sup>*

## Online consultations

First online consultation, 15 January–7 February 2020

The Committee received 325 unique responses from individuals and organizations in 32 countries; 45 responses came from organizations, mostly in the United States (15), United Kingdom (5) and Mexico (3). Organizations providing responses included biotechnology associations, professional scientific bodies, patient groups and bioethics committees

*Second online consultation, 14 July 2020–19 August 2020*

The Committee received 69 unique responses from individuals and organizations in 23 countries. Countries with the highest response rates included Burkina Faso, United States, United Kingdom and Japan. Respondents were mostly affiliated with universities and medical schools, associations, foundations and councils, research centres and institutes, as well as professional organizations and societies.

## Webinars

*Public engagement on human genome editing, 9 April 2020*

- **Council of Europe’s Guide to Public Debate on Human Rights and Biomedicine**

### **Ms Tesi Aschan**

Chair, Council of Europe Committee on Bioethics

Jurist, Senior legal adviser for the National Board of Health and Welfare, Socialstyrelsen

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### **Dr Laurence Lwoff**

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<sup>41</sup> [https://ec.europa.eu/info/news/governing-genome-editing-humans-ec-and-who-committee-probe-ethical-questions-together-2020-dec-03\\_en](https://ec.europa.eu/info/news/governing-genome-editing-humans-ec-and-who-committee-probe-ethical-questions-together-2020-dec-03_en) (accessed 7 May 2021).

- **Global Observatory for Genome Editing**

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*Indigenous perspectives on human genome editing, 30 April 2020*

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*Faith perspectives on human genome editing, 28 May 2020*

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*Biohackers, DIY community labs and transhumanist perspectives on human genome editing, 11 June 2020*

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*Groups and organizations that made statements on human genome editing, 9 July 2020*

- **European Group on Ethics in Science and New Technologies (2016). Statement on Gene Editing**

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- **Roberto Andorno, Françoise Baylis, Marcy Darnovsky, Donna Dickenson, Hille Haker, Katie Hasson, Leah Lowthorp, George J. Annas, Catherine Bourgain, Katherine Drabiak, Sigrid Graumann, Katrin Grüber, Matthias Kaiser, David King, Regine Kollek, Calum MacKellar Jing-Bao Nie, Osagie K. Obasogie, Mirriam Tyebally Fang, Gabriele Werner-Felmayer and Jana Zuscovova (2020). Geneva Statement on Heritable Human Genome Editing: The Need for Course Correction**

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- **The Hinxton Group. An international consortium on stem cells, ethics & law (2015). Statement on Genome Editing Technologies and Human Germline Genetic Modification**

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*Engagement with human genome editing, 30 July 2020*

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*Whistleblowing and human genome editing, 1 October 2020*

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*Epigenetics and human genome editing, 8 October 2020*

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*Stem cells and human genome editing, 13 October 2020*

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*Ethics dumping and human genome editing, 22 October 2020*

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*Patents and human genome editing, 3 November 2020*

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*Scientific updates on human genome editing, 3 December 2020*

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*Perspectives of patient groups and genetics professionals on human genome editing, 21 January 2021*

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*Launch of the final outputs of the Committee, 28 January 2021*

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*Perspectives of regulators on human genome editing, 18 February 2021*

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