

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

REPORT OF THE SECOND MEETING

Geneva, Switzerland, 26–28 August 2019

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

## REPORT OF THE SECOND MEETING

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### 1. Background

The World Health Organization (WHO) has established a global, multi-disciplinary expert advisory committee to examine the scientific, ethical, social and legal challenges associated with human genome editing (both somatic and germline).<sup>1</sup> The Committee includes members from Africa, Asia, Europe, the Middle East, Oceania, North America and South America.<sup>2</sup>

The Committee has been tasked to advise and make recommendations on appropriate institutional, national, regional and global governance mechanisms for human genome editing. During the course of its work, the Committee will review literature on current human genome editing research and its applications, consider existing proposals for governance and relevant ongoing initiatives, as well as solicit information about societal attitudes towards the different uses of this technology. The Committee will explore how best to promote transparent and trustworthy practices and how to ensure appropriate assessments are performed prior to any relevant work being undertaken.

The recent application of tools, such as CRISPR-Cas9, to edit the human genome with the intention of treating or avoiding disease has highlighted the need for robust oversight in this area. The Committee will work in a consultative manner and build on existing initiatives to develop a responsible and responsive governance framework for the application of genome editing technologies going forward. It will liaise with relevant UN and other international agencies, and communicate with Academies of Science and Medicine as well as with other national or professional bodies, patient groups and civil society organizations that have worked, or are working, in this area.

The Committee held its first meeting from 18–19 March 2019. The first meeting included a review of the current state of relevant science and technology and briefings on existing initiatives and reports relevant to its work. Participants also began to identify and discuss specific issues, mechanisms and stakeholders that could comprise, or contribute to the development of, a governance framework. The Committee also considered how these elements may differ at international, regional, national or local levels. The group made three recommendations to the Director-General: (1) to develop a registry to provide a more structured mechanism for collecting and curating details of planned and ongoing relevant research and development; (2) that “it would be irresponsible at this time for anyone to proceed with clinical applications of human germline genome editing” and that the Director-General should communicate this view to relevant regulatory bodies around the world; and

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<sup>1</sup> <https://www.who.int/ethics/topics/human-genome-editing/en/>

<sup>2</sup> <https://www.who.int/ethics/topics/human-genome-editing/committee-members/en/>

(3) to enhance WHO's capacity to share information with, and collect information from, both technical and lay audiences. Each of these recommendations was aligned with one of the guiding principles adopted by the Committee: (a) transparency; (b) the responsible stewardship of science; and (c) inclusivity. A report of the meeting is available online.<sup>3</sup>

In a statement issued on 26 July 2019, the Director General formally and publicly endorsed the Committee's recommendation that it would be irresponsible for anyone to proceed with clinical applications of human germline genome editing.<sup>4</sup> He stated regulatory authorities in all countries should not allow any further work in this area until its implications have been properly considered. The WHO has begun communicating this opinion to its regional and country offices.

## **2. Work of the meeting**

From 26–28 August 2019, all 18 members of the Committee, observers from 12 organizations, and nine invited experts met in Geneva, Switzerland (Annex 1). The meeting was opened by Dr Tedros Adhanom Ghebreyesus, Director-General of the WHO.

In its first substantive session, the meeting was briefed by members on relevant activities in their countries, as well as:

- (i) The US National Institutes of Health on genome editing technologies, associated advances, and their governance,
- (ii) The Organization for Economic Cooperation and Development on responsible innovation in neurotechnology,
- (iii) The US National Academies of Science, Engineering, and Medicine on the International Commission on the Clinical Use of Human Germline Genome Editing,
- (iv) The Association for Responsible Research and Innovation in Genome Editing, introducing its activities and forthcoming meeting,
- (v) UNESCO on meetings on genome editing technologies to be hosted by the International Bioethics Committee and the World Commission on the Ethics of Scientific Knowledge and Technology,
- (vi) The Bioethics Committee of the Council of Europe on their consultation on Article 13 of the Convention on Human Rights and Biomedicine (the Oviedo Convention), and
- (vii) The European Commission on new funding opportunities for public engagement on genome editing technologies.

At its second substantive session, the meeting was briefed by the Committee's working groups on: establishing a registry of relevant research and development, including efforts to make use of WHO's International Clinical Trials Registry Platform; and responsible scientific stewardship, on their work on whistleblowing and ethics dumping. The meeting was also briefed on a background document on elements for a governance framework captured during its first meeting and subsequent discussions.

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<sup>3</sup> <https://www.who.int/ethics/topics/human-genome-editing/GenomeEditing-FirstMeetingReport-FINAL.pdf>

<sup>4</sup> <https://www.who.int/news-room/detail/26-07-2019-statement-on-governance-and-oversight-of-human-genome-editing>

The Committee concluded the first day of the meeting in a private session reflecting on the day's discussions and preparing for the next day. The second day of the meeting was dedicated to evidence-gathering. The committee received briefings by external experts on three aspects of its mandate: the composition and implementation of governance frameworks, including in other fields; the potential implications of regulation and governance for the development and availability of clinical applications; as well as an initial round of insights from relevant stakeholders.<sup>5</sup>

During the expert sessions, the meeting was briefed by:

- Gary Marchant, from Arizona State University on New tools for international technology governance,
- Ubaka Ogbogu, from the University of Alberta on “R”egulation to “r”egulation: legal governance of human genome editing in a global context,
- Mohamed Iqbal Parker, from the University of Cape Town on Governance frameworks in emerging technologies: an African perspective,
- Pawel Lukow, from the University of Warsaw on Two kinds of enhancement and democratic regulation of human genome editing,
- Andrea Boggio, from Bryant University on Towards a human rights framework for the regulation of human germline genome modification,
- Janet Lambert, from the Alliance for Regenerative Medicine, on A gene editing perspective from industry,
- Allan Cook, from Deloitte on The reality of digital reality. Ethical considerations for AR & VR,
- Essra Ridha, from Sangamo Therapeutics,
- Tim Hunt, from Editas Medicines.

The evidence-gathering sessions concluded with a panel discussion between invited experts and members of the Committee. The Committee then met in private to consider the insights provided.

During the third day of the meeting, the Committee spent the first substantive session discussing a range of scenarios which could be used to help develop and test the governance framework, as well as broader outreach and engagement activities (consistent with the principle of inclusivity). The Committee discussed considerations important for scenario development, issues that might be explored in scenarios, and specific mutations and diseases that might illustrate key issues across a range of geographical locations. The Committee agreed to continue to work on scenario development in advance of and during its third meeting.

During its second substantive session, the Committee discussed opportunities for education, engagement and empowerment. The Committee considered work that has already been done in this space, work that the Committee might accomplish, and work that is perhaps best done by others. The Committee discussed the differences in approach, desired impact, and tools associated with each of the three topics. The Committee discussed an online consultation to

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<sup>5</sup> The views expressed were those of the speakers and did not necessarily reflect those of the Committee.

gather additional input into its work. The Committee agreed to work on this topic in advance of and during its third meeting.

During the final working sessions of the meeting, the Committee met again in private to consider its work plan and next steps, including arrangements for the online consultation and its third meeting.

### 3. Outcomes

The Committee reviewed its charge from the Director-General and was comfortable that its scope covers both human somatic and germline genome editing. The Committee recognised that there was a need to examine the scientific, ethical, social and legal challenges associated with public health implications for human germline genome editing; and that given recent events, there was a need to prioritise this work. The Committee also recognised that relatively few countries have established an appropriate translational pathway for somatic treatments involving human genome editing, with robust regulation and oversight to ensure patient safety and public confidence.

Developing a governance framework that can be adopted by a much wider range of countries, in particular low and middle income countries, will facilitate broader and more effective engagement with human genome editing. This could enable more countries to partner in research and development and to develop their own genome editing industry that can be responsive to the needs of their own populations. A more widely adopted governance framework would also deter bad actors and rogue clinics from offering unproven or off label interventions.

The Committee highlighted the unique nature of its work, noting the truly global reach of the WHO, the value of having existing public health networks (including the WHO regional and country offices) to help disseminate the results of its work, and through the WHO a well-established, motivated and engaged international organization to translate decisions into effective action.

The Committee stressed that as human genome editing moves towards clinical application, an effective and just governance framework would maximise potential benefits, while minimizing potential harms. The **principles of fairness and social justice**, were added to those identified at the first meeting to inform and direct the work of the Committee. These principles will be of critical importance in ensuring that the benefits of scientific advances in genome engineering are shared equitably and are widely available throughout the world.

In accordance with the **principle of transparency**, the Committee agreed that a better understanding of existing regulatory regimes would help to highlight what more needs to be done. The Committee welcomed efforts by WHO to conduct a more comprehensive assessment of rules currently in place and looked forward to receiving details of relevant measures to be provided by regional and country offices. The Committee agreed that as more comprehensive information becomes available, it would be valuable to feed this into discussions of specific issues to bear in mind when exploring possible minimal standards for regulations and drafting national rules.

The Committee heard that a number of relevant laws and regulations exist around the world covering both somatic and germline human genome editing. The Committee also heard that there were differences in approaches and degrees of oversight and enforcement among these measures. The Committee identified a number of challenges to these laws and regulations and their implementation, including differences in terminology and scope. The Committee was convinced that there is considerable work still to be done in integrating regulatory approaches into an effective global governance framework for relevant technologies, including engaging with the majority of countries which seem to lack relevant laws and regulations. The Committee established a working group on oversight issues, which will *inter alia* consider the information provided by WHO on existing measures and begin to clarify key terminology. The Committee will invite representatives of other relevant organizations to participate in the work of this working group.

On the development of a registry of relevant research and in accordance with the **principles of inclusivity and transparency**, the Committee felt that an additional rationale was that there was a pressing need for better information about what research and development is happening so as to be able inform appropriate governance. The Committee agreed on a phased approach, with an initial focus on clinical applications and subsequent efforts to incorporate relevant basic research on human embryos and germline cells. The Committee agreed to begin piloting the first phase of the Registry and begin to consult with those communities most likely to generate relevant work.

The Committee agreed the Registry will make use of existing tools that underpin WHO's clinical trials registry, adapted and updated as necessary. The Committee recommended to the Director-General that following the creation of a registry, he make it clear that failure to register any work that falls within its scope must be considered as a fundamental violation of the **principle of responsible stewardship of science**. The Committee further recommended to the Director-General that WHO begin working with those funding, regulating and publishing relevant work to establish requirements for registration with the Registry. The Committee requested WHO to provide a briefing on progress on the Registry at its next meeting.

On education, engagement, and empowerment in relation to fostering societal deliberation on human genome editing technologies and in accordance with the **principles of inclusivity, fairness, and social justice**, the Committee acknowledged that considerable further work is needed. The Committee recognised that WHO has a role to play but that such efforts will need to be much wider. The Committee noted parallels with similar efforts on other emerging technologies, such as neurotechnology, and the desirability of greater synergy and exchanges of experiences between efforts. The Committee decided to establish a working group on education, engagement and empowerment. The working group will focus on this issue with specific relevance to the governance of human genome editing, aiming to identify a much wider range of experts, organizations, groups and communities who should be engaged into deliberations on the governance of human genome editing, and consider opportunities for a global dialogue, or dialogues, on these issues.

On plans for online consultations and in accordance with the **principle of inclusivity**, the Committee agreed to two rounds of consultation in the autumn/winter of 2019 and in the spring of 2020. The consultation will expand the views that feed into its work on the governance of human genome editing. The first round will seek input for the development a governance framework, and the second round will help test a draft of the framework before it

is provided to the Director-General. The education, engagement and empowerment working group will continue to develop plans and tools for the online consultation. The Committee requested WHO to make use of its regional and country offices, and their social media presences as well as other channels, to promote the consultation as widely as possible. WHO should consider targeted efforts to engage groups whose views are: (a) of particular relevance to its work; or (b) often under-represented in international science policy consultations. The Committee will be briefed on the consultation at its next meeting.

On reports of plans to initiate pregnancies using embryos with edited genomes, and in accordance with the **principle of responsible stewardship of science**, the Committee believes those who prematurely attempt human genome germline editing for reproduction are engaged in unscrupulous behaviour. These individuals risk a backlash, making it impossible for science to progress in a responsible manner. The Committee recognises that efforts to consider the societal, scientific and ethical aspects of decision making in this area are ongoing. The Committee is working towards a governance framework that will give the public confidence that proper and inclusive governance and oversight mechanisms are being developed.

In accordance with the **principle of responsible stewardship of science and the principles of fairness and social justice**, the Committee agreed that there is a need to improve the reporting of relevant research and development activities. The working group will look to identify mechanisms for enhanced accountability and exploring broader cultural issues with scientific practice and whistleblowing in both academic and commercial settings. Particular focus will be placed on ensuring privacy protections for individuals making reports and those being reported, as well as protections from retribution for those reporting relevant activities. The working group on responsible scientific stewardship will continue to work on this issue and will report back to the Committee's next meeting.

In accordance with the **principles of fairness, social justice, and the responsible stewardship of science**, the Committee agreed on the importance of considering how to prevent instances where researchers or companies locate relevant activities in countries with weaker regulatory infrastructure for no reason other than to avoid regulation and ethics guidelines that exist in other countries (some describe this as “ethics dumping” others speak of “risk havens”). The Committee noted there was considerable potential for work on capacity building and standardization of regulatory and oversight regimes. This issue will be discussed at a satellite meeting of the Global Forum on Bioethics in Research<sup>6</sup> meeting in Singapore in November 2019. The working group on responsible scientific stewardship will continue to develop a workplan and list of draft recommendations for the Committee.

On the development of a governance framework, the Committee has identified key issues, different mechanisms, and relevant stakeholders (annex). It has considered how these elements may be combined at the international, regional, national and institutional levels, in different ways and for different purposes. The Committee began to explore a range of scenarios to highlight key issues, explore challenges to governance, and foster greater engagement. The Committee recognised the importance that these scenarios explore both somatic and germline genome editing, make use of past and current real-world experiences and possible future developments, and are tailored to and target different types of audience (ranging from patient groups to transhumanists). The Committee began the process of

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<sup>6</sup> <http://www.gfbr.global/>



identifying aspects of governance that may be unique or of special importance for human genome editing. The results of the Committee's discussions to date will be fed into the first round of the online consultation due to follow the meeting. Views gathered during the consultation will be reviewed at its next meeting and used to further refine the governance framework.

#### **4. Future work of the Committee**

The Committee agreed that its next meeting will take place in late February 2020. The next meeting of the Committee will focus on expanding the number of voices contributing to the Committee's work, in particular those from Low- and Middle-Income Countries. In advance of that meeting, the WHO will facilitate an online consultation to gather additional views relevant to the Committee's work. The Committee will continue to work on the governance of both somatic and germline editing but will clearly delineate where necessary. The Committee will consult remotely between meetings and make use of working groups as appropriate.

## **Annex 1. List of participants**

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## Annex 2. Agenda

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

#### Second Meeting

WHO Headquarters, Salle D, 7<sup>th</sup> floor, Geneva, Switzerland, 26–28 August 2019

#### Agenda

##### DAY 1 – Monday, 26 August 2019

Time	Topic: Recap and Updates
	Chairs: Edwin Cameron & Peggy Hamburg
10:00–10:30	Committee Catch-up (closed session)
10:00–10:30	<b>Welcome coffee &amp; pastries</b>
10:30–11:00	Welcome – Dr Tedros Ghebreyesus Introductions & DOI
11:00–12:30	Updates since the last meeting, including: country level updates, updates from Committee members and observers Presentations from: Carrie Wolinetz – US NIH David Winickoff – OECD Anne-Marie Mazza – NASEM Xiaomei Zhai – Update from China Kazuto Kato – Update from Japan
12:30–14:00	<b>Lunch</b>
	Chairs: Edwin Cameron & Peggy Hamburg
14:00–14:30	Working Group: Registry
14:30–15:00	Working Group: Responsible Scientific Stewardship
15:00–16:00	Governance Framework
16:00–16:30	<b>Coffee break</b>
16:30–18:00	Stocktake & Review of purpose of Day 2 (closed session)
18:00	End of Day 1
19:00	Dinner at Restaurant (Self-paid) <a href="https://www.hoteledelweissgeneva.com/fr/edelweiss.html">https://www.hoteledelweissgeneva.com/fr/edelweiss.html</a>

**DAY 2 – Tuesday, 27 August 2019**

<b>Time</b>	<b>Topic: Governance – Expert Evidence Session</b>
	Chair: Peggy Hamburg
09:00– 09:30	Gary Marchant – Arizona State University
09:30– 10:00	Ubaka Ogbogu – University of Alberta
10:00– 10:30	Mohamed Iqbal Parker – University of Cape Town
10:30– 11:00	<b>Coffee break</b>
11:00– 11:30	Pawel Lukow – University of Warsaw
11:30– 12:00	Andrea Boggio – Bryant University
12:00– 12:30	Janet Lambert – Alliance for Regenerative Medicine
12:30– 14:00	<b>Lunch</b>
	Chair: Edwin Cameron
14:00– 14:30	Allan Cook – Deloitte
14:30– 15:00	Essra Ridha – Sangamo Therapeutics
15:00– 15:30	Tim Hunt – Editas medicines
15:30– 16:00	<b>Coffee break</b>
16:00– 17:00	Round table discussion with experts and committee
17:00– 18:00	Committee discussion (Closed session)
18:00	End of Day 2



**DAY 3 – Wednesday, 28 August 2019**

<b>Time</b>	<b>Topic: Round up &amp; next steps</b>
	Chairs: Edwin Cameron & Peggy Hamburg
09:00– 10:30	Governance Framework
10:30– 11:00	<b>Coffee break</b>
11:00– 12:30	Engagement & online consultation
12:30– 14:00	<b>Lunch</b>
14:00– 15:00	Work plan & next steps (closed session)
15:00– 15:30	<b>Coffee break</b>
15:30– 16:30	Work plan & next steps (closed session)
16:30	<b>Closing</b>