

# Genome Editing for Human Benefit: Ethics, Engagement and Governance

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## Guidance and policy paper: ‘Societal consensus’ as a requirement for germline gene editing

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### Brief description of the context

Over the past years, a large number of reports, statements, and commentaries have specified the conditions under which editing of the human germline should be permissible.<sup>1</sup> Several of these documents propose, among other things, that there needs to be ‘societal consensus’ for any germline intervention before that intervention can go ahead. Without committing ourselves to endorsing this requirement here, we wish to examine some challenges that arise when it is applied outside the context of high-income nations with existing frameworks for public or societal consultations on such issues.

### Commentary

The first document that put forward the requirement for ‘societal consensus’ was the 2015 International Summit Statement.<sup>2</sup> It held that it would be “irresponsible to proceed with any clinical use of germline editing unless and until [...] there is broad societal consensus about the appropriateness of the proposed application”. Several ethics reports, statements, and commentaries have subsequently adopted this requirement, sometimes with reference to the 2015 statement.<sup>1</sup>

Notably, the 2015 Statement was ambiguous as to whether the required ‘societal consensus’ should hold, broadly, on the international level or whether, more modestly, a national societal consensus would be sufficient. Here we bracket this ambiguity and assume that the proposal implies societal consensus *within* each nation. This assumption is also in line with the reports and commentaries that were published after the 2015 Statement, which tend to require societal consensus only within nations. However, even this more modest nation-specific requirement may prove challenging once we consider resource constraints and political realities in many countries:

#### 1. Resources for public consultation

The requirement for societal consensus is often proposed with an implicit assumption that the consensus must emerge from a certain type of deliberation, with broad civil participation. In discussing the process for establishing societal consensus, Lander et al. propose, for instance, that “it is essential [for the public consultation] to include those representing perspectives outside science and medicine — including people with disabilities, patients and their families, economically disadvantaged communities, historically marginalized groups, religious groups and civil society at

large.”<sup>3</sup> Such a process, which must include outreach and education, is a resource-intensive exercise. This is even more pronounced in genomics where outreach and education are still in their infancy due to the rapid developments in this field.<sup>4</sup> Conducting public consultations of this type would prove especially challenging in countries, including many low- and middle-income countries (LMICs), with little existing capacity for engaging the public in robust bioethical debate. Given the resource constraints of these countries and the costliness of robust public consultation, it is not clear how they could meet the moral threshold of establishing societal consensus.

Furthermore, there is a concern that LMICs will be influenced in their domestic consensus-seeking process because resource-rich countries are the only ones that can take the steps to reach societal consensus. The views reached by resource-rich countries may skew subsequent deliberations within LMICs by the force of precedent, despite the potentially very different local circumstances and worldviews.

## 2. *Ideals of public consultation*

Proponents of the ‘societal consensus’ requirement seem to think that societal consensus holds normative importance if and because it emerges from a certain type of deliberative democratic process. According to some proponents, only one way of public deliberation yields a valid ‘societal consensus’.<sup>5</sup> However, this restrictive view faces the challenge of what to do in cases where the ideal type of deliberation is not available. For example, in many countries religious institutions may play an outsized role in public deliberation, even though their views do not necessarily reflect the views of the wider public. Other proponents take a more moderate view that offers some flexibility on how societal consensus is reached. For example, Charo holds:

“public consensus will be relevant within each individual country. *Using their own political systems*, each country’s citizens can express their views and decide whether to ban germline editing, even if it is shown to be safe and effective.” [emphasis added]<sup>6</sup>

However, even such flexible accounts of how societal consensus may be reached face a formidable challenge: many countries make societal or policy decisions through governing authorities without open consultation or public deliberation. It is unrealistic to expect these countries to reform their political culture. Accordingly, the proposal that germline is ethical only if societal consensus is established by open consultation lacks resonance in these countries.

## **Conclusion**

The requirement for establishing societal consensus on the application of human germline editing poses formidable challenges on its own. Additional challenges arise when the requirement in contexts that is descriptive of some LMICs. Some nations might be unable to establish societal consensus because resources and capacity are lacking. Meanwhile, in other countries, where governing authorities tend to make decisions without open consultation in matters of social import, the requirement to reach societal consensus via a deliberative democratic process or open public consultation would be at odds with the country’s larger political culture.

## **Recommendations**

1. Establishing societal consensus via public consultation under idealized conditions may be desirable. However, this may set up an unrealistically high bar for countries that lack resources and capacity to undertake such consultations.
2. It needs to be clarified how the requirement to reach ‘societal consensus’ should be applied in countries that make societal or policy decisions through governing authorities without open consultation.

## References

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