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## Building Capacity for a Global Genome Editing Observatory: Conceptual Challenges

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## Abstract

A new infrastructure is urgently needed at the global level to facilitate exchange on key issues concerning genome editing. We advocate the establishment of a global observatory to serve as a center for international, interdisciplinary, and cosmopolitan reflection. This article is the first of a two-part series.

## Keywords

CRISPR; gene editing; bioethics; science policy; science studies; ethics

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The technological revolution in genome editing has elicited significant concern about what it means for human dignity and integrity. New techniques like CRISPR promise to rewrite the code of life at the most fundamental molecular level with greater precision than ever before. Of innumerable potential applications, the most ethically challenging are those that would make heritable genetic alterations in human beings. The potential for editing the human

germline has elicited international concern about the essence of human integrity and the norms that should guide and govern biology's newfound editorial ambitions. At stake are questions of moral overreaching, responsibilities to future generations, and appropriate forms of deliberation in judging which biotechnological futures to welcome or reject on behalf of the entire human community [1].

Few would claim that mere acquisition of editorial capacity authorizes scientific hands to write whatever they please. The human futures now being imagined reach beyond the biological arrangements of nucleotide texts. They encompass the values—social and moral—of the forms of life that are foreseen by biology's roving editorial eye. If genome editing has opened a “crack in creation” [2], the integrity of life and the shared norms that underwrite and safeguard it must not be allowed to slip carelessly into that opening.

Recognizing the need to catalyze a conversation on these issues, scientific leaders took some initial steps. In December 2015, the US National Academies, the Royal Society (of the United Kingdom and the Commonwealth), and the Chinese Academy of Sciences co-hosted an International Summit on Human Gene Editing. At the end of the Summit, the Organizing Committee affirmed that genome editing technologies pose novel governance challenges because they affect the future of the human species. They noted it would be irresponsible to proceed with clinical germline genome editing until there is a demonstration of “safety and efficacy,” a “broad societal consensus about the appropriateness of the proposed application,” and corresponding regulatory oversight. They called upon the “international community” to “strive to establish norms” for guiding the uses of this technology and noted the need for an “international forum” embracing “a wide range of perspectives and expertise” [3]. More recently, reports of gene editing in human embryos elicited further calls for transnational cooperation [4].

These assertions raise important questions: To what extent are existing scientific and political institutions capable of initiating the forms of deliberation that the prospect of editing life demands? Are these institutions qualified to ask the right questions? What are the respective rights, roles and responsibilities of scientific experts, policymakers, publics, and scholars in working toward a “broad societal consensus”? What new modes and mechanisms of participation, deliberation, and representation are needed?

We summarize the perspectives of an international, interdisciplinary group of scientists, social scientists, ethicists, philosophers, religious thinkers, legal scholars and policy practitioners on these issues. Grouped under each salient word in the Summit's call for a “broad societal consensus,” are highlighted concerns about the terms of deliberation, the need for ongoing interdisciplinary exchange and global deliberation on developments at this rapidly moving frontier, and the implications for applications of transformative biotechnologies to future lives, with uncertain impacts across generations.

## How Broad Is “Broad”?

The 2015 International Summit recognized the need for two kinds of breadth: geopolitical, in the sense of including perspectives from multiple nations; and substantive, as reflected in

the call for “a wide range of perspectives and expertise.” Both kinds of breadth are critically important. National policy positions are shaped by divergent legal and philosophical traditions and political histories. These have led to definitions of human integrity, rights and dignity that justify different treatments of biotechnological constructs such as in vitro embryos, stem cells, and cell lines. The norms governing such objects reflect deep-seated conceptions of human flourishing that deserve to be identified, learned from, and debated in international fora.

The starting-points of discussion vary across societies. In Germany, for example, the touchstone for evaluating human genome editing is an explicit, constitutional commitment to human dignity [5]. Canadian law on assisted reproduction calls for protecting “human individuality and diversity, and the integrity of the human genome” [6]. The 29 countries that have ratified the Oviedo Convention see the fundamental question as one of human rights and associated notions of human dignity and integrity [7]. In the United States, the primary legally enforceable governance mechanism is the FDA’s authority to regulate clinical applications of genome editing, but this is limited by law to questions of safety and efficacy [8].

Within nations, too, perspectives often differ. Attitudes may depend on whether someone is working at the cutting edge of the life sciences, has stakes in a discovery’s commercial applications, represents a religious or ethical tradition with particular views of what is natural, or has experienced devastating genetic illness within the family. Any forum for deliberating on the future of biotechnologies such as CRISPR must be constituted so as to encourage intellectual hospitality and friendship toward these divergent views. Such an approach would not only foster constructive engagement, but also facilitate mutual understanding, encouraging creative rethinking of parochial convictions.

Nations, moreover, are not situated on a level playing field with respect to research at the frontiers of biology. Hidden forms of power—cultural as well as institutional—pervade international collaborations in the life sciences. Internationalism can function as imperialism unless care is taken to investigate and confront such imbalances, such as those latent in intellectual property laws, immigration restrictions, or even such mundane administrative instruments as non-disclosure agreements.

## **A Societal Issue**

Even if long-term side effects were wholly predictable, editorial interventions into human biology would not occur only at the level of individual bodies and physical health. Any editing, especially of the human germline, represents an act of intentional design. While the biological effects on edited individuals might be beneficial, the social meanings of departing from an order in which all persons come into being with equally unique and unplanned genetic futures—and thus are equally subservient to the hazards of being born—are significant. Even minor edits to the DNA of a developing human embryo would, in the view of many, redefine fundamental social relationships (between parents and children, individuals and communities, citizens and states), and associated notions of responsibility and care. Put differently, what is at stake is not only the biological future of edited children,

but, potentially, the meaning of broader norms and legal rights and duties that underpin society.

Therefore, questions regarding CRISPR's future cannot be segregated into distinct technical and ethical domains, the former treated as universal, independent of national or cultural differences, and a matter for scientific experts, and the latter as expressions of divergent local values. To begin, the very possibility of human germline genome editing arose out of a huge range of prior arrangements that reflect local values. It built on economic, legal, and social circumstances that enabled groundbreaking research on human reproduction, the development of assisted reproductive technologies, and the corollary availability of human gametes and embryos in some countries. Such contextual features vary importantly across societies, with the consequence that different cultural communities entertain different understandings of how technology should be integrated into existing oversight regimes. Indeed, questions of risk and benefit, accountability and governance, public engagement and deliberation, commercialization and liability are at once culturally variable and linked in fundamental respects. These linkages shape what scientific work is encouraged and what is ruled out of bounds.

### **Consensus: About What, Among Whom?**

If scientific consensus predetermines which issues are worth debating, we lose the possibility of learning from the wide range of moral ideas that human societies have developed over millennia. Thus, a narrow consensus on the safety and efficacy of clinical applications, whether affirming or prohibiting, would ignore deep cultural differences in modes of reasoning and taking responsibility. Failure to engage seriously with differences in moral, religious, social, political, and legal discourses would be costly. It would bypass the productive work of centuries of disciplined thought that lie behind and are embedded in different cultural and legal norms. It would also preclude testing and recalibrating any society's taken-for-granted approaches in the light of versions developed in other societies. Engagement with diverse ways of thought is a prerequisite for developing the cosmopolitan ethic (Box 1) that, in our view, needs to inform a broad societal consensus.

The notion of consensus must be broadened beyond whether particular applications of human genome editing are acceptable or unacceptable. Consensus-building should focus instead on laying the foundation for more robust international deliberation—for instance, consensus about what is (or is not) at stake, what risks do (or do not) warrant immediate concern, and what common ground is needed to achieve shared and mutually acceptable endpoints for scientific and technological intervention. Achieving these forms of consensus will require us to encounter, engage and draw understanding from the full range of humanity's moral imagination and insights. This demands, in turn, building new forms of institutional capacity animated by a cosmopolitan ethic.

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**Box 1:****Cosmopolitan Ethic**

The notion of a *cosmopolitan ethic* surfaced repeatedly during our discussions. Cosmopolitanism in the context of debate about genome editing and other technologies that touch upon fundamental dimensions of life means, at a minimum, that the parties involved in deliberation acknowledge the possibility of *more than one valid way to analyze what is at stake in the application of such technologies*. Differences may derive from religious traditions that accord divergent meanings to human life, philosophical schools that characterize the nature of life and the essence of human-ness in different terms, constitutional and legal histories that stipulate which aspects of life should be treated as inviolable, and investments in science and technology that incorporate specific understandings of what constitutes health and wellness. Divergences may also arise from deeply entrenched ideas about the governance of science: how much autonomy should be granted to science; what forms of ethical oversight are appropriate in research settings; if research should be held to the same standards, regardless of whether it is publicly or privately funded; and how public consensus and policy settlements should be reached in areas of irreconcilable normative disagreement. These issues often remain contested, even within single nations. As yet, there are few international bodies with the capacity to forge global agreements on fundamental questions, although examples exist of a partial consensus, as in the 1997 *Oviedo Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine* [7]. To make progress toward wider, more reflective agreements, it will be necessary to adopt a stance of openness and willingness to understand and engage with other perspectives—and a commitment to building processes and infrastructures for achieving it. Science’s viewpoints will be of key importance in the development of a cosmopolitan ethic, but science cannot be granted primacy over other sources of disciplined ethical reflection, whether from religion, philosophy, law, or culture.