

This response was submitted to the Call for Evidence held by the Nuffield Council on Bioethics on *Genome editing* between 27 November 2015 and 1 February 2016. The views expressed are solely those of the respondent(s) and not those of the Council.

To: Nuffield Council on Bioethics – Genome Editing Working Group  
From: Marcy Darnovsky, PhD, Executive Director, Center for Genetics and Society  
Re: Open Call for Evidence  
Date: 1 February 2016

1. Thank you for the opportunity to contribute evidence toward your investigation of genome editing. We appreciate the thoroughness and openness of the Working Group’s call for evidence.
2. The Center for Genetics and Society is a public-interest non-governmental organization working to encourage responsible uses and effective societal governance of human genetic and reproductive technologies and other emerging technologies. We work with a vibrant network of scientists, health professionals, civil society leaders, and others. The Center supports benign and beneficent medical applications of these technologies, and opposes those applications that objectify and commodify human life and threaten to divide human society.
3. In keeping with our organizational mission, our comments focus on two sections of the call for evidence: “Perspectives on genome modification” and “Biomedical research and human applications.” Unless indicated otherwise, our comments refer to the application of genome editing techniques to human reproduction (which we will refer to here as “human germline gene editing”).
4. Here we summarize the points that follow:
  - Human germline gene editing for reproductive purposes would constitute a rupture both with past medical practice, and with all previous forms of human reproduction.
  - It would be very difficult if not impossible to limit applications of human germline gene editing for reproduction to the prevention of inherited genetic diseases. Opening the door to one form of germline modification would mean opening it to all forms.
  - Predictable social, commercial, and cross-border dynamics would make human germline gene editing a society-altering technology.
  - New forms of moral, political, social, and ethical analysis are called for.
  - New forms of public deliberation and policy making, involving a wide range of civil society perspectives, are called for.
  - The existing widespread agreement that human germline modification should be prohibited, and the many established laws to that effect, should be respected unless a different “broad societal consensus” is reached.
5. Genome editing in general is a potentially transformative technology. It is both a breakthrough that could deliver expanded biological knowledge and a range of beneficial applications, and a potential driver of applications (in particular human germline gene editing for reproduction) that could lead to dangerously harmful biological and societal outcomes, including greatly

exacerbated social inequality and norm-based discrimination. Whether to use genome editing tools to effect heritable changes in future human children and generations is a social and political question that goes far beyond scientific or technical factors. Human germline gene editing for reproduction would be a rupture with past practices of medicine, as well as with any human experience of reproduction.

6. Human germline gene editing would be unlike past practices of medicine. Germline intervention is not a medical treatment, in the sense that preventing particular aspects of genetic inheritance does not treat a patient with symptoms. It is understandable that parents would want to avoid passing on a genetic inheritance that could endanger the life chances of their child. Parents so situated can make use of pre-implantation genetic diagnosis and/or prenatal genetic testing. Parents who cannot produce embryos unaffected by familial genetic mutations can have children via third-party gametes, among other family formation alternatives. The aforementioned genetic selection technologies pose their own set of ethical and social risks, and they follow a history of often eugenic and discriminatory child selection practices. But these genetic selection options do not allow parents and scientists—as germline gene editing could—to attempt specific modifications with unknown consequences reverberating from the modified germ cells to the grown adult and their future offspring.
7. Genetic parentage may be preferred by some, but it is not a medical need. Assertions about the paramount importance of having a genetically related child have not been thoroughly analyzed or documented. Though this has been advanced as a purported “right,” it is a claim without legal precedent. Furthermore, it is dubious whether government health systems like the National Health Service would have an obligation to cover fertility treatments to provide genetically altered offspring.
8. Human germline gene editing would be unlike all previous forms of human reproduction. Proposals to use genome editing in this way must be assessed in light of the likely unstoppable momentum and “mission creep” that would be created by permitting it for any reason. Even if initially limited to specified indications (which could only be attempted by the few jurisdictions in the world with unusual levels of regulatory control), there would be strong commercial and other pressures to allow germline modification for additional reasons, including the pre-determination of non-medical traits and “enhancements.” Permitting human germline gene editing would be introducing an unprecedented level of control by one generation (whether parents, fertility doctors, researchers, or governments) over subsequent generations. Efforts to genetically optimize children with “preventative alleles” or trait enhancements would constitute non-consensual design far beyond existing norms of socialization and environmental influence. This would almost certainly map onto or exacerbate existing disparities in life chances based on race, sex, ability, political identity, and especially economic situation. The possible and likely individual, familial, and societal implications of such a radical departure from past human experience have not been well analyzed.
9. Proposals to introduce human germline gene editing should be thoroughly investigated using a framework grounded in established moral principles of social justice, human rights, the public interest, democratic governance, and the common good. The narrow focus that has come to characterize the field of bioethics, which privileges individual autonomy and informed consent, must be only a part of such an assessment: these conventional bioethical approaches are wholly

inadequate to the assessment of a society-altering technology such as human germline editing for reproduction.

10. It is also imperative to recognize that existing moral principles may not fully capture the challenges posed by human germline gene editing. As the renowned social theorist Jürgen Habermas wrote in *The Future of Human Nature* (Polity, 2003), “the breadth of biotechnological interventions raises moral questions that are not simply difficult in the familiar sense but are of an altogether different kind.”
11. The unprecedented nature of the political, intellectual, and moral collective challenge posed by the prospect of human germline gene editing resonates with the statement made by the organizing committee at the recent summit co-organized by the US National Academies of Sciences and Medicine 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.” We are still in the very early stages of such a reckoning in the U.K. and U.S., let alone other countries.
12. Some stakeholders (especially scientists, research funders, biotechnology and pharmaceutical companies, and professional bioethicists) have begun to shape the field of discourse. But the notion of “stakeholders” is too narrow to fully encompass the level of public discussion and support necessary to reach legitimate decisions about society-altering genetic engineering interventions. The public discussion is still being framed, and the vast majority of the public has yet to meaningfully participate in deliberations about human germline gene editing. A legitimate process will need to be wide-ranging, thoughtful, broadly inclusive, and extended in time. It will need to reach far beyond the scientific and technical experts, and to highlight the probable societal consequences of a decision taken one way or the other.
13. The wide range of perspectives that must participate in these deliberations must include civil society groups, artists and cultural producers, community-based organizations, rights and justice advocates, and social movements. It cannot be assumed that these groups will be heard unless serious efforts are made to reach out to them. A few representative groups are shown here.
  - **Disability rights and justice advocates** locate disability in a social rather than medical framework of understanding. The social model of disability is critical to an analysis of human germline gene editing. Disability rights advocates can speak to the historical experience of social stigmatization, medicalization, and pathologization, as well as corrective or normalizing medical treatment at the hands of a well-meaning but sometimes misguided medical establishment.
  - **Racial justice advocates** speak to recent trends toward reviving a discredited concept of “race” as a biological rather than social and political category.
  - **Economic and reproductive justice advocates** are in a position to evaluate the likelihood that novel and expensive assisted reproductive technologies would be taken up in socially stratified patterns that would be likely to exacerbate existing health disparities and social inequities.
  - **Lesbian, Gay, Trans\*, Bisexual, Queer, and Intersex rights and justice advocates** can speak to the dubious but persistent speculation about a “gay gene,” as well as to the particular vulnerability of intersex individuals to genetic “interventions” in light of the

well-established surgical practices that require parental consent to “normalize” minors with atypical yet non-suffering bodies, and established pharmaceutical interventions that can affect embryonic sex development.

- **Public health and policy advocates** will be able to assess the opportunity costs of devoting biomedical resources and talent to purportedly medical approaches that would be accessible to the very few, rather than to tackling the many urgent health challenges that affect the many.
14. Despite the rupture with past medical and reproductive practice that permitting human germline gene editing would represent, suggestions about the dynamics that could likely ensue can be drawn from a range of other historical and contemporary developments. Most generally, insights might be drawn from studies of past socially transformative technologies, from the printing press to nuclear fission to the digital computer. More specifically, a thoughtful consideration of the histories and legacies of twentieth-century eugenics movements, and the similarities and differences with political, cultural, and economic dynamics that could be set in motion by permitting human germline modification, would be relevant. In addition, the lessons of medical tourism—for instance, for surrogacy, cosmetic procedures, and unproven stem cells treatments—would be helpful in considering the systemic incentives and drivers of change and control that would likely shape the marketing and development of human germline gene editing.
  15. UNESCO, the World Medical Association, and the Human Genome Organization assert that the human genome is, in a symbolic sense, part of the “common heritage of humanity.” This widely accepted principle gives genome scientists a special societal obligation, beyond what scientists in general owe to the public. A deeper understanding of this principle should inform the needed deliberations.
  16. More than 40 countries, including the United Kingdom, prohibit germline modification by law or regulation. The Council of Europe’s Oviedo Convention also prohibits it. In the U.S., proposals for clinical trials involving human germline editing will not be accepted at this time by the NIH. A deeper understanding of these legally codified prohibitions should inform the needed deliberations.
  17. Just as the decision to unleash atomic weapons has haunted modern science and societies, so too would a decision to permit heritable genetic modification. In the absence of a broadly democratic process of decision-making, any effort to deploy germline gene editing would likely exacerbate public disillusionment with the scientific enterprise, and public distrust of scientists. This would be the case whether such an effort were to be made by privately funded researchers moving among and around national borders, or by a single country or jurisdiction contravening decades of international legal precedent and a widespread consensus against human germline gene editing. Any government that would authorize germline intervention at this stage would be going out on a societally precarious limb.
  18. The perils of unilaterally embarking on human germline editing caution against the temptations of appeals to national competitiveness, or to spectacular technological developments that have little real medical or public health value. Genome editing is a powerful and scientifically exciting new tool, but its beneficial potentials can be realized, and the public interest served, only if

appropriate distinctions are made that put societally dangerous applications such as germline modification off limits.

## Resources and References

We show here references that we believe members of the Working Group may not have previously seen, and that we hope will be helpful to its deliberations. We have included very brief summaries of why we believe each is relevant to the Working Group's investigations.

### Authored by the Center for Genetics and Society

- [Human gene editing is a social and political matter, not just a scientific one](http://www.theguardian.com/science/2015/dec/04/human-gene-editing-is-a-social-and-political-matter-not-just-a-scientific-one), Marcy Darnovsky, *The Guardian* (December 4, 2015), <http://www.theguardian.com/science/2015/dec/04/human-gene-editing-is-a-social-and-political-matter-not-just-a-scientific-one>
  - Darnovsky argues that existing alternatives for preventing the transmission of genetic diseases are far less dangerous than germline gene editing, both medically and socially, and that questions of technical capacity cannot supplant a wide-ranging inquiry focused on societal and global impacts.
- [Extreme Genetic Engineering and the Human Future: Reclaiming Emerging Biotechnologies for the Common Good](http://geneticsandsociety.org/article.php?id=9000), Pete Shanks (Center for Genetics and Society and Friends of the Earth, November 30, 2015), <http://geneticsandsociety.org/article.php?id=9000>
  - This report summarizes for a lay audience the current capacities and broad social implications of synthetic biology; and in particular, the rise and shape of the CRISPR-Cas9 gene editing debate and the policy implications of permitting human germline gene editing tools for reproductive purposes.
- [Open Letter Calls for Prohibition on Reproductive Human Germline Modification](http://www.geneticsandsociety.org/article.php?id=8999) (Center for Genetics and Society, November 2015), <http://www.geneticsandsociety.org/article.php?id=8999>
  - Some 200 scientists and scholars urge a ban on using germline gene editing for reproductive purposes.
- [Genetically Modified Humans? Seven Reasons to Say "No"](http://geneticsandsociety.org/downloads/7_Reasons.html) (Center for Genetics and Society, May 2015), [http://geneticsandsociety.org/downloads/7\\_Reasons.html](http://geneticsandsociety.org/downloads/7_Reasons.html)
  - Summarizes the social and safety arguments against human germline gene editing: profound health risks for future children, thin medical justification, treating human beings like engineered products, violating the common heritage of humanity, undermining widespread policy agreements among dozens of democratic nations, eroding public trust in responsible science, and reinforcing inequality and discrimination.

### Bioethics and social sciences articles

- [Can We Cure Genetic Diseases Without Slipping Into Eugenics?](http://www.thenation.com/article/can-we-cure-genetic-diseases-without-slipping-into-eugenics/), Nathaniel Comfort, *The Nation* (July 16, 2015), <http://www.thenation.com/article/can-we-cure-genetic-diseases-without-slipping-into-eugenics/>
  - A rich historical examination of eugenics in the United States as the social and political context of CRISPR-Cas9, which Comfort argues is the "latest chapter in a long, darkly comic history of human genetic improvement."

- [Gene Editing: Hope, Hype, and Caution](#), Daniel Callahan, *The Hastings Center Bioethics Forum* (December 8, 2015)  
<http://www.thehastingscenter.org/Bioethicsforum/Post.aspx?id=7688&blogid=140>
  - Callahan argues that those who call for moratoria are well aware of the potential benefits of research, but that in the debate they are castigated by “a double standard: speculative harms are treated as fear mongering while speculative benefits are allowed to run wild.”
- [Gene editing: Govern ability expectations](#), Gregor Wolbring, *Nature* 527, 446 (November 26, 2015), <http://www.nature.com/nature/journal/v527/n7579/full/527446b.html>  
Commenting on the statement by members of the Hinxton Group, Wolbring offers a disability-rights perspective on the goals of gene editing.
- [Gene editing: Heed disability views](#), Tom Shakespeare, *Nature* 527, 446 (November 26, 2015), <http://www.nature.com/nature/journal/v527/n7579/full/527446a.html>
  - Abstract: “CRISPR–Cas9 is a gene-editing tool of great potential, although not necessarily from a disability-rights perspective (see [D. J. H. Mathews et al. \*Nature\* 527, 159–161; 2015](#)). People with disabilities are, in my view, unlikely to be queuing up for genetic modification: their priority is to combat discrimination and prejudice.”
- [Could DTC Genome Testing Exacerbate Research Inequities?](#), Christine Aicardi, Maria Damjanovicova, Lorenzo Del Savio, Federica Lucivero, Maru Mormina, Maartje Niezen & Barbara Prainsack, *The Hastings Center Report* (January 20, 2016),  
<http://www.thehastingscenter.org/Bioethicsforum/Post.aspx?id=7711&blogid=140>
  - This article argues that the focus on personal genomics may skew research toward therapies desired by people who can afford expensive and highly sophisticated genetic treatments, and exacerbate resource allocation disparities.

#### Law review articles

- [Who Defines “Healthy”? Ethical Dilemmas Across Competing Interest Groups on Genetic Manipulation and Gene Patents](#), Haley Guion, 17 *DePaul J. Health Care L.* 47 (2015),  
<http://via.library.depaul.edu/cgi/viewcontent.cgi?article=1317&context=jhcl> [pdf]
  - “With the potential that gene therapy research and development holds in the field of medicine comes significant ethical dilemmas about the definition of ‘illness.’”
- [Health Law as Disability Rights Law](#), Jessica L. Roberts, 97 *Minn. L. Rev.* 1963 (2013),  
[http://www.minnesotalawreview.org/wp-content/uploads/2013/05/Roberts\\_MLR.pdf](http://www.minnesotalawreview.org/wp-content/uploads/2013/05/Roberts_MLR.pdf)
  - “[D]espite the groundswell of support within the disability rights movement, civil rights laws have failed to address the serious health disparities that the disability community faces...The Article concludes that to achieve holistic equality for people with disabilities, disability rights advocates must move beyond the civil rights paradigm by integrating other kinds of legal protections into their agendas for change.”
- [Law, Race, and Biotechnology: Toward a Biopolitical and Transdisciplinary Paradigm](#), Dorothy Roberts, 9 *Ann. Rev. L. & Soc. Sci.* 149 (2013),  
<http://www.annualreviews.org/doi/abs/10.1146/annurev-lawsocsci-102612-134009>

- Considers “future directions for research in this field [gene-based technological innovation] needed to attend to the serious political implications of increasing race consciousness in genomic research and technology at a time when color blindness and postracialism are gaining popularity. I argue for a biopolitical and transdisciplinary paradigm that is committed to our common humanity and to the need for social change.”