

## **ASHG Policy Statement on Human Germline Genome Editing**

*Jointly written and affirmed by NSGC, CAGC, IGES, AGNC*

**Members: Ormond and Mortlock (Co-Chairs); Bombard, Brody, Cradick, Faucett, Garrison, Hercher, Isasi, Middleton, Musunuru, Scholes (ASHG staff), Shriner, Virani**

Participating organizations:

- ASHG: American Society of Human Genetics
- CAGC: Canadian Association of Genetic Counsellors
- IGES: International Genetic Epidemiology Society
- NSGC: National Society of Genetic Counselors
- AGNC: Association of Genetic Nurses and Counsellors (UK and the Republic of Ireland)

In the past few years, striking advances in *genome-editing* technology—most notably the development of CRISPR/Cas9 systems—have allowed researchers around the world to quickly, cheaply, and efficiently create modifications in DNA sequences inside living cells, with a rapidity and precision not previously known. The Cas9 protein and a CRISPR “guide RNA” combine to find a target gene among the thousands of genes in a cell’s nucleus and cut both DNA strands at the target site. If a separately engineered DNA strand is also provided, the cell’s repair machinery may use this as a “template” to fix the DNA break. In this way, mutations that cause disease could potentially be corrected, or, new mutations could be introduced that alter normal gene function. Somatic applications of gene editing fall under already established guidelines and ethical considerations for gene therapy and are therefore not addressed in this statement

In early 2015, researchers published the first experiments demonstrating that CRISPR/Cas9 could be used to modify genes in unviable human embryos. This work raised the possibility that genome-editing techniques could be incorporated into human-assisted reproduction procedures and thereby introduce changes that are passed on to future generations. Given the new potential for germline genome editing to prevent disease, as well as the considerable associated safety and ethical issues, our organizations believe it is important to provide our perspective on a path forward for research and medicine. Accordingly, we have come to agreement on the positions below, which we explain in detail, along with ethical justifications, in the accompanying white paper.

1. At this time, given the nature and number of unanswered scientific, ethical and policy questions, it is unacceptable to perform germline gene editing that culminates in human pregnancy.
2. Currently, there is no reason to prohibit *in vitro* genome editing on human embryos and gametes, with appropriate oversight and consent from donors, to facilitate research on the possible future clinical application of gene editing. There should be no prohibition on making public funds available to support this research.

3. Future clinical application of human germline genome editing should not proceed unless, at a minimum, there is a) a compelling medical rationale, b) an evidence base that supports its clinical use, c) an ethical justification, and d) a transparent public process to solicit and incorporate stakeholder input.