

ISSCR Supports the Development of International Guidelines on Human Embryo Genome Modification

The ISSCR supports international efforts to evaluate the potential benefits as well as the significant ethical, societal, and safety considerations related to human embryo genome modification. In light of the paucity of studies on the safety of these procedures and the lack of a broad consideration of the ethical and societal implications, the ISSCR concludes that it is premature to use genome modification on human embryos at this time.

Genetic modifications in embryos have the potential to affect most or all cells in the body, including the germline, resulting in modifications that could be passed on to future generations. Heritable modifications raise greater safety and ethical considerations than nonheritable somatic gene therapy, in which genetic modifications are limited to non-germline cells in specific tissues. While gene editing may provide significant benefits for preventing serious inherited diseases, we need to more fully understand the potential long-term risks of human embryo genome modification, including the potential consequences of genetic mosaicism and off-target effects, if these cannot be eliminated. Since many genes encode proteins that have multiple functions, the pleiotropic effects of genetic changes must be carefully considered, including potential effects on fetal development, adult tissue homeostasis, and on the risks of diseases that are directly or indirectly affected. This technology cannot be safely or ethically used clinically in human embryos until the risks are better understood and there is reasonable consensus about the circumstances in which it would be appropriate to perform embryo genome modification.

Regulatory approaches must be developed to accurately predict, detect, and evaluate both on- and off-target effects of gene edits, and weigh the potential risks and benefits relative to other approaches for preventing or treating disease. The ISSCR supports the efforts led by the [World Health Organization](#), national and transnational academies of science and medicine, and other organizations to guide policymakers as they weigh potential uses of this technology. We believe that human embryo genome modification should only be considered for serious medical problems for which other solutions are inadequate. We also recognize that different cultures or different countries may balance the ethical considerations differently.

The ISSCR calls upon the international research community to coordinate with stakeholder groups and the public to establish regulatory frameworks and standards before any further clinical applications of human embryo genome modification are undertaken.