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THE ISSCR STATEMENT ON HUMAN GERMLINE GENOME MODIFICATION

The International Society for Stem Cell Research calls for a moratorium on attempts at clinical application of nuclear genome editing of the human germ line to enable more extensive scientific analysis of the potential risks of genome editing and broader public discussion of the societal and ethical implications.

Genome editing, the purposeful modification of the DNA sequence in a cell, has played an essential role in biomedical research for several decades, allowing scientists to investigate disease and develop new medical treatments. After many years of foundational research on gene transfer into mammalian cells, numerous clinical trials are currently underway that employ genome editing approaches in somatic (non-reproductive) cells and represent promising strategies for correcting inherited immune deficiencies or treating cancer.

Technologies used to introduce changes into the DNA sequence of cells have advanced rapidly, making genome editing increasingly simple. For example, zinc finger nuclease-, TALEN- and CRISPR-Cas9- based technologies are being used by researchers around the world to introduce or correct mutations in gene sequences in a wide range of cell types. Genome editing is feasible, not just in the somatic cells of an adult organism, but also in early embryos, as well as the gametes (sperm and egg) that carry the inheritable, germline DNA. Research involving germline nuclear genome editing has been performed to date in many organisms, including mice and monkeys, and applications to human embryos are possible.

Any consideration of applying nuclear genome editing to the human germ line in clinical practice raises significant ethical, societal and safety considerations. Current genome editing technologies carry risks of unintended genome damage, in addition to unknown consequences. These are of much greater concern in the context of the germ line, where, unlike changes in subsets of somatic cells, genetic changes in the germ line alter the genetic makeup of every cell in the body and are passed down to future generations. Moreover, consensus is lacking on what, if any, therapeutic applications of germ line genome modification might be permissible. For example, some argue that the ability to eradicate disease justifies attempts at therapeutic editing of the human germ line, while others emphasize the difficulty of drawing clear distinctions between applications in human disease and attempts at human enhancement.

The ISSCR calls for a moratorium on attempts to apply nuclear genome editing of the human germ line in clinical practice. Scientists currently lack an adequate understanding of the safety and potential long term risks of germline genome modification. Moreover, the ISSCR asserts that a deeper and more rigorous deliberation on the ethical, legal and societal implications of any attempts at modifying the human germ line is essential if its clinical practice is ever to be sanctioned.

In calling for the above moratorium, the ISSCR is not taking a position on the clinical testing of mitochondrial replacement therapy, a form of germline modification that entails replacing the mitochondria (found outside the nucleus) in the eggs of women at risk of transmitting certain devastating diseases to their children. Mitochondrial replacement therapy does not entail direct modification to the nuclear genome and depends upon distinct technologies. Thoughtful scientific and ethical discussions of this technology have recently occurred in the United Kingdom and are underway in the United States and elsewhere in the world. The ISSCR applauds these current efforts as a model for deliberations on germline nuclear genome editing technologies.

At this time, the ISSCR supports in vitro laboratory research, performed under proper ethical oversight, to enhance basic knowledge and to better understand the safety issues associated with human genome editing technologies, including their potential for application in somatic tissues. The ISSCR also calls for broad public and international dialogue on the capabilities and limitations of these technologies and on the implications of their application to the human germ line. The ISSCR is committed to playing a role in catalyzing both the scientific and broader ethical deliberations about germline genome editing.

About the ISSCR

The International Society for Stem Cell Research (ISSCR) is an independent, nonprofit organization established to promote and foster the exchange and dissemination of information and ideas relating to stem cells, to encourage the general field of research involving stem cells and to promote professional and public education in all areas of stem cell research and application.