Consensus Statement: Gene Editing, Genetic Testing and Reproductive Medicine in Canada

The 2004 Assisted Human Reproduction Act (AHRA) and the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2, 2014) are key elements of the Canadian regulatory framework for emerging technologies in reproductive medicine, such as gene editing.

The promised review of the provisions and operations of the AHRA a few years following enactment did not occur. Since 2004, considerable advances in human reproductive medicine and genetics research, with implications for selection and modification in humans have occurred. In response, the Stem Cell Network and the Centre of Genomics and Policy (McGill University), along with other partners, convened and published the results of these four policy workshops. Following these workshops, the signees listed below prepared this Consensus Statement, which reflects their conclusions and recommendations.

Our Recommendations are based on the following principles:

1. Ensuring the human right of Canadians to benefit from the advancement of science and its applications (article 27 of the Universal Declaration of Human Rights, 1948 and article 15(b) of the International Covenant on Economic, Social and Cultural Rights, 1966);
2. Avoiding criminal bans, as they are an unsuitable policy instrument to regulate human genetic and reproductive medicine research;
3. Providing proportional, regulatory limits and oversight guided by evidence of risks and benefits; and,
4. Appropriately distinguishing between research and clinical practice through the implementation of a distributed governance model for research ethics and professional regulation.

Recommendations for gene editing, genetic testing and reproductive medicine in Canada:

- Basic and pre-clinical research on human germ cells and embryos in the earliest stages of development should be allowed.
- The current definition of the human embryo in the AHRA should be maintained but not include synthetic embryo-like structures not intended to create a human being.
- At this time, the 14-day limit on human embryo research should be maintained, as should the ban on the reproductive uses of clones and chimeras.
- The creation of human embryos for research purposes including by somatic cell nuclear transfer should be permitted.
- Mitochondrial replacement therapy to prevent the transmission of serious mitochondrial diseases should be permitted when demonstrated to be safe and effective.
- Pre-implantation genetic testing should be subject to professional guidance, rather than federal legislation. Such guidelines should be based on a patient-centered approach and include considerations related to familial and cultural contexts.
- The regulation of research and practice should respect individual autonomy in reproductive and health decision-making. Additionally, an evidence-based and current understanding of Canadian societal values and concerns should guide regulatory reform of research and practice, for example, the regulation of non-medical sex selection through PGD.

The implementation of these recommendations requires: a democratic engagement process of public consultation - led by Health Canada; a strengthening scientific literacy about human genetic research and reproductive medicine to enable ongoing review of Canadian laws and policies, including the AHRA; and, an independent review body charged with guiding ongoing reforms to the AHRA and the TCPS in light of emergent technologies for genetic testing and that utilize human reproductive materials.

The undersigned are committed to continuing our work on this Consensus Statement through a series of consultations with relevant governmental agencies/departments and professional societies so as to incorporate further advice and respond to criticisms.

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