Consultation Process Questions on the Consensus Statement (2017)

1. Do you think that the current criminalization in Canada of: a) germline modification; b) creation of embryos for research purposes; and c) mitochondrial replacement therapy should be maintained?

   a) Germline modification: ☐ Yes ☐ No

   b) Creation of embryos for research purposes: ☐ Yes ☐ No

   c) Mitochondrial replacement therapy: ☐ Yes ☐ No

2. If yes, why?

   a) Germline modification

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   b) Creation of embryos for research purposes

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   c) Mitochondrial replacement therapy

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3. If no, what would you propose for Canada? (*Select among the following*)

   ☐ Create a national oversight body to approve research in a, b, and/or c.

   ☐ Ask Health Canada to:

   ☐ Clarify the interpretation / permissibility of section 5(1)(f) of the *Assisted Human Reproduction Act* (AHRA) that seems to prohibit basic and pre-clinical research on human germ cells and embryos, even when there is no intent to implant;

   ☐ Modify the legal status of mitochondrial replacement therapy under section 5(1)(f) of the AHRA;

   ☐ Permit the creation of embryos for research purposes including by somatic cell nuclear transfer, prior to 14 days.

☐ Engage with professional organizations to create guidelines for pre-implantation genetic testing.

☐ Add specific sections on a, b, and c to the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (2014) Guidance (it recognizes the AHRA as governing these aspects), which currently states:

a) **Germline modification (ch. 13):** "Gene alteration involves the transfer of genes into cells to induce an altered capacity of the cell. Viruses are commonly used vectors (carriers) to introduce the gene into the host genome. Gene alteration is irreversible – the cell and its descendants are forever altered and introduced changes cannot be removed. The possible use of germ line alteration implies changes that could be transmitted to future generations. Gene transfer research that involves alteration of human germ line cells is governed in Canada by the *Assisted Human Reproduction Act* and its *Regulations*. Researchers should be aware of how this law applies to their work, such as the Act's prohibition on knowingly altering the genome of a cell of a human being, or in vitro embryo, such that the alteration is capable of being transmitted to descendants."

b) **Creation of embryos for research purposes (ch. 12):** "For the purposes of this Policy the following definition apply: Embryo means a human organism during the first 56 days of its development following fertilization or creation, excluding any time during which its development has been suspended, and includes any cell derived from such an organism that is used for the purpose of creating a human being."
Research on embryos may be ethically permissible if:
   - They have been created for reproductive purposes, provided that certain conditions are met: research is intended to benefit the embryo; research will not compromise the care of the woman/subsequent fetus and will closely monitor the safety and comfort of the woman/embryo; and consent has been provided by the gamete donors.
   - They are leftover embryos that were created for reproductive purposes, provided that certain conditions are met: consent has been provided by the gamete donors; embryos will not be transferred for continuing pregnancy; and research will only take place in accordance with the 14-day rule.

c) **Mitochondrial replacement therapy:** Same as for germline modification.

☐ Other (specify):

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4. Moving forward, what do you consider to be the key ethical, social, legal, and regulatory issues that should be addressed in Canadian law and policy as it relates to emerging technologies in reproductive/genetic/regenerative medicine (e.g. genetic enhancement, PGD criteria/guidance, organoids, etc.)?

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