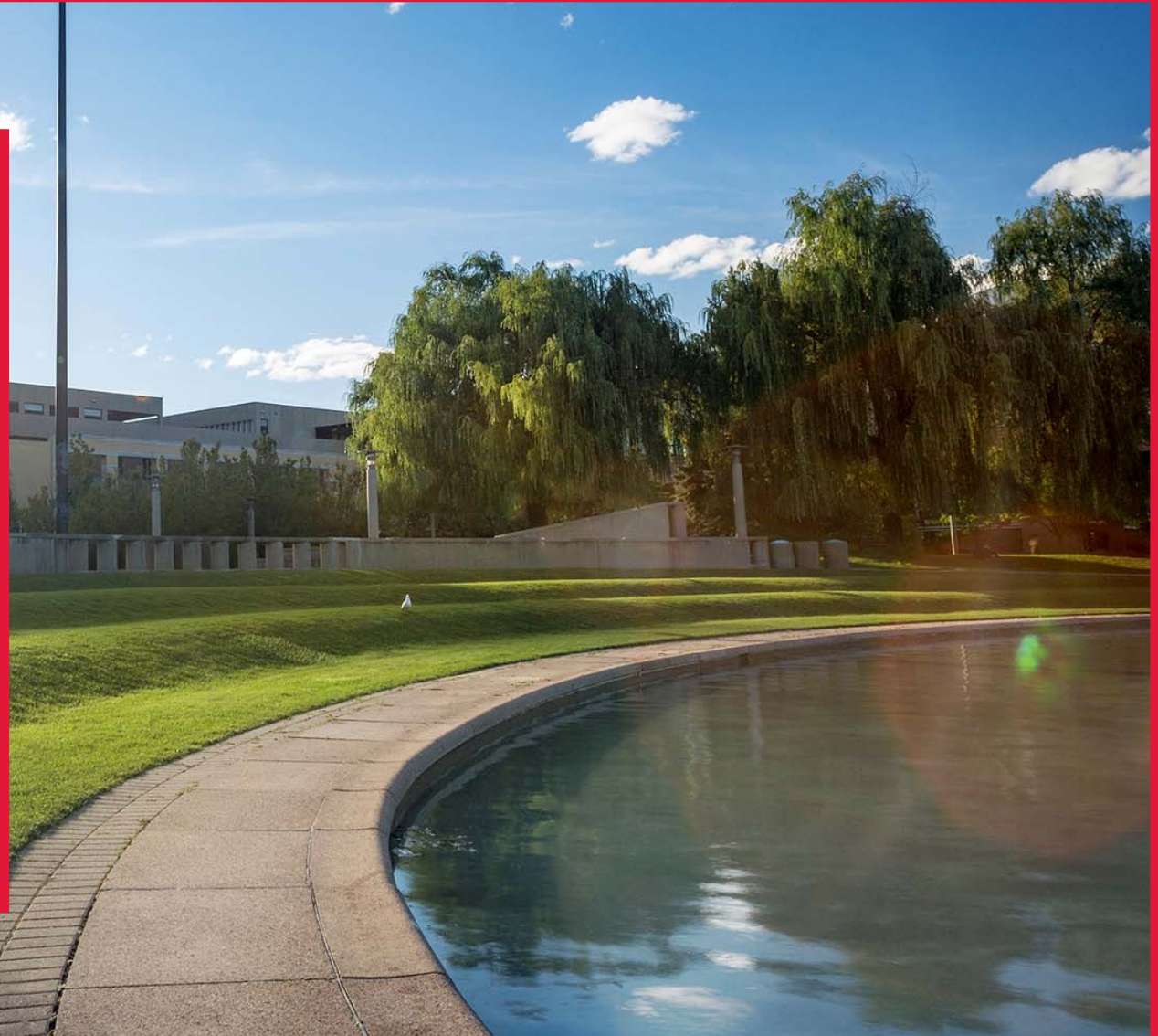


Ethical and Legal Concerns about Human Germline Genome Editing

Ian Stedman, Assistant Professor, Canadian
Public Law and Governance.

+ Rare disease patient and parent.

YORK 



ETHICAL CHALLENGES AND CONCERNS

- Balancing health equity / autonomy & social justice
- Monitoring safety & efficacy (inter-generational trials?)
- Impact on parenting & concerns about designer babies
- Risk of medicalizing/pathologizing difference
- Fear about stigmatization or even eugenics
- Commercialization vs. public health goals



LEGAL CONSIDERATIONS

- Intellectual Property rights & Public access to the technology
- Risk of discrimination (e.g. Genetic Anti-Discrimination Act)
- Who regulates & how (implications for AG, Medicine, Food, Human Rights, etc.)
- Human trials and consent standards
- The technology and its potential application is constantly evolving, so regulation must be flexible
- What laws do we need now and in the future?



LEGAL PROHIBITIONS

*Canada's Assisted Human Reproduction Act,
2004*

Prohibited Procedures:

Section 5(1)(f): No person shall knowingly alter the genome of a cell of a human being or in vitro embryo such that the alteration is capable of being transmitted to descendants.

Offence and Punishment:

Section 60 says that you could be fined (up to \$500,000) and even imprisoned.





POLICY CONSIDERATIONS

- Can germline modifications be acceptable? If so, when?
- Social architecture needed
- Tri-Council Policy Statement (i.e. research ethics policy) update?
- Deciding on (& calculating) acceptable levels of risk
- Defining a “serious” condition
- Reducing healthcare costs vs. freedom to choose
- Commercialization vs public health efforts
- Nefarious uses (e.g. gene drives and warfare)



“

CONTINUING DIALOGUE

- Patients (common and rare disorders, persons w\ disabilities, etc.)
- Scientists (incl.
- Social scientists (e.g. ethicists, economists, etc.)
- Healthcare providers
- Legislators & lawyers
- Faith leaders.
- Diverse NGOs
- Industry
- Research funders
- You!

”

LET'S ENGAGE IN THAT DIALOGUE!

