WHERE TO FROM HERE?
A Canadian strategy for AHR

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Key challenges with the current AHR Act

Alternative oversight mechanisms for AHR-specific activities, currently overseen by the AHR Act

AHR-specific activities for which federal oversight may be appropriate and/or needed?
Key challenges
Key challenges: Grey market
Key challenges:
Disdain for the law

Canadian Fertility Consulting: fees of about $7,500
Canadian Surrogacy Options: fees of about $7,500
Surrogacy in Canada Online: fees of about $5,000
Key challenges:
Harms to egg donors

Real egg donor stories, behind the scenes.

If you're looking for honest, judgment-free conversations about egg donation, you're in the right place.

We Are Egg Donors was founded by three egg donors to create a safe space for donors to connect and talk about the issues that matter most to us. Today, we have a booming community of more than 1,000 past and current egg donors -- and we're so excited to share this wealth of information with you!

Our free group for egg donors is a Facebook group that is secret - the most private, locked down setting. Not visible to the public. It's a safe space where egg donors connect about anything and everything related to egg donation and women's health.

We are now accepting new members. And... it's free!

ACCESS SECRET FB GROUP READ THE BLOG

THE SCARY TRUTH ABOUT DONATING YOUR EGGS
There are some frightening cracks in the do-good, feel-good industry — with some donors reporting infertility or the development of persistent health problems. Here's what donating your eggs can really do to your physical and mental health.
Key challenges: Medical tourism
Activities overseen by AHR Act

Prohibited Activities
Prohibited procedures
5 (1) No person shall knowingly
(a) create a human clone by using any technique, or transplant a human clone into a human being or into any non-human life form or artificial device;
(b) create an in vitro embryo for any purpose other than creating a human being or improving or providing instruction in assisted reproduction procedures;
(c) for the purpose of creating a human being, create an embryo from a cell or part of a cell taken from an embryo or foetus or transplant an embryo so created into a human being;
(d) maintain an embryo outside the body of a female person after the fourteenth day of its development following fertilization or creation, excluding any time during which its development has been suspended;
(e) for the purpose of creating a human being, perform any procedure or provide, prescribe or administer any thing that would ensure or increase the probability that an embryo will be of a particular sex, or that would identify the sex of an in vitro embryo, except to prevent, diagnose or treat a sex-linked disorder or disease;
(f) alter the genome of a cell of a human being or an in vitro embryo such that the alteration is capable of being transmitted to descendants;
(g) transplant a sperm, ovum, embryo or foetus of a non-human life form into a human being;
(h) for the purpose of creating a human being, make use of any human reproductive material or an in vitro embryo that is or was transplanted into a non-human life form;
(i) create a chimera, or transplant a chimera into either a human being or a non-human life form;
(j) create a hybrid for the purpose of reproduction, or transplant a hybrid into either a human being or a non-human life form.
Criminal bans are not a suitable instrument...

Mitochondrial Replacement Therapy: The Road to the Clinic in Canada

Bartha Maria Knoppers, PhD; Arthur Leader, MD; Stacey Hume, PhD; Eric A. Shoubridge, PhD; Rosario Isasi, MPH; Forough Noohi, MSc; Ubaka Ogbogu, SJD; Vardit Ravitsky, PhD; Erika Kleiderman, LLB

Criminal bans are not a suitable instrument to regulate MRT.

Human gene editing: revisiting Canadian policy

Criminal bans are not a suitable instrument to regulate scientific research.

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.

Avoiding criminal bans, as they are an unsuitable policy instrument to regulate human genetic and reproductive medicine research.
Should use the criminal law when

• The objective is to protect the health and safety of the public and to prevent unethical activity (AHR legislative history — evidence of a pressing and substantial concern)

• A ban is both rationally connected to the objective and necessary to achieve the objective — if the objective is to prevent the activity from happening, then a ban is the most effective means to this end.

• The deleterious effects of the ban are balanced by its salutary effects
  • means chosen are proportionate to the objective
  • there are available alternatives
  • avoids harm of genetically modified children
  • avoids risk of harms to egg providers
  • Attentive to opportunity costs re investment of time, talent, and treasure
Should use the criminal law …

- Criminal law is a suitable instrument to regulate scientific research, just as it is a suitable instrument to regulate medicine. See CC “Offences against the person” E.g., MAiD

- A criminal ban should be used for conduct that the federal government has deemed against “public health, safety and morality”. See legislative history and preamble to AHR Act.

- Proposals to use “distributed governance model” (research ethics and professional self-regulation) are seriously flawed – structural conflict of interest.
  - National, independent review body (SCOC/CIHR)
  - CMA, SOGC, CFAS
CIHR failed in its self-imposed obligation to ensure compliance with CIHR Stem Cell guidelines.

Stem Cell Oversight Committee and Governing Council amended the CIHR stem cell guidelines in 2005 to align the guidelines with current research practice “to recognize that fresh embryos (and not just frozen embryos) are also being used for stem cell research.”
“While refraining from taking a positional stance”

Canada is an outlier with respect to its strict criminal prohibition on all forms of human germline gene editing, though few jurisdictions expressly permit preclinical applications of the technologies or allow the creation of human embryos for purposes other than reproduction.
“While refraining from taking a positional stance”

On the other hand, if current prohibitions remain, Canadian researchers may fall behind on the international scene. Going forward, restrictive research policies may lead to medical tourism, as has been the case in stem cell research.17

If human germline gene editing were to be decriminalized, without being replaced by federal or provincial regulations, other options for regulation and guidance include:

- **Professional self-regulation**: Clinical practice standards could be applied to human germline gene editing, which could fall to those responsible for medical licensing standards, as well as the Canadian Medical Association (CMA), the Society of Obstetrics and Gynecology of Canada (SOGC), the Canadian Fertility and Andrology Society (CFAS), and relevant provincial and territorial partners.

- **Funding policy**: Funding organizations could outline the conditions under which they would be willing to support research that involves human germline gene editing (for example, through provisions in the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans).
HC: Ensure proper oversight

• **Believe** in the legislation
• **Complete the legislation**: Write the regulations (do not incorporate CSA standards by reference as they include elements that are contrary to the legislation),
• **Educate** public, users, providers, and law enforcement about the legislation
• **Enforce** the legislation (e.g., instruct RCMP)
HC: Enforce the legislation

- Health Canada Oversight Office -- Introduce and manage a formal grievance process (ombudsperson) e.g. problems with third-party intermediaries

- Undertake periodic review (as per original legislation); once the law is fully in place and operationalized.
Empirical research: MRT
International scan: egg selling

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UNITED STATES TAX COURT

MICHELLE G. PEREZ, Petitioner v.
COMMISSIONER OF INTERNAL REVENUE, Respondent


P received large sums of money in exchange for undergoing procedures to donate her eggs to infertile couples. Under P’s contracts, the sums she received were designated compensation for pain and suffering. P did not report these amounts on her 2009 tax return. It issued a notice of deficiency.

Held: Compensation for pain and suffering resulting from the consensual performance of a service contract is not “damages” under I.R.C. section 104(a)(2) and must be included in gross income.

It’s Not Donating. It’s Selling.

Fertility clinics’ feeble justifications for fixing the price of human eggs.

By Eric Peters

If a woman supplies one of her own eggs to a fertility clinic, how much should she be paid? Under the economic laws of supply and demand, the price of the egg will reflect a balance between the willingness of one party, usually an infertile couple, to pay and the cost in pain, risk, and trouble undergone by the woman who provides the egg. Prices could be as high as $30,000, or more, but women are typically paid $5,000–$10,000. That’s because of a price-fixing conspiracy among medical clinics—according to a lawsuit that is making its way through federal court.
FPT Cooperation/Harmonization

- Model consent forms so that all patients are getting the right information.
- Reimbursement of receipted expenditures
- Family law (protection for families created using donor gametes and for donors);
- Grievance process (ombudsperson) e.g. problems with third-party intermediaries;
- Medical tourism: international intended parents who are taking advantage of CDN health care system
- Strategies for removing barriers to accessing AHR and adoption
- Birth certificates – who is the mother?
- Policy re: donor anonymity
- Non-binding guidelines for limits on # of embryos transfer; limit on # births per donor
- Harmonized data collection (personal health information registry; data about health of egg providers, surrogates, offspring; success rates)
- Harmonized response to medical tourism (international patients) & transnational trade in reproductive tissues
  - Statistically significant results
  - National data for comparison with other jurisdictions
  - Comparable data across provinces and territories