Office of Legislative and Regulatory Modernization
Policy, Planning and International Affairs Directorate
Health Products and Food Branch
Health Canada
3000A, 11 Holland Avenue, Suite 14
Ottawa, Ontario
K1A 0K9

January 10, 2019

To Whom It May Concern:

Thank you for this opportunity to comment on the publication of proposed regulations and the related *Guidance Document: Interpretation of the Proposed Regulations under the Assisted Human Reproduction Act* (Guidance Document) to bring into force sections 10, 12, and 45 to 58 of the *Assisted Human Reproduction Act* (the Act). We are pleased that the federal government is taking steps to develop much-needed regulations to enable the implementation of the Act, and to provide clarity in this field.

We are writing this submission as a group of academic researchers, including legal scholars, bioethicists, and political scientists whose research focuses explicitly on the governance of assisted human reproduction in Canada and its implications for key stakeholders, namely donor-conceived people, gamete donors, women who act as surrogates, and intended parents. We are frequently called upon to provide our expertise to the Government of Canada and others in the development of laws and regulations related to assisted reproduction in Canada, and we have all published extensively on the challenges of governing in this field.

While we support the federal government's development of these long-awaited regulations, there are a number of areas of concern raised by the proposed regulations and we have specific recommendations to address them. We have grouped these recommendations into three categories as related to: A) Safety of Sperm and Ova Regulations; B) Reimbursement under the Assisted Human Reproduction Act Regulations and C) Regulations Amending the Assisted Human Reproduction Act.

Université d'Ottawa
Faculté de droit
Section de common law

University of Ottawa
Faculty of Law
Common Law Section

613-562-5794
613-562-5124

57 Louis-Pasteur
Ottawa ON K1N 6N5
Canada

uOttawa.ca

You will find below three sections that outline and explain these recommendations and comprise the remainder of our submission:

I. A list of recommendations
II. A list of recommendations with relevant reasoning
III. An outline of other concerns

In particular, we would like to draw your attention to our recommendation B1, which addresses the constitutionality of the inspection and requirement powers under the proposed reimbursement regulations. Specifically, as the Act is grounded exclusively in the criminal law power, the requirement to provide documents to inspectors under section 12 of the reimbursement regulations would violate the Charter protected rights to silence, to be free from unreasonable search and seizure, and the principle against self-incrimination (as established in *R v Jarvis*).[1] To this end, we recommend that the inspection and requirement powers under the reimbursement regulations be removed and that the protections outlined in *Jarvis* be afforded to record holders.

Thank you for the opportunity to provide feedback on the discussion document and the regulatory process. We would be pleased to discuss any aspect of this response with you, and to provide comments or input on future iterations of these regulations.

Sincerely,

Vanessa Gruben, Associate Professor, Faculty of Law and Centre for Health Law, Policy and Ethics, University of Ottawa

Alana Cattapan, Assistant Professor, Johnson Shoyama Graduate School of Public Policy, University of Saskatchewan

Angela Cameron, PhD, Associate Professor, Faculty of Law, University of Ottawa, Shirley Greenberg Professor of Women in the Legal Profession

Karen Busby, Professor of Law and Director of the Centre for Human Rights Research, University of Manitoba

Davinder Singh, MD, MSc Faculty of Law, University of Manitoba

Françoise Baylis, University Research Professor, Faculty of Medicine, Dalhousie University

Stefanie Carsley, Doctoral Candidate, McGill University, Faculty of Law

[1] [2002] 3 SCR 757

Isabel Côté, PhD., professeure agrégée en travail social, Université du Québec en Outaouais.

Katy Fulfer, Assistant Professor of Women's Studies and Philosophy, University of Waterloo

Kévin Lavoie, PhD(c) in applied social sciences, Université de Montréal (Montréal, Canada)

Kathleen Hammond, PhD , B.C.L./LL.B candidate, McGill University

Angel Petropanagos, PhD, Quality Improvement Ethicist, William Osler Health System

Pamela M. White, LLM. PhD, Specialist Associate Lecturer, Kent Law School

I. List of Recommendations

We recommend the following changes to the proposed regulations:

A. Safety of Sperm and Ova Regulations

A1. We recommend that Health Canada clarify how it will ensure the effectiveness of the proposed regulatory oversight when most of the relevant establishments may fall outside of the reach of Canadian regulators, as many of those engaged in relevant activities are located outside of Canada.

A2. We recommend that Health Canada create a standard (model) screening questionnaire for donors and make this available to primary establishments who may elect to use this. This would help to promote uniformity and make the introduction of regulations less onerous for clinics across the country.

A3. We recommend that Health Canada include a list of genetic diseases in the Guidance Document to ensure transparency and consistency across primary establishments.

A4. We recommend that, based on the evidence, the *Safety* regulations (including the Guidance Document) be reviewed again to ensure that they:

a) do not use selective discriminatory screening criteria based on sexual orientation;
b) are updated to reflect current HIV testing capabilities (that is, testing the donor three weeks after donating sperm, and retesting the donor after the six month quarantine period (because of seroconversion for other infections like hepatitis C—see Appendix A);
c) recognize that if a donor is HIV+ but their condition is well managed through anti-retroviral treatment and the sperm is washed, the risk of HIV transmission is likely negligible and there should be no barriers to known donation.

A5. We recommend that Health Canada clarify what will happen when a proposed gamete donor is not able to provide information regarding the presence of a genetic disorder in three generations of the sperm or ova donor's family genetic history.

A6. We recommend that the *Safety* regulations be modified to specify initial disclosure to the prospective donor, and only thereafter to the intended recipient(s) if the prospective donor decides to proceed with donation and consents to disclosure.

A6. We recommend that anonymized/de-identified information about errors and accidents as well as adverse reactions be made publicly available.

A7. We recommend that all records be retained indefinitely (rather than the proposed 10 year period specified in the *Safety* regulations), to ensure that records, including all health or genetic information, are potentially available to donor conceived people.

B. Reimbursement under the Assisted Human Reproduction Act Regulation

B1. We recommend that the inspection and requirement powers under the regulations be removed and that the regulations expressly require that:

a) the person facing criminal liability must be provided with a proper warning;
b) no statements may be compelled under inspection and requirement powers;
c) no written documents may be inspected or examined, except by way of judicial warrant; and
d) no documents may be required from the record holder or any third party for the purpose of advancing the criminal investigation.

B2. We recommend including an additional expense category for the pregnancy-related dietary needs of surrogate mothers.

B3. We recommend including expenses for pet care, including but not limited to: kennelling, walking, grooming, transfer and pet sitting under the expense category of care of dependents.

B4. We recommend including the possibility for a surrogate to request reimbursement for loss of college or university school tuition fees if a surrogate is a part-time or full-time student who becomes unable to attend their classes and complete their semester on account of health challenges resulting from the pregnancy.

C. Regulations Amending the Assisted Human Reproduction (Section 8 Consent) Regulations

C1. We recommend against including any provisions that seek to strengthen donor anonymity.

II. List of Recommendations with Relevant Reasoning

A. Safety of Sperm and Ova Regulations

***A1. We recommend that Health Canada clarify how it will ensure the effectiveness of the proposed regulatory oversight when most of the relevant establishments fall outside of the reach of Canadian regulators*.**

The *Regulatory Impact Analysis Statement* [Impact Statement] explains that the *Safety of Sperm and Ova Regulations* are structured so as to "place the most regulatory oversight and administrative burden upstream in the supply chain on those establishments responsible for the activities that bear the most health risk (i.e.. screening and testing of sperm and ova donors)." However, most of these establishments—at least those currently engaged in the relevant activities—are doing so outside of Canada. Although the Impact Statement characterises these establishments as conducting activities that are "integral to the safety of donor sperm and ova," the burden of these regulations apply to primary establishments which are largely located outside of Canada raising questions about extraterritorial application of the Act and these regulations. If Health Canada is to remain committed to the health and safety of sperm and ova, these regulations and plans to ensure effectiveness require clarification.

A2. We recommend that Health Canada create a standard (model) screening questionnaire for donors and provide this form to primary establishments.

The proposed regulations (ss. 23, 34) stipulate that donors shall be required to undergo screening. The Guidance Document stipulates that the Medical Director of a primary establishment is responsible for preparing a structured questionnaire to screen the donor (p. 7). To ensure consistent screening between primary establishments, we recommend that Health Canada create a standard (i.e., model) screening questionnaire and provide this form to primary establishments. We understand that use of such a form would be elective, but we believe that many primary establishments would welcome a standardized form and this would improve quality and uniformity.

A3. We recommend that Health Canada include a list of genetic diseases in the Directive to ensure transparency and consistency across primary establishments.

The *Safety* Regulations require that establishments perform donor screening in accordance with the requirements set out in the Directive (s. 23). The *Draft Health*

Canada Directive: Technical Requirements for Conducting the Suitability Assessment of Sperm and Ova Donors [the Directive] provides that donors undergo genetic disease screening (2.1.2). Yet, there is little indication as to what qualifies as a "genetic disease." The Directive indicates that donors would be screened for "autosomal dominant, autosomal recessive and X-linked diseases." The Guidance Document indicates that genetic disorders include but are not limited to cystic fibrosis, Tay-Sachs disease and Duchenne muscular dystrophy (p. 8). As a result, the scope of the disorders screened for is unclear. We recommend that a list of genetic diseases be provided in the Directive to ensure that donors are aware what diseases will be screened for and to promote consistency across primary establishments. The Canadian Standards Association (CAN/CSA-7900.2.1-17), for example, has provided a more comprehensive list of relevant disorders for which screening could occur.

A4. We recommend that, based on the evidence, the Safety regulations (including the Guidance Document) be reviewed again to ensure that they:

a) do not use selective discriminatory screening criteria based on sexual orientation;
b) are updated to reflect current HIV testing capabilities (i.e., testing the donor three weeks after donating sperm, and retesting the donor after a six month quarantine period—because of seroconversion for other infections like hepatitis C);
c) recognizes that if a donor is HIV+ but their condition is well managed through anti-retroviral treatment and the sperm is washed, the risk of HIV transmission is likely negligible and there should be no barriers to known donation

The exclusion of men who have sex with men (MSM) as sperm donors in the *Safety* Regulations (and the Guidance Document) is based on prejudicial and discriminatory thinking and out-of-date science. Some MSM and some HIV positive men want to donate sperm anonymously; others want to help friends become parents; and some want to work with a surrogate or friend to produce a genetically-related child. Under the current regulations, MSM and those who are HIV positive face a lifetime ban on sperm donation (with some narrow exceptions for MSM). The *Safety* regulations and the Guidance Document will require donor *screening, physical examination and testing for, among other things, HIV. The Safety* regulations, if adopted, will exclude at the screening stage all sperm donors who have had sex with a man in the last six months without proceeding to examination or testing. The *Safety* regulations will also continue the current rule of excluding anyone who is HIV+ from making a sperm donation regardless of viral load or the potential to use sperm washing. The *Safety* regulations have an important new exception: a sperm donation, including a fresh donation, from

an excluded donor may be directed to a known recipient if the doctor is satisfied that the recipient is fully apprised of risks based on screening, examination and testing.

A closer look at the scientific evidence (as set out in Appendix A) suggests that the new regulations should not exclude through initial screening MSM from anonymous sperm donation solely out of concern for HIV transmission. Rather:

a) All donors should be tested three weeks after providing the sperm donation.
b) If no infections are found at the first screening test, the sperm should be quarantined for six months.
c) The donor should be retested at six months post donation (because of seroconversion for other infections like hepatitis C). The use of two screens will identify virtually all sperm donors who have HIV and other infections. The presence of infections at either screen should result in exclusion from anonymous donation.

Where the sperm donor is known, the recipients should have a greater range of options as long as they are informed of risks. If they know and trust a donor's representation of low risk activity, they may be willing to use fresh sperm rather than wait six months for a second screen/quarantine period. Or they may be willing to work with an HIV+ donor who is on an effective ART regime whose sperm is washed as the risk of HIV transmission in these circumstances is likely less than 1 in a million (see Appendix A).

A5. We recommend that Health Canada clarify what will happen where a proposed gamete donor is not able to provide information regarding the presence of a genetic disorder in three generations of the sperm or ova donor's family genetic history.

As discussed above, the *Safety* regulations require that establishments perform donor screening in accordance with the Directive. The Directive requires that the donor provide information regarding the presence of a serious autosomal dominant, autosomal recessive, or X-linked genetic disorder in three generations of the sperm or ova donor's family genetic history. However, it is possible that a proposed donor may not be able to provide a complete genetic history for three generations for a number of reasons (e.g., they may not know all biological progenitors, may be adopted, etc.). The consequences of not providing this information requires clarification.

A6. We recommend that the Safety regulations be modified to specify initial disclosure to the prospective donor, and only thereafter to the intended recipient(s) if the prospective donor decides to proceed with donation and consents to disclosure.

The focus of the *Safety* regulations is on communicating risk to the recipient(s) (s. 31(4)). There is no requirement that risks be communicated to the donor. Yet, this information is relevant to the donor's own health status and to whether they wish to proceed with donation. It also implicates the donor's right to privacy regarding health information. In our view, this information should not first be disclosed to the recipient(s). Disclosure to the recipient(s) would only be authorized where the proposed donor is aware of the risk, decides to proceed with donation, and consents to disclosure.

A7. We recommend that anonymized/de-identified information about errors and accidents as well as adverse reactions be made publicly available.

The *Safety* regulations require reporting of suspected errors and accidents as well as suspected adverse reactions to the recipient(s) and the Minister under specified circumstances. However, there is no requirement to report confirmed errors, accidents or adverse reactions to the public. An establishment or health professional that conducts an investigation into a suspected error or accident that could lead to an adverse reaction must notify the recipient to whom it distributed the implicated sperm or ova as well the Minister (within 72 hours after the start of the investigation) (ss. 61 *ff*). Similarly, a primary establishment must report suspected adverse reactions to the Minister (ss. 69 *ff)*. Anonymized/de-identified information about *confirmed* errors, accidents and adverse reactions may be relevant to members of the public who are considering donating or receiving sperm or ova from an establishment or health professional, or who have already received treatment in the same context. In our view, public reporting will improve safety and quality of care.

A8. We recommend that records be retained indefinitely, rather than 10 years, to ensure that records are potentially available to donor conceived people.

The *Safety* regulations require that records be retained for a 10 year period (s. 77). This retention period and the use of these records appears to be focused on ensuring that information is available for donors and recipients (ss. 76-84). Health and genetic information related to donors is of crucial importance to donor conceived people. If records are destroyed after 10 years, this will almost certainly preclude donor

conceived people from accessing these records. In our view, the Regulations should be revised to reflect the importance of these records for donor conceived people.

To address the potential difficulties with retaining records being held indefinitely (e.g. clinic closure, physician retirement), Health Canada should consider developing a repository or registry to ensure the records of donor-conceived people are maintained in perpetuity and potentially accessible to donor conceived people.

B. Reimbursement Related to Assisted Human Reproduction Regulations

B1. We recommend that the inspection and requirement powers under the reimbursement regulations be removed and that the regulations expressly require that:

- ***a) the person facing criminal liability must be provided with a proper warning;***
- ***b) no statements may be compelled under inspection and requirement powers;***
- ***c) no written documents may be inspected or examined, except by way of judicial warrant; and***
- ***d) no documents may be required from the record holder or any third party for the purpose of advancing the criminal investigation.***

In our view, section 65(1)(r) of the *Act* and the sections of the *Safety* regulations which require the person who has reimbursed a surrogate to keep all receipts and declarations and to produce this documentation to the Minister upon demand, violate the *Canadian Charter of Rights and Freedoms*.

Specifically, the *Act* and section 12 of the *Safety* regulations violate the *Charter* protected rights to silence and to be free from unreasonable search and seizure and the principle against self-incrimination. The Supreme Court of Canada established in *R v Jarvis* that "where predominant purpose of a question or inquiry is the determination of penal liability, the "full panoply" of *Charter* rights is engaged."[2] As the only purpose of the Ministerial requirement in the *Act* and proposed regulation is to expose the person who made the payment (who will usually be the intended parent) to possible penal liability, C*harter*-compliance is required. More specifically the person who made the payment must be provided with a proper warning that they may face penal consequences; they cannot be compelled under inspection and requirement powers to make a statement; they cannot be required to provide written documents for inspection or examination unless a judicial warrant has been obtained; and neither

[2] *Jarvis, supra* note 1 at para 96

they or a third party can be required to produce documents for the purpose of advancing the criminal investigation without a warrant.

***The Act* is valid solely under the criminal law power**

The federal power over assisted reproduction is grounded exclusively in its power to enact criminal law.[3] The federal exercise of power must therefore be aimed at suppressing an evil or injurious activity; prohibit that activity (rather than regulate it); and enforce the prohibition by penalizing a breach (rather than, for example, facilitating contract compliance or regulating the practice of medicine). The penalties under the *Act* are significant: anyone who offers to pay a surrogate mother is guilty of an offence and is liable to a $500,000 fine or a ten year prison term and anyone who reimburses a surrogate other than in accordance with the regulations is guilty of an offence and is liable to a $250,000 fine or five years imprisonment. Thus, anyone who pays a surrogate other than in accordance with the regulations commits a criminal offense. An investigation by the Crown into payments made is only permissible with a view to determining whether a criminal offense has been committed and not for some other purpose.

Nature and importance of the rights affected

The principle against self-incrimination has been referred to by the Supreme Court of Canada as an "overarching", "fundamental" principle and "the single most important organizing principle in criminal law".[4] A right to silence provides that witnesses are not required to testify if the purpose of obtaining their testimony is to expose them to penal liability. The principle against self-incrimination is an elemental canon of the Canadian criminal justice system, standing for the notion that individuals should not be conscripted by the state to promote a self-defeating purpose.[5]

Regulatory compliance or penal liability?

On first glance, the proposed compliance mechanism in the regulations appear to be similar to the self-reporting and on-demand inspection compliance mechanisms in other statutes such as the federal *Income Tax Act* (*ITA*) and therefore appear to be unproblematic from a *Charter*-perspective. The *ITA* is essentially a regulatory statute. In *Jarvis* the Court noted that voluntary compliance and self-assessment comprise the essence of the ITA's regulatory structure and therefore the tax system is equipped with persuasive inducements to encourage taxpayers to disclose their income. These

[3] *Ref re Assisted Human Reproduction Act* [2010] 3 SCR 457
[4] *R v Henry*, [2005] 3 SCR 609
[5] *R v S (RJ)*, [1995] 1 SCR 451

range from compliance audits to tax evasion investigations. However while taxpayers are statutorily bound in the ordinary course to co-operate with CRA auditors for tax assessment purposes (which may result in the application of regulatory penalties), the Court noted that "an adversarial relationship…crystallizes between the taxpayer and the tax officials when the predominant purpose of an official's inquiry is the determination of penal liability."[6] Thus, *Charter* compliance is required as soon as the purpose for which information is sought shifts from compliance audits to penal liability.

Unlike the *ITA*, the *Act* is not a regulatory statute; its "pith and substance" is solely penal. While information inquiries under the *ITA* can be either regulatory or penal, depending on the factors set out in *Jarvis*, the *only* information inquiries a Minister can make under s. 12 of the *Act* and the regulations are for the purpose of determining penal liability. As such full *Charter* compliance is required.

Investigation powers when penal liability is at stake

In *Jarvis,* the Court noted that the constitutional protections against self-incrimination prohibit CRA officials who are investigating *ITA* offences from having recourse to the powerful inspection and requirement tools contained in the *Act*. More particularly the Court stated that:

> In our view, where the predominant purpose of a particular inquiry is the determination of penal liability, CCRA officials must relinquish the authority to use the inspection and requirement powers under ss. 231.1(1) and 231.2(1). In essence, officials "cross the Rubicon" when the inquiry in question engages the adversarial relationship between the taxpayer and the state.[7]

The notice provision and obligation to provide records provisions contained in section 12 of the *Act* are similar to the requirement powers set out in the *ITA*. Since the investigation under the *Act* is inevitably penal, s.12 violates the *Charter* principle that statements and documents cannot be compelled or required for the purpose of advancing a criminal investigation.

What protections must be afforded to reimbursement record holders if they are under investigation? *Jarvis* clearly establishes that:

a) The person facing criminal liability must be provided with a proper warning.
b) No statements may be compelled under inspection and requirement powers.

[6] *Jarvis, supra* note 1 at para 2.
[7] *Ibid.* at para 88.

c) No written documents may be inspected or examined, except by way of judicial warrant.
d) No documents may be required from the record holder or any third party for the purpose of advancing the criminal investigation.

In our view, s. 12 either fails to provide for or trammels these basic protections and thus violates the *Charter* protected rights to silence and to be free from unreasonable search and seizure and the principle against self-incrimination. Therefore, in order to be *Charter* compliant, the inspection powers under the regulations should be removed from the regulations and the protections outlined in Jarvis must be afforded to record holders.

B2. We recommend including an additional expense category for dietary needs for surrogate mothers

As currently drafted, there is no category for dietary needs. Expenses related to dietary needs related to pregnancy should be eligible for reimbursement. These dietary expenses could include dietary supplements relating to the pregnancy or additional food expenses that may be incurred by the surrogate mother as a result of increased or changed dietary requirements, such as increased caloric intake, organic or kosher food.

B3. We recommend including expenses for pet care, including but not limited to: kennelling, walking, grooming, transfer and pet sitting under care of dependants

Although the regulations permit a surrogate mother to be reimbursed for care of dependants (s. 4(f)), the regulations do not include or exclude expenses relating to pets, such as dog kenneling while the surrogate mother is in hospital. In our view, these expenses should be eligible for reimbursement.

B4. We recommend including the possibility for a surrogate to request reimbursement for loss of college or university school tuition fees if a surrogate is a part-time or full-time student who becomes unable to attend their classes and complete their semester on account of health challenges resulting from the pregnancy.

As currently drafted, there is no category for loss of college or university tuition fees. Surrogates who are part-time or full-time students should have the opportunity to request reimbursement for tuition if they are unable to complete their semester because of the health challenges resulting from the pregnancy. A surrogate should

have to provide documents, similar to those set out in the proposed reimbursement regulations, such as: her name and address, the beginning and end dates during her pregnancy when she did not attend school for a reason certified by a qualified medical practitioner, and the amount requested for reimbursement.

C. Regulations Amending the Assisted Human Reproduction (Section 8 Consent) Regulations

C1. We recommend against including any provisions that seek to strengthen donor anonymity

There is no requirement for donor anonymity in the enabling legislation or elsewhere. The Impact Statement and the Guidance Document note that these provisions were added in response to concerns raised by sperm banks that the consent regulations "may unintentionally compromise the anonymity of third-party donors of reproductive material and IVEs by requiring the disclosure of information that may reveal their identity."

Many donor conceived people and donors maintain that anonymity is not possible (or desirable) and cannot be promised in the age of direct-to-consumer genetic testing and online genealogical tracing. Further, a majority of Parliamentarians at the time of the Act's passage were committed to eliminating donor anonymity in 2004 and donor conceived people and their advocates remain committed to this goal.

The additional requirements to address anonymity do not mitigate these concerns and indeed, make it more difficult for people who are trying to access their health and genetic records. If Health Canada remains committed to the Act's principles, namely that "the health and well-being of children born through the application of assisted human reproductive technologies must be given priority in all decisions respecting their use" it will not strengthen donor anonymity or work to preserve it.

Further, Health Canada should work with the provinces to strengthen family law to ensure there is clarity about parentage. This will allow families of donor conceived people to engage in family building consistent with the intentions of the donor and intended parent(s).

III. Other Concerns

In addition to specific recommendations on the proposed regulations, we have a number of areas of interest/concern. Here we outline a number of ways that the proposed regulations could be revised to strengthen the *AHRA*.

1. Embryos

We are concerned that the *Act* and the proposed regulations apply in limited situations to embryo donation. First, the infectious disease and genetic screening requirements only apply to sperm and ova but not to embryos, which may carry similar risks. Further, the *Act* neither provides for nor prohibits reimbursement to embryo donors for expenses associated with counselling or legal advice. As the Act does not explicitly prohibit screening requirements or reimbursement for embryo donation, we recommend that the regulations be revised and extended to address the needs of those considering embryo donation.

2. Egg Donors

The *Act* does not explicitly prohibit the reimbursement of work-related income for egg donors. The regulations could include a narrow provision related to reimbursement of work-related income for health reasons. The extraction of eggs is a medical procedure involving both the administration of powerful fertility drugs, and surgical removal of the ova themselves. The negative side effects of both the fertility drugs, and surgery, can be severe and prolonged for some donors. These can include ovarian hyperstimulation, pain at the surgical site, and drug-related complications. We recommend that egg donors be eligible for reimbursement of work-related income when health issues related to the egg donation are the cause of the loss of income.

3. *Reimbursement of Surrogate Mother for Loss of Work-Related Income Under Subsection 12(3) of the Act*

Section 12 of the *Act* is restricted to reimbursement for loss of work-related income during pregnancy, not following delivery. It is possible that a surrogate mother may experience post-partum complications which may require reimbursement for loss of work-related income during this period. Further, while there are provisions for loss of work-related income through the Government of Canada, it is unclear how these benefits would be coordinated in the case of a surrogate mother. We recommend providing clarity both about the possibility of post-partum reimbursement of work-related income as well as the coordination of benefits.

4. Forms

We recommend that Health Canada create a standard (model) form for travel reimbursements that reflects the requirements under the regulations. While the use of such a form would be elective, we believe that this would facilitate travel reimbursement claims by surrogates.

5. Extra-territorial application for surrogates and egg donors

It is currently unclear how the Act and *Reimbursement* regulations will apply to intended parents, surrogates or donors who live outside of Canada. As Pamela White has documented, there are an increasing number of Canadian women who act as surrogates for foreign intended parents. [8] In the case of egg donors, Jocelyn Downie and Françoise Baylis have argued that there is the potential for qualified territorial application of the Act where there is a "real and substantial connection" exist between a violation of the Act and Canada.[9] The same legal argument extends to surrogates and intended parents. However, these authors also point out that the parameters around such a nexus are absent from the Act. While we are not advocating either for or against extra-territoriality, given the consequences of violating the Act (a large fine or a prison sentence), such clarification is needed.

[8] Pamela M. White, "Why We Don't Know What We Don't Know" About Canada's Surrogacy Practices and Outcomes" in Gruben et al, Eds. Surrogacy in Canada: Critical Perspectives in Law and Policy (Toronto: 2018, Irwin Law) 51-80 at 76-77.
[9] Jocelyn Downie and Françoise Baylis "Transnational Trade in Human Eggs: Law, Policy and (In) action in Canada" (2013) 4191 *Journal of Law, Medicine and Ethics* 224-239 at 230.

Appendix A: What does the science say?

(a) Evidence on two screens and sperm washing

The 95% confidence interval for the sensitivity of the fourth-generation antigen/antibody blood test is 97.7-100%.[10] Assuming that the true sensitivity is the low end (97.7%) and we are testing a population with an extremely high prevalence of HIV (using 10%), if you were to test 100,000 people, the result would be:

	Infected with HIV	Not Infected
Test Positive	9,770	
Test Negative	230 (false negatives)	90,000
	10,000 (prevalence 10%)	90,000 (100% specific)

Therefore, with the first screen, at collection, 230 people out of 10,000 show false negatives for HIV. However, according to the protocol, they are tested again at 6 months before any semen is allowed to be used. At this point, there are 90,230 people being tested because all the people who tested positive in the first step would have been excluded, and the prevalence of HIV in this group is 0.25%.

With the second screen, the result is:

	Infected with HIV	Not infected
Test Positive	225	
Test Negative	5 (false negatives)	90,000
	230	90,000

After both screens, 5 people out of the 10,000 with HIV (10% of 100,000) show false negatives. Then, the sample is processed, which involves sequential density gradient

[10] Emily H.Adhikari et al. Diagnostic accuracy of fourth-generation ARCHITECT HIV Ag/Ab Combo assay and utility of signal-to-cutoff ratio to predict false-positive HIV tests in pregnancy. American Journal of Obstetrics and Gynecology. Volume 219, Issue 4, October 2018, Pages 408.e1-408.e9

and swim-up techniques (sperm washing).[11] "Using this method of sperm preparation, less than 1 percent of sperm samples from HIV-infected men test positive."[12]

As well, in a systematic review following serodiscordant couples with an HIV infected man and non-infected woman, "[n]o HIV transmission occurred in 11,585 cycles of assisted reproduction with the use of washed semen among 3,994 women."[13] Twenty-eight percent of the men were known to have not achieved viral suppression. Only 40% of the men were known to be taking anti-retroviral treatment (ART) at the time of sperm washing. The numbers for those not on ART and without viral suppression could be higher since this information was not known for all the men. The study also suggested that "among the subset of HIV-infected men without plasma viral suppression at the time of semen washing, no HIV seroconversions occurred among 1,023 women after 2,863 cycles of assisted reproduction with the use of washed semen. Studies that measured HIV transmission to infants reported no cases of vertical transmission."[14] An earlier systematic review from 2014 concluded that, "[n]o HIV transmission was observed in 8,212 IUI and 1,254 IVF cycles, resulting in 95% confidence that the true rate is 4.5 transmissions per 10,000 IUI cycles or less."[15]

From those 5 people with false negatives, statistically none would have any HIV virus in the sample after sperm washing and the chances of transmission overall would be less than 1 in 20,000,000 (after including the 2 screening tests for HIV).

The above calculations used the absolute worst-case scenario, with an unrealistically high prevalence of HIV and unrealistically low sensitivity for the test. For every 10-fold decrease in HIV prevalence, the number of false negatives in our example also decreases 10-fold. Therefore, if the prevalence of HIV was 1% in the 100,000 people initially tested (again a much higher prevalence than in the general population), there would be 23 false negatives after the first round of screening, and 0.5 false negatives after the second round. If the sensitivity was 99% (which is still on the low side of

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[11] https://www-uptodate-com.uml.idm.oclc.org/contents/use-of-assisted-reproduction-in-hiv-and-hepatitis-infected-couples?topicRef=7413&source=see_link#H18

[12] *Ibid*

[13] Effectiveness of semen washing to prevent human immunodeficiency virus (HIV) transmission and assist pregnancy in HIV-discordant couples: a systematic review and meta-analysis. Zafer M, Horvath H, Mmeje O, van der Poel S, Semprini AE, Rutherford G, Brown J . Fertil Steril. 2016;105(3):645. Epub 2015 Dec 11.

[14] Effectiveness of semen washing to prevent human immunodeficiency virus (HIV) transmission and assist pregnancy in HIV-discordant couples: a systematic review and meta-analysis. Zafer M, Horvath H, Mmeje O, van der Poel S, Semprini AE, Rutherford G, Brown J . Fertil Steril. 2016;105(3):645. Epub 2015 Dec 11.

[15] Efficacy and safety of intrauterine insemination and assisted reproductive technology in populations serodiscordant for human immunodeficiency virus: a systematic review and meta-analysis. Barnes A, Riche D, Mena L, Sison T, Barry L, Reddy R, Shwayder J, Parry JP. Fertil Steril. 2014 Aug;102(2):424-34. Epub 2014 Jun 18.

expected), in our original scenario with 10% prevalence, the initial false negative number would be 100, and the number of false negatives after the second round would be 1. Then, of course, sperm washing reduces the possibility of transmission to almost zero (less than 1 in 200,000,000 overall, including the two screening tests for HIV). With two screens and sperm washing, there is no realistic possibility of transmission of HIV.

If a donor is HIV+ but on an effective ART regime, they should probably nonetheless be categorically screened out (effectively meaning they cannot anonymously donate).

The risk of transmission in known HIV+ donors on ART is more difficult to quantify because there are more unknowns in the data. There is only one study of relevance: it investigated if the genital tract of HIV infected men, who are receiving ART, and who have no detectable virus in the peripheral plasma (<50 copies at the time of the study), harbor replication-competent virus. This study is from 1998 and had a sample size of 7.[16] Two had virus in the semen that could replicate. The number of copies of virus in the seven people's samples ranged from <5 to 90 copies per mL. This is compared to untreated men with 1,500 to 75,000 copies per mL using the same assay.[17] This process did not include sperm washing. We do not know if levels of virus this low are clinically relevant. However there have been no documented cases of HIV transmission where the blood serum viral load is <200 copies per mL, including with condomless sex, and the risk is estimated to be between 1 in 100,000 and zero.[18]

Then after adding sperm washing, the risk again is negligible, likely less than 1 in 1,000,000 based on the above evidence on sperm washing.[19] From a medical perspective, if someone reported that she received a sperm sample from someone with HIV who had an undetectable viral load and the sperm was processed properly, we would tell the person not to worry (since her yearly risk of being injured by a lightning strike is 1 in 300,000).[20] But with the history surrounding blood contamination in the past in Canada, the risk is not well defined enough to include HIV+ men for anonymous donation, even with an undetectable viral load. Some might

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[16] Human Immunodeficiency Virus Type 1 in the Semen of Men Receiving Highly Active Antiretroviral Therapy. Hui Zhang et al. December 17, 1998. N Engl J Med 1998; 339:1803-1809.
[17] *Ibid*.
[18] Myron S Cohen, "HIV infection: Risk factors and prevention strategies", online: (2018) UpToDate < https://www-uptodate-com.uml.idm.oclc.org/contents/hiv-infection-risk-factors-and-prevention-strategies?search=risk%20factors%20for%20hiv&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1>.
[19] *Supra* note 2.
[20] Government of Canada, "Lightning in Canada: frequently asked questions" (13 August 2018), online: <https://www.canada.ca/en/environment-climate-change/services/lightning/frequently-asked-questions.html>.

say that this is certain enough, but we don't think Health Canada would accept this risk.

However, we do think this risk is low enough that there should be no barriers to a known donation from these men. As long as the patient is comfortable with an approximately 1 in 1,000,000 chance of transmission of HIV, the donation should proceed.

Even if the semen itself was tested for HIV RNA, instead of just serology, we don't know that our answer would change since one of those 2 samples that had virus in the semen that could replicate was found with a semen viral load of 5 copies per mL.[21] So even by excluding all semen samples with any virus detected before sperm washing, we can't say how much different the risk would be.

(b) Quarantine periods

How long should a quarantine period last? Based on the current testing (blood serology – not the semen itself),[22] for HIV, you would only need a 3-week quarantine period.[23] However, for hepatitis C, since they use the antibody test, you would need a 6-month quarantine period to rule it out. If they were using a hepatitis C RNA test, it could probably be shorter.[24] The quarantine period might also be shortened if the semen was tested instead of just the donor. The outer limit for syphilis incubation is 3 months.[25] This quarantine period should apply to everyone.

(c) Evidence regarding intravenous drug use

The exclusion of those who have injected drugs could be set at one year to lower the prevalence of infectious diseases in the donor population (be being screened for infectious diseases for some other reason over this time period) and allow time for any incubating infections to have presented (making the sensitivity of the tests higher). A year was chosen instead of 6 months to account for recall bias of when someone last engaged in one of these activities.

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[21] *Supra* note 10.
[22] https://www.canada.ca/en/health-canada/services/drugs-health-products/biologics-radiopharmaceuticals-genetic-therapies/applications-submissions/guidance-documents/semen-special-access-program/technical-requirements-therapeutic-donor-insemination.html
[23] *Supra* note 1.
[24] https://www.gov.mb.ca/health/publichealth/cdc/protocol/hepc.pdf
[25] https://www.gov.mb.ca/health/publichealth/cdc/protocol/syphilis.pdf