Canadian Blood Services BLOOD PLASMA STEM CELLS ORGANS & TISSUES

Nova Scotia Bill 133 – Human Organ and Tissue Donation Act

A. Introduction

Canadian Blood Services appreciates the opportunity to provide this submission with respect to *Bill 133 – Human Organ and Tissue Donation Act* ("Bill 133") to the Nova Scotia Legislative Assembly - Law Amendments Committee (the "Committee"). The purpose of this submission is to provide our review of Bill 133, identify our concerns with the current drafting and provide the Committee our recommendations for amendments.

B. About Canadian Blood Services

Canadian Blood Services is a unique organization in Canadian health care. While it provides national, integrated services across Canada, the organization was created and is funded by the provincial and territorial governments (except Quebec). As a biologics manufacturer, it also falls under the regulatory powers of Health Canada.

Canadian Blood Services is also a non-profit, arm's-length, charitable corporation. Provincial and territorial ministers of health serve as members of the corporation under the Canada Not-for-Profit Corporations Act and appoint its board of directors. The ministers of health collectively approve our three-year corporate plan and annual budget.

In addition to managing the national blood supply system, we are also responsible for managing:

- the stem cell supply for patients in need of lifesaving stem cell transplants through the Canadian Blood Services Stem Cell Registry and Canadian Blood Services' Cord Blood Bank
- stem cell processing, testing and storage services
- transfusion and transplantation testing services.

Since 2008, at the request of federal, provincial and territorial governments (except Quebec), Canadian Blood Services has played a leadership role in the national system for organ and tissue donation and transplantation ("OTDT"). In our national OTDT role, we review legislation from across the country to ensure adequacy to manage our programs and consistency across jurisdictions, where appropriate. Collaboratively with provincial programs, we provide national programs and services to advance the practice of organ and tissue donation and transplantation in Canada (the "OTDT Mandate"), including:

- Strategic plan development and implementation.
- Canadian Transplant Registry programs.
- System performance improvement.
- Leading practices, professional and public education.

The Canadian Transplant Registry includes:

- **The Kidney Paired Donation (KPD) program.** The KPD program matches incompatible living donor and recipient pairs to find matches for patients requiring kidney transplantation.
- **The National Organ Waitlist (NOW).** The NOW has replaced the previous paper-based system for interprovincial organ listing and sharing.
- **The Highly Sensitized Patient (HSP) program.** The HSP program provides a national database for deceased donation, enabling real-time identification of potential matches for patients, who, due to a sensitized immune system, are the most difficult to match for possible organ transplantation.

As part of the matching process in the Canadian Transplant Registry, health-care professionals, referral centres, living donor centres, transplant centres and organ donation programs/ organizations (collectively, "OTDT Programs") from across the country are required to disclose personal information, including medical history and lab test results (e.g., transmissible diseases and blood group), of potential organ recipients and donors to Canadian Blood Services in order that the registry may identify potential matches. In turn, Canadian Blood Services is required to disclose personal information (pseudonymized, where possible) of matched recipients and donors to OTDT Programs from across the country so that the matches may be assessed and the transplants may proceed.

C. Review of Bill 133

Canadian Blood Services supports Nova Scotia in drafting legislation designed to increase organ and tissue donation. Countries that have similar *deemed* consent models generally have higher donation rates, but the particular consent model is only one of many key components for an optimal OTDT system. We reviewed Bill 133, and are pleased that Nova Scotia has included a number of these key components in the draft. These additional components of an optimal OTDT system include mandatory referral of all potential donors (section 19 of Bill 133), public reporting of missed/potential donors (section 20 of Bill 133) and permitting donation after cardiocirculatory determination of death ("DCD") and neurological determination of death ("NDD") (sections 2(g) and 2(s) of Bill 133). We do note that for an OTDT system to be optimal, there must be mechanisms for mandatory sharing of recipient and donor personal information for OTDT system

performance. However, Bill 133 remains silent on this key component (please see discussion below on our specific request for information sharing). Other non-legislative components of an optimal OTDT system include utilizing donation personnel in hospitals and regional health authorities (e.g. nurse coordinators and donation physicians) and ensuring adequate resources are available for ER, ICU, OR, and surgical organ and tissue retrieval and transplant teams and activities. If all are implemented, Nova Scotia will be a leader in the country for ensuring that one of the key mechanisms for an optimal OTDT system are in place.

While we support the overall intent of Bill 133, we are pleased to take this opportunity to provide our comments on certain provisions in the draft where we have identified concerns and recommend amendments, where appropriate, for addressing these concerns.

D. Specific Recommendations for Bill 133

i. Sharing of Personal Information

For Canadian Blood Services to fulfil its OTDT Mandate and to ensure a robust system for OTDT data collection is put in place, we recommend that provisions be included in Bill 133 that will permit Nova Scotia OTDT Programs to share living and deceased donor and recipient personal information, including personal health information, with Canadian Blood Services *without consent* for purposes of (1) facilitating the donation, retrieval and/or transplantation of organs, and (2) measuring OTDT system performance.

When the Canadian Transplant Registry was in development, a consent-based model was designed for the sharing of recipient and donor personal information between Canadian Blood Services and OTDT Programs as it was the most expedient path to implementation across jurisdictions.[1] In a consent-based model, consent must be given for the collection, use and disclosure of personal information. This consent-based model allows for consent to be withheld, withdrawn or to limit the collection, use or disclosure of certain personal information, all of which impairs the ability of Canadian Blood Services to collect and use comprehensive information for OTDT system performance. Collection and use of OTDT system performance data can assist with benchmarking, strategic planning, annual reporting to governments and the public, as well as identifying opportunities for improvements to enhance donation and transplantation across the country. We respectfully submit that the collection and use (by Canadian Blood Services) and disclosure (by participating OTDT Programs to Canadian Blood Services) *without consent* is essential and must be permitted to achieve these objectives. Otherwise, individuals could

[1] Data sharing agreements were negotiated with participating OTDT Programs for the sharing of personal information and personal health information for Canadian Transplant Registry purposes outlining each party's obligations for the protection of the information. The agreements include provisions relating to the purpose for sharing, access requirements, security, termination, secure destruction etc.

withhold, withdraw or limit their consent for these purposes, resulting in incomplete and inaccurate OTDT system performance data. We note that there is precedent in Nova Scotia for the sharing of personal health information for purposes of health system performance on a *without consent* model with respect to the Canadian Organ Replacement Registry ("CORR"), managed by the Canadian Institute for Health Information.[2] Without similar legislative authority, our ability to fulfill our OTDT Mandate is impacted.

Section 28 of Bill 133 prohibits any person, without consent, to disclose or give to any other person, other than the health-care professionals involved in the person's care and in the transplantation process, any information or document that identifies any person, living or dead. From a plain reading of this clause, Canadian Blood Services (in its role as manager of the Canadian Transplant Registry and related programs) would not be considered a health-care professional, and thus Nova Scotia OTDT Programs would not be permitted to disclose personal information of donors or recipients to Canadian Blood Services without consent.

We respectfully submit that the Committee amends Bill 133 regarding the sharing of personal information and personal health information for the purpose ofdonation and transplantation. In particular, by amending section 28 of Bill 133, Nova Scotia would be able to permit: participating OTDT Programs to share *without consent* living and deceased donor and recipient personal information and personal health information with Canadian Blood Services for the purposes of (i) facilitating the donation, retrieval and/or transplantation, and (ii) OTDT system performance (including post-donation / post-transplantation information); and Canadian Blood Services to collect, use and disclose *without consent* living and deceased donor and recipient personal information and personal health information across jurisdictions for these purposes.

This amendment will authorize Canadian Blood Services to fulfil its OTDT Mandate, in particular for system performance improvements, and will also ensure that a robust system for the collection of OTDT system performance data is in place — one that is not dependent upon individual consent, which can be withheld, withdrawn or limited. Canadian Blood Services has in place stringent privacy controls for the protection of personal information and personal health information that is collected, used and disclosed by Canadian Blood Services, which are applied nationally.[3][4] Canadian Blood Services recognizes the need to consider and balance privacy rights and access to quality and timely information. In this case, the significant benefits realized by OTDT system performance for recipients, donors and governments should outweigh any potential privacy concerns. These benefits include an increase in transplants for Canadian patients currently on waiting lists and economic benefits to governments when patients receive

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[2] *Personal Health Information Act*, SNS 2010, c 41, s. 38(1)(i).

[3] See Canadian Blood Services privacy policies online at www.blood.ca/en/about-us/important-notices.

[4] Current data sharing agreements may require revisions to reflect updated legislation.

transplants and no longer require costly treatments such as dialysis.[5] Other benefits realized through ODT system performance include the ability to (1) improve the quality of patient care, thus improving the lives of Canadian recipients and living donors long term, and (2) identify any currently unknown long-term risks to living donation in the future, thus permitting donors to make better informed decisions that are right for each individual.

Alternatively, we respectfully submit that Bill 133 be amended to include a provision under section 2 of Bill 133 that clarifies that consent under the act (including *deemed* consent) includes the authority to collect, use and disclose personal information for the purpose of facilitating organ and tissue donation and transplantation across jurisdictions, including for purposes of process improvement and measurement. This alternative is not preferred, as consent under Bill 133 only applies to donation, and would not provide Canadian Blood Services the ability to collect robust OTDT patient data for purposes of OTDT system performance improvement.

ii. Mandatory Data Reporting

As noted above, Bill 133 is silent on mandatory OTDT data reporting. In the above section, we respectfully submitted that Bill 133 be amended to *permit* the sharing of OTDT personal information, including personal health information with and by Canadian Blood Services for the purposes of (i) facilitating the donation, retrieval and/or transplantation, and (ii) OTDT system performance (including post-donation / post-transplantation information). However, it is our opinion that Bill 133 should also require mandatory data reporting by applicable OTDT Programs for purposes of OTDT system performance, such as other jurisdictions have done (e.g. United States), for the benefits described above in the previous section. We respectfully submit that Bill 133 be amended to include a provision that will *require* OTDT Programs to submit OTDT data, including personal information and personal health information, to the organization that has responsibility for OTDT system performance as designated by the Minister. This "designated organization" could be Canadian Blood Services, CORR (Canadian Institute for Health) or another organization.

iii. Definition of Death

Bill 133 introduces a new definition of "death" for Canada; which will set a precedent for not only OTDT purposes, but for all deaths in the absence of a definition in other legislation. Canadian Blood Services is currently reviewing definitions of death and respectfully submits that the

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[5] See *Organ Donation and Transplantation in Canada: System Progress Report 2006–2015,* Canadian Blood Services online at www.blood.ca/sites/default/files/ODT_Report.pdf.

Committee and the Nova Scotia Legislature works with Canadian Blood Services on this issue prior to finalizing the definition in Bill 133.

iv. Registering Consent

Section 7 of Bill 133 provides that an individual may consent to or refuse donation after death for transplantation by providing information to the Registry. Subsection 21(1) further states that a person (or their substitute decision maker) may provide consent for scientific research and educational purposes. Many registries obtain consent for scientific research and educational purposes at the time the individual registers their intent to donate after death. Section 15 of Bill 133 would also permit a substitute decision maker to consent to these purposes in the event that a refusal to consent to these purposes was registered. We respectfully submit that

- section 7 of Bill 133 be amended to include an ability to register a consent to donation after death for scientific research and educational purposes;
- the section 15(2) of Bill 133 be amended to indicate that consent under subsection (1) be full authority to use a donation for scientific research and educational purposes; and
- subsection 21(1) be deleted in its entirety.

v. Checking the Registry

Section 10 of Bill 133 provides that no physician or Chief Medical Examiner can undertake transplantation activities until *they* have checked the Registry to determine whether an individual has registered consent or refusal to consent to donate after death. Section 19 of Bill 133 provides that *[w]here an individual dies, or in the opinion of a physician death is imminent, in a hospital or in circumstances set out in Sections 9 to 12 of the Fatality Investigations Act, the hospital or the Chief Medical Examiner shall, as soon as possible, provide to the organ-donation program and the tissue bank information to confirm whether the individual has registered a consent or refusal to consent to donate after death.* From a plain reading of Bill 133, these provisions would imply that the hospital (or Chief Medical Officer) must inquire whether the individual has registered consent or refusal to consent in the Registry under section 19 when death has occurred or is imminent, but prior to the retrieval of organs or tissues, the physician would again need to check the Registry for consent or refusal to consent. We respectfully submit that there is no need to duplicate checking the Registry for purposes of ensuring a consent or refusal of consent was registered both at the time of death and prior to retrieval. We assume that the intent is to ensure that transplantation activities are not undertaken until a Registry check is complete (i.e. under section 19), and not that a duplicate check is required by

the physician. We recommend that section 10 of Bill 133 be amended to clarify that section 10 does not require a secondary check of the Registry by the physician or Chief Medical Examiner.

vi. Medical Assistance in Dying ("MAID")

Bill 133 is silent on consent requirements in the context of MAID. For MAID, an individual may provide "first person" consent to donation after death while they have *capacity* to consent. Subsection 12(1) of Bill 133 provides that an individual is not deemed to consent for purposes of the act if the individual lacked the *capacity* to make a decision respecting donation after death for a significant period prior to death. Subsection 12(2) of Bill 133 provides that a "significant period" means a sufficiently long period as would lead a reasonable person to conclude that it would be in appropriate for consent to be deemed. We have concerns that remaining silent on MAID may create future issues in the event that "first person" consent has been provided, but prior to MAID, the individual has lost capacity for a period of time prior to the MAID procedure and subsequent organ and/or tissue procurement. We respectfully submit that the Committee consider including provisions specific for MAID that permit reliance on the individual's "first person" consent to donate after death, regardless of the loss of capacity following the giving of consent, if the individual still meets the requirement for the MAID procedure under applicable law.

vii. Fatality Investigations Act

Section 18 of Bill 133 permits the Chief Medical Officer to allow the removal of organs or tissues in circumstances that require notification to the Chief Medical Officer (e.g. (1) death (a) as a result of violence, accident or suicide; (b) unexpectedly when the person was in good health; (c) where the person was not under the care of a physician; (d) where the cause of death is undetermined; or (e) as the result of improper or suspected negligent treatment by a person, (2) death probably related to employment or occupation, (3) death in custody or detention, and (4) death in health-care facility), *if* consent for donation after death has been *obtained*. From a plain reading of this provision, it would suggest that in these circumstances, consent to donate cannot be deemed. We assume that this was not the intention of the NS Legislature, and respectfully submit that subsection 18(c) be amended to include a provision that consent may be obtained *or deemed* in accordance with the act for donation after death if the Registry is checked to determine whether the individual has registered a consent or refusal to consent under section 19 of Bill 133.

viii. Consent for Pre-death Transplantation Optimizing Interventions

Section 22 stipulates that consent to donate organs does not imply consent to pre-death transplantation optimizing interventions. It is assumed that this prohibition applies in the context of a consent registered under section 8 of Bill 133, a consent deemed under section 11 of Bill 133 and a consent provided by a substitute decision maker under section 15 of Bill 133. We have concerns regarding this provision for the following reasons:

1. Subsection 22(2) provides that an individual with capacity may give voluntary and informed consent to the use of pre-death transplantation optimizing interventions in writing signed by the individually or orally in the presence of two witnesses and those witnesses must sign documentation evidencing the consent at the time consent was given. It is unclear whether a consent registered under section 8 of Bill 133 would meet this requirement. We respectfully submit that sections 8 and 22 be amended to make clear that at the time of registering a consent with the Registry, consent to donate also includes the consent to pre-death transplantation optimizing interventions.

2. Nova Scotia has indicated that the main driver for introducing this legislation is to increase organ and tissue donation. It is the first jurisdiction in North America that has introduced a deemed consent to donation after death. However, the restriction in section 22 of Bill 133 will likely negate most benefits gained by introducing a deemed consent model as substitute decision maker consent will be required for pre-death transplantation optimizing interventions in an ever-increasing number of cases. As noted in our *Organ Donation and Transplantation in Canada System Progress Report – 2017 Update*, improving Canada's deceased donation rate will require a continued focus on implementation and evaluation of donation after DCD programs.[6] As noted in the report, in 2017, 25 per cent of all deceased donor organ transplants were realized through DCD and accounts for the largest increase in deceased donation over time and, next to ensuring consistent donor identification and referral, constitutes the greatest opportunity to continue to increase donation potential. By including this qualifier in Bill 133, the decision to donate organs after death will still be left up to the substitute decision maker as they can withhold consent to pre-death transplantation optimizing interventions; thus potentially making deemed consent for DCD null and void, as donation cannot proceed without these interventions. We note that this requirement is not contained in deemed consent legislation in other jurisdictions that we are aware of. We respectfully submit that the Committee consider

[6] See *Organ Donation and Transplantation in Canada System Progress Report – 2017 Update,* Canadian Blood Services online at < https://professionaleducation.blood.ca/sites/msi/files/system_progress_report_2017_update_final_en_8.pdf >.

how the net benefit of deemed consent legislation will be impacted by the inclusion of section 22 in Bill 133.

3. The current wording of Bill 133 would prohibit the introduction of uncontrolled DCD in all cases. Uncontrolled DCD refers to organ retrieval after a cardiac arrest that is unexpected and from which the patient cannot or should not be resuscitated. (In contrast, controlled DCD takes place after death which follows the planned withdrawal of life-sustaining treatments that have been considered to be of no overall benefit to a critically ill patient in hospital.)

   Although uncontrolled DCD has not been implemented in Canada, a pilot project is currently underway at St Paul's Hospital in Vancouver related to the use of ECMO-CPR for out of hospital cardiac arrests. Early results suggest such programs can primarily benefit patient's survivability, and secondarily positively impact the number of potential donors as well. In tertiary and quaternary hospitals, where logistics don't prevent consideration of such programs, it is foreseeable that some jurisdictions could consider moving forward with such programs in the near future.

   In cases of uncontrolled DCD, pre-death transplantation optimizing interventions may need to be applied prior to having the opportunity to obtain consent from the individual's substitute decision maker for these interventions, resulting in a lost donation opportunity. In addition, individuals suffering from unexpected cardiac arrest are also unlikely to be in a hospital or in the vicinity of a physician, and the health care professionals / emergency medical technicians / fire fighters responding to the emergency may be required to implement these pre-death transplantation optimizing interventions (but which do not hasten death) to preserve the opportunity to donate. If Nova Scotia intends on implementing an uncontrolled DCD program, we respectfully submit that provisions in Bill 133 will be required that (i), permit pre-death transplantation optimizing interventions in this circumstance; (ii) substitute decision maker consent is not required to perform these interventions in this circumstance, and (iii) provide authority for a health care professional or emergency personnel to perform such interventions, not just physicians and hospitals, in this circumstance.

ix. Living Donation

Section 24 of Bill 133 provides that a substitute decision maker may consent on behalf of an individual who does not have capacity in accordance with a previous personal directive of the individual unless

- there are expressions of a contrary wish made subsequently by the individual while the individual had the capacity;
- technological changes or medical advances make the instruction inappropriate in a way that is contrary to the intentions of the individual; or

- circumstances exist that would have caused the individual to set out different instructions had the circumstances been known based on what is known of the values and beliefs of the individual and from any other written or oral instructions.

We respectfully submit that subsection 24(2) of Bill 133 be amended to add an additional exception that consent may not be given if the procedure is not in the best interest of the individual. This would align with the requirements laid out in section 25 of Bill 133 for living donation with respect to an individual who lacks capacity and does not have a personal directive.

x. Deemed Consent and Senate Bill S-240

Currently, the federal government is considering Senate *Bill S-240, An Act to amend the Criminal Code and the Immigration and Refugee Protection Act (trafficking in human organs)* ("Bill S-240"). When in force, Bill S-240 will create the following new offences for everyone who:

- obtains an organ to be transplanted into their body or into the body of another person, knowing that the person from whom it was removed did not give informed consent to the removal, or being reckless as to whether or not that person gave informed consent;

- carries out, participates in or facilitates the removal of an organ from the body of another person, knowing that the person from whom it was removed did not give informed consent to the removal, or being reckless as to whether or not that person gave informed consent; or

- acts on behalf of, at the direction of or in association with a person who removes an organ from the body of another person, knowing that the person from whom it was removed did not give informed consent to the removal, or being reckless as to whether or not that person gave informed consent.

Anyone who commits one of these offences is guilty of an indictable offence and liable to imprisonment for a term of not more than 14 years. There is a question of whether deemed consent in Bill 133 would meet the consent requirements of Bill S-240, as deemed consent is not generally considered *informed.* While the intent of Bill S-240 is to curb organ trafficking, there may be unintended consequences on provincial OTDT systems given the potential applicability of Bills S-240 on individuals working in those systems who obtain an organ, carry out, facilitate, or participate in the removal of an organ from an individual who provided deemed consent, and not "informed" consent.

Bill S-240 was introduced in the Senate, and having passed by the Senate, was sent to the House of Commons, where it recently passed second reading and was then discussed at the House Standing Committee on Foreign Affairs and International Development. In Report 23, the House

Standing Committee recommended amendments which require further approval by the Senate prior to receiving third reading in the House, and eventual Royal Assent. Canadian Blood Services has made representatives in Nova Scotia Department of Health and Wellness aware of Bill S-240 and its potential implications on deemed consent prior to the release of Bill 133. We have since been provided information that suggests for purposes of provincial deemed consent legislation, that any conflict between the federal law and the provincial law could be addressed by including a provision in provincial legislation that deemed consent is considered informed consent for purposes of any federal legislation. We respectfully submit that Nova Scotia consider how/whether to address Bill S-240 in Bill 133 to avert any possible conflict between federal and provincial consent to donate legislation.

E. Contact information

Questions or comments concerning this submission may be directed to the attention of:

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F. Closing

On behalf of Canadian Blood Services, we thank you for the opportunity to provide this submission. We hope that the Committee will seriously consider our recommendations for developing an optimal OTDT system. We would be happy to discuss our comments and recommendations further with the Committee or other Nova Scotia government representative.