A Tool Kit to Assist Transplant Programs in the Use of

Increased Risk Donors for Organ Transplantation

February 2016

Trillium Gift of Life Network

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1. Increased Risk Donor Tool Kit

1.1 Tool Kit Purpose

This toolkit was developed to summarize recommendations on the use of Increased Risk Donors (IRDs) for Organ Transplantation as well as provide useful information and guidance that could help Ontario increase organ utilization and improve access to organ transplantation for patients. It is intended for use by Transplant Physicians, hospital administration and transplant programs who are directly or indirectly involved with patient care in a transplant setting. This toolkit includes recommended tools and templates to support transplant programs in providing information to patients on the use of increased risk donors for transplantation.

The objectives of this tool kit are to:

- Educate all healthcare providers along the transplant continuum about IRDs;
- Provide guidance to healthcare administrators about incorporating IRDs into their clinical and administrative processes;
- Provide information to healthcare providers to educate patients about IRDs;
- Provide tools to support informed patient consent at the time of transplant.

1.2 Tool Kit Development Process

In March 2013, the Canadian Society of Transplantation (CST) and the Canadian National Transplant Research Program (CNTRP) held a conference and developed a framework guidance document that outlines recommendations for utilization of IRDs in Canada. The conference included experts from Canada in organ and tissue donation and transplantation, transplant infectious diseases, laboratory medicine, and epidemiology. Additional content expertise was provided by Health Canada, several major Canadian Organ Procurement Organizations (OPOs), and Canadian Blood Services (CBS). This tool kit is based on the recommendations developed by the CST/CNTRP Increased Risk Donor Working Group published in the journal *Transplantation* (27 August 2014, Vol 98, Issue 4, p 365-369).

The process for the development of this toolkit included:

- Detailed review of CST and CNTRP recommendations;
- Literature research on current practices;
- Review of TGLN policies and procedures;
- Consultation sessions with transplant medical leads;

2. Introduction to Increased Risk Donors

2.1 What is an Increased Risk Donor?

Increased Risk Donors (IRDs) are donors who identify certain lifestyle behaviours that are of higher risk who may transmit infectious diseases to transplant recipients. These donors may test negative for infectious diseases, but there may still be a risk for transmitting Human Immunodeficiency Virus (HIV), Hepatitis C Virus (HCV), and Hepatitis B Virus (HBV) to recipients, due to a window period of time where the infection(s) is not detectable.

2.2 Donation Protocols for Increase Risk Donors

TGLN is responsible for determining the safety of deceased organs for transplantation through donor screening, donor testing and donor suitability assessment as per the Health Canada requirements for the Safety of Human Cells, Tissues, and Organs for Transplantation regulations (CTO regulations). All persons are considered to be a potential organ donor, regardless of age, health status, or social behavior. Potential donors that are referred to TGLN are assessed on an individual basis and go through a screening process as well as medical suitability testing to determine if organs are safe for transplantation. As part of the screening process, the family and/or close friends of every potential donor is asked a series of detailed questions about the social medical history of their loved one, and the donor's lifestyle is considered to assess the potential for the transmission of infectious disease to the recipient.

Potential donors with identified increased risk behaviors may be eligible to donate, via a process of "exceptional distribution". Exceptional distribution is permitted if another standard organ is not immediately available, and the transplant physician has authorized the use of the organ based on their clinical judgment. The transplant program communicates the risk to the potential recipient so they can make an informed decision about whether to consent to accepting the offered organ.

The CTO regulations relating to exceptional distribution can be found in **Appendix A**.

2.3 Criteria for Increased Risk Behaviour

Behavioural risk factors for HIV, HCV and HBV are assessed by a history and physical examination of the donor. Table 1 outlines the behaviours that are considered increased risk by the Canadian Standards Association.

Table 1: Behaviours associated with a higher risk of HIV, HBV, and HCV identified by the Canadian Standards Association

Factors and behaviours associated with a higher risk of Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV), and Hepatitis C Virus (HCV)
E.1: The assessment of donors **11 years of age or older** shall include the following risk factors and risk behaviours associated with HIV, HBV, and HCV: A) persons who report nonmedical intravenous, intramuscular, or subcutaneous injection of drugs in the preceding five years; B) men who have had sex with another man in the preceding five years; C) persons who have engaged in sex in exchange for money or drugs in the preceding five years; D) persons who have had sex in the preceding 12 months with any persons described in Items (a) to (d) or with a person known or suspected to have HIV, or clinically active HBV or HCV; E) persons who have been exposed, in the preceding 12 months*, to known or suspected HIV-, HBV-, and/or HCV-infected blood through percutaneous inoculation or through contact with an open wound, nonintact

skin, or mucous membrane;

F) persons who have been in juvenile detention, lock up, jail, or prison for more than 72 consecutive hours in the preceding 12 months;

G) persons who within 12 months* preceding donation have undergone tattooing, ear piercing, or body piercing in which sterile procedures were not used (e.g., contaminated instruments and/or ink were used, or shared instruments that had not been sterilized between uses were used); and

H) persons who have had close contact within 12 months preceding donation with another person having clinically active viral hepatitis (e.g., living in the same household, where sharing of kitchen and bathroom facilities occurs regularly).

**The 12 month period specified in Items (e) and (g) may be reduced to 6 months if nucleic acid testing (NAT) is used for the tests specified in Clause 14.2.6.1(a) to (c).*

E.2: The assessment of donors **less than 11 years of age** shall include the following risk factors and risk behaviours associated with HIV, HBV, and HCV:

A) persons who have been exposed, in the preceding 12 months*, to known or suspected HIV-, HBV-, and/ or HCV - infected blood through percutaneous inoculation or through contact with an open wound, nonintact skin, or mucous membrane;

B) persons who within 12 months* of donation have undergone tattooing, ear piercing, or body piercing in which sterile procedures were not used (e.g., contaminated instruments and/ or ink were used, or shared instruments that had not been sterilized between uses were used);

C) persons who have had close contact within 12 months preceding donation with another person having clinically active viral hepatitis (e.g., living in the same household, where sharing of kitchen and bathroom facilities occurs regularly);

D) persons who have been breast-fed within the past 12 months of donation by women with or at risk for HIV, HBV, HCV; and

E) persons less than 18 months of age who are born to women with or at risk for HIV, HBV, HCV infection.

**The twelve-month period specified in Items E.2(a) and E.2(b) may be reduced to 6 months if NAT is used for the tests specified in Clause 14.2.6.1(a) to (c).*

Source: Canadian Standards Association, 2012.

3. Risk Assessment of Increased Risk Donor Organs

3.1 Infectious Disease Testing

1) General Donor Testing Requirements

In order to evaluate the safety of organs for transplantation, TGLN facilitates infectious disease testing for all potential donors. STAT pre-transplant serological testing is required for:

- human immunodeficiency virus I/II (HIV I/II);
- human T-cell lymphotrophic virus (HTLV I/II);
- venereal disease research lab test (VDRL);
- hepatitis B surface antigen (HbsAg);
- hepatitis C virus (HCV);
- antibody to hepatitis B core antigen (anti-HbcAb);
- cytomegalovirus (CMV); and,
- West Nile virus (WNV) between May to October.

Additionally, retrospective (non-STAT) testing is required for:

- Epstein Barr virus (EBV);
- Toxoplasmosis IgG (toxo) for all potential heart donors

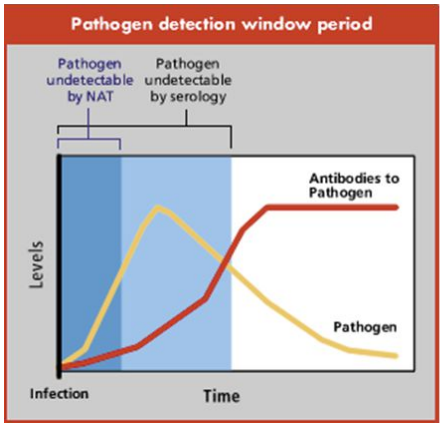
For pediatric cases, maternal serology is required if the potential pediatric donor is ≤ 18 months of age and/or has been breast-fed within the last 12 months.

Test results are documented in the TGLN donor chart, and reported to the appropriate transplant program(s) at the time of offer. Positive results do not automatically preclude donation, as exceptional distribution may be considered. If the potential donor is assessed as being an increased risk, Nucleic Acid Testing (NAT) should be performed in addition to the required pre-transplant STAT serological testing.

2) Nucleic Acid Testing

NAT is a method of testing for diseases in an individual's blood and it is the recommended method of infectious disease testing for living and deceased donors. It detects viruses earlier than other screening methods; thus, narrowing the detection window period of HIV, HCV, and HBV infections. Figure 1 below outlines the difference in pathogen detection window periods between serology and NAT testing methods.

Figure 1: Pathogen Detection Window Periods by Testing Method



Pathogen	Serology	NAT
HIV	17-22 days	5-6 days
HCV	~ 70 days	3 –5 days (best test; many assume 7 days)
HBV	35-44 days	20-22 days

Source: Humar et al, 2010.

NAT aims to reduce the risk to the recipients of contracting diseases from organs that are recovered from deceased organ donors; in particular those donors that have been identified as having increased risk behavior. In general, NAT should be performed on deceased organ donors in circumstances where a decision is made to use exceptional distribution protocols from a donor with a history of increased risk behavior.

TGLN has implemented a process for requesting NAT testing for donors with confirmation of increased risk criteria having occurred as per Health Canada guidelines, especially if increased risk behaviors have occurred within the serology window period. Additionally, NAT should be requested for donors for which there is no way to confirm whether or not increased risk criteria has occurred in serology testing window period and who also have physical evidence of recent risk exposure. The process for requesting individual NAT testing based on the patient assessment can be found in **Appendix B**.

3.2 Risk of Infection from Increased Risk Donor Organs

The potential risk for transmission of an infectious disease is the most important consideration in conducting a risk vs. benefit analysis when organs from IRDs become available. Residual risk estimates have been published based primarily on U.S. epidemiologic data. A systematic review of prevalence and incidence studies was conducted to determine the risk in a Canadian population (CST/CNTRP Increased Risk Donor Working Group, 2014).

Estimates of residual risk are provided in Tables 2 and 3 below per 10,000 donors if enzyme-linked immunosorbent assay (ELISA) or NAT is used for screening. Furthermore, the estimate is converted to a ratio to provide a number that can be more easily conveyed to patients during the informed consent process. Risk estimates assume the behavior(s) occurred right up until the moment of donation. Additional factors may need to be considered when determining the actual risk to the patient, such as length of hospitalization prior to donation with risk generally decreasing as duration of hospitalization increases.

Table 2: Risk per 10,000 donors of an HIV infection occurring during the window period, by ELISA and NAT (Assumes a Window Period of 21 days for ELISA and 7 days for NAT).

Risk Category	ELISA Per 10,000	NAT + ELISA Per 10,000	Risk of window period infection expressed as ratio
Men who have sex with men	5.8 (5.2-6.6)	2.4 (2.1-2.7)	1: 4167
Intravenous drug use	6.6 (6.1-7.2)	2.7 (2.5-3.0)	1:3704
Commercial sex worker	3.7 (3.0-4.8)	1.5 (1.2-2.0)	1:6667
Sex with a partner in above categories	0.7 (0.5-0.9)	0.3 (0.2-0.4)	1:33,333
Percutaneous injury resulting in HIVexposure through blood	1.5 (0.8-2.4)	0.6 (0.4-1.0)	1:16,667
Incarcerated	1.0 (0.8-1.2)	0.4 (0.3-0.5)	1: 25,000

Source: CST/CNTRP Increased Risk Donor Working Group, 2014.

Table 3: Risk per 10,000 donors of an HCV infection occurring during the window period, by ELISA and NAT (Assumes a Window Period of 21 days for ELISA and 7 days for NAT).

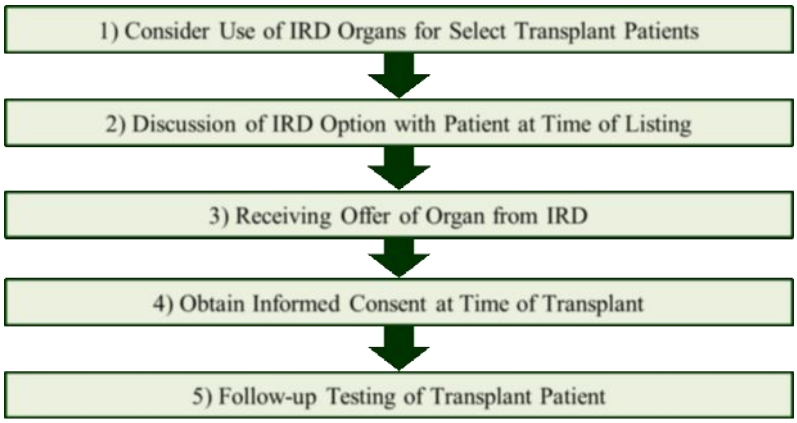
Risk Category	ELISA Per 10,000	NAT + ELISA Per 10,000	Risk of window period infection expressed as ratio
Men who have sex with men	14.3 (10.7-17.3)	1.5 (1.1-1.8)	1: 6667
Intravenous drug use	377.4 (346.0-412.1)	40.8 (37.4-44.6)	1:245
Commercial sex worker	270.8 (242.6-298.9)	29.1 (26.1-32.2)	1:344
Sex with a partner in above categories	168.3 (157.7-191.4)	18.0 (16.9-20.5)	1:556
Percutaneous injury resulting in HCV exposure through blood	13.9 (2.9-44.6)	1.4 (0.3-4.3)	1:7143
Incarcerated	107.8 (102.4-116.7)	11.5 (10.9-12.5)	1: 870

Source: CST/CNTRP Inscreased Risk Donor Working Group, 2014.

4. Guidance for Utilization of Increased Risk Donor Organs

4.1 Process for Use of Increased Risk Donor Organs

The diagram below shows the recommended sequence of activities in the IRD organ utilization process. Information and guidance on each of the activities are outlined in the following section.



4.2 Guidance for Increased Risk Donor Organ Utilization

1) CONSIDER USE OF IRD ORGANS FOR SELECT TRANSPLANT PATIENTS

The number of organs and tissue needed in Ontario continues to be higher than the number available. When determining the risks vs. benefits of an organ from an IRD, physicians should consider the following facts:

- There is a shortage of organs and tissue that can be used for transplant;
- There are nearly 1,500 Ontarians waiting to get life-saving organ transplants;
- Every three days, someone dies while waiting for an organ transplant;
- The waiting times for organ transplants can be up to several years depending on the organ.

Given the significant discrepancy between donor organ supply and demand, the use of organs from IRDs should be considered for some patients. Using these organs offers an opportunity for shortening wait times while providing good outcomes. Furthermore, utilizing NAT testing during the screening process can further reduce the risk of disease transmission.

Physicians should consider the following factors when identifying potential candidates for organ transplant from an IRD:

1. Estimated time the patient may be on the wait list if he/she waits until the next offer.
2. Estimated wait-list mortality if he/she waits until the next offer.
3. Risk of becoming too sick that a transplant may not be possible.

Ultimately, the transplant physician must determine that the benefits of transplanting a particular patient with an IRD organ are greater than the risks. Otherwise, the patient should continue to wait for an organ from a standard donor.

2) DISCUSSION OF IRD OPTION AT TIME OF LISTING

Information on the use of organs from IRDs should be provided to potential recipients at the time of listing and again at the time of offer. The discussion should take place with the transplant physician, although other members of the team may also be involved. The goal of the discussion is to ensure the patient is given the information, support and time needed to understand the option to accept an IRD organ and to make a decision that best reflects the patient's wishes.

The information provided to patients should be accurate and non-leading and the risk should be contextualized in a clear and understandable manner. In the discussion, the transplant physician should ensure, at a minimum, that the patient understands the:

- Patient benefits of accepting an IRD organ vs. waiting for a standard organ;
- Risk of acquiring an infectious disease;
- Support available throughout and after the transplant;
- Post-transplant monitoring and testing requirements;
- Impact to wait list status from declining option.

Although a patient may decline this option at the time of listing, this could be reassessed throughout the waiting period and again at the time of offer because the patient's health status may change. The patient's decision should be noted in the medical chart and reviewed with the patient on a regular basis.

3) RECEIVING OFFER OF ORGAN FROM IRD

Organs from IRDs will be offered to transplant programs via a process of exceptional distribution. TGLN, as source establishment, is permitted to offer exceptionally distributed organs, if the following conditions are met:

- an organ that has been determined safe for transplantation is not immediately available;
- the transplant physician authorizes the exceptional distribution;
- the transplant establishment obtains the informed consent of the recipient.

The organ(s) are distributed to a transplant program based on reasons related to the benefit of the recipient. Organs distributed via exceptional distribution are of a known risk, and adverse event reporting and investigation are not necessitated in the event of any reactions due to this known risk. TGLN will offer the organ(s) as per the allocation algorithm and indicate it as an exceptional distribution case. When making the offer to transplant programs, TGLN will ensure that the transplant physician is aware of the reason(s) for the exceptional distribution.

Exceptional distribution requires the transplant physician to authorize the use of the organ and obtain informed consent from the recipient (see following section). The decision by the transplant physician around utilization or non-utilization may take into account the timing of increased risk behaviour, the window period for the specific test used, the status of the recipient as well as other recipient-specific circumstances.

If the transplant physician decides to accept the IRD organ, TGLN will request and document the transplant physician's justification for accepting the organ in the *Notice of Exceptional Distribution* form (see **Appendix C**) and the clinical notes. TGLN will ensure that the TGLN portion of the form is complete and send the form to the transplant program Medical Director where it will be completed and returned to TGLN. TGLN will place a copy of the completed form in the TGLN donor chart.

4) OBTAIN INFORMED CONSENT AT TIME OF TRANSPLANT

Obtaining appropriate informed consent for potential recipients of organs from IRDs is essential. The informed consent must be obtained before the transplant takes place. To support the practitioner in providing their patient with accurate and timely information at the time of consent, a Frequently Asked Questions (FAQ) document (**Appendix D**) has been developed. The information in the FAQ provides an overview of the risk and benefits in the utilization of IRD's.

A recommended template for a standardized informed consent script that can be read at the time of offer is provided in **Appendix E**. This script may be modified as needed to align with hospital specific practices. Standardizing the informed consent process may contribute to an increased utilization of organs from IRDs.

It is essential to document the informed consent process. Hospital requirements may vary as to the format of documentation in the medical record and hospital specific protocols should be followed. A sample IRD Organ Informed Consent Form is included in **Appendix F**.

5) FOLLOW-UP TESTING OF TRANSPLANT PATIENT

If organs from IRDs are utilized, post-transplant monitoring and testing of recipients is recommended for early detection of potential transmissions. Since delayed seroconversion may occur, post-transplant screening with NAT for HIV and HCV is recommended along with NAT or HBsAg testing for HBV. A potential proposed algorithm for testing is shown below in Table 5.

Table 4: A potential testing algorithm for post-transplant assessment of recipients of organs from increased risk donors

Post-Transplant Test	Timing of Test
• HIV NAT • HCV NAT • Anti-HBc, HBsAg (± HBV NAT)	• At 1 month and at 3 months post-transplant
• Anti-HBs, Anti-HBc, and HBsAg	• At 12 months post-transplant

Source: CST/CNTRP Increased Risk Donor Working Group, 2014.

In the unlikely case that the patient acquires an infection from the IRD organ, the infectious disease specialists should treat the patient as required.

4.3 Suggested IRD Protocol Development Guidelines

Utilization of IRDs may require formal changes to clinical and administrative processes within hospitals, including education of healthcare providers. Every hospital has different processes and procedures to implementing new protocols. Suggested guidelines for development of IRD protocols are:

1. Review hospital based protocol development, approval, and implementation guidelines

a. *Typically, each hospital has protocol development guidelines. Refer to these prior to initiating the development or revision of existing protocols to ensure the IRD utilization protocol reflects the process required for your facility.*
b. *Consider who should be involved and what the current process is in your hospital to initiate protocol development.*

2. Identify existing exceptional distribution protocols

a. *Locate and review and existing protocols on the use of IRDs; determine when the last revisions were completed.*

3. Review recommended IRD utilization process steps and compare with existing protocols

a. *Identify any inconsistencies between existing and recommended process steps.*
b. *Identify any information that may require revisions or changes in practices within the protocols.*
c. *Review sample protocols, which have been provided as guidelines to integrate content requirements.*

4. Draft protocols to reflect all steps of the process, including the IRD utilization process identified by TGLN

a. *Draft IRD protocols to reflect donation process steps.*
b. *Incorporate hospital specific IRD practices.*

5. Proceed with hospital specific process for approval and implementation of IRD utilization protocols

a. *Follow hospital specific process for revision, approval, and implementation of IRD protocols.*

5. Conclusion

One donor can save up to eight lives and improve the lives of up to 75 people. Yet, there is a constant shortage of organs and tissue available for transplantation, and the demand for organs and tissue needed in Ontario continues to exceed the available supply. This document is intended to support transplant physicians and programs in the use of organs from IRDs so that more organ transplants can be given to patients who need them.

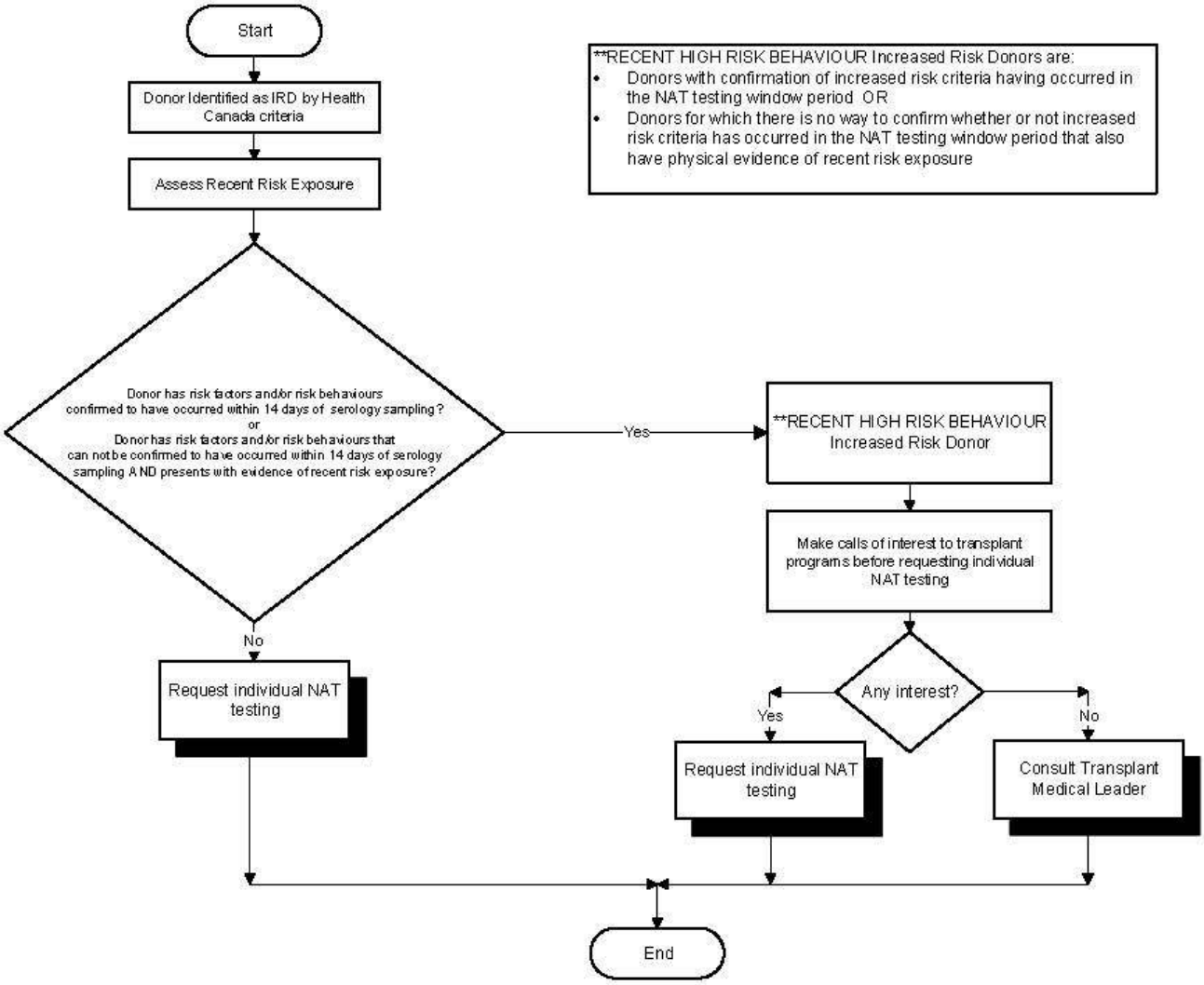
The use of organs from IRDs should be performed in a safe and ethical manner. This includes rigorous informed consent of potential recipients and appropriate testing of donors. It is recommended that transplant programs discuss their protocols with hospital senior leadership before finalizing policies to ensure that they are aligned with hospital requirements. Overall, a more standardized approach across Ontario and the rest of Canada should lead to optimized utilization practices and a significant increase in the number of organ transplants.

Appendix A: CTO Regulations for Exceptional Distribution

CTO Regulations: Exceptional Distribution
40. A source establishment may distribute cells, tissues or organs that have not been determined safe for transplantation if all of the following conditions are met: (a) a cell, tissue or organ that has been determined safe for transplantation is not immediately available; (b) the transplant physician or dentist, based on their clinical judgment, authorizes the exceptional distribution; and (c) the transplant establishment obtains the informed consent of the recipient. **41.** (1) A source establishment that distributes cells, tissues or organs under section 40 must keep a copy of the notice of exceptional distribution in its records. (2) The transplant establishment must keep a copy of the notice of exceptional distribution in its records. (3) A notice of exceptional distribution must contain all of the following information: (a) the name of the transplanted cell, tissue or organ; (b) the provisions of these Regulations with which the cell, tissue or organ is not in compliance at the time of its distribution; (c) the justification for the distribution that formed the basis for the transplant physician's or dentist's decision to authorizeit; (d) the name of the source establishment that distributed the cell, tissue or organ; (e) the name of the transplant establishment and of the transplant physician or dentist who authorized the distribution; and (f) the time and date of the written authorization of the distribution and a copy of the authorization signed by the transplant physician or dentist. **42.** A source establishment that distributes a cell, tissue or organ under section 40 before the donor suitability assessment is complete must, after the distribution, complete the assessment, carry out any other appropriate follow-up testing and notify the relevant transplant establishment of the results.

Source: Safety of Human Cells, Tissues and Organs for Transplantation Regulations.

Appendix B: Individual NAT Testing Algorithm



Appendix C: Notice of Exceptional Distribution Form

NOTICE OF EXCEPTIONAL DISTRIBUTION (ExD)

TGLN DONOR ID #: _____

Trillium Gift of Life Network
522 University Avenue, Suite 900
Toronto, ON M5G 1W7
Telephone (24/7): 1.888.603.1399
Facsimile: 1.866.557.6100
Website: www.giftoflife.on.ca

Reason for ExD *(Check all that apply and explain where appropriate)*

☐ Unknown Sexual History	☐ History of IV Drug Use: _____	☐ Diluted Blood Sample for Serology
☐ Positive Serology: _____	☐ Unknowns on MSHx	☐ Tattoo/Piercing in unlicensed facility <12 months
☐ Travel to/lived in: _____	☐ Incarcerated: _____	☐ Other: _____

Organ/Composite Tissue	Heart	Lung	Liver	Pancreas	Kidney (Rt)	Kidney (Lt)	*Other:* _____
TGLN Recipient # (if known)							
Accepting Transplant Program							
Accepting Transplant Physician							
Justification for ExD Acceptance							
Date/Time of Verbal Acceptance of ExD	__/__/__ dd/mmm/yyyy __:__ hh:mm	__/__/__ dd/mmm/yyyy __:__ hh:mm	__/__/__ dd/mmm/yyyy __:__ hh:mm	__/__/__ dd/mmm/yyyy __:__ hh:mm	__/__/__ dd/mmm/yyyy __:__ hh:mm	__/__/__ dd/mmm/yyyy __:__ hh:mm	__/__/__ dd/mmm/yyyy __:__ hh:mm
CSC who documented acceptance							
Date/Time Sent to Transplant Program	__/__/__ dd/mmm/yyyy __:__ hh:mm	__/__/__ dd/mmm/yyyy __:__ hh:mm	__/__/__ dd/mmm/yyyy __:__ hh:mm	__/__/__ dd/mmm/yyyy __:__ hh:mm	__/__/__ dd/mmm/yyyy __:__ hh:mm	__/__/__ dd/mmm/yyyy __:__ hh:mm	__/__/__ dd/mmm/yyyy __:__ hh:mm

POST RELEASE: *Was donor suitability assessment incomplete at time of ExD (i.e. missing information or un-resulted tests)?*

☐ Yes ☐ No

If Yes, complete the following:

Details of Information/ Result Obtained							
Date/Time of Verbal Notification (Physician noted above)	__/__/__ dd/mmm/yyyy __:__ hh:mm	__/__/__ dd/mmm/yyyy __:__ hh:mm	__/__/__ dd/mmm/yyyy __:__ hh:mm	__/__/__ dd/mmm/yyyy __:__ hh:mm	__/__/__ dd/mmm/yyyy __:__ hh:mm	__/__/__ dd/mmm/yyyy __:__ hh:mm	__/__/__ dd/mmm/yyyy __:__ hh:mm
CSC who communicated results							
Date/Time Results faxed to Transplant Program	__/__/__ dd/mmm/yyyy __:__ hh:mm	__/__/__ dd/mmm/yyyy __:__ hh:mm	__/__/__ dd/mmm/yyyy __:__ hh:mm	__/__/__ dd/mmm/yyyy __:__ hh:mm	__/__/__ dd/mmm/yyyy __:__ hh:mm	__/__/__ dd/mmm/yyyy __:__ hh:mm	__/__/__ dd/mmm/yyyy __:__ hh:mm

Note: If "Yes" checked above, re-send form once missing information has been sent to the programs.

To be completed by Transplant Program:

I (or my authorized designate) have had a conversation with the recipient and/or next of kin/substitute decision maker in which I explained the reason(s) for Exceptional Distribution as defined above, and the risks associated with this reason(s). I have obtained informed consent from the recipient and/or next of kin/substitute decision maker and I authorize the acceptance of the organ(s) described above for Transplant.

Authorizing Program's Name: _____ *(Please Print)*

Authorizing Signature: _____ *Date:* __/__/__ *Time:* __:__
Medical Director or Designate, Transplant Program — dd/mmm/yyyy — hh:mm

To meet requirements of the Health Canada Regulations, please FAX (amended, if necessary) signed form to TGLN: (416) 214-7797 (GTA only) or 1-866-557-6100 (rest of province)

August 12, 2014

Appendix D: Patient FAQ on Getting an Organ from an IRD

The information in the following FAQ should be provided to the patient at the time of transplant assessment or listing to ensure understanding of the risks and benefits of accepting an IRD organ.

1. WHAT IS AN INCREASED RISK DONOR ORGAN?

This is an organ from a donor who identifies certain lifestyle behaviours that are of higher risk of transmitting infectious diseases to transplant recipients. These donors may test negative for infections, but they may still be a risk for spreading Human Immunodeficiency Virus (HIV), Hepatitis C Virus (HCV), and Hepatitis B Virus (HBV) to transplant patients, due to a window period where the infection(s) cannot be detected from the tests. Organs are considered an increased risk if the donor has identified the following behaviours:

- persons who have injected non-medical drugs into the blood, muscles, or under the skin in the last 5 years;
- men who have had sex with another man in the last 5 years;
- persons who have had sex in exchange for money or drugs in the last 5 years;
- persons who have had sex with any persons described above or with a person who has or may have HIV, HBV or HCV infection in the last 5 years;
- persons who have been in contact with the blood and/or bodily fluids of a person who has or may have HIV, HBV, and/ or HCV in the last 12 months;
- persons who have been in prison, lock-up, jail, juvenile detention for greater than 72 hours in the last 12 months;
- persons with a tattoo or piercing where sterile procedures were not used in the last 12 months; and,
- persons who have had close contact with another person having clinically active viral hepatitis (e.g., living in the same house where kitchen and bathroom are shared) in the last 12 months.

You might be offered an organ from a deceased donor that has an increased risk of passing on infections, such as HIV, HBV, and HCV. You will be informed if this is an increased risk organ when it is offered to you.

2. WHAT IS THE DIFFERENCE BETWEEN AN ORGAN FROM AN INCREASED RISK DONOR AND ONE FROM A STANDARD DONOR?

The increased risk from the donor does not affect how well the organ will work. It means that the donor engaged in activities before their death that increase the chances of having an infection. All donors are screened for infectious diseases. This includes testing for HIV, Hepatitis B, and Hepatitis C. Even with negative test results, there is still a very small chance that an organ from an increased risk donor has an infection such as HIV or Hepatitis. There are treatments available for these diseases but they are not curable. On average, increased risk donors tend to be of younger age with better organ function.

3. WHY WOULD I THINK ABOUT ACCEPTING AN ORGAN FROM AN INCREASED RISK DONOR?

Deciding to accept an organ from an IRD may increase your chance of getting a transplant. These are the facts:

- There is a constant shortage of organs and tissue that can be used for transplant.
- There are nearly 1,500 Ontarians waiting to get life-saving organ transplants.
- Every three days, someone dies while waiting for an organ transplant.
- The waiting times for organ transplants can be up to several years depending on the organ.

You will only be offered an increased risk organ if a transplant doctor at your hospital feels that the benefits of transplanting you with the organ are greater than the risk. Otherwise the organ will not be offered to you. A transplant doctor will speak to you about the risks and benefits of accepting the increased risk organ versus waiting for another organ.

4. HOW WILL I KNOW IF I DEVELOP AN INFECTION?

If you decide to accept the organ, you will be monitored after your transplant to be sure that you did not get an infection. In the unlikely case that you do get an infection, treatments are available. The infectious disease doctors will treat you, if needed.

5. WHO DECIDES IF I SHOULD ACCEPT AN INCREASED RISK ORGAN?

The decision to accept the increased risk organ is YOURS. The right choice for you depends on the state of your health. You need to talk about this with your medical team and all your doctors. The best answer for you may change if the state of your health changes.

If you have questions about organs from IRDs, talk with a member of your healthcare team while you are waiting for your transplant. If you are offered an organ from an increased risk donor, it will be helpful to have already thought about this information.

6. IF I DO NOT AGREE TO ACCEPT AN INCREASED RISK ORGAN, WILL IT HURT MY CHANCES OF GETTING A STANDARD ORGAN?

No. Everyone has a different level of how much risk they are willing to accept for themselves. The decision to accept the organ is yours. If you decide NOT to accept the organ, you will NOT lose your place on the waiting list.

Appendix E: Template for Standardized Informed Consent Script

The following script may be read, as written, to the patient at the time of the organ offer. The patient should be encouraged to ask questions to ensure that s/he understands and appreciates the content. The patient must verbally confirm that he/she is accepting this offer. The patient's affirmation should be documented in the patient's chart as applicable.

Script for Obtaining Informed Consent
You are being offered an organ from a deceased donor that the Canadian Standards Association guidelines defines as being at increased risk for transmitting infections, such as HIV, HBV, and HCV. There is always some risk with every donor. Please think back to discussions you have had about the risks in accepting an organ. The increased risk does not affect how well the organ works. Instead, we mean that this donor engaged in behaviors before their death that increase their chances of having an infection. You need to balance the slightly increased risk of accepting this organ with the likely benefits of being transplanted at this time instead of waiting for another organ. This donor has already had two types of screening for infections. They had required testing for HIV, hepatitis B, and Hepatitis C. They also had special testing for HIV and Hepatitis C [± HBV NAT if done]. All of these tests results were negative. Even with negative test results, there is still a very small chance that this donor has an infection such as HIV or hepatitis. Based on information on similar donors with the same behaviors and negative test results, your risk of getting an infection may be in the range of: (only read statistics pertaining to this donor's specific behavior from Table 2, and Table 3. It is not necessary to name the behaviour, only the level of risk.) A transplant physician at your hospital has carefully looked at information about this donor. She/he recommends that you consider this organ. In his/her opinion, the potential benefits of accepting the organ outweigh the risks of getting an infection from this donor. If you decide to accept this organ, you will be monitored after your transplant to be sure that you did not get an infection. IF you get an infection, treatments are available. The infectious disease doctors will treat you, if needed. Everyone has a different level of how much risk they are willing to accept for themselves The decision to accept this organ is yours. If you decide NOT to accept the organ, you will not lose your place on the waiting list. Do you have any questions?
Additional points may be discussed with the patient depending on type of transplant (e.g. kidney vs. non-kidney) and other factors. These points include:
1. Estimated time the patient may be on the wait list if he/she waits until the next offer 2. Estimated wait-list mortality if he/she waits until the next offer 3. Risk of becoming so sick a transplant may not be possible

Source: CST/CNTRP Increased Risk Donor Working Group, 2014. *Adapted from standardized informed consent used at Northwestern University Feinberg School of Medicine (Provided courtesy of Michael G. Ison).

Note: A separate standardized informed consent template may be needed for kidney vs. non-kidney recipients given the availability of dialysis for support of end stage renal failure patients.

Appendix F: Sample IRD Organ Informed Consent Form

Increased Risk Donor Organs
Informed Consent

WE INVITE YOU TO CONSIDER ACCEPTING AN INCREASED RISK DONOR ORGAN.

Increased Risk Donor (IRD) organs may not meet the strict criteria of a standard organ donor.

IRD donors identify certain lifestyle behaviors that are of an increased risk of spreading illnesses to patients compared to standard donors.

You are being offered an IRD organ because:

- You are waiting for an organ transplant
- Your doctor feels that you will benefit from having an IRD organ. An IRD organ will allow you to be transplanted sooner, rather than waiting a longer period of time for a standard criteria organ.

Please take your time to make your decision about accepting an IRD organ. Feel free to ask questions.

Patient Sign-Off

I, the undersigned, have been informed about the purpose, procedures, possible benefits and risks of accepting an IRD organ, and I have received a copy of this informed consent document. I have been given the opportunity to ask questions and I have been told that I can ask questions in the future. All my questions have been answered to my satisfaction.

☐ **Yes, I am willing to accept an organ from an Increased Risk Donor.**

_____

Patient's Name (please print)

_____ _____

Signature of Patient **Date**

Transplant Program Sign-Off

As a representative of this transplant program, I have explained the purpose, the procedures, the possible benefits and the risks that are involved with an organ from an Increased Risk Donor (IRD). Any questions that have been raised have been answered to the best of my knowledge.

_____

Name of person obtaining the consent (please print)

_____ _____

Signature of person obtaining the consent **Date**

Appendix G: Glossary of Terms

Canadian National Transplant Research Program: a national initiative designed to increase organ and tissue donation in Canada and enhance the survival and quality of life of Canadians who receive transplants.

Canadian Society of Transplantation: the professional organization for physicians, surgeons, scientists and allied health professionals dedicated to leading, advancing, and advocating for patient care, research, and education in donation and transplantation in Canada.

Canadian Standards Association: a not-for-profit standards organization which develops and published standards in a variety of areas and provides training and advisory services.

Exceptional Distribution: the process and conditions under sections 40 to 42 of the CTO regulations whereby a source establishment may distribute cells, tissues or organs that have not been determined safe for transplantation.

Enzyme-Linked Immunosorbent Assay (ELISA): is a common laboratory technique which is used to measure the concentration of an analyte (usually antibodies or antigens) in solution.

Hepatitis B Virus (HBV): a DNA virus belonging to the Hepadnaviridae family of viruses. The virus causes the disease hepatitis B, a viral infection that attacks the liver and can cause both acute and chronic disease.

Hepatitis C Virus (HCV): a small, enveloped, positive-sense single-stranded RNA virus of the family Flaviviridae. The virus causes the disease Hepatitis C, a bloodborne virus that can cause both acute and chronic hepatitis infection.

Human Immunodeficiency Virus (HIV): a retrovirus that infects cells of the immune system, destroying or impairing their function.

Increased Risk Behaviour: certain lifestyle behaviours that are of higher risk of transmitting infectious diseases to transplant recipients.

Increased Risk Donor (IRD): organ or tissue donor who identifies certain lifestyle behaviours that meet the criteria for being a higher risk of transmitting infectious diseases to transplant recipients.

Informed Consent: process for getting permission before conducting a healthcare intervention on a person.

Nucleic Acid Testing (NAT): a molecular technique used to detect a virus or a bacterium. It detects viruses earlier than other screening methods; thus, narrowing the detection window period.

Residual Risk: the risk of infectious disease transmission when the screening test is negative.

Serology: a blood test to detect serum antibodies or antibody-like substances that appear specifically in association with certain diseases.

Source Establishment: entity responsible for the processing of cells, tissues and organs, whether the processing is carried out by the source establishment itself or by another establishment, and for determining whether the cells, tissues and organs are safe for transplantation.

Trillium Gift of Life Network (TGLN): a not-for-profit agency of the Government of Ontario that plans, promotes, coordinates and supports organ and tissue donation and transplantation across Ontario.

Window Period: the time between first infection and when a test can reliably detect that infection.

Appendix H: References

1. Atul Humar et al., "Nucleic Acid Testing (NAT) of Organ Donors: Is the 'Best' Test the Right Test? A Consensus Conference Report," *American Journal of Transplantation* 10, No.4 (2010): 889–899.

2. Canadian Standards Association. "Annex E (normative): Factors and Behaviours associated with a higher risk of HIV, HBV, and HCV," *Cells, tissues, and organs for transplantation: General requirements*. Mississauga: CSA Group, 2012.

3. CST/CNTRP Increased Risk Donor Working Group. "Guidance on the Use of Increased Infection Risk Donors for Organ Transplantation," *Transplantation* 98, No. 4 (2014): 365-369.

4. *Safety of Human Cells, Tissues and Organs for Transplantation Regulations*, SOR/2007-118. http://laws-lois.justice.gc.ca/PDF/SOR-2007-118.pdf