CLINICAL GUIDELINES FOR ADULT LIVE DONOR LIVER TRANSPLANTATION

Revised on Sept 20, 2016
AMB.03.008 Rev 05 Eff Date: 14-Nov-2016
# Table of Contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 INTRODUCTION</td>
<td>3</td>
</tr>
<tr>
<td>2 DONOR ASSESSMENT</td>
<td>6</td>
</tr>
<tr>
<td>2.1 How the Process Starts (Self-Referral Process)</td>
<td>6</td>
</tr>
<tr>
<td>2.2 Minimizing Coercion and Compensation</td>
<td>8</td>
</tr>
<tr>
<td>2.3 Costs</td>
<td>8</td>
</tr>
<tr>
<td>2.4 Eligibility Criteria</td>
<td>9</td>
</tr>
<tr>
<td>2.5 Exclusionary Criteria or Contraindications</td>
<td>9</td>
</tr>
<tr>
<td>2.6 Live Donor Suitability Assessment Process</td>
<td>14</td>
</tr>
<tr>
<td>2.6.1 Med Social Questionnaire</td>
<td>14</td>
</tr>
<tr>
<td>2.6.2 Blood Type Compatibility</td>
<td>17</td>
</tr>
<tr>
<td>2.6.3 Serological Testing</td>
<td>17</td>
</tr>
<tr>
<td>2.6.4 Laboratory and Other Studies</td>
<td>20</td>
</tr>
<tr>
<td>2.6.5 Physical Exam</td>
<td>21</td>
</tr>
<tr>
<td>2.6.6 Test Recording and Reporting</td>
<td>21</td>
</tr>
<tr>
<td>2.6.7 Clinic Visit and Liver Transplant Team Evaluation</td>
<td>22</td>
</tr>
<tr>
<td>2.6.8 Assessment Outcome</td>
<td>23</td>
</tr>
<tr>
<td>2.6.9 Final Pre-Operative Donor Testing</td>
<td>23</td>
</tr>
<tr>
<td>2.7 Exceptional Distribution</td>
<td>25</td>
</tr>
<tr>
<td>3 DOCUMENTATION</td>
<td>26</td>
</tr>
<tr>
<td>4 RECIPIENT ASSESSMENT</td>
<td>30</td>
</tr>
<tr>
<td>4.1 Domino Liver Transplants</td>
<td>30</td>
</tr>
<tr>
<td>5 OPERATIVE PROTOCOL</td>
<td>31</td>
</tr>
<tr>
<td>5.1 Operating Room Booking</td>
<td>31</td>
</tr>
<tr>
<td>5.2 Surgical Consent</td>
<td>31</td>
</tr>
<tr>
<td>5.3 Donor Admission</td>
<td>31</td>
</tr>
<tr>
<td>5.4 Donor Liver Surgery</td>
<td>31</td>
</tr>
<tr>
<td>6 POST OPERATIVE PROTOCOL</td>
<td>32</td>
</tr>
<tr>
<td>6.1 Post-Op Live Donor Follow-Up</td>
<td>32</td>
</tr>
<tr>
<td>6.2 Recipient Follow-Up</td>
<td>33</td>
</tr>
<tr>
<td>7 APPENDICES</td>
<td>34</td>
</tr>
</tbody>
</table>
1. INTRODUCTION

**Purpose of the Clinical Guidelines:**
The Clinical Guidelines are a Provincial statement of consensus of BC Transplant (BCT) and healthcare professionals regarding their views of currently accepted approaches to treatment in adult patients. The Guidelines supplement specific agency / hospital Standard Operating Procedures (SOPs).

The purpose of the Clinical Guidelines is as follows:

1) To describe currently accepted approaches and best practices to living donor liver screening/assessment, testing, and post-donation follow-up;

2) To describe the required Provincial standards of practice to ensure compliance with Health Canada and thereby help ensure the optimal health and safety of both potential donors and recipients.

**Role of BC Transplant and its Partner Hospitals**
BC Transplant (BCT), an agency of the Provincial Health Services Authority (PHSA), is a comprehensive health care organization, established in 1986 to coordinate and lead all activities related to organ donation and transplantation in B.C. BCT has provincial oversight of the full spectrum of clinical, fiscal and organizational aspects of organ donation and transplantation. BCT is accountable to the BC Ministry of Health for living and deceased donation.

BCT contracts for the living donor liver program at Vancouver General Hospital (VGH). All living donor liver assessments and transplants are performed at VGH. All transplants are adult only.
Compliance with Health Canada

Human cells, tissues and organs that are to be used in transplantation are regulated under Health Canada’s Safety of Human Cells, Tissues and Organs for Transplantation Regulations (CTO Regulations). The CTO Regulations apply to all individuals and establishments in Canada that handle, process, distribute or import human organs for use in transplantation in another individual. This includes livers both from deceased and living donors.

The CTO Regulations are standard-based regulations, which means that they make reference to specific community standards developed and maintained by the Canadian Standards Association (CSA Standards), thereby making the referenced sections mandatory (See Appendix J FAQ for Living Donors).

The purpose of the CTO Regulations and CSA Standards is to minimize the potential health risks to Canadian recipients of human organs by addressing the safety in the processing and handling of these products. Source establishments must determine that donors are not unsuitable to donate on the basis of the contraindications or exclusion criteria set out in the Regulations.

As per Health Canada: an organ may be released by an Organ Donation Organization (ODO) only after:

1. All donor suitability assessment requirements have been met, and testing has been completed; and
2. The requirements of the exclusionary criteria have been met (See Table 2, 3).

BC Transplant and VGH are fully committed to meeting all requirements of Health Canada.

This includes but is not limited to:

- Processing of the organ, even if some or all of the processing activities were carried out by another establishment on behalf of the source establishment. In the case of organs, processing includes, donor suitability assessment, donor screening, donor testing, packaging and labelling as well as testing and measurements performed on the organ after it has been retrieved;
- Determining that the liver is safe for transplantation;
- Record keeping, investigating and reporting suspected error/accidents and adverse reactions and quality assurance which includes standard operating procedures and audit; and
- Exceptional distribution, personnel qualification and training programs, facilities, equipment and supplies etc.
**Addtional Resources**

For any further questions related to Health Canada or regulatory compliance, contact:

**BCT Quality Assurance at 604-877-2240.**

CSA Standard Z900.1-12 Cells, Tissues, and Organs for Transplantation: General Requirements;
CSA Standard Z900.2.3-12 Perfusable Organs for Transplantation;

Available at: [Health Canada website](#)

Available at: [BC Transplant website](#), under Healthcare Professionals:
- Clinical Guidelines for Liver Transplantation
- Clinical Guidelines for Transplant Medications
2. Donor Assessment

In Living Donor Liver Transplantation (LDLT), a piece of healthy liver is surgically removed from a living person and transplanted into a recipient, immediately after the recipient’s diseased liver has been entirely removed. LDLT has emerged as a preferred treatment option for patients with end stage liver disease, such as cirrhosis, and/or hepatocellular carcinoma.

There are several advantages to having a living donor transplant:

**Advantages**

- *It provides the greatest chance of a successful transplant outcome*
- *It allows the potential for pre-emptive transplantation*
- *It allows the recipient to avoid a lengthy wait on the deceased donor transplant list*
- *As the date of transplantation is known, it facilitates planning for the transplant*
- *It helps to alleviate the critical shortage of organs from deceased donors*
- *It reduces the chance of marginal liver organ donation*

2.1 How the Process Starts (Self-Referral Process)

Potential donors do not need a physician referral for initiation of the assessment process (i.e., Self-referral). The Live Donor Liver Program does not actively canvass donors because of the potential for unwelcome pressure. Interested donors should contact the SOT Clinic at VGH to indicate their willingness to explore donation. When a potential liver donor contacts the SOT clinic, they are supplied with information regarding the program, including a copy of the booklet, *Live Liver Donation: a Potential Donor’s Guide*.

- Donors must have an established relationship with the recipient (e.g., spouse, friend, relative).
- Currently there is no anonymous donation.

More than one donor may come forward for assessment for each recipient. All contact is confidential. Currently there is no anonymous donation in BC.
Out of Province Donors
If a potential living liver donor lives in another province, arrangements will be made for assessments to be performed at a center closer to the donor’s home. Donors may also be required to travel to VGH for assessment. Final bloodwork and serology is always performed in BC, unless specific logistics do not permit.

Out of Country Donors
If a potential living liver donor lives outside of Canada, arrangements may be made for preliminary assessments to be performed in their country of residence. The VGH liver program must be satisfied that the relationship between the donor and recipient meets the eligibility criteria (See Section 2.4). In addition, initial testing to determine compatibility and general suitability will be requested and reviewed by the VGH liver program. Through discussion with the VGH team, the donor may decide to continue assessment in Canada. Some donors may require a temporary visa and will need to comply with Immigration Canada policies.

Once in Canada, the potential donor must undergo a full assessment to establish him or her as a suitable donor. These potential live donors will be required to sign an additional Out of Country Consent form (See Appendix A).

Medical costs for donors out of country for donor assessment and/or surgery will be covered by the recipient’s medical plan. Any medical costs not related to donor assessment and/or surgery must be through a 3rd party provider.

For ALL DONOR REFERRALS Contact:
Clinical Coordinator
Living Donor Liver
Solid Organ Transplant Clinic
Pre-Transplant Assessment
Gordon and Leslie Diamond Center 5th Floor
2775 Laurel Street, Vancouver, B.C. V5Z 1M9
Phone: 604-875-5182
Fax: 604-875-5236
2.2 Minimizing Coercion and Compensation

- BCT/VGH does not solicit live donors;
- Donors must come forward voluntarily;
- Donors may withdraw at any time - without providing a reason;

The living donation team promotes the best interests of each donor. This includes helping to ensure protection of their rights, and assisting them in obtaining information on the living donation process. The desire to seek information about donating or proceeding with the donor testing does not oblige one to donate. The potential donor is informed that they can withdraw at any time – without providing a reason.

An individual’s motivation and expectation to donate will be explored by the transplant assessment team. In addition, the transplant team ensures, to the best of its ability, that no material rewards or financial incentives are influencing the individual’s decision to donate a portion of their liver.

Information shared between the donor, family physician and the transplant centre is confidential (Also see Section 3 Documentation - Privacy and Confidentiality of Information).

When required, the hospital assists the living donor with accessing professional interpretation services. It is recommended that family members not act as interpreters.

2.3 Costs

The BC Medical Services Plan (MSP) covers the medical costs of the Live Donor assessment for Live Donors living within Canada. Some out-of-pocket non-medical expenses may be partially reimbursed through the Living Organ Donor Expense Reimbursement Program (LODERP). The LODERP is administered through the Kidney Foundation of Canada, BC Branch.

In some cases arrangements may be made to cover the costs of tests conducted for potential Live Donors living outside of Canada.

The Travel Assistance Program (TAP BC) offers free travel on BC Ferries and discounted air travel when authorized by a physician. These forms can be obtained through family physicians or the Transplant social worker.
2.4 ELIGIBILITY CRITERIA

The following is the minimum eligibility requirements for which an individual must meet in order to donate a portion of their liver for transplant:

- Compatible Blood Group;
- Must be 19-55 (Physiologic years);
- Compatible in size with the Recipient;
- Medically suitable to donate;
- Psychologically stable;
- Capable of giving informed consent;

2.5 EXCLUSIONARY CRITERIA OR CONTRAINDICATIONS

The following are general exclusions or contraindications for potential living donors.

Table 1. Absolute and Relative Contraindications for Live Liver Donation

<table>
<thead>
<tr>
<th>Absolute Contraindications for Live Liver Donation</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Smoking *(Must quit 6 weeks before time of donation);</td>
</tr>
<tr>
<td>• History of liver disease or liver surgery;</td>
</tr>
<tr>
<td>• Coronary artery disease (assessed and deemed significant by an independent specialist);</td>
</tr>
<tr>
<td>• History of deep vein thrombosis;</td>
</tr>
<tr>
<td>• Bleeding or clotting disorders;</td>
</tr>
<tr>
<td>• Major abdominal surgery;</td>
</tr>
<tr>
<td>• Past exposure to tuberculosis;</td>
</tr>
<tr>
<td>• Had malaria at any time in the past;</td>
</tr>
<tr>
<td>• Financial inducement, or evidence of coercion;</td>
</tr>
<tr>
<td>• Inability to obtain appropriate long term medical follow-up;</td>
</tr>
<tr>
<td>• Psychiatric illness of significance;</td>
</tr>
<tr>
<td>• Active Alcoholism or frequent heavy alcohol use;</td>
</tr>
</tbody>
</table>

Psychosocial:
- Inability to give informed consent;
- Psychological instability;
- Evidence of coercion;
- Evidence of possible financial reward;
- Inability to obtain appropriate long-term medical follow-up;
Table 1 (Con't).

<table>
<thead>
<tr>
<th>Relative Contraindications for Live Liver Donation</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Hormonal therapy;</td>
</tr>
<tr>
<td>• History of Diabetes;</td>
</tr>
<tr>
<td>• Body Mass Index &gt; 30;</td>
</tr>
<tr>
<td>• Hypertension;</td>
</tr>
</tbody>
</table>

Health Canada Contraindications:

Table 2 and Table 3 show the various Health Canada contraindications and exclusionary criteria for living donors. Potential donors identified with any of the criteria in Table 2, 3 cannot be transplanted, unless they are authorized under Exceptional Distribution (See Section 2.7 Exceptional Distribution.)
Table 2. Health Canada Contraindications and Exclusionary Criteria

CONTRAINDICATIONS / EXCLUSIONARY CRITERIA

A living donor shall be excluded if any of the following contraindications apply\textsuperscript{1,2}:

(a) persons with prion-related disease (\textit{e.g.}, Creutzfeldt-Jakob disease, variant CJD, and other transmissible spongiform encephalopathies);
(b) recipients of human growth hormone within the following time frames:
   (i) prior to 1986, if the treatment took place in Canada or the US; or
   (ii) if the treatment took place in a country other than Canada or the US, anytime that human-derived pituitary growth hormone was available for therapeutic use in that country.

\textbf{Note:} This Item refers to growth hormone extracted from human pituitary glands, used for therapeutic purposes prior to 1986. The human-derived product was removed from the market in Canada and the US and replaced with a recombinant manufactured product, due to a possible link between the human-derived product and Creutzfeldt-Jakob Disease.

(c) recipients of dura mater;
(d) persons with active encephalitis or meningitis of infectious or unknown etiology;
(e) persons with a history of dementia or degenerative neurologic disorders of viral or unknown etiology (\textit{e.g.}, Parkinson's, subacute sclerosing panencephalitis, progressive multifocal leukoencephalopathy, Lou Gehrig's) (\textit{See OPTN Guidance, below}\textsuperscript{3})
(f) persons with rabies or persons who, within the past six months, were bitten by an animal and treated as if the animal was rabid;
(g) persons with HIV, HCV, or a current or previous HBV infection; and
(h) persons at higher risk for HIV, HBV, or HCV infections as specified in Annex E (\textit{see Table 3}).

In addition, the following additional contraindications or exclusion criteria shall apply\textsuperscript{4}:

(a) persons with unexplained lymphadenopathy mass or mucocutaneous lesions;
(b) persons with needle tracks or other signs of injection drug abuse;
(c) persons with active infections of clinical significance;
(d) persons with syphilis;
(e) persons with a malignancy, except for a cutaneous basal cell or squamous cell carcinoma that has been treated.
Table 2 (Continued)

Additional contraindications or exclusion criteria as specified in Clause 13.1.2 shall also apply and shall be assessed through physical examination, donor screening questions, and laboratory tests as appropriate.

The physical examination shall also be used to assist in determining whether there is evidence of a) high risk behavior for HBV, HCV, or HIV (See Annex E of CAN/CSA-Z900.1); or b) the contraindications specified in Clause 13.1.3 of CAN/CSA-Z900.1.

1As per CSA Z900.1-12 Section 13.1.3.
2Exceptional distribution may be considered for organs from donors to whom any of the contraindications/exclusionary criteria in Table 2 apply.
3Reference, UNOS - OPTN Guidance: Guidance for Recognizing CNS Infections in Potential Deceased Organ Donors; What to Consider During Donor Evaluation and Organ Offers
4As per CSA Z900.2.3-12 13.1.2
Table 3. Health Canada’s Assessment of Donors for Risk Factors and Behaviours associated with HIV, HBV, and HCV.

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.\textsuperscript{1,2}

(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 (c) 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 HIV I, II, HBV, HCV.

\textsuperscript{1} As per Annex E, Clause E.1 of CSA Z900.1-12 General Requirements. Clause E.2 not shown as there are no donors 11 years of age or younger with regards to the Living Donor Liver Program.

\textsuperscript{2} Exceptional distribution may be considered for organs from donors to whom any of the risk behaviour criteria in Table 3 apply.
2.6 Live Donor Suitability Assessment Process (Stages)

Donor suitability assessment is fully documented and based on medical and social history, physical examination and tests. The Live Donor assessment process is a staged process that may be adapted for each potential Live Donor at the discretion of the Live Donor Team (See Figure 1, Table 4).

The potential Live Donor must meet all requirements for each phase of the assessment process before proceeding to the next phase. The Donor Evaluation Process also depends on recipient’s diagnosis and prognosis, donor’s health status, and medical team clinical decisions. The target is to complete the evaluation within 3 months. Duration of the assessment may be influenced by recipient factors, testing schedule, and donor’s decision to move forward.

All discussions and evaluations of a potential Live Donor are kept strictly confidential. If the potential Live Donor is deemed unsuitable, the Recipient will be informed by the Clinical Coordinator only that the potential donor is not a suitable candidate.

Each stage of the assessment is reviewed by the living donor team. If suitable, the donor may choose to proceed. The Live Donor is informed that they may withdraw from the assessment process at any time up to and including the date of the OR.

A donor can withdraw from the evaluation process at any time

2.6.1 Medical Social History Questionnaire (MSHQ)

A standardized questionnaire reviewing medical and psychological history, social and behavioural risks shall be completed by each potential Live Donor (See Appendix B).

For those donors who may not read or speak English, the questionnaire may be completed by an interpreter. The name of the person completing the questionnaire on behalf of the potential donor, and the reason, is to be documented on the med-social.

The Clinical Coordinator will review every question and discuss any concerns with both the donor and medical team as applicable. If no concerns are raised the Live Donor will move to the next step of the assessment process. A Med-Social rationale is used as a reference tool.

If the potential donor is ruled out as a result of the information received on the questionnaire, the Clinical Coordinator will inform the donor.
Figure 1. Live Donor Liver Assessment

- **Stage 1. Prescreening. Med-Social Questionnaire and ABO Blood Group**
- **Stage 2. Blood Work (including Serology) and Organ Function Tests**
- **Stage 3. Initial Diagnostic Testing (e.g. Echos, Ultrasounds)**
- **Stage 4. Definitive Diagnostic Tests to Determine Anatomy Suitability (Abdominal CT, MRCP)**
- **Stage 5. Final Suitability Assessment by Transplant Team**
- **Stage 6. OR Booking (Final Blood Work, Serology, and 30-Day Questionnaire)**
Table 4. Minimum Required Donor Medical History as per Health Canada.

**DONOR MEDICAL HISTORY** *(as per CSA Z900.2.3-12; Section 12.2.2.3)*

<table>
<thead>
<tr>
<th>(a)</th>
<th>any history of malignancy or tuberculosis, hepatitis, HIV infection, Creutzfeldt-Jakob disease (CJD), or other communicable disease;</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Note:</strong></td>
<td>Other communicable diseases that could be of concern include (but are not limited to):</td>
</tr>
<tr>
<td>(a)</td>
<td>EBV;</td>
</tr>
<tr>
<td>(b)</td>
<td>CMV;</td>
</tr>
<tr>
<td>(c)</td>
<td>Syphilis; and</td>
</tr>
<tr>
<td>(d)</td>
<td>Herpes;</td>
</tr>
<tr>
<td>(b)</td>
<td>any history of other major illnesses, previous hospitalizations, previous surgical procedures, previous blood or blood-product transfusions, current medications, and any drugs administered within the previous 48 hours;</td>
</tr>
<tr>
<td>(c)</td>
<td>any history of disease or abnormality of any of the consented organs or tissues;</td>
</tr>
<tr>
<td>(d)</td>
<td>any suspected or confirmed diagnosis of West Nile virus, or recent travel to areas where WNV is endemic;</td>
</tr>
<tr>
<td>(e)</td>
<td>any suspected or confirmed diagnosis of SARS;</td>
</tr>
<tr>
<td>(f)</td>
<td>any behaviour or history associated with higher risk of HIV, HBV, and HCV as specified in Annex E of CAN/CSA-Z900.1 (See Table 2);</td>
</tr>
<tr>
<td>(g)</td>
<td>travel in the past six months;</td>
</tr>
<tr>
<td>(h)</td>
<td>history of residence outside Canada in the past six months;</td>
</tr>
<tr>
<td>(i)</td>
<td>history of animal bite in the past six months; and</td>
</tr>
<tr>
<td>(j)</td>
<td>any history of allergy</td>
</tr>
</tbody>
</table>

**Notes:**

1. *Information gathered in the donor history is used to evaluate the donor’s risk of having a transmissible disease. An identified risk will not necessarily lead to exclusion; however, it is important information for the purpose of clinical decision-making.*

2. *The information in Item (j) (history of allergy) should be communicated to the recipient if it is considered to be clinically significant. For example, information on the presence of a life-threatening allergy in the donor, with potential to be transferred to the recipient, would alert the recipient to avoid the allergen(s) in question and/or seek appropriate testing (Cases of donor allergies transferred to recipients have been reported for organ transplants, including potentially fatal allergies to nuts, seafood, penicillin, and latex (Health Canada Guidance 2013)).*

**Additional Resources**

**CBS Med-Social Rationale**

**Travel History:**

- CDC Malaria Risk Information
- CDC West Nile Virus
- WHO
- Public Health Agency of Canada
- CDC - Zika Virus
- Government of Canada - Zika Virus
2.6.2 Blood Type Compatibility

- The Donor and Recipient blood types will be verified by the Clinical Coordinator. See Table 5.
- Prior to the organ retrieval, the ABO blood group shall be re-verified by the Clinical Coordinator. A hard copy must be kept in the Live Donor chart.

### Table 5 Blood Type Compatibility

<table>
<thead>
<tr>
<th>Blood Type</th>
<th>Donate Blood To</th>
<th>Receive Blood From</th>
</tr>
</thead>
<tbody>
<tr>
<td>A+</td>
<td>A+, AB+</td>
<td>A+, A-, O+, O-</td>
</tr>
<tr>
<td>O+</td>
<td>O+, A+, B+, AB+</td>
<td>O+, O-</td>
</tr>
<tr>
<td>B+</td>
<td>B+, AB+</td>
<td>B+, B-, O+, O-</td>
</tr>
<tr>
<td>AB+</td>
<td>AB+</td>
<td>Everyone</td>
</tr>
<tr>
<td>A-</td>
<td>A+, A-, AB+, AB-</td>
<td>A-, O-</td>
</tr>
<tr>
<td>O-</td>
<td>Everyone</td>
<td>O-</td>
</tr>
<tr>
<td>B-</td>
<td>B+, B-, AB+, AB-</td>
<td>B-, O-</td>
</tr>
<tr>
<td>AB-</td>
<td>AB+, AB-</td>
<td>AB-, A-, B-, O-</td>
</tr>
</tbody>
</table>

2.6.3 Serological Testing

At a minimum, donors undergo Health Canada required serological testing as described in Table 6. In addition potential live donor liver candidates are tested for

- *Herpes Simplex Virus* (HSV)
- *Varicella Zoster Virus* (VZV)

The living donor is notified of any positive or reactive results when confirmed and informed that the results will be reported to regulatory agencies, as required by law and their family practitioner.
Table 6. Minimum Donor Serological Testing

<table>
<thead>
<tr>
<th>Health Canada Minimum Required Tests (Prior to Transplant)</th>
</tr>
</thead>
<tbody>
<tr>
<td>MUST BE REPEATED WITHIN 30 DAYS OF DONATION1</td>
</tr>
<tr>
<td>• HIV-1 and HIV-2 (Anti-HIV I, II)</td>
</tr>
<tr>
<td>• HTLV I, II (Anti-HTLV I, II)</td>
</tr>
<tr>
<td>• Hepatitis B (Hep B Surface antigen) (HBsAg)</td>
</tr>
<tr>
<td>• Hepatitis B (Total antibody to Hep B core antigen) (Anti-HBc, IgG and IgM; or HBC Ab)</td>
</tr>
<tr>
<td>• Hepatitis B (Antibody to Hep B Surface antigen) (Anti HBs or HBs Ab)2</td>
</tr>
<tr>
<td>• Hepatitis C (Anti-HCV) (Antibodies to Hepatitis C Virus)</td>
</tr>
<tr>
<td>• Syphilis (RPR)3</td>
</tr>
<tr>
<td>• EBV (antibody to EBV) (Anti EBV IgG)4,5</td>
</tr>
<tr>
<td>• CMV (antibody to CMV) (Anti CMV IgG)4,5</td>
</tr>
<tr>
<td>• WNV (nucleic acid for WNV) (WNV NAT)</td>
</tr>
<tr>
<td>• Health Canada Recommended. Seasonal, restricted testing by BCCDC; Review travel history of potential donor.</td>
</tr>
<tr>
<td>• NAT Testing for HIV-1 and HCV</td>
</tr>
<tr>
<td>• Health Canada Recommended where clinically indicated, e.g. high risk behaviour</td>
</tr>
</tbody>
</table>

1It is not necessary to re-test for disease markers for which the donor is already known to be positive (e.g., CMV, EBV)
2Program Required
3For syphilis, a liver may be released for transplantation if the donor’s blood sample is reactive for a nontreponemal test, but negative or nonreactive for a treponemal-specific confirmatory assay. If only the treponemal-specific assay for syphilis is performed, the liver shall not be released for transplantation if the donor’s specimen is reactive or positive.
4May be reported retrospectively
5For CMV and EBV, liver may be released for transplant if a donor’s blood sample is positive, or if the tests results are pending. It is not necessary to use exceptional distribution. Results must be communicated to the recipient program.
Interpretation of Infectious Disease Test Results
Donor eligibility determination shall include the interpretation of the infectious disease test results as outlined below:

1) **Repeatedly Reactive or Positive**
   For HIV-1 and 2, HBV, HCV and HTLV-I and II, a liver shall not be released for transplantation if the donor’s specimen is *repeatedly reactive or positive* or for any of the markers of these infectious disease agents (Health Canada Guidance 2013)

   *(note: repeatedly reactive means a single blood sample from the donor is reactive on initial testing (i.e., initially reactive), and either one or both samples are reactive when the same test (i.e., using the same test kit from the same manufacturer but not necessarily the same lot) is repeated in duplicate on the same blood sample).*

   In cases where additional tests are performed to confirm or supplement the repeat reactive test results (e.g., for the purpose of donor or next-of-kin notification), the liver shall not be released for transplantation, unless the exceptional distribution provisions are met, even if the confirmatory or supplemental test results are negative or non-reactive.

2) **NAT Testing**
   If an establishment performs additional tests that are not mandatory (e.g., nucleic acid testing (NAT) for HIV-1, HCV, HBV and WNV etc), or obtains such test results for a shared donor from another establishment, the results must be taken into consideration when determining donor eligibility if they are available prior to transplant of the liver.

   **Positive Serology / Negative NAT:** If a donor has a positive serological test, but is found to be negative using NAT the liver can only be transplanted using exceptional distribution (Health Canada Guidance 2013)

3) **Indeterminate Test Results**
   Test results stated to be indeterminate/equivocal, are discussed with the Medical Director (or designate). It is recommended to also consult with the on-call microbiologist. As equivocal results may be indicative of potential infection, an Exceptional Distribution may be required.
### 2.6.4 Laboratory and Other Studies

To qualify as a liver donor, the donor must be in good health with excellent liver function. To evaluate this, the following minimum tests are required:

<table>
<thead>
<tr>
<th><strong>Laboratory</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Serum electrolytes, including BUN and Creatinine, eGFR</td>
<td></td>
</tr>
<tr>
<td>Alkaline Phosphatase, Total Protein, Total and Direct Bilirubin, Albumin, AST, ALT</td>
<td></td>
</tr>
<tr>
<td>Amylase or Lipase</td>
<td></td>
</tr>
<tr>
<td>Ca, PO₄</td>
<td></td>
</tr>
<tr>
<td>GGT</td>
<td></td>
</tr>
<tr>
<td>Blood glucose</td>
<td></td>
</tr>
<tr>
<td>AFP (Alpha-Fetoprotein)</td>
<td></td>
</tr>
<tr>
<td>CEA (Carcinoembryonic antigen)</td>
<td></td>
</tr>
<tr>
<td>CA 19-9</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Hematology</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>CBC with platelets</td>
<td></td>
</tr>
<tr>
<td>INR (International Normalized Ration) &amp; PTT (Prothrombin Time)</td>
<td></td>
</tr>
<tr>
<td>Factor V Leiden</td>
<td></td>
</tr>
<tr>
<td>Prothombin Gene Mutation (PGM)</td>
<td></td>
</tr>
<tr>
<td>Protein electrophoresis</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Urine</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Urinalysis</td>
<td></td>
</tr>
<tr>
<td>Pregnancy screen (urine)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Radiology Studies</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Chest X-ray</td>
<td></td>
</tr>
<tr>
<td>Mammogram (females &gt;40 within 2 years)</td>
<td></td>
</tr>
<tr>
<td>ECG</td>
<td></td>
</tr>
<tr>
<td>Echocardiogram</td>
<td></td>
</tr>
<tr>
<td>Abdominal ultrasound with doppler flow studies</td>
<td></td>
</tr>
<tr>
<td>CT scan with volumetric measurements</td>
<td></td>
</tr>
<tr>
<td>MRCP (bile duct anatomy)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Other</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>PSA (males &gt; 40)</td>
<td></td>
</tr>
<tr>
<td>PAP (all females)</td>
<td></td>
</tr>
<tr>
<td>Tb skin test (if risk factors identified, ex travel to endemic area)</td>
<td></td>
</tr>
<tr>
<td>Height/weight, BMI</td>
<td></td>
</tr>
</tbody>
</table>

The following may be required but are not limited to:

- Liver biopsy
- Arteriogram
- ERCP
- Consultants (i.e. Cardiology, Respiratory)
The results of these tests are reviewed. Additional tests may be performed as required by Health Canada or the medical team.

2.6.5 Physical Exam
The physical examination of a living donor shall be performed by a physician and/or surgeon and include:

a. An assessment of the risks associated with the anaesthetic and operative procedure;
b. A determination of the health of the organ to be donated;
c. An assessment of potential impact of donation on the long-term health of the donor;
d. Any evidence of high-risk behavior for HBV, HCV, or HIV (as per Table 3) [Note - BC Transplant physicians hereby define high-risk behaviour for living donors as needle tracks indicating possible drug use];
e. Any evidence of contraindications as per Table 2,3 (reviewed with Med-social);
f. Signs of bacterial, fungal, parasitic or viral infections of clinical significance and signs of malignancy (Health Canada Guidance 2013);
g. Persons with unexplained lymphadenopathy mass or mucocutaneous lesions;

If the conclusions of the physical exam confirm the presence of suspected risk factors (Table 2), the liver can only be released under exceptional distribution (See Section 2.7) (Health Canada Guidance 2013).

Timing of Physical Exam
It is recommended (Health Canada Guidance 2013) that the physical exam be performed within 30 days of scheduled OR date. In the best interests of the patient and for logistical purposes in donor assessment and planning a physical exam may occur before this time. If the physician requires a repeat physical exam within the 30 day period, this will be documented on either the “QA Patient Chart Review Form – Living Donor Programs” (Form No. VCH.VA.DC.0034; Appendix H).

Results of physical examinations shall be documented in the donor chart.

2.6.6 Test Recording and Reporting
All test results will be reviewed by the Clinical Coordinator and become a confidential part of the Live Donor’s chart (See Section 3 Documentation). Copies of all investigations will be provided to Family Physicians. Any abnormal test results will be reviewed with the Live Donor Team. The Live Donor along with his/her Family Practitioner will also be notified of abnormal results. Positive serology tests shall be reported to the appropriate health authorities in accordance with federal and provincial notification protocols (**Note: Not applicable for CMV/EBV).
2.6.7 Clinic Visit & Liver Transplant Team Assessment

The Live Donor will be assessed by the following individuals. Other consultations may be required as deemed appropriate by the Live Donor Team. Completed assessment notes will be placed in chart.

Clinical Coordinator: Is a Registered Nurse that coordinates the assessment process for all potential Live Donors. Provides Live Donors and their families with information about the process of donation, including the testing required and clarifies any questions. Risks, benefits and outcomes of donation are reviewed. Follow-up protocols are discussed.

Transplant Surgeon: Discusses the surgical approaches to donor liver resection. Surgical risks and post-operative recovery are reviewed in detail. The Surgeon assesses all assessment data, examines the patient and must be assured that the Live Donor is physically able to undergo the surgery, capable of giving informed consent and is not being subjected to coercion.

Transplant Social Worker: Conducts a psychosocial interview to determine suitability for donation. The interview includes an assessment of social support, financial resources and the Live Donor’s motivation. The assessment evaluates the potential donor’s psychological, emotional and social stability; and the decision to donate is made freely without pressure or coercion. Any concerns of donation are reviewed.

Transplant Psychologist: Conducts a psychological assessment to determine emotional and psychological suitability of the Live Donor. The evaluation will include exploration of the Live Donor’s ability to give informed consent, the Donor’s and Recipient’s relationship, psychological motivation for donation and the possible psychological pitfalls are discussed in the event of a successful or unsuccessful transplant. In addition, the Live Donor is assessed for financial incentives or coercion that may be present.

Spiritual Care: A chaplain is available to provide spiritual care to potential donors.

Independent Medical Examiner: Conducts a full history and physical exam to determine Live Donor suitability independent of the Live Donor Team. The Independent Medical Examiner is provided with all lab and imaging assessment data for review. In addition, the Independent Medical Examiner assesses motivation and understanding of the procedure to ensure that the Live Donor has been notified of all risks and benefits and is making an informed decision. Assesses the patient to ensure that there has been no coercion or bias by members of the transplant team.

A language interpreter will be used for the above interviews when necessary.
2.6.8 Assessment Outcome

Approval

Once all assessments and documentation are complete the potential donor’s case shall be reviewed by the Live Donor Team at weekly rounds. A review of the donor’s medical records is performed. A decision will then be made to approve or decline the potential Live Donor. The decision will be relayed to the Live Donor by the Clinical Coordinator. If the Live Donor is approved, steps will be taken to secure an OR booking and the Family Practitioner will be notified of the approval (See Section 5 Operative Protocol). The Live Donor Liver Program Candidacy Approval form will be completed by the Transplant Surgeon (See Appendix D).

The Transplant Surgeon will complete the Live Donor’s and Recipient Pre- and Post-Transplant Orders at this time. They will be included in the OR booking package.

Donor unsuitability

Individuals who are declined as donor candidates will be notified by the Clinical Coordinator citing the reason. The potential Recipient will also be notified that the Live Donor is unacceptable; however, the reason will remain confidential.

2.6.9 Final Pre-Operative Donor Testing

After approval, a surgical date will be requested. Vancouver General Hospital will book the Live Donor for a Pre-Anesthesia Clinic appointment within 30 days of the planned date. Without approval from the Anesthesia Department, a Live Donor Surgery will not go forward (Setting the Operating Date – See Section 5).

2.6.9.1 Re-testing of Serology

All serology must be re-tested within 30 days prior to the surgery (Refer to Table 5). It is not necessary to re-test for disease markers for which the donor is already known to be positive (e.g., CMV, EBV).

It is recommended that all final serological testing (BC Donors and Out of Province/Out of Country) be performed at PHSA Labs (BCCDC). Ensure blood samples are requisitioned in time for those potential donors who are out of province.

For any final serology testing performed by a lab other than BCCDC, a current list of test kits with identification numbers used by the testing lab must be received and reviewed by BCT Quality Assurance.
2.6.9.2 Confirmation of Blood Type
Repeat blood typing of donor/recipient will be confirmed prior to OR. Final compatibility is reviewed by the transplant surgeon.

2.6.9.3 Additional Testing
Additional laboratory testing may be required pre-operatively.

2.6.9.4 Living Donor 30-DAY Med-Social Questionnaire (Mini-Med-Social)
The Clinical Coordinator (or designate) will ensure completion of the Living Donor 30-Day Med-Social Questionnaire (Appendix C) within 30 days of surgery. The Clinical Coordinator will review every question and discuss any concerns with both the donor and medical team as applicable.

2.6.9.5 Consents
All potential live donors shall sign:
- A two part consent covering Surgical Consent/Blood Product Transfusion Consent prior to OR as per hospital protocol (see Appendix F).
- Documentation of the Decision to be Assessed for Liver Donation (see Appendix G)
- All out of country live donors shall sign "Consent for Jurisdiction of Treatment (Non-Resident of Canada) form (See Appendix A).
2.7 EXCEPTIONAL DISTRIBUTION

It is recognized that in exceptional circumstances a liver may be transplanted even when there appears to be a contraindication (See Section 2.5 Exclusionary criteria and Tables 2, 3). If these conditions exist, an organ may be released only under exceptional distribution. The requirements as per Health Canada are as follows:

1. A tissue or organ that has been determined safe for transplantation is not immediately available.

2. The transplant physician (or surgeon), based on their clinical judgement, authorizes the exceptional distribution.

3. The transplant establishment obtains the informed consent of the recipient.

The process will be documented on a BCT Living Donor Exceptional Distribution form [BCT Doc No. AMB-GEN.04.010 / RQA.04.010] (or equivalent) (See Appendix E) with copies in both the donor and recipient chart. In addition, the BCT Organ Donation and Hospital Development Department (ODHD) must be notified when exceptional distribution circumstances exist, prior to time of transplant. Refer to BCT SOP, Exceptional Distribution [RQA.02.018] for further information.

Follow-up with Recipients
Each exceptional distribution is to be reviewed and assessed by the team for any follow-up treatment and diagnosis. It is important that in all cases, appropriate follow-up of recipients is performed by the post-transplant medical care team. Also refer to Clinical Guidelines for Liver Transplantation Program.

Additional Resources
BCT SOP Exceptional Distribution [RQA.02.018]
Clinical Guidelines for Liver Transplantation Program (available on BCT Website, under Health Professionals)
3. DOCUMENTATION

All records related to the Live Donor shall be kept secure, confidential, accurate, complete, legible and indelible. All records must identify the person performing the activities carried out and the dates of the various entries. All transcriptions of test results must be independently verified (i.e., the transcription must be verified by another individual (Health Canada Guidance 2013)).

The Clinical Coordinator or designate will complete the QA Patient Chart Review Form (Appendix H) which ensures all Health Canada required documentation is in chart.

Accurate records are kept of all information related to the donor inclusive of but not limited to:

<table>
<thead>
<tr>
<th>GENERAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>✔ Name, address and current contact information</td>
</tr>
<tr>
<td>✔ Date of birth</td>
</tr>
<tr>
<td>✔ Date of initial contact</td>
</tr>
<tr>
<td>✔ Date of interview(s)</td>
</tr>
<tr>
<td>✔ Date of approval for donation</td>
</tr>
<tr>
<td>✔ Date of retrieval and transplantation</td>
</tr>
<tr>
<td>✔ Name of Recipient (PROMIS Face sheet)</td>
</tr>
<tr>
<td>✔ Donor’s unique BCT identification number (assigned at time of transplant)</td>
</tr>
<tr>
<td>✔ Name of the healthcare professional that reviewed the questionnaire(s) and medical records.</td>
</tr>
<tr>
<td>✔ Identification of all individuals involved in donor assessment</td>
</tr>
<tr>
<td>✔ Consult letters</td>
</tr>
<tr>
<td>✔ Copies of all correspondence pertaining to the Live Donor during both assessment process and post donation.</td>
</tr>
<tr>
<td>✔ Documentation of all significant steps and activities performed by team members from referral to follow-up</td>
</tr>
</tbody>
</table>
**TEST RESULTS**

| ✓ | Manually transcribed test results and interpretation where applicable |
| ✓ | Hard copy of ABO blood type |
| ✓ | Hard copy of cross-match and tissue typing results from the Immunology Laboratory |
| ✓ | Hard copy of all laboratory results and tests with dates. At a minimum this includes: CBC, levels of serum electrolytes, Bilirubin, AST or ALT, levels of creatinine, PT or INR, and chest x ray. |
| ✓ | Hard copy of serology results from the Provincial Laboratory or other designated laboratory |
| ✓ | Height and weight |
| ✓ | Date and results of physical examination |

*Results of all tests, including those that are optional, must be included in the donor record (HC Guidance, 2013).*

**FORMS**

| ✓ | PROMIS Face sheet (Donor/Recipient Demographics and Identification numbers) |
| ✓ | Completed Medical Social History Questionnaire (MSHQ) and date of completion *(See Appendix B)* |
| ✓ | Completed Donor Consent Forms as per Section 2.6.9 |
| ✓ | Donor Candidacy Approval Form *(See Appendix D)* |
| ✓ | Living Donor 30-Day Med-Social Questionnaire *(See Appendix C)* |
| ✓ | QA Patient Chart Review Form: Living Donor Programs *(See Appendix H)* |
| ✓ | Donor assessment worksheet(s)* |
| ✓ | Coordinator Nurse Progress Notes (OPD) |
| ✓ | Exceptional Distribution Form (if applicable) |

*Worksheets used by Hospital staff and associated personnel are considered as tools to assist in collection of data and are deemed non-official and outside the scope of formal document control practices. Refer to BCT SOP, Document Management Program [RQA.02.001].*
Retention Time
The Donor Chart is kept for a retention time meeting applicable regulatory, Health Authority, and BCT Health Information requirements. Current requirements are “indefinite”. Refer to BCT SOP, Document Management Program [RQA.02.001].

3.1 Tracking of Donors and Recipients

Each Live Donor (where the referral culminates in a transplant) is assigned a unique Donor Identification Number (Donor ID Number). The Donor ID number is assigned by BCT ODHD (Organ Donation and Hospital Development) at the time of transplant.

Each potential transplant recipient is also provided a unique BCT Recipient ID Number upon registration with BC Transplant.

- The Name, PHN Number and BCT Recipient ID number of the RECIPIENT is linked to the donor in PROMIS.
- The Name, PHN Number and BCT Donor ID number of the DONOR is linked to the Recipient in PROMIS.

A PROMIS face sheet which describes the linkage of the Donor and Recipient is printed and included in the donor chart. It includes the demographics of both donor and recipient, date of transplant and Donor ID number / Recipient ID Number.

- If the Recipient is not a BC patient and the Live Donor travels outside the province to donate referrals are registered in PROMIS as per the usual protocol; however, the name of the Recipient and the Recipient transplant center is mentioned in the comments. Further tracking at the time of transplant is done as per the Recipient institutions’ policies.

3.2 Confidentiality and Privacy of Information

Patient charts include, or reference, all medical information pertinent to the patient, as the information applies to the patient’s involvement in the transplant program. External access to patient and/or donor information is controlled by current regulatory and privacy of information requirements. The living donor programs may collect, use and share this information under the authority of the Hospital Act, the Health Authorities Act and other legislation including the Hospital Insurance Act, Continuing Care Facilities Act, Health Act and Mental Health Act. BCT and the Hospital may also obtain personal information from external sources for medication details, diagnostic results or from the Ministry of Health to confirm patient’s identity and personal health number. A Notice to Patients describing how their information may be stored is posted in the patient wait areas (Appendix I).
All living donor staff and physicians will ensure that patient’s information is collected, used and shared in a **confidential** manner in accordance with the [BC Freedom of Information and Protection of Privacy Act (i.e. FOIPPA)](https://www2.gov.bc.ca/docs/default-source/laws-and-regulations/freedom-of-information-and-protection-of-privacy-act). The VGH Health Information Dept will ensure requests for release of information are appropriately authorized and follow required FOIPPA requirements.

All records must be stored in either designated secured areas and/or locked filing cabinets.

Patient’s information will only be used and shared as authorized by FOIPPA to:

- Maintain patient’s care and service needs
- Contact patient
- Provide educational support
- Support research as outlined under Section 35 of FOIPPA
- Uphold any matter as required by law
- Arrange payment
- Assist in improving the quality of our care and services

Requests for health record information from individuals or organizations other than the attending medical/care team are submitted to VGH Health Information Dept. A sample request form is shown in Appendix I.

**Additional Resources**

- Vancouver Coastal Policy (available through VCH Connect): Information Privacy and Confidentiality (IM_101)
4 RECIPIENT ASSESSMENT

For complete details on pre-transplant investigations of recipients, refer to Clinical Guidelines for Liver Transplantation (available at: BC Transplant website, under Healthcare Professionals).

4.1 Domino Liver Transplants

A patient may undergo a liver transplant and at the same time, donate their liver (Domino Transplant). Commonly this is performed as a result of the patient having a disorder such as familial amyloidotic polyneuropathy (FAP). Those patients that are being considered for a “Domino” liver transplant must be assessed using the same criteria as Living Donors (See Section 2).

How the process starts:
Patients are to discuss the option of a domino transplant with the surgeon at one of the pre-liver transplant recipient clinic visits and consent to evaluation. The Surgeon (or authorized designate) will perform a physical exam as per section 2.6.5). A Fibroscan® will be used to measure liver inflammation and fibrosis. Following review of the fibroscan results, the surgeon will discuss with patient and decide to continue. A liver biopsy will also be required.

If the liver is acceptable on fibroscan and the liver biopsy, then all remaining donor assessment tests are performed, including the medical social questionnaire, social worker/psychologist review.

Final Pre-Operative testing (Exceptional Distribution Requirement)
Health Canada requires all final serological testing to be performed within 1 month of OR date. In addition the Living Donor 30-Day Med-Social Questionnaire must be completed within 30 days before donation. As a domino liver transplant requires a deceased donor, the actual OR date can not be planned ahead of time. Thus, an exceptional distribution (See Section 2.7) is recommended to be completed following physician/surgeon approval indicating that these requirements may not be met.

Additional Resources

5 Operative Protocol

5.1 OPERATING ROOM BOOKING

Donor and recipient must both be approved and medically ready to proceed, prior to booking surgery. A surgical booking date is arranged by one of the liver transplant surgeons in consultation with the Clinical Coordinator, physician, donor and recipient.

5.2 Surgical Consent

Surgical consents are signed in accordance with the Hospital’s Policies and Procedures. All out of country live donors shall sign "Consent for Jurisdiction of Treatment (Non-Resident of Canada) form (See Appendix A).

5.3 Donor Admission

The admission protocols are determined by the transplanting hospital (VGH).

5.4 Donor Liver Surgery

The donor surgery is carried out according to accepted medical practice. Refer to Patient Handbooks at VGH.

Live donor liver transplants are done in a similar fashion to the standard liver transplant described in Clinical Guidelines for Liver Transplantation, except that instead of the whole organ, a portion of the organ is transplanted. In the case of Live Donor Liver Transplantation, usually half of the liver is removed from a Live Donor without cross clamping, perfused at the back table and stored just as though a whole organ is being transplanted. The remaining liver in the donor is more than adequate to maintain liver function and regeneration occurs within weeks to restore liver to normal function and several months to return to near normal mass.

Donor organ packaging and labelling is performed by BCT Organ Donation and Hospital Development (ODHD).
6 Post-Operative Protocol

6.1 POST-OP LIVE DONOR FOLLOW-UP

- The Live Donors Family Practitioner will receive copies of all clinical data;
- Live Donors who live outside the Vancouver area should have a follow-up clinic visit to see the Clinical Coordinator and the Transplant Surgeon before returning to their home;
- Live Donors should arrange a follow-up visit with their Family Practitioner within one month of discharge;

The following is the planned routine post-operative follow-up schedule. This may vary at the discretion of the Transplant Medical team.

<table>
<thead>
<tr>
<th>TIME FRAME</th>
<th>FOLLOW-UP REQUIREMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>4 to 6 weeks</td>
<td>Follow up with Clinic (Clinical Coordinator and Surgeon)</td>
</tr>
<tr>
<td>3 months</td>
<td>Abdominal imaging (usually with Doppler studies) and liver function blood tests with adjunctive studies</td>
</tr>
<tr>
<td>6 months</td>
<td>Abdominal imaging (usually with Doppler studies) and liver function blood tests with adjunctive studies</td>
</tr>
<tr>
<td>1 year</td>
<td>Abdominal imaging (usually with Doppler studies) and liver function blood tests with adjunctive studies</td>
</tr>
<tr>
<td>1 year</td>
<td>Clinic visit (Clinical Coordinator and Surgeon)</td>
</tr>
<tr>
<td>2 to 5 years</td>
<td>Abdominal imaging (usually with Doppler studies) and liver function blood tests with adjunctive studies</td>
</tr>
<tr>
<td>5 years</td>
<td>Yearly blood work. The need for imaging to be reassessed by surgeon and booked as deemed appropriate</td>
</tr>
</tbody>
</table>
6.2 RECIPIENT FOLLOW-UP

Standard recipient follow-up is described in Clinical Guidelines for Liver Transplantation and Clinical Guidelines for Transplant Medications (available at: BC Transplant website, under Healthcare Professionals).

Adverse Events
For any suspected recipient errors, accidents or adverse reactions that may be a result of donor disease transmission, the event will be immediately communicated to the immediate manager, Liver Medical Director, and the Department Director of ODHD (Operations Director), BC Transplant.

The event will be documented using the Patient Safety Learning System (PSLS). All adverse events and incidents will be fully reviewed, investigated, followed-up, and meet all hospital and regulatory requirements.

Refer to the following policies:

- BCT SOP, Errors, Accidents and Adverse Reactions [RQA.02.020]
# 7. Appendices

<table>
<thead>
<tr>
<th>Appendices</th>
<th>Example of Consent for Jurisdiction of Treatment (Non-Resident of Canada) (Vancouver Coastal)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appendix A</td>
<td>Example of Donor Disclosure and Med-Social Questionnaire</td>
</tr>
<tr>
<td>Appendix B</td>
<td>Example of Living Donor 30-Day Med-Social Questionnaire</td>
</tr>
<tr>
<td>Appendix C</td>
<td>Example of Donor Candidacy Approval Forms</td>
</tr>
<tr>
<td>Appendix D</td>
<td>Example of Live Donor Exceptional Distribution Form</td>
</tr>
<tr>
<td>Appendix E</td>
<td>Example of Consent for Medical Health Care / Blood Products</td>
</tr>
<tr>
<td>Appendix F</td>
<td>Example of Donor Participation Agreement &amp; Authorization for Release of Information</td>
</tr>
<tr>
<td>Appendix G</td>
<td>Example of QA Patient Chart Review Form</td>
</tr>
<tr>
<td>Appendix I</td>
<td>Notice to Patients on Collection of Personal Information</td>
</tr>
<tr>
<td>Appendix J</td>
<td>Health Canada Frequently Asked Questions – Living Donor Program</td>
</tr>
</tbody>
</table>

---

1 Note: Appendices may vary depending upon requirements of specific Hospital policies. Please refer to BCT-Quality Assurance and Vancouver Coastal Intranet (VCH Connect) for most current form versions and policies.
Appendix A

GOVERNING LAW & JURISDICTION AGREEMENT

Governing Law

I hereby agree that:

a) all aspects of the relationship between me and Vancouver Coastal Health Authority (as well as its agents, delegates, employees and any physicians and other independent health care practitioners providing medical or other health care and treatment to me at or in association with Vancouver Coastal Health Authority) including without limitation any medical or other health care treatment provided to me, and

b) the resolution of any and all disputes arising from or in connection with that relationship, including any disputes arising under or in connection with this Agreement

shall be governed by and construed in accordance with the laws of the Province of British Columbia and the laws of Canada applicable therein.

Jurisdiction

I hereby acknowledge that the medical or other health care and treatment I receive from Vancouver Coastal Health Authority will be provided in the Province of British Columbia, and that the Courts of the Province of British Columbia shall have exclusive jurisdiction to hear any complaint, demand, claim, proceeding or cause of action, whatsoever arising from or in connection with that medical or other health care and treatment, or from any other aspect of my relationship to Vancouver Coastal Health Authority.

Date and Time

Name of Patient (Please print)  Signature of Patient

Substitute decision-maker on behalf of patient

Name of Witness (Please print)  Signature of Witness
Appendix B

Dear Potential Donor:

Complete and return the following documents to:

Clinical Coordinator
Living Donor Kidney and Liver Program
Solid Organ Transplant Clinic
Pre-Transplant Assessment
Gordon and Leslie Diamond Center 5th Floor
2775 Laurel Street, Vancouver, B.C. V5Z 1M9

Phone: 604-875-5182
Toll-free: 1-855-875-5182
Fax: 604-875-5236

Completion of the questionnaire is necessary to comply with Health Canada Regulations for organ and tissue donation, and your hospital program standards. To ensure donation will be safe for both you and the person you would like to donate to, we need to ask questions about your current and past health. Many of the questions asked are similar to those asked when donating blood. Please answer all of the questions to the best of your knowledge and complete the forms yourself. If for any reason you cannot complete the forms yourself, please document a reason on page 10. All information is private and confidential and is used only to assess your suitability as a potential organ donor.

If you have any questions or concerns, contact the Living Organ Donor Program.

Yours sincerely,
Living Organ Donor Program
1. DONOR DEMOGRAPHICS

<table>
<thead>
<tr>
<th>First Name (Legal):</th>
<th>Middle Name (Legal):</th>
<th>Surname (Legal):</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preferred Name:</td>
<td>Birthdate:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(Day) / (Month) / (Year)</td>
<td></td>
</tr>
<tr>
<td>Personal Health Insurance No. / Care Card No.:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other Health Coverage Plan:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Health Insurance Expiry Date (**For Non-BC Health Coverage Only):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Height:</td>
<td>Weight:</td>
<td></td>
</tr>
<tr>
<td>Allergies (including medications, peanuts, shellfish or wasp/bee and other insect stings):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ethnic origin(s):</td>
<td>Blood Type if known:</td>
<td></td>
</tr>
</tbody>
</table>

If you have not previously provided the following information, please complete the section below:

Home Address: ____________________________________________________________

Home phone number: ____________ Cell phone number: ____________

Work phone number: ____________ Fax number: ____________

Which phone number is best to reach you?:

Email address: __________________________________________________________

Family Doctor Name: ____________

Address: ________________________________________________________________

Telephone: ____________________________ Fax: ________________________________

What organ does your intended recipient require? Please circle one of the following:

- Kidney
- Liver
2. DONOR DISCLOSURE

Acknowledgement of Human Tissue Gift Act of BC

As per Section 10 of the BC Human Tissue Gift Act (HTGC):
Sale of tissue prohibited
"A person must not buy, sell or otherwise deal in, directly or indirectly, for a valuable consideration, any
tissue for a transplant, or any body or parts other than blood or a blood constituent, for therapeutic
purposes, medical education or scientific research".

I________________________________________ have read the HTGC statement above, and I agree that I have not
and will not accept gifts, money, or incentives, directly or indirectly, in exchange for donating an organ.

I acknowledge and understand that the buying and selling of organs in Canada is illegal.

Print Name (Potential Donor) ______________________________ Signature __________________________
Date (dd/mm/yyyy)

Witnessed by:

________________________________________ / / /
Witness Name ________________________________ Witness Signature __________________________
Date (dd/mm/yyyy)

Relationship of Witness** __________________________ ("Can NOT be intended recipient)

If Translator Used:

________________________________________ / / /
Translator Name ________________________________ Translator Signature __________________________
Date (dd/mm/yyyy)

Relationship of Translator to Donor** __________________________ ("Can NOT be intended recipient)

FOR OFFICE USE ONLY – Initials of Reviewer: __________________________

Pg 3 / 10
3. MEDICAL AND SOCIAL HISTORY QUESTIONNAIRE

**COMPLETE IN INK – Do Not Use Pencil. Answer All Questions.**
You may provide additional comments for any question on page 9.

### GENERAL QUESTIONS ABOUT DONATION

1. What is the name of the person you want to donate to: ____________________________
   
   What is your relationship to the intended recipient (please be specific)? ________________
   
   How did you learn that the intended recipient could benefit from an organ transplant?: ____________________________
   
   Have you told the intended recipient of your wish to donate?:  [ ] Yes  [ ] No

2. Why do you wish to donate?: ____________________________
   
   ________________________________________________________________
   
   ________________________________________________________________
   
   ________________________________________________________________

3. Are you married or in a steady relationship?:  [ ] Yes  [ ] No
   
   Have you told your family or friends of your plan to donate?:  [ ] Yes  [ ] No
   
   Has anyone expressed any concerns about your plans to donate?:  [ ] Yes  [ ] No
   
   If yes, please explain: ________________________________________

4. Organ donation is major surgery and requires approximately 6 to 8 weeks off work to recover.
   
   What do you do for work?: __________________________________________
   
   Do you think you are able to take this time off without affecting your position?:  [ ] Yes  [ ] No
   
   Additional Comments: __________________________________________

### QUESTIONS ABOUT YOUR HEALTH

5. Do you consider yourself in:  [ ] Excellent Health  [ ] Good Health  [ ] Poor Health
   
   Do you see a family doctor or specialist for any on-going or chronic health concerns?:  [ ] Yes  [ ] No
   
   If yes, provide details: __________________________________________
6. Have you ever been admitted to a hospital?: □ Yes □ No
Have you ever had any operations or surgical procedures?: □ Yes □ No
   **If yes,** describe the reason for admission; date of admission and name of specialist or surgeon (if known):

   __________________________________________________________
   __________________________________________________________
   __________________________________________________________

7. Have you ever been diagnosed or treated for: **If yes** to any question, provide details:

<table>
<thead>
<tr>
<th>Condition</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heart disease</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stroke</td>
<td></td>
<td></td>
</tr>
<tr>
<td>High blood pressure</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diabetes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kidney stones</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kidney disease</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bladder or Kidney Infection</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lung disease (e.g., asthma, emphysema, COPD)</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Liver disease</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hepatitis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HIV, HTLV or AIDS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cancer (e.g., skin cancer, leukemia, lymphoma or any malignancy)</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Stomach disorders (e.g., Crohn’s disease, bloody stools, ulcerative colitis)</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Creutzfeldt-Jakob disease (CJD) (Mad-cow) or any prion-related disease</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Communicable diseases - Viral, bacterial, fungal; e.g. HIV, H1N1, rubella, measles, meningitis, encephalitis</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Dementia or Neurological Disorders (e.g., Parkinson’s, Lou Gehrig’s)</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Sexually transmitted infections (e.g., Syphilis, herpes, genitalia)</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>An animal bite that was suspected of carrying rabies?</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>
8. Have you ever had a psychiatric or emotional illness?: □ Yes □ No
   Did you, or are you currently seeing any mental health professionals?: □ Yes □ No
   If yes to any question, provide details: ____________________________

9. Do you take any medications (including prescription and non-prescription, over-the-counter, herbal)?: □ Yes □ No
   If yes, complete the following:
<table>
<thead>
<tr>
<th>Name of Medication</th>
<th>Dosage</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

10. Have you ever received: □ Yes □ No
   If yes to any question, provide details:
   Human growth hormone injections?: □ Yes □ No
   An organ or tissue transplant (e.g., bone, cornea, skin)? □ Yes □ No
   A graft or transplant of dura-mater (brain/spinal) tissue? □ Yes □ No
   Injected bovine insulin? □ Yes □ No
   Blood transfusions or other blood products (e.g., platelets, fresh frozen plasma, fibrinogen etc.)? □ Yes □ No
   If, were any of the products from the United Kingdom / Africa / Europe since 1980? □ Yes □ No

11. Have you ever been refused as a blood donor or asked not to donate?: □ Yes □ No
   If yes, why?: ____________________________

12. Tuberculosis Testing (TB) - Have you ever:
   Had a positive TB skin test?: □ Yes □ No
   Received treatment for TB?: □ Yes □ No
   Been vaccinated for TB?: □ Yes □ No
   Been exposed to someone with active TB?: □ Yes □ No
   If yes to any question, provide details: ____________________________

13. For females only:
   Have you had any pregnancies? □ Yes □ No
   If yes, were you ever diagnosed with gestational diabetes? □ Yes □ No
   If yes, describe any treatment: ____________________________
   Did you have high blood pressure during pregnancy? □ Yes □ No
   If yes, describe any treatment: ____________________________
   Are you currently trying to become pregnant? □ Yes □ No
   Do you have any plans for future pregnancies? □ Yes □ No
### QUESTIONS ABOUT YOUR FAMILY HISTORY

14. Do you have any children?  
   [ ] Yes  [ ] No  
   If yes, do any of them have any health concerns?  
   [ ] Yes  [ ] No  
   If yes, provide details:  

15. Do you have any siblings?  
   [ ] Yes  [ ] No  
   If yes, do any of them have any health concerns?  
   [ ] Yes  [ ] No  
   If yes, provide details  

16. Has anyone in your family been diagnosed or treated for:  
   If yes to any question, provide details:  
   - Heart disease  
   [ ] Yes  [ ] No  
   - Diabetes  
   [ ] Yes  [ ] No  
   - Stroke  
   [ ] Yes  [ ] No  
   - Cancer  
   [ ] Yes  [ ] No  
   - Kidney disease  
   [ ] Yes  [ ] No  
   - Liver disease  
   [ ] Yes  [ ] No  
   - CJD, Mad-cow or any prion-related disease  
   [ ] Yes  [ ] No  
   - Any other major disease?  
   [ ] Yes  [ ] No  

### QUESTIONS ABOUT YOUR TRAVEL HISTORY

17. In the past 12 months have you resided outside of Canada?  
   [ ] Yes  [ ] No  
   In the past 12 months have you traveled anywhere?  
   [ ] Yes  [ ] No  
   If yes to any question – where, when (Month/Year)  

18. Since 1980, have you spent 3 or more months outside of North America?  
   [ ] Yes  [ ] No  
   For example, Europe, Africa, Middle East?  
   If yes, where, when and for how long?  

19. Have you ever been exposed to, diagnosed, or suspected of having the following travel related diseases:  
   If yes to any question, provide more details:  
   - SARS (severe acute respiratory syndrome)  
   [ ] Yes  [ ] No  
   - West Nile Virus  
   [ ] Yes  [ ] No  
   - Malaria  
   [ ] Yes  [ ] No  
   - Chagas’ Disease  
   [ ] Yes  [ ] No  
   - Any other travel disease?  
   [ ] Yes  [ ] No
### QUESTIONS ABOUT YOUR PERSONAL HISTORY

As mentioned, our program wants to remind you of the sensitive and personal nature of some of these questions. We are required by law to ask these questions about all potential donors.

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>20. Do you currently smoke?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>If yes, how long have you smoked?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>How much do you smoke?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>If no, did you smoke in the past?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>How long did you smoke for?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>How much did you smoke?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>When did you quit smoking?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>21. Do you currently drink alcohol?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>If yes, how often?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>How much?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>If no, did you drink alcohol in the past?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>If yes, for how long?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>How much did you drink?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>22. Have you ever used non-prescription street drugs, e.g., Heroin, cocaine, crack, LSD, Crystal Meth, benzos, uppers, downers, marijuana, hashish, speed, ecstasy or anabolic steroids?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>If yes, what and how long?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Was a needle used?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>In the past 12 months have you:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Had sex with someone whose sexual background you don't know?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Been in a juvenile detention, lock-up, jail or prison for more than 72 consecutive hours?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Been exposed to known or suspected viral hepatitis or HIV infected blood through an accidental needle stick or through contact with an open wound, saliva, non-intact skin, or mucous membrane?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Had close contact with another person who has active viral hepatitis or yellow jaundice (e.g., lives in the same household, and shares kitchen and bathroom facilities)?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Have you or any sexual partner had sex with anyone who has AIDS, hepatitis B or C, HIV, or HTLV?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Had a tattoo, touch-up of a tattoo or an ear/body piercing?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>For Females only:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>In the past 12 months have you had sex with a man who had sex, even one time in the past 5 years with another man?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
24. In the past 5 years have you: If yes to any question, provide details:

- Have you or any sexual partner ever used a needle to inject drugs into your veins, muscle, or under the skin for non-medical use? [ ] Yes [ ] No ____________________________
- Have you or any sexual partner ever exchanged sex for money or drugs? [ ] Yes [ ] No ____________________________
- For Males only: In the past 5 years, have you had sex, even one time, with a man? [ ] Yes [ ] No ____________________________

25. Have you ever had sexual contact with anyone who was born in or lived in Central or West Africa? [ ] Yes [ ] No

If yes, please explain:

26. Is there any reason why you think you should not be an organ donor? No explanation is necessary. [ ] Yes [ ] No

ADD ANY ADDITIONAL INFORMATION, QUESTIONS OR COMMENTS YOU MAY HAVE:

________________________________________________________________________________________
________________________________________________________________________________________
________________________________________________________________________________________
________________________________________________________________________________________
________________________________________________________________________________________
________________________________________________________________________________________
________________________________________________________________________________________
________________________________________________________________________________________

FOR OFFICE USE ONLY – Initials of Reviewer: ____________
Name of Potential Donor

Signature of Potential Donor

Date

Was this Medical and Social History Questionnaire completed by person other than the potential donor

☐ Yes   ☐ No

If yes, reason it was completed by another person:

__________________________________________________________________________________________

__________________________________________________________________________________________

__________________________________________________________________________________________

Print Name of Person Completing Form if not the Potential Donor

Signature of Person Completing Form if not the Potential Donor

Date

For Office use only:

Comments / Follow up:

__________________________________________________________________________________________

__________________________________________________________________________________________

__________________________________________________________________________________________

Questionnaire reviewed by: ___________________________  Data: ___________________________

Full Signature
### LIVING DONOR 30-DAY MED-SOCIAL QUESTIONNAIRE
(To be completed within 30 days of scheduled surgery)

<table>
<thead>
<tr>
<th>General Health Questions</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Have you recently seen a doctor for any new health concern?</td>
</tr>
<tr>
<td>2. Have you had any recent health changes such as a cold, flu, fever?</td>
</tr>
<tr>
<td>3. Have you had any recent skin changes such as open sores, rashes, infected cuts?</td>
</tr>
<tr>
<td>4. Are you taking any prescription medications, non prescription medications including OTC (over-the-counter), or natural health products (e.g. herbas)? If yes, please list: Please inform the donor nurse if there is any change in any of your medication(s) (prescription/non-prescription, OTC, herbal) prior to your donation date.</td>
</tr>
<tr>
<td>5. Have you been vaccinated for any reason in the last 8 weeks? If yes, what vaccinations?</td>
</tr>
<tr>
<td>6. In the past 6 months have you resided outside of Canada or traveled anywhere? If yes - when and where?</td>
</tr>
</tbody>
</table>


| 7. Do you have any history of allergies (e.g., reaction to bee/wasp stings, peanuts, shellfish, latex)? If yes, what are you allergic to, and explain what happens when you have a reaction (e.g., anaphylaxis, life-threatening breathing problems, rash, etc) |
| 8. Do you currently smoke? If yes, when was your last cigarette? |
| 9. Patient aware to contact Clinical Coordinator (24 hours a day) if any concerns? |
| 10. Do you have arrangements for transportation to and from the hospital? |
| 11. Have you read your instructions for preparations for surgery from the pre-admission clinic? i.e., dietary restrictions, NPO, bowel prep? |
| 12. Where will you be staying the night before admission? |
| 13. What are your plans for staying in Vancouver following discharge? |
| 14. Additional contact names and numbers: |

VCH.VA.DC.0032 | APR.2016
It is a Health Canada requirement that the following questions are asked within 30 days of surgery.

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>15. In the past year have you had close contact with another person having clinically active viral hepatitis (e.g., living in the same household, where sharing of kitchen and bathroom facilities occurs)?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>16. In the past year have you been exposed to known or suspected viral hepatitis or HIV infected blood through an accidental needle stick, or through contact with an open wound, non-intact skin or mucous membrane?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>17. In the past year have you had sex with any person known or suspected to have HIV or clinically active hepatitis?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>18. In the past year have you had sex with someone whose sexual background you don’t know?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>19. In the past year have you had a tattoo, or ear/body piercing where shared or non-sterile instruments were used?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>20. In the past year have you ever been in a correctional facility, prison, or jail for more than 72 consecutive hours?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>21. In the past year have you been bitten by any animal?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>22. In the past five years, have you or any sexual partner received blood transfusions or other blood products?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>If yes, were any of the products human-derived clotting factor concentrates?</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>23. In the past five years, have you or any sexual partner ever used a needle to inject drugs into your veins, muscle, or under the skin for non-medical use?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>24. In the past five years, at any time have you or any partner ever exchanged sex for money or drugs?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>25. Male donors: Have you had sex with a man, even one time in the past five years?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>26. Female donors: In the last 12 months have you had sex with a man who had sex, even one time in the past five years with another man?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>27. Having answered all questions about medical conditions and behavioral risk factors is there any reason why you think you should not be an organ donor?</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

You do not have to give an explanation for your answer.

For Office use only:

Questions 1-3, 6, 7, 15-26 ALL YES ANSWERS TO BE REVIEWED WITH MEDICAL TEAM. Document any applicable required medical follow-up below. Document if this questionnaire completed by someone other than the potential donor (i.e. interpreter)

Comments:

Questionnaire reviewed by: ____________________ Date: ____________
Appendix D

**LIVE DONOR LIVER PROGRAM**

**CANDIDACY APPROVAL FORM**

Patient Name:
The above patient’s file including completed donor suitability assessment has been reviewed and she/he has been accepted as a candidate to undergo a liver resection for live liver donation.

Transplant Surgeon Signature  
Transplant Surgeon Printed Name

Date

<table>
<thead>
<tr>
<th>Completed Assessments:</th>
<th>Name</th>
<th>Date</th>
<th>Approved</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgeon:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Psychologist:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Social Worker:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Independent Medical Examiner:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other:</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

For Office Use:

Date Discussed in Activation Rounds: ___________________________

Approval Date: ___________________________

Decision Date for Surgery: (DR date to be requested) ___________________________

VCH.VA.DC.0054 | JULY 2013
# Appendix E

## BCT Live Donor Exceptional Distribution Form

<table>
<thead>
<tr>
<th>Name of Person Completing Form:</th>
<th>Date:</th>
</tr>
</thead>
</table>

### Part A

- Direct Donation
- Anonymous Donation
- KPD
- List Exchange

**KPD Donor Registry #:**

**For Direct Donation Only: Name of Donor:**

**PHN No.:** ___________________________  **BCT Donor ID #:** ___________________________

**Date of OR:** ___________________________

- Name of Organ: Liver
- Source Establishment: 
  - BC Transplant / Living Donor Program St. Paul’s (Kidney)
  - BC Transplant / Living Donor Program VGH (Kidney)
  - BC Transplant / Living Donor Program VGH (Liver)
- Other: Name:

### Reason for Exceptional Distribution:

(include all tests not completed or conditions not met and risk of disease transmission)

<table>
<thead>
<tr>
<th>Reason for Exceptional Distribution</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>--</td>
</tr>
<tr>
<td></td>
<td>--</td>
</tr>
</tbody>
</table>

### Part B – FOR TRANSPLANTING PHYSICIAN

*The justification for acceptance is for compassionate reasons related to the interests of the recipient, including medical emergency.*

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.

<table>
<thead>
<tr>
<th>Name</th>
<th>Signature</th>
<th>Date</th>
<th>Time</th>
</tr>
</thead>
</table>

**Recommended Recipient Medical Follow-up:**

[See Back of Form for Recommended Testing for Risk of Viral Mediated Disease Transmission]

<table>
<thead>
<tr>
<th>Reason for Exceptional Distribution</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>--</td>
</tr>
<tr>
<td></td>
<td>--</td>
</tr>
</tbody>
</table>
Vancouver Coastal Health Authority

Consent:

1. Health Care: Medical or Surgical

On behalf of the patient named above, I (the patient or his or her substitute decision maker) agree to the following treatment or procedure

________________________________________________________________________

(describe treatment/procedure) under the direction of ________________________________ (doctor’s name), M.D./D.D.S./Other ____________________________ (type of doctor)

The nature, anticipated effects, available alternatives and significant risks of the treatment, surgical operation, or procedure described above have been explained to me, and I understand the explanation.

I also agree to receive anesthesia and such anesthetics as may be considered necessary. I understand and agree that for the purpose of medical education and improvement of services: 1) there may be residents/students attending my treatment/procedure, either watching or participating, 2) that tissues, bodily fluids, devices, or implants removed in this procedure become the property of the hospital and may be used for such purposes, including teaching or research, as is approved by the hospital, 3) for quality improvement and other follow up, information about follow-up care in my doctor or dentist's office may be given to the hospital by my doctor or dentist, and 4) if receiving an implant, personal information such as my name and address must be sent to the provider of that implant, and will be subject to the laws of the country in which the implant originated.

I further agree that, if he or she finds it necessary, the health care provider named above may have other surgeons, physicians and hospital staff assist him or her and may permit them to order and/or perform all or part of my treatments, surgical operation, or procedure. I also agree that these other health care providers may have the same discretion in my treatment, operation, or procedure as the provider named above.

I also consent to such additional or alternative treatments, surgical operations, or procedures as the health care provider named above finds immediately necessary.

Signed: ________________________________ (Patient, or person legally authorized to give consent) / Hrs

(Date & Time of Patient Signature)

______________________________ (Relationship to patient if not the patient)

Signature of M.D./D.D.S.: ________________________________ (Provider obtaining consent)

Print Name: ________________________________

(if not patient)

Witness: ________________________________ (Witness)

(Where MD not present at time of signing)

Print Name: ________________________________

(Witness)

2. Administration of Blood Products

1. My doctor ________________________________ (doctor/surgeon’s name) has told me that during the treatment, ____________________________________________, it may be necessary for me to receive administration (transfusion, infusion, or injection) of blood products (blood, blood components or other blood products) such as red blood cells, plasma, cryoprecipitate, factor concentrate, platelets, albumin or immunoglobulins (IM or IV).

2. My doctor has told me about the risks of receiving blood products from volunteer donors. I understand that risks exist even though the blood products have been tested. I understand that in most cases the risks are small; however, serious injury and/or death may result in some cases.

3. My doctor has discussed autologous blood donation and other suitable alternatives with me. I have been told that even if my own blood is used, it may still be necessary for me to receive other blood products.

4. I have been given information on administration of blood products and the chance to ask questions about the benefits and risks of blood products. My doctor has answered my questions to my satisfaction.

I consent to the administration of blood products if it becomes necessary during my treatment.

Signed: ________________________________ (Patient, or person legally authorized to give consent) / Hrs

(Date & Time of Patient Signature)

______________________________ (Relationship to patient if not the patient)

Signature of M.D./D.D.S.: ________________________________ (Provider obtaining consent)

Print Name: ________________________________

(if not patient)

Witness: ________________________________ (Witness)

(Where MD not present at time of signing)

Print Name: ________________________________

(Witness)
Appendix F (Cont)

Vancouver Coastal Health Authority

Consent:
Special Considerations

1. Health Care: Medical or Surgical
2. Administration of Blood Products

Declaration by Interpreter:
I have accurately translated this document and acted as interpreter for the patient, who told me that he/she understood the explanation and consents to the treatment described on the other side of this form.

Signature of Interpreter

Print Name:

Interpreter

Telephone Consent: Health Care, and/or Blood Products
I have discussed the procedure outlined on the other side of this form and the anticipated effects of such treatment, surgical operation, or special procedure, including the significant risks and alternatives outlined with ____________________________, who is the patient's (state relationship) ____________________________, and he/she has given verbal consent for the procedure named above.

Signature of M.D./D.D.S.:

Print Name:

Provider

Certificate of Need for Urgent/Emergency Health Care

Medical Opinion(s) Regarding the Need for Urgent/Emergency Health Care — Including Blood Products
I hereby certify that it is necessary to provide the following health care: ____________________________, without delay in order to save the adult's life, to prevent serious physical or mental harm, or to alleviate severe pain, and the adult is, in my opinion, incapable of giving or refusing consent, and has not previously indicated (in the case of blood products, to preserve life or health) that consent would be refused.

I have been unable to consult with any available substitute decision-maker, within a reasonable time in the circumstances.

Signature of M.D./D.D.S.:

Print Name:

Provider

It is recommended, but not mandatory, that a second medical staff member of the Vancouver Coastal Health Authority — not a resident — sign this form.

I agree with the need for the health care set out above for this patient and with the opinion on incapability. This patient's condition poses an immediate threat to his/her life or health and emergency or urgent treatment is required.

Signature of M.D./D.D.S.:

Print Name:

Provider

Comments

__________________________________________________________________________

__________________________________________________________________________

__________________________________________________________________________

__________________________________________________________________________

__________________________________________________________________________

__________________________________________________________________________
Appendix G

DONOR PARTICIPATION AGREEMENT & AUTHORIZATION FOR RELEASE OF INFORMATION

AGREEMENT TO COMPLY WITH VCH's LIVER DONOR ASSESSMENT PROCESS, PREPARATION FOR SURGERY, AND REQUIREMENTS FOR FOLLOW-UP

I wish to proceed with the evaluation to find out if I can be a donor. I have received and read the Live Liver Donation, A Potential Donor's Guide. I understand the risks, benefits and alternatives to living liver donation. I am aware that if I have any questions or concerns at any time, I can obtain more information about living liver donor transplants by talking with the coordinator or on of the surgeons.

I understand that liver donation surgery offers no direct medical benefit to the donor. I am aware that I can opt out of the donor assessment process at any time.

I hereby agree to comply with the proposed processes and requirements for donors described in the information document. If I undergo the donor surgery I understand that I will require careful follow-up and that the Living Donor Coordinator will contact me from time to time after this surgery to inquire about my health and overall wellbeing.

CONFIDENTIALITY
I give permission to the hospital personnel who are involved in the course of my care to access my medical record, recognizing that they health care personnel are required to maintain confidentiality as per the BC Freedom of Information and Protection of Privacy Act and the policy of Vancouver Coastal Health Authority (VCH). If I do become a donor, I give consent to release data about my case, which may include my identity, to third parties involved in the transplant process as permitted by law, including the independent medical examiner, your family doctor and others as may be authorized by law.

RESEARCH
I consent to the release of aggregate donor data, without individual identifiers, for this research or for the purposes of public presentations.

SIGNATURES

Printed name of potential donor:

Signature          Date

Printed name of witness:

Signature          Date

VCH DRAFT | 03/2018
## QA PATIENT CHART REVIEW FORM
### LIVING DONOR PROGRAMS

<table>
<thead>
<tr>
<th>DONOR NAME:</th>
<th>RECIPIENT ID No.:</th>
</tr>
</thead>
<tbody>
<tr>
<td>OR Date:</td>
<td>Program: □ Living Kidney / □ Living Liver</td>
</tr>
</tbody>
</table>

### DONOR CHART

<table>
<thead>
<tr>
<th>DONOR CHART</th>
<th>COMPLETE</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Living Donor 30-Day Mid-Social Questionnaire [within 30 days of tx date]</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>PROMIS Summary Sheet (Recipient # / Donor ID #)</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Medical Social Questionnaire [signed and dated]</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Medical Evaluation</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Surgical Evaluation</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Social Worker Evaluation</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Psychologist Evaluation</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Donor Program Candidacy Approval Form</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

### Hospital Forms
- Pre Operative Patient Questionnaire
- Consent for Med. or Surg. Care / Admin of Blood Prod.

<table>
<thead>
<tr>
<th>Height:</th>
<th>Weight:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date Completed:</td>
<td></td>
</tr>
</tbody>
</table>

#### ABO Blood Group
- Chest X Ray
- CBC (WBC, RBC, Hgb, HCT, platelets)
- Na, K, Cl, Creatinine, Ca, PO4, BUN, eGFR
- UraInalysis
- Tbil, DBil, AST, ALT, INR, PT (liver)
- Histocompatibility / Tissue Typing

#### Mandatory Serological Testing
- anti-HTLV-1 and anti-HTLV-II
- anti-HIV-1 and anti-HIV-2
- HBV [HbAg □; HbAb □; HbAb (total) □]
- anti-HCV (HCV Ab or anti-HCV)
- syphilis (VDRL or RPR)
- CMV IgG
- EBV IgG

#### Other (CSA Recommended Testing)
- WNV (Seasonal / or based on travel risk)

#### To be completed within 30 days of OR Date
RN has verified with Dr. ____________ that an additional physical exam: □ IS □ IS NOT required
Date: ____________ Initiate: ____________

#### Is this an Exceptional Distribution?
If Yes - contact ODH and complete an E.D. form prior to OR date. Provide copy to BCT QA/ODHD
- Yes □ No □

Comments: ____________

Completed By: ______________________ DATE: ______________________
QA REVIEW: ______________________ DATE: ______________________

VCH/VADC.0034 | APR.2016

Assigned Donor ID No.: ____________
Appendix I

Notice to Patients - Personal Information Collection.

Caring for Your Information
Notice to our Patients, Clients and Residents

Collecting, Using and Sharing Your Personal Information

When you are receiving care, treatment and services at Vancouver Coastal Health Authority, our staff and physicians will collect personal information from you. Where permitted, we may ask your family, friends, or other organizations to give us information about you (e.g. copies of records, medication information or test results).

Your information may be entered into our electronic health information systems to assist authorized persons in quickly accessing pertinent information wherever you may be receiving care or services.

We collect, use and share your personal information under the primary authority of the BC Freedom of Information and Protection of Privacy Act ("FIPPA"). FIPPA and other legislations authorize us to use and share your personal information for these reasons:

- to identify you and keep in contact with you about your health care
- to provide ongoing care and support of care activities
- to help us plan, monitor, maintain and improve our care and services,
- for education and training (e.g. medical students) and to conduct research with consent or as permitted by law
- to know your eligibility for benefits and services and to arrange medical services billing
- to enable parties (e.g. Ministry of Health Services, Canadian Institute of Health Information) to confirm your identity, conduct planning and improvement activities, measure performance and fund healthcare
- to analyze, manage and control disease outbreaks and monitor the overall health of people
- as required by law (e.g. court order, reportable conditions) and as authorized by FIPPA

Your health information will be provided to your referring physician, other authorized health care professionals and their support staff, or health care agencies and facilities involved in your care to support continuous and consistent care and service. In some cases, these health professionals may look up your health information in our electronic health information systems in order to provide you with direct or supporting services.

If you are a patient in the hospital or residential care, we will provide your family or close friends who phone and ask about you with information confirming your admission and location. If you do not wish us to release this information, please inform a staff member within Patient Registration or within your care area.

eHealth and Your Information

eHealth is a provincial initiative that allows certain aspects of your health information to be accessed by authorized health care professionals throughout the province and not just within a particular region. Each Health Authority sends specific health information to a province-wide electronic information system, where it is stored with strict protections and used for limited and authorized purposes. For more information about eHealth, please visit the government eHealth website at http://www.health.gov.bc.ca/ehealth.

For more information

If you have any questions about this Notice and the protection of your personal information please go to www.vch.ca, search for “your privacy” and click on the link provided or contact the VCH Information Privacy Office at (604) 875.5568 or email: privacy@vch.ca

Revised July 2012
APPENDIX I (Cont)
Authorization for Release of Health Records Form

AUTHORIZATION FOR THE RELEASE OF HEALTH RECORDS
Please fax or mail your completed request to each hospital/facility you are requesting records from.
ATTENTION: Health Information Management, Release of Information Office

<table>
<thead>
<tr>
<th>Part 1. Patient / Resident Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>LAST NAME OF PATIENT</td>
</tr>
<tr>
<td>MAILING ADDRESS</td>
</tr>
<tr>
<td>TELEPHONE NO. (INCLUDING AREA CODE)</td>
</tr>
<tr>
<td>PERSONAL HEALTH NUMBER (CARECARD)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Part 2. Records Requested</th>
</tr>
</thead>
<tbody>
<tr>
<td>HOSPITAL(S)/FACILITY:</td>
</tr>
<tr>
<td>□ VISIT SUMMARY</td>
</tr>
<tr>
<td>□ PROOF OF VISIT (less may apply)</td>
</tr>
<tr>
<td>DATE(S) OF RECORDS REQUESTED:</td>
</tr>
<tr>
<td>If you do not know exact dates please provide your best estimate</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Part 3. Person Receiving Records</th>
</tr>
</thead>
<tbody>
<tr>
<td>NAME OF COMPANY OR ORGANIZATION (IF APPLICABLE)</td>
</tr>
<tr>
<td>Mailing Address</td>
</tr>
<tr>
<td>TELEPHONE NO. (INCLUDING AREA CODE)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Part 4. Patient Authorization (12 years of age or older)</th>
</tr>
</thead>
<tbody>
<tr>
<td>I, the patient, authorize the Hospital(s)/Facility to release the records requested to the person named in the “Person Receiving Records” section.</td>
</tr>
<tr>
<td>SIGNATURE OF PATIENT:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Part 5. Authorization on behalf of Patient (Please complete page 2 of form)</th>
</tr>
</thead>
<tbody>
<tr>
<td>If patient is under 12 years of age or unable to authorize the release of personal information.</td>
</tr>
<tr>
<td>By signing below I confirm that I have legal authority to act on behalf of the patient and I hereby authorize the Hospital(s)/Facility to release the records requested to the person named in the “Person Receiving Records” section.</td>
</tr>
<tr>
<td>□ I have indicated my relationship to the patient on page 2 of this form; and</td>
</tr>
<tr>
<td>□ If applicable, I have attached documentation to show my status as legal representative or guardian (e.g. copy of will, court order, legal agreement, or other documentation).</td>
</tr>
<tr>
<td>REASON FOR REQUEST:</td>
</tr>
<tr>
<td>YOUR FULL NAME:</td>
</tr>
<tr>
<td>YOUR SIGNATURE:</td>
</tr>
</tbody>
</table>

Internal Use Only

<table>
<thead>
<tr>
<th>ID OBSERVED:</th>
<th>PATIENT/REP SIGNATURE (on pickup)</th>
<th>DATE OF RELEASE</th>
<th>STAFF INITIAL</th>
</tr>
</thead>
</table>

This authorization must be signed by the patient/resident/authorized representative and must be dated within 6 months of the request being submitted. The BC Freedom of Information and Protection of Privacy Act (FOIPPA) allows (30) business days to respond to all requests.

Personal information contained on this form is collected under s. 26(2) of FOIPPA and will be used only for the purpose of responding to your request. If you have questions please contact the Health Information Management Release of Information Office.

Form No: PHC-MRS91 (Aug 26-15) Page 1 of 2
**Complete this side only if Part 5 on front of form is completed**

### Authorization on behalf of an incapable adult

Any of the following, acting within their duties or powers, may provide authorization on behalf of an adult:

- ☐ Committee appointed by court order (where records are required to carry out committee's duties)
- ☐ Person acting under a Power of Attorney (where records are required for financial or legal matters)
- ☐ Litigation Guardian (where records are required for litigation)
- ☐ Representative under a Representation Agreement (where records are required to carry out representative's duties)

If none of the above have been appointed, please explain relationship to patient:

### Authorization on behalf of an incapable minor

Complete this section if patient is a minor:

- under 12; or
- under 19 and not actively involved in decisions about health care.

Note: Patient authorization is required if patient is involved in decisions about care or has provided consent for care.

**Guardian:**

- ☐ by court order
- ☐ under a legal agreement
- ☐ parent who has lived with or regularly cared for child and there is no order or agreement removing my guardianship

### Authorization on behalf of a deceased patient

#### Decedent Adult

- ☐ Committee appointed by court order
- ☐ If there is no Committee, Personal Representative (Executor or Administrator of Estate)

  If there is no Committee or Personal Representative:

  **Nearest Relative:** first person referred to in the following list who is willing and able to act on behalf of deceased:

  - ☐ Spouse
  - ☐ Adult child
  - ☐ Parent
  - ☐ Adult brother or sister
  - ☐ Other adult relation other than by marriage: ____________________________
  - ☐ An adult immediately related by marriage: ____________________________

#### Decedent Minor (under 19)

- ☐ Personal Representative (Executor or Administrator of Estate)
- ☐ If there is no Personal Representative, Guardian (appointed by court, under an agreement, or a parent who has lived with or regularly cared for child)

  If there is no Personal Representative or Guardian:

  **Nearest Relative:** first person who is willing and able to act on behalf of deceased:

  - ☐ Spouse
  - ☐ Parent
  - ☐ Adult brother or sister
  - ☐ Other adult relation other than by marriage: ____________________________
  - ☐ An adult immediately related by marriage: ____________________________
1. How are Cells, Tissues and Organs regulated?

Human cells, tissues and organs that are to be used in transplantation are regulated under the Safety of Human Cells, Tissues and Organs for Transplantation Regulations (CTO Regulations). The CTO Regulations apply to all individuals and establishments in Canada that handle, process, distribute or import human organs or minimally manipulated cells and tissues for homologous use in transplantation in another individual.

The purpose of the CTO Regulations is to minimize the potential health risks to Canadian recipients of human CTO by addressing the safety in the processing and handling of these products.

The CTO Regulations are standard-based regulations, which means that they make reference to specific community standards developed and maintained by the Canadian Standards Association (CSA standards), thereby making the referenced sections mandatory. For example, specific sections of the following two CSA standards are referenced in the Regulations for the processing of perfusable organs for transplantation (refer to Question# 14 for the link to the CSA’s website):

- Z900.1-03 Cells, Tissues, and Organs for Transplantation and Assisted Human Reproduction: General Requirements (general standard) and
- Z900.2-03 Perfusionable Organs for Transplantation (organ standard)

As the CSA standards are living documents, continually revised and refreshed to address changing requirements and emerging technologies, all stakeholders play a key role in keeping the standards up-to-date. The stakeholders are encouraged to direct their comments, specific to the referenced sections of the Standards, to the CSA.

2. Why is it critical that organs be regulated under the CTO Regulations?

There have been known cases of disease transmission via organ transplantation, therefore, it is critical to regulate organs in order to minimize the potential health risks from organ transplantation. Furthermore, the recently reported case of a transmission of HIV in the United States, via an infected kidney from a living donor, underlines the need for regulatory requirements.

3. Who is responsible for processing and for determining whether the organ is safe for transplantation?

Under the CTO Regulations, the source establishments are responsible for processing organs, whether the processing activities are carried out by the source establishment or by another establishment. The source establishment is responsible determining whether an organ is safe for transplantation.

4. What are the responsibilities of the source establishment for living organ donor transplant program?

The source establishment is responsible for meeting all applicable sections of the CTO Regulations, including:

a. processing of the organ, even if some or all of the processing activities were carried out by another establishment on behalf of the source establishment.

In the case of organs, processing includes, donor suitability assessment, donor screening, donor testing, packaging and labelling as well as testing and measurements performed on the organ after it has been retrieved;

b. determining that the organs are safe for transplantation;

c. record keeping, investigating and reporting suspected error/accidents and adverse reactions and quality assurance which includes standard operating procedures and audit; and

d. exceptional distribution, personnel qualifications and training programs, facilities, equipment and supplies, etc.
5. In the case of an organ from a living donor, which establishment is considered the source establishment?

In the case of an organ from a living donor, the transplant establishment is considered the source establishment. This reflects the fact that the transplant program typically carries out the donor suitability assessment and determines whether the organ is safe for transplantation.

6. In the case of kidney transplants facilitated through the Canadian Blood Services’ Live Donor Paired Exchange Registry, which establishment is considered the source establishment?

The transplant establishment continues to be the responsible source establishment irrespective of the establishment that carries out the assessment of the donor or the organization that facilitates the matching of the donor and the recipient.

7. What are some of the key elements of the donor suitability assessment regulatory requirements?

The donor suitability assessment means an evaluation based on the information collected during donor screening and all donor testing results. It is critical that donors are screened to elicit general health information and to identify the risk factors that could potentially impact the safety of the organs.

- The donor must be screened in accordance with the sections 18 and 22 of the CTO Regulations. The assessment of a donor is based on the medical and social history, clinical status, physical examination, and tests. The information regarding the donor’s medical/social history and clinical status can be obtained through a donor interview and a review of the donor’s medical records or charts. The interview must be conducted using a medical/sexual/social history questionnaire that includes the applicable contraindications/exclusion criteria and other relevant questions required as per the CTO Regulations, and should be documented in the form of a checklist where the response/outcome for each criterion is recorded. This screening should be done as near as possible to the time of donation to ensure that the responses accurately reflect the current medical and social history of the donor.

www.healthcanada.gc.ca/inspectorate

- Also, in accordance with sections 18 and 22 of the CTO Regulations, a physical examination of the donor must be conducted and is considered to be one of the necessary components for determining donor suitability. The examination must be performed by a qualified person and include the assessment for evidence of high-risk behaviour and signs of infections. The results and date of the examination must be documented in the donor’s record. In the case of a living organ donor, the physical examination must be performed as part of the preoperative assessment process. In addition to assessing the health of the specific organ to be transplanted, the assessment of the donor for risk factors associated with anaesthetic and operative procedure must also be considered.

- Source establishments must determine that donors are not unsuitable to donate on the basis of the contraindications or exclusion criteria set out in section 13.1.3 and Annex E of the general standard and on the basis of the exclusionary criteria in section 13.2.2 of the organ standard.

- In the case of living organ donors, infectious disease tests must be performed on blood specimens taken within one month prior to surgery. The required tests are: antibodies to the human immunodeficiency virus, type 1 and type 2 (anti-HIV-1 and anti-HIV-2), hepatitis B surface antigen (HBsAg), total antibody to hepatitis B core antigen (anti-HBc, IgG and IgM), antibodies to hepatitis C virus (anti-HCV), antibodies to human T-lymphotropic virus type 1 and type II (anti-HTLV-I and anti-HTLV-II), syphilis using a non-treponemal or a treponemal-specific assay. In cases where the organs are not stored in a culture media at 4°C for more than 24 h. This is in addition to the tests specified in sections 14.1.2 and 14.3.2 of the organ standard.

- It is recommended that living donors be rescreened and retested at the time of donation, even if the test results will not be available before the time of transplantation; and

- For the detailed description of the regulatory requirements for donor suitability assessment, establishments must refer to the CTO Regulations, CSA Standards and the Guidance Document (Guidance Document for Cell, Tissue and Organ Establishments Safety of Human Cells, Tissues and Organs for Transplantation).
8. Do the transplant establishments as the source establishment for living organ donor transplant program need to register with Health Canada?

Yes, the transplant establishments are required to register with Health Canada as they are considered the source establishment under the CTO Regulations.

9. What is the process for registering with Health Canada?


As part of the registration, the medical or scientific director must certify that the establishment is in compliance with the CTO Regulations. This provides assurance to Health Canada that the establishment acknowledges its responsibilities under the CTO Regulations and that CTO imported, processed, or distributed in Canada meet the safety requirements set out in the CTO Regulations, and that procedures are in place to protect the Health and safety of transplant recipients.

10. Does Health Canada inspect the source establishment and what is the impact of a non-compliant rating on a registered establishment and the organ supply in Canada?

The safety of CTO for transplantations is paramount. In order to fulfill its responsibility, Health Canada conducts inspections, compliance verification activities, and investigations of CTO establishments under the authority of Section 23 of the Food and Drugs Act. Establishments are prohibited from distributing CTO that are not processed in accordance with the CTO Regulations. Health Canada works closely with the establishments to assist them with coming into compliance with the Regulations; however, a number of enforcement options such as the cancellation of their Health Canada registration are available particularly when the regulated party is unable or unwilling to correct their non-compliances.

Given the urgent and life-saving/life-enhancing nature of transplantations, in the cases where fully compliant organs are not immediately available, the Regulations provide a mechanism, referred to as Exceptional Distribution which allows for the distribution of organs that may not meet all of the requirements of the CTO Regulations. Exceptional Distribution is based on the clinical judgment of the transplant physician and requires the informed consent of the recipient.

11. What have Health Canada’s inspections of registered Canadian CTO establishments uncovered to date?

In general, the inspections have uncovered some deficiencies in the areas such as donor screening, donor testing, labelling, quality assurance system, training, and record keeping. Inadequate screening and/or testing of donors could result in an increased risk of disease transmission.

12. How often does Health Canada inspect CTO establishments?

Health Canada started the CTO inspections in August 2009, and it is anticipated that all the registered Canadian CTO establishments will be inspected by March 2012. In addition, where necessary, follow-up inspections will be conducted to assess whether corrective actions have been implemented. Currently, Health Canada is working towards the development of a comprehensive CTO inspection strategy where frequency of inspections will be established.

13. What are the key areas assessed during CTO inspections?

The key areas assessed during CTO inspections are: processing which includes donor screening, donor testing, donor suitability assessment, and labelling/packaging; quarantine; storage; exceptional distribution; records; personnel; facilities; equipment and supplies; error, accident and adverse reaction; quality assurance system including audits.

Health Canada has also developed a pre-inspection package that provides the establishment with a better understanding of the areas that Health Canada’s inspectors focus on during an inspection. A copy of this package is sent to the establishment prior to the inspection. A copy of this package can be obtained by sending the request to BTOX_STOX@hc-sc.gc.ca.

www.healthcanada.gc.ca/inspectorate
14. Where can one find more information regarding the CTO Regulations?

CTO Regulations:

Canadian Standards Association:
CAN/CSA-Z900.1-03 Cells, Tissues, and Organs for Transplantation and Assisted Reproduction: General Requirements
CAN/CSA-Z900.2.3-03 Perfusable Organs for Transplantation
http://www.shopcsa.ca/onlineshop/

Guidance Document:
Guidance Document for Cell, Tissue and Organ Establishments Safety of Human Cells, Tissues and Organs for Transplantation

Error/Accident Preliminary Reporting Form:
Human Cells, Tissues and Organs for Transplantation - Error or Accident Preliminary Investigation Report Form (FRM-0172)

Adverse Reaction Reporting Form:
Canada Vigilance Adverse Reaction Reporting Form

Regional Inspectorate Programs - Contact information
Inspectorate Program, Atlantic Region
Regions and Programs Branch (RAPB)
16th floor, suite 1825
1505 Barrington Street
Halifax, Nova Scotia B3J 3Y6
Telephone: 902-426-2100
Toll Free: 1-800-267-8675
Facsimile: 902-426-6676
Email: insp.acd-cao@hc-sc.gc.ca
Provinces: Nova Scotia, New Brunswick, Prince Edward Island, Newfoundland

Inspectorate Program, Quebec Region
Regions and Programs Branch (RAPB)
1001 St-Laurier Street West
Longueuil, Quebec J4K 1C7
Telephone: 450-646-1353
Toll Free: 1-800-661-3350
Facsimile: 450-928-4456
Email: gpo.coq@hc-sc.gc.ca
Province: Quebec

Inspectorate Program, Ontario Region
Regions and Programs Branch (RAPB)
2301 Midland Avenue
Toronto, Ontario M1P 4R7
Telephone: 416-973-1600
Toll Free: 1-800-207-9575
Facsimile: 416-973-2934
Email: insp.ONCC-CCQ@hc-sc.gc.ca
Province/Territory: Ontario and Nunavut

Inspectorate Program, Manitoba / Saskatchewan Region
Regions and Programs Branch (RAPB)
510 Lagimodiere Blvd
Winnipeg, Manitoba R2J 3Y1
Telephone: 204-984-1241
Toll Free: 1-800-984-9675
Facsimile: 204-984-2156
Email: insp.MSQC-CCQMS@hc-sc.gc.ca
Provinces: Manitoba and Saskatchewan

Inspectorate Program, Alberta Region
Regions and Programs Branch (RAPB)
720 - 9700 Jasper Ave.
Edmonton, Alberta T5J 4C3
Telephone: 780-495-2262
Toll Free: 1-800-207-9575
Facsimile: 780-495-2262
Email: insp.atl-coa@hc-sc.gc.ca
Province/Territory: Alberta and Northwest Territories

Inspectorate Program, British Columbia Region
Regions and Programs Branch (RAPB)
Suite 400 - 4505 Canada Way
Burnaby, British Columbia V5G 1J9
Telephone: 604-566-3350
Toll Free: 1-800-267-8675
Facsimile: 604-565-3149
Email: insp.BVCC-CCQ@hc-sc.gc.ca
Province/Territory: British Columbia and Yukon

www.healthcanada.gc.ca/inspectorate