



Clinical Guidelines for Living Donor Kidney Transplantation 2023





We aim to serve our patients with expert and exceptional care regardless of age, ethnicity, gender, race, religion, sexual orientation, gender identity or socioeconomic background and strive to embrace diversity, equity, belonging and inclusive excellence through our actions, policies and culture.



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1. INTRODUCTION

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

Purpose of the Clinical Guidelines:

- 1) To describe currently accepted approaches and best practices to living kidney donor 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), a program of the Provincial Health Services Authority) ([PHSA](#)) is responsible to coordinate and lead all activities related to organ donation and transplantation in B.C.

BCT contracts for living donor programs at three partner hospitals:

- Vancouver General Hospital (VGH)
- St. Paul's Hospital (SPH)
- BC Children's Hospital (BCCH) (peri-operative services only)

Living donor assessments may be performed at VGH or SPH.

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 kidneys both from deceased and **living** kidney 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 III [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 1](#)).*

BC Transplant and its partner hospitals are committed to meeting all requirements of Health Canada. As required, BCT has registered with Health Canada the following:

- BCT – Living Donor Program VGH (Kidney) Reg No. 100107
- BCT – Living Donor Program St. Paul’s Hospital (Kidney) Reg No. 100106

Additional Resources

BCT Quality Manual [RQA.02.100]

CSA Standard Z900.1 Cells, Tissues, and Organs for Transplantation: General Requirements; *Current version*.

CSA Standard Z900.2.3 Perfusable Organs for Transplantation; *Current version*.

[Kidney Paired Donation Protocol for Participating Donors 2014](#). Transplantation Oct 2015. Vol 99 Number 10S-1. Pg. S1 toS88

Available at: [Health Canada website](#)

- Health Canada Guidance Document. Safety of Human Cells, Tissues and Organs for Transplantation, *Current version*.
- Health Canada Guidance Document for Source Establishments – Reporting Adverse Reactions to Human Cells, Tissues and Organs, 2010.

Available at: [BC Transplant website](#) under Health Professionals:

- *Clinical Guidelines for Kidney Transplantation*

2. DONOR ASSESSMENT

Kidney transplantation from a living donor is the preferred treatment option for end-stage renal disease. 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*
- *You can plan for the date of the transplant*
- *It helps to alleviate the critical shortage of organs from deceased donors*
- *The National Kidney Paired Donation Program (CBS) makes live donor transplantation feasible for a greater number of individuals (see [Section 3](#) KPD & NDAD)*

2.1 How the Process Starts (Self-Referral Process)

Recipients are referred to one of three transplant centers (VGH, St. Paul's or BC Children's). Therefore, the potential kidney donor should contact the corresponding centre. Potential donors do not need a physician referral for initiation of the assessment process (i.e., Self-referral) (See Figures 1, 2).

- Donors must be at least 19 years of age
- Donors must come forward voluntarily

The transplant centers do not actively canvass donors because of the potential for unwelcome pressure. Interested donors should contact the transplant centre to indicate their willingness to explore donation. When a potential kidney donor contacts the transplant centre, they are supplied with information regarding the program.

More than one donor may come forward for assessment for each recipient.

The donor assessment process typically takes several months to complete (See Figures 1, 2). The duration of the assessment may be influenced by how straight forward the donor work-up is, scheduling, the donor's decision to move forward, or recipient factors such as readiness for it.

If donor tests show that the donor is unsuitable, no further testing is carried on. If the donor and recipient are not compatible the assessment process is stopped, unless both want to participate in the CBS Kidney Paired Donation Program (KPD) ([Section 3](#) KPD & NDAD).

Figure 1. Living Donor Assessment

Living Donor Assessment Pathway -SPH

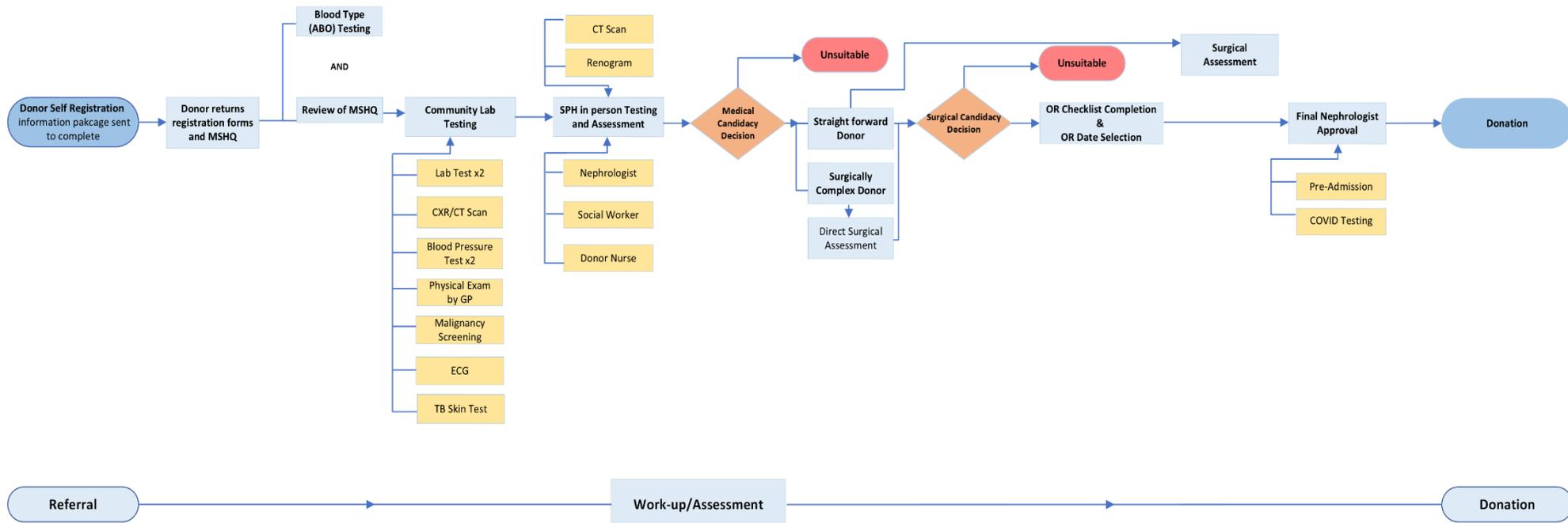


Figure 2. Overview of Living Donor Assessment Process.

Living Donor Transplant Process Overview

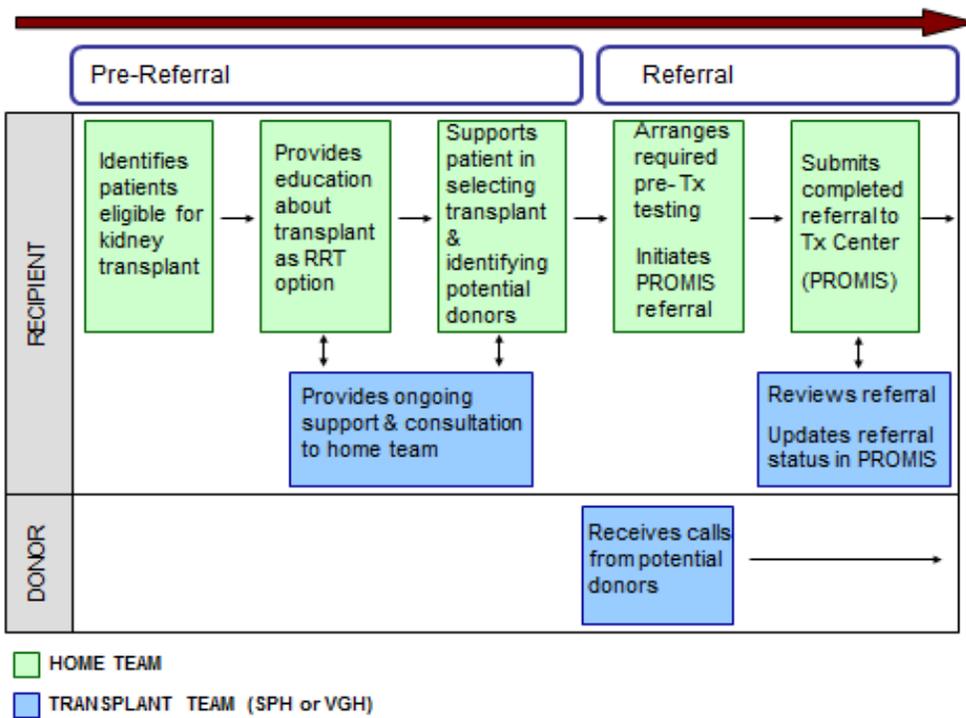
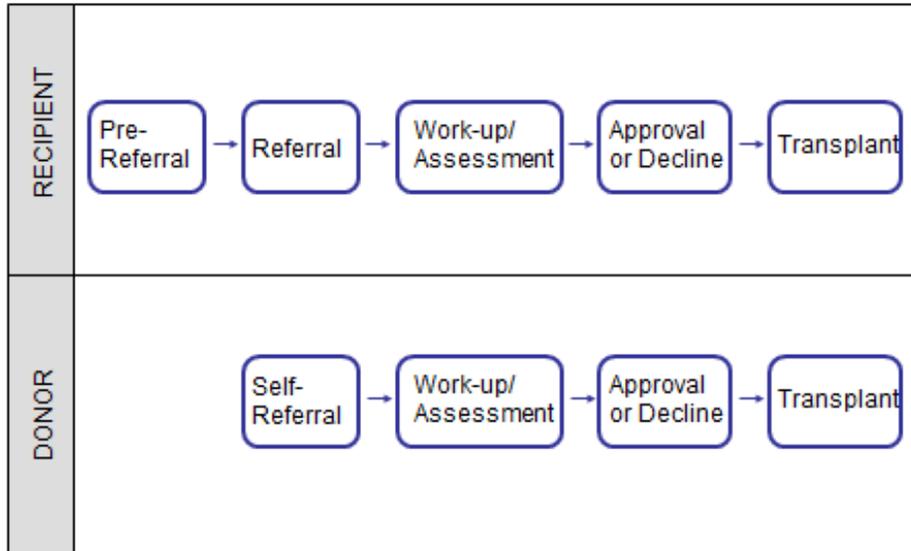
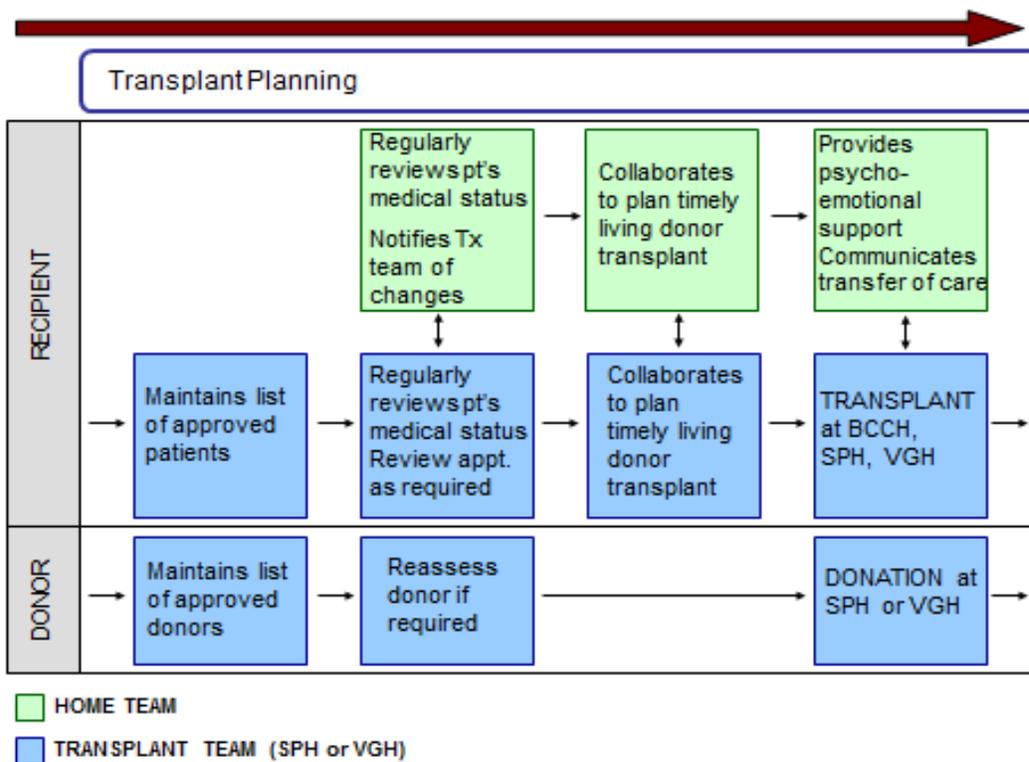
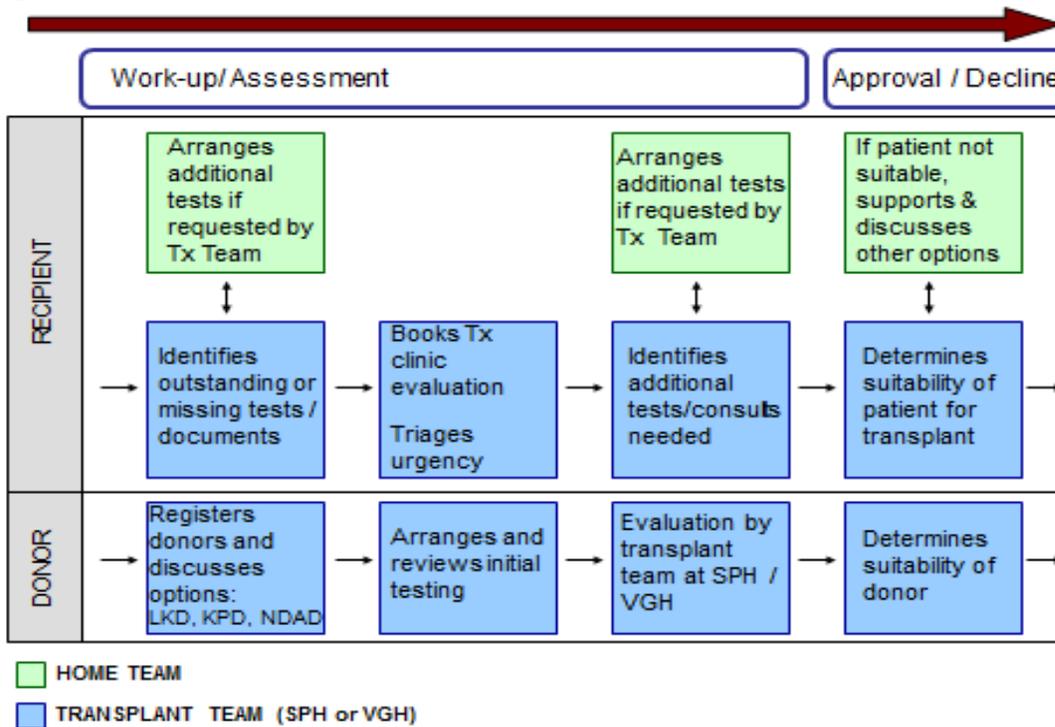


Figure 2. Continued.



Out-of-Province Donors

If a potential living kidney donor lives in another province, arrangements will be made for assessments to be performed at a centre closer to the donor's home. Donors may also be required to travel to the transplant centre in BC 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 kidney donor lives outside of Canada, the transplant centre must be satisfied that the relationship between the donor and recipient meets the eligibility criteria (See [Section 2.4 Eligibility Criteria](#)). The transplant center may make arrangements for preliminary assessments to be performed in the donor's country of residence. Initial testing to determine compatibility and general suitability will be requested and reviewed by the transplant centre.

Following the initial testing, some donors may travel to Canada to complete their testing. If a donor requires a temporary visa, they will need to comply with Immigration Canada policies. Out of country donors will be required to sign an additional Out-of-Country Consent form at the time of surgery.

The medical costs for donors out of country for donor assessment and/or surgery will be covered by the recipient's medical plan, once the donor is in B.C. Any medical costs not related to donor assessment and/or surgery must be through a third party provider.

Refer to Ambulatory Reference Document, Assessment and Approval of Living Donors from Out-of-Country [AMB.02.009].

Additional Resources

- Reference, Assessment and Approval of Living Donors from Out-of- Country [AMB.02.009]
- Form, Governing Law and Jurisdiction Agreement (Non-Resident of Canada) Vancouver Coastal Health

Donor Contact Information:

For Vancouver General Hospital:

Clinical Coordinator
Living Donor Kidney 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: 604-642-8812
Email: Kidneydonornurse@vgh.ca

For St. Paul's Hospital:

Clinical Nurse Leader / Nurse Coordinator
Living Donor Kidney Program
St. Paul's Hospital
Unit 6A – Providence Building
1080 Burrard St, Vancouver, B.C., V6Z 1Y6
Phone: 604-806-9027
Toll-free: 1-877-922-9822
Fax: 604-806-9873
Email: donornurse@providencehealth.bc.ca

For BC Children's Hospital:

Clinical Coordinator
BC Children's Hospital Transplant Clinic
Building K, 4F
4480 Oak Street, Vancouver, B.C., V6H 3V5
Phone: 604-875-3613
Fax: 604-875-2943

2.2 Minimizing Coercion and Compensation

- Donors must come forward voluntarily
- There should not be any pressure or coercion to donate a kidney
- Donors may withdraw at any time

The living donation team promotes the best interests of each donor. This includes helping to ensure protection of their privacy, 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.

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

Information shared between the donor, family physician and the transplant centre is **confidential** (Also see Section [4.2 - Privacy and Confidentiality of Information](#)).

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

Refer to Ambulatory Reference, Solicitation for Living Kidney Donors [AMB.02.006].

2.3 Costs

The BC Medical Services Plan (MSP) covers the medical costs of the living donor assessment for 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](#)

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

- Must be 19 years of age
- 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:

Medical:

- Age < 19 years
- Blood type incompatibility / Immunological incompatibility for direct donation (*see Kidney Paired Donation (KPD) & Non-Directed Anonymous Donation (NDAD)*, [Section 3](#))
- History of medical renal disease
- High risk of future renal disease
- Inadequate kidney function
- Significant proteinuria or microalbuminuria
- Uncontrolled hypertension
- Significant history of renal stones
- Morbid obesity
- Diabetes
- Significant medical illness or infectious disease
- Inability to obtain appropriate long-term medical follow-up
- Persons with rabies

Psychosocial:

- Inability to give informed consent
- Psychological instability
- Evidence of coercion
- Evidence of possible financial reward

Health Canada Contraindications:

The BCT SOP, [Exceptional Distribution](#) (Appendices I, II) [RQA.02.018] shows the various Health Canada contraindications and exclusionary criteria for living donors. Kidneys from potential donors identified with any of the criteria in Appendix I, II cannot be transplanted, unless they are authorized under Exceptional Distribution (Also see [Section 2.8](#) Exceptional Distribution and Reference Document: *Summary of Exceptional Distribution Criteria* [RQA.05.012])

Additional Resources (available on PHSA SHOP):

BCT SOP, [Exceptional Distribution](#) [RQA.02.018]

BCT Reference, Summary of Exceptional Distribution Criteria [RQA.05.012]

[Health Canada Policies](#)

Health Canada Guidance Document for CTO Establishments, [Safety of Cells, Tissues and Organs for Transplantation](#). *Current Version*.

CSA Standard Z900.1 *Cells, Tissues and Organs for Transplantation: General Requirements, Current version*.

- See Annex E – Factors and behaviours associated with a higher risk of HIV, HBV and HCV

CSA Standard Z900.2.3 *Perfusable Organs for Transplantation, Current version*.

- See Sections 13.1.2, 13.2.2

2.6 Living Donor Suitability Assessment Process

Donor suitability assessment is fully documented and based on:

- a) Medical Social History
- b) Testing
- c) Physical Examination, and
- d) Psychosocial Evaluation

A donor can withdraw from the evaluation process at any time

a) Medical Social History

Table 1 shows the minimum required donor medical history as per Health Canada. History of the donor is collected through chart review and administration of the Medical Social Questionnaire.

Medical Social History Questionnaire (MSHQ)

A standardized questionnaire reviewing medical and psychological history, social and behavioral risks shall be completed by each potential Live Donor (*i.e. the CBS KPD Protocol: Potential Donor Disclosure & Medical & Social History Questionnaire Doc No. F800854, or equivalent*). The Donor Nurse will review every question and discuss any concerns with both the donor and medical team as applicable.

The RN will review the questionnaire to ensure that no questions have been left unanswered or incomplete by the potential donor. This includes the Sections – “Questions about your Health”, “Personal History”, “Travel History” and “Family History”. These sections all need a response Yes, No, or Unsure. Where applicable, the RN will follow-up with the potential donor for further information and document on the Med-Social or in Clinical Notes. Further, the current CBS Med-Social rationale (Doc No. J800186) may be used as a reference guide.

For those donors who may not read or speak English, the questionnaire may be completed with the assistance of an interpreter such as a family member or a close friend, in exception to which the interpreter cannot be the intended transplant recipient. 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. A professional interpreter will be used by RN/coordinators when reviewing the completed MSHQ. If the potential donor is ruled out as a result of the information received on the questionnaire, the Donor Nurse will inform the donor.

Also see: [Living Donor 30 day Med Social Questionnaire](#)

Table 1. Minimum Required Donor Medical History as per Health Canada.

<i>DONOR MEDICAL HISTORY (as per CSA Z900.2.3; Section 12.2.2.3)</i>
<p>(a) any history of tuberculosis or positive skin-testing for tuberculosis, hepatitis, HIV infection, Creutzfeldt-Jakob disease (CJD), or other communicable disease; Note: <i>Other communicable diseases that could be of concern include (but are not limited to):</i></p> <ul style="list-style-type: none"> (a) <i>EBV (Epstein-Barr virus);</i> (b) <i>CMV;</i> (c) <i>Syphilis; and</i> (d) <i>Herpes;</i>
<p>(b) any history of malignancy, or other major illnesses, previous hospitalizations, previous surgical procedures, previous blood or blood-product transfusions, and current medications;</p>
<p>(c) any history of disease or abnormality of any of the consented organs or tissues;</p>
<p>(d) any suspected or confirmed diagnosis of West Nile virus (WNV) within the last 120 days, or travel in the preceding 56 days to areas where WNV is endemic;</p>
<p>(e) any suspected or confirmed diagnosis of an emerging infectious disease;</p>
<p>(f) any behaviour or history associated with higher risk of HIV, HBV, and HCV as specified in Annex E of CAN/CSA-Z900.1 (See Exceptional Distribution (Appendix II))</p>
<p>(g) history of travel or residence outside Canada and the United States <i>Note: establishments should develop Sops in conjunction with an infectious diseases specialist. Travel history and timeframe of travel history in conjunction with donor symptoms, medical records, and findings of the physical exam can help rule out active infections that could be acquired abroad. Travel related diseases to consider include the following: malaria, Chagas, Zika, Ebola, Dengue, Strongyloides, and WNV</i></p>
<p>(h) history of animal bite in the past six months; and</p>
<p>(i) any history of potential life-threatening allergy**</p>
<p>Notes:</p> <p>(1) <i>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.</i></p> <p>(2) <i>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 2018)).</i> See Documentation of a Serious Donor Allergy Alert, below</p>

Documentation of a Serious Donor Allergy Alert

The Living Donor RN will communicate a serious allergy alert to the recipient program and document as follows:

- For VGH - on the QA Patient Chart Review Form ([Appendix I](#))
- For SPH - on the Final Approval Checklist - Physician Form ([Appendix II](#))

b) Testing

Donor testing is comprised of (including but not limited to) blood typing for compatibility, immunological compatibility, serological testing for infectious disease, and laboratory and other studies.

i) Blood Typing Compatibility

The donor and recipient blood types will be verified by the Donor Nurse. See Table 2.

Table 2 Blood Type Compatibility¹

There are 4 basic blood types: A, B, AB, and O.		
If you are:	You can receive from:	You can donate to:
O*	O	A, B, AB, O
A	O, A	A, AB
B	O, B	B, AB
AB**	A, B, AB, O	AB

Universal donor *

Universal recipient ** It is not necessary for the donor and recipient to have the same Rh (rhesus) factor + / -.

¹Note: incompatible donor-recipient pairs (blood type or immunological) may be eligible for the National Kidney Paired Donation (KPD) program. See [Section 3](#).

ii) Immunological Compatibility

An initial immunological cross-match and HLA typing will be completed during the assessment.

The results are reviewed to determine compatibility between the donor(s) and recipient. Results are communicated to the potential donor(s).

iii) Serological Testing

At a minimum, donors undergo serological testing as described in Table 3. The living donor is notified of any positive or reactive results when confirmed and informed that the results will be reported to their family practitioner and regulatory agencies, as required by law.

Table 3. Minimum Donor Serological Testing

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

¹*It is not necessary to re-test for disease markers for which the donor is already known to be positive (e.g., CMV, EBV)*

²**For syphilis**, kidney(s) 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 kidney(s) shall not be released for transplantation if the donor's specimen is reactive or positive.

³*May be reported retrospectively*

⁴**For CMV and EBV**, kidneys 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.

ALL TEST RESULTS RECEIVED AT ANY TIME FROM REFERRAL DATE TO DAY OF DONATION, INSIDE OR OUTSIDE OF 30 DAY WINDOW WILL FOLLOW THE SAME PROCESS.

All POSTIVE / FALSE POSITIVE / INDETERMINATE or EQUIVOCAL serology results¹ are to be released through Exceptional Distribution.

- **This includes any repeat testing or NAT in which the supplemental /additional testing is NEGATIVE.**
- **This includes any previous testing results from time of donor referral.**

¹ HBV, HCV, HIV, HTLV, Syphilis, WNV

a) Incomplete/Pending Results:

If test results described in Table 3 are not available prior to transplant - **Exceptional Distribution required** (except for EBV, CMV, Hep B Surface Antibody).

b) Positive Infectious Disease Results:

i) Hep B,C, HIV, HTLV, Syphilis, WNV:

Exceptional Distribution required. Communicate the results to the transplant programs.

ii) EBV, CMV, Hep B Surface Antibody:

Exceptional Distribution **NOT** required. Communicate the results to the transplant programs
May be reported retrospectively.

c) Positive Serology Test / Negative NAT

Exceptional Distribution required. If a donor has a positive serological test, but is found to be negative using NAT, the organ(s) can only be transplanted using exceptional distribution ([Health Canada Guidance 2018](#)).

d) False Positive Result

Exceptional Distribution required.

If a test result is initially positive for HEP B, C, HIV, HTLV, Syphilis or WNV it may be repeated by the BCCDC Lab. If the supplemental or confirmatory test is negative (ie. “false positive”), an Exceptional Distribution is still required to be completed.

e) Repeat Reactive

Exceptional Distribution required.

If a serology test is still positive on repeat testing, it is documented as “repeat reactive”.

f) Indeterminate/Equivocal Results

Exceptional Distribution required (Except EBV, CMV, Hep B Surface Antibody)

Discuss the results with the Medical Director (or designate) and microbiology consultant. As equivocal/indeterminate results may be indicative of potential infection, all organ programs are made aware of the results.

▪

Exceptional distribution **MUST be used if the donor specimen is repeatedly reactive or positive for infectious disease agents.**

See Section 2.8 [Exceptional Distribution](#)

For further information of interpretation of infectious disease results consult: [Health Canada Guidance 2018](#) and Transplant Infectious Diseases Specialist.

Additional Resources

CBS Med-Social Rationale

BCT Reference, Summary of Exceptional Distribution Criteria [RQA.05.012]

Travel History:

- [CDC Malaria Risk Information](#)
- [CDC West Nile Virus](#)
- [WHO](#)
- [Public Health Agency of Canada](#)
- [CDC - Zika Virus](#)
- [Government of Canada - Zika Virus](#)

Ambulatory Reference Document, Education of Potential Live Donors [AMB.02.002]

iv) COVID Screening for Living Donors

The Nephrologist will assess each donor for risk of COVID-19 and determine the requirement for Exceptional Distribution. The following COVID general screening protocol at VGH/SPH is current as of Nov, 2022 but may change based on clinical decisions of the Nephrologist and/or transplant infectious disease. Specific hospital policies may also vary concerning Ambulatory follow-up plan.

PRIOR TO DONATION POTENTIAL DONORS WILL:

1. Complete a COVID-19 screening questionnaire (*Recommend minimum within 24-72 hrs pre-op*)
2. Receive a COVID-19 test (NP Swab, Rapid, or other approved test) (*Recommend minimum within 24-72 hrs pre-op; dependent on vaccination status; a previous COVID positive result*)
3. Self-isolation in home/social distancing for 14 days prior to OR (*assessment on a case by case basis, e.g., vaccination status*)

EXAMPLE OF COVID-19 SCREENING QUESTIONNAIRE

1. Have you had a diagnosis of COVID in the last 28 days?
2. Have you been admitted to hospital within the last 28 days?
3. Have you been tested for COVID in the last 28 days?
4. Do you have any of the following symptoms: fever/feverish, new or existing cough, difficulty breathing, diarrhea/nausea/vomiting, new fatigue, loss of smell or taste?
5. Have you had any of these symptoms in the last 28 days?
6. Have you traveled internationally or domestically within the last 14 days?
7. Have you had contact with a confirmed or probable COVID-19 case?
8. Have you had contact with a person with acute respiratory or GI illness in the last 28 days?
9. Have you been self-isolating in the last 14 days?

*Exceptional Distribution required for any COVID positive test within past 28 days of donation

Note – in most cases surgery will be postponed if patient has/had a COVID infection within 28 days of scheduled surgery. Surgery date will be delayed a minimum of 28 days post-infection or until asymptomatic if symptoms persist beyond that.

All potential living donors should be advised to practice significant social distancing for 14 days prior to surgery. All living donors should not travel and be very careful to avoid contact with others who have respiratory or flu like symptoms in the 14 days prior to donation.

References

Health Canada. Notice Mar 13, 2020. [Measures to Address the Potential Risk of Transmission of the Novel Coronavirus Responsible for COVID-19 by Human CTO](#)

[CBS Consensus Guidance for Organ Donation and Transplantation Services during COVID-19 Pandemic. Current Version.](#)

v) Laboratory and Other Studies

To qualify as a kidney donor, the donor must be in good health with excellent kidney function. To evaluate this, the following minimum tests are required¹:

Health Canada Mandatory Tests

- a) **Height**
- b) **Weight;**
- c) **ABO Blood Type**
- d) **Complete Blood Count (CBC)** to include at minimum hemoglobin, hematocrit, white blood cell (WBC), platelet counts
- e) **Levels of serum electrolytes**, to include at minimum sodium and potassium
- f) **Levels of creatinine;**
- g) **Chest X ray or CT Scan**
- h) **Urinalysis**
- i) **Urea Testing (BUN)**

Laboratory

- Electrolytes, Urea, Creatinine (x2), Uric acid
- Calcium, Phosphate, Magnesium
- Alkaline Phosphatase, Total protein, Total and direct Bilirubin, Albumin, AST, GGT
- Fasting blood sugar
- Full lipid profile
- CBC and differential, Platelets, PTT, INR

Urine

- Urinalyses (x2)
- Midstream urines for culture and sensitivity (x2)
- Urines for ACR (x2)

Radiology Studies

- Chest X-ray
- Electrocardiogram
- Abdominal ultrasound (*if indicated*)
- Mammogram for females (*dependent on age & family history. Refer to BCCA Guidelines*)
- Nuclear renogram and GFR with differential split
- 3D spiral CT scan

Other

- Blood pressure readings
- PAP smear for females (*As clinically indicated. Refer to BCCA Guidelines*)
- PSA for men > 45 years
- Pregnancy test (if indicated)
- Height/weight
- TB skin test or IGRA (*for BC Donors*)
- FIT (Fecal Immunochemical Test) or colonoscopy (> 50 years)

These are the minimum required tests required for donors being worked up in BC (Other Canadian programs may have different requirements)

The results of these tests are reviewed. Additional tests may be performed as required by Health Canada or the medical team.

vi) Test Recording and Reporting

All test results will be reviewed by the Donor Nurse and become a confidential part of the Live Donor's chart (See Section 4 [Documentation](#)). Test results will be given to the donor and family physician only. 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*).

c) Physical Examination

In the case of a potential living donor, all donors **must** be given a physical exam by a physician and/or surgeon and includes (as per CSA Z900.1 Sections 12.3, 13.1.3, 13.2, Annex E & CSA Z900.2.3 Sections 12.2.3.4, 12.2.3.7, 13.1.2, 13.2.2):

- a. A determination of the health of the organ (Kidney) to be donated;
- b. Any evidence of high-risk behavior for HBV, HCV, or HIV (As per Appendix II in SOP, [Exceptional Distribution](#)) [*Note - BC Transplant physicians hereby define high-risk behaviour for living donors as needle tracks or other signs of injection drug abuse*];
- c. Any evidence of contraindications as per Appendix I in SOP [Exceptional Distribution](#) and [Section 2.5](#) Exclusionary Criteria (reviewed in conjunction with Med-social and donor history);
- d. Persons with unexplained lymphadenopathy mass or mucocutaneous lesions;
- e. Signs of bacterial, fungal, parasitic or viral infections of clinical significance and signs of malignancy ([Health Canada Guidance 2018](#));

If the conclusions of the physical exam confirm the presence of any suspected risk factors (as per SOP, [Exceptional Distribution](#) Appendices I, II), the kidney can only be released under Exceptional Distribution (See [Section 2.8](#)).

Repeat Physical Examinations

If the social or medical history contains evidence that could indicate high-risk behavior, or if a risk factor is identified in the living prospective donor, a new physical exam shall be performed. The exam shall assess any physical evidence that could indicate high-risk behavior associated with the presence of a transmissible disease (CSA Z900.1 13.2.3).

Documentation of the Physical Exam

It is recommended that the CBS Physical Exam form (Doc No. F800857), or equivalent be used to document the physical exam. In lieu of the CBS form, a detailed Physician letter describing the physical exam of the donor (and meeting Health Canada requirements) will be included in the donor chart.

Timing of Physical Exam

It is recommended ([Health Canada Guidance 2018](#)) 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:

- For Patients at VGH: “QA Patient Chart Review Form – Living Donor Kidney” (Form No. VCH.VA.DC.0034) ([Appendix I](#))
- For Patients at St. Paul’s: “Living Donor Transplant FINAL Approval Checklist Physician” form (Form No. RU201) ([Appendix II](#)).

d) Clinic Visit / Transplant Team Evaluation (including psychosocial evaluation):

A clinic visit and donor team evaluation is booked if the donor and results are acceptable, and they wish to proceed. This portion of the evaluations includes the following:

Donor Nurse: Provides donors and their families with information about the process of donation either through direct or paired donation, including the testing required and clarifies any questions. Follow-up protocols are discussed. The donor is given an opportunity to decline further testing and donation.

Transplant Nephrologist: Carries out a medical history and physical examination. Assessment of the potential kidney donor includes an assessment of their current clinical status, anesthetic, surgical risks and long-term health risks, as well as assessment for the quality of the kidney to be donated. Transplant success rates and possible outcomes for both the donor and recipient are discussed. The donor's motivation to donate is explored. The physician must be assured that the donor is capable of giving informed consent and is not being subjected to coercion.

Transplant Surgeon: Discusses the surgical approaches to donor nephrectomy. Surgical risks and post-operative recovery are reviewed in detail. The Surgeon must be assured that the donor is capable of giving informed consent and is not being subjected to coercion. Surgical approval is documented on the applicable VGH or SPH Donor Candidacy Form. In addition, a Surgical Consult letter and/or the CBS Living Kidney Donor Surgical Review Form (Doc No. F800859) may be used.

Social Worker: Conducts a psychosocial interview to determine suitability for donation. The interview includes an assessment of social support, financial resources and the donor 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. The psychosocial assessment is documented and discussed with the transplant team. Whenever possible, the CBS Psychosocial Assessment Form (Doc No. F800858) is used.

Transplant Psychologist (where applicable, e.g. NDAD): Conducts a psychological interview to determine emotional suitability for donation. The donor and recipient's relationship is explored. Psychological motivation for donation is determined. The possible psychological pitfalls are discussed in the event of a successful or unsuccessful transplant. The Psychologist must be assured that the donor decision is not being influenced by financial incentives or coercion. In addition, the Psychologist must be assured that the donor is capable of giving informed consent. The results of this interview are recorded in the patient chart and discussed with the transplant team.

A professional language interpreter will be used for the above interviews when necessary.

The transplant team may consult with an ethicist or spiritual care as needed.

2.7 Final Donor Suitability Assessment

a) Assessment Outcome

All potential donors undergoing a transplant team assessment will be reviewed at regular multidisciplinary donor team rounds, where a review of the donor's medical and team evaluation is done. At that time, a decision will be made about the donor's candidacy based on the guidelines as previously outlined. A Donor Program Candidacy Approval Form (Doc No. VCH.VA.DC.0035 or RU198), is completed and placed in the donor file.

If further investigations or consultations with other specialists are required to make a final adjudication about the donor candidacy, the donor file will be reviewed again once those results are available.

i) Donor Suitability - Approval for Final Donor Testing & Questionnaire

If a donor is approved, he or she is informed by the Donor Nurse. If the donor chooses to proceed, an appropriate surgical date is chosen in collaboration with the donor and recipient teams. The recipient and their primary nephrologist will be notified of the surgical date.

ii) Donor Unsuitability

Individuals who are declined as donor candidates will be notified by the Donor Nurse citing the reason. Where a medical issue is identified, a letter will be sent to the individual's family physician, outlining the reason(s) that the donor was turned down and suggestions for further follow-up.

b) Final Pre-operative Donor Testing

i) Final Cross-match

Final immunological testing (i.e. cross-match) between the donor and recipient is arranged preferably 10-14 days before the scheduled OR date (not to exceed 4 weeks prior). Final results are reviewed prior to transplant and any changes/concerns discussed with the transplant nephrologist.

ii) Re-testing of Serology (Final Testing)

All serology must be re-tested within 30 days of the surgery (Refer to [Table 4](#)). It is not necessary to re-test for disease markers for which the donor is already known to be positive (e.g., CMV, EBV).

All final serological testing (BC Donors and Out of Country) is to be performed at an approved qualified lab such as PHSA Labs (BCCDC). Ensure blood samples are requisitioned in time for those potential donors who are out of province. All laboratories performing "Final" serological testing must use test kits licensed by Health Canada.

For donors out of province (e.g., Kidney Paired Donation), final serological testing may be performed in their province of residence if the following conditions are met:

- i) Final serological testing is performed within 30 days of transplant date; **and**
 - ii) A current list of test kits with identification numbers used by the testing laboratory has been received and reviewed by the BCT Quality Program. Also refer to BCT SOP, Audit Program [RQA.02.004] and BCT Supplier Management Program [RQA.02.012].
- OR iii) Completion of a *CBS Retrieval Establishment - Approval of Living Donors for Shipping of Kidneys Checklist* (Also see Section [3.3 Shipping of Kidneys](#))

BCT Quality Program is responsible for ensuring that laboratories meet the requirements of Health Canada testing.

iii) Living Donor 30-DAY Med-Social Questionnaire (Mini-Med-Social)

The Donor Nurse will ensure completion of the Living Donor 30-Day Med-Social Questionnaire (CBS KPD Protocol: Potential Donor 30-Day Medical & Social History Questionnaire, Doc No. F800855). The Donor Nurse will review every question and discuss any concerns with both the donor and medical team as applicable. All questions must have a response.

30 Day Questionnaire – completed longer than 30 days from OR retrieval date.

As per HC Guidance, *“in the event that more than one month has elapsed since the donor screening questionnaire was completed and the retrieval has not yet occurred, Health Canada recommends reviewing the living donor screening results with the donor as close to the time of retrieval as feasible in order to ascertain whether any of the information has changed. In such instances an abbreviated donor screening questionnaire would be acceptable provided it addresses all the necessary exclusion criteria”*.

If a review prior to OR was not possible with the donor, then a BCT Quality review with the Medical Director or Nephrologist should be performed in order to determine any risk of disease transmission and possible reporting to Health Canada.

iv) Confirmation of Blood Type

Repeat blood typing of donor/recipient will be confirmed prior to OR.

v) Additional Testing

Additional testing such as electrolytes, CBC, CXR, ECG, COVID and a pregnancy screen may be required pre-operatively.

c) Final Assessment (Donor Safe to Proceed to OR)

The RN will communicate any contraindications to donation as reviewed in the final 30 day Med Social questionnaire or serology (as per [Table 3](#)) to the medical and/or surgical team. **It is the responsibility of a qualified** transplant nephrologist to complete a final review of all available clinical information and donor history as per CTO Regulations and Clinical Guidelines.** This includes careful review of Appendix I, II in SOP [Exceptional Distribution](#), [Table 1](#), [Table 3](#), and determining there have been no significant changes since earlier completion of the Donor Candidacy Form and original Physical Exam.

The nephrologist will make a final assessment of the donor being:

Safe to Proceed for Organ Donation
Or
Accepted to Proceed for Organ Donation under the Provisions of Exceptional Distribution.

Documentation of the Final Assessment

The final assessment is documented on:

- For Patients at VGH: “QA Patient Chart Review Form – Living Donor *Kidney*” (Form No. VCH.VA.DC.0034) ([Appendix I](#))
- For Patients at St. Paul’s: “Living Donor Transplant FINAL Approval Checklist Physician” form (Form No. RU201) ([Appendix II](#)).

***For a current listing of qualified physicians refer to BCT Listing of Authorized Physicians for BCT Health Canada Registered Programs [RQA.05.013].*

Responsibility of Transplant Site for Final Donor Assessment (Source Establishment)

Definitions:

Retrieval Establishment: The hospital in which the living donor undergoes the nephrectomy and the kidney is perfused and packaged for shipping.

Transplant Establishment (Source Establishment): The hospital that receives the retrieved organ and completes the transplant surgery.

As per [Health Canada Guidance 2018](#), the Hospital in which the transplant occurs is the “Source Establishment”. As such the transplant site is responsible for obtaining and reviewing the appropriate documentation and determining the safety of the organ. For example, if the donor workup was at VGH with the transplant at St. Paul’s; St. Paul’s is responsible for making a final assessment of the donor being safe to proceed to OR. This includes a donor who travels from the program where the donor workup and testing occurred or that involves an organ that is shipped from out of province for transplantation. The transplant establishment is still considered the source establishment.

The transplant establishment does not, however, need to repeat all of the donor screening and testing if it considers the existing results acceptable.

[Note, BCCH performs perioperative services only. It is not a Source Establishment, therefore all donor screening and checks are the responsibility of the adult Living donor program where the adult donor will be donating].

Additional Resources

Ambulatory References (on PHSA SHOP):

- *Protocol for a living donor Kidney EXPORTED for transplant in the KPD program [AMB.02.007]*
- *Protocol for a living donor kidney IMPORTED for transplant in the KPD program [AMB.02.008]*

2.8 Exceptional Distribution

It is recognized that in exceptional circumstances a kidney may be transplanted even when there is a contraindication (See [Section 2.5](#) Exclusionary criteria and Appendix I, II in SOP [Exceptional Distribution](#)). 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.*

Documentation of Exceptional Distribution for a Living Donor

The process will be documented on a [Live Donor Exceptional Distribution Form](#) [BCT Doc No. AMB-GEN.04.010] (or equivalent). Ensure a copy of the Form is provided to BCT Quality Program (bctqualityassurance@bct.phsa.ca)

Refer to BCT SOP, [Exceptional Distribution](#) [RQA.02.018], and [Summary of Exceptional Distribution Criteria](#) [RQA.05.012] 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 (See *Page 2 of the [Live Donor Exceptional Distribution Form](#) for follow-up of recipients transplanted under increased risk for disease transmission*);).

Additional Resources (on PHSA SHOP):

- BCT SOP [Exceptional Distribution](#) [RQA.02.018]
- BCT Reference, [Summary of Exceptional Distribution Criteria](#) [RQA.05.012]

3. KIDNEY PAIRED DONATION & NON-DIRECTED ANONYMOUS DONATION (KPD & NDAD)

3.1 Kidney Paired Donation

Incompatible donor-recipient pairs (blood type or immunological) may be eligible for the National Kidney Paired Donation (KPD) program. The KPD program is administered nationally by the [Canadian Blood Services](#) (CBS). [Figure 3](#) shows examples of how a KPD exchange is possible. Both the donor and recipient must be approved and medically ready to proceed before they can be listed in this program.

KPD Requirements

- Only donors that live in Canada should be considered
- Informed consent of both donor and recipient required
- Donor travel may be necessary
- All pairs will remain anonymous to each other
- Surgeries happen at the same time or in carefully planned sequence

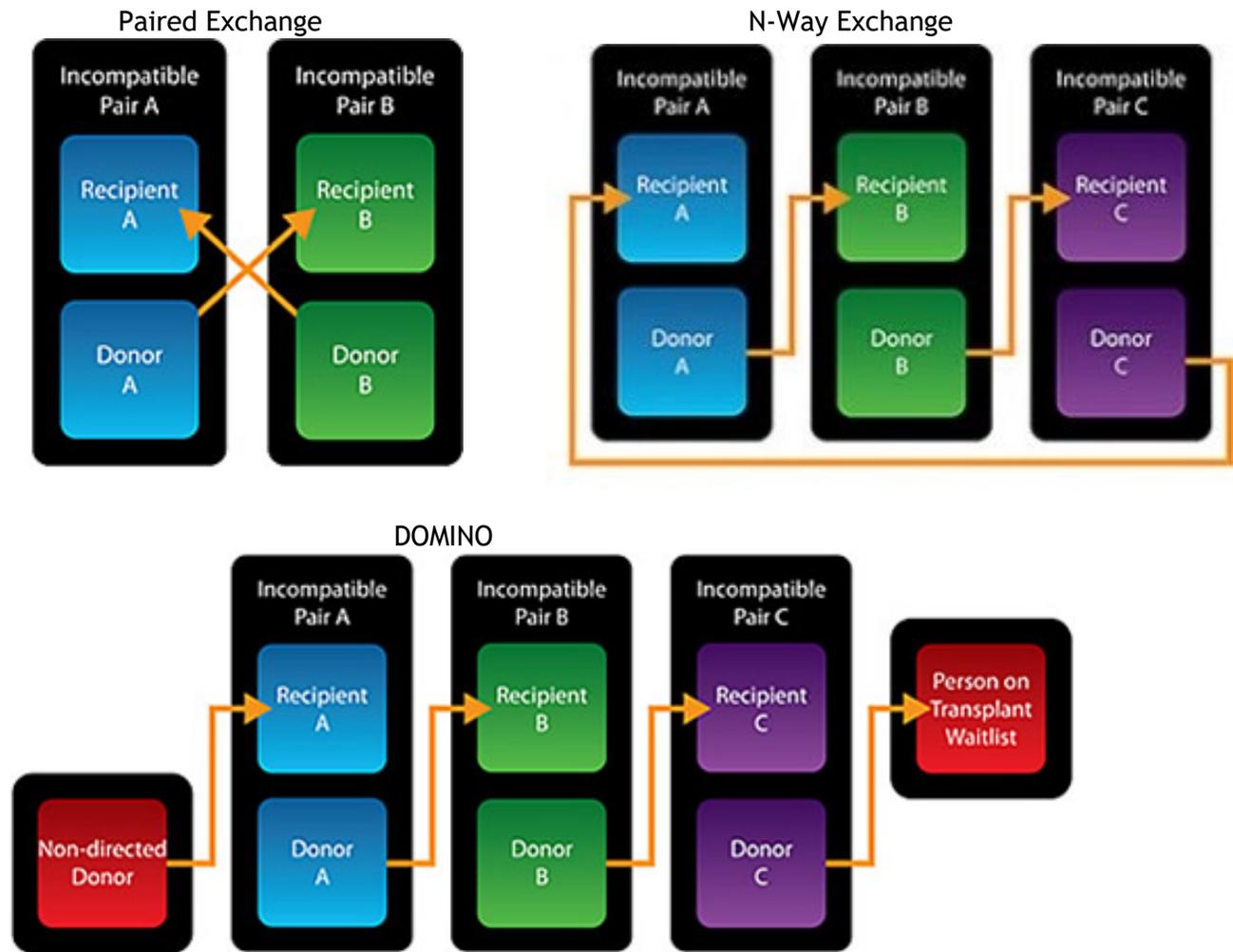
Note that for all kidney transplants facilitated through the KPD, the transplant establishment (i.e., VGH, SPH) is considered the source establishment, and as such is responsible for obtaining and reviewing documentation and determining the safety of the organ ([Health Canada Guidance 2018](#)).

NATIONAL KPD REGISTRY

The KPD Registry is a computer database administered by CBS. It contains medical information about registered donor-recipient pairs from across Canada. Approximately three times annually, the Registry compares the medical information on all the pairs in the database and identifies pairs that might be able to exchange donors (see [Figure 3](#)).

All potential recipients/donors must complete a consent form prior to their registration in the database.

Figure 3. Examples of KPD.



1) **Paired Exchange**

Donor A wishes to donate a kidney to Recipient A, but they are not a match. Donor B would like to donate a kidney to Recipient B, but they are not a match.

However, Donor A is a match with Recipient B and Donor B is a match with Recipient A.

2) **N-Way Exchange**

An n-way exchange is similar to a paired exchange, except there are more pairs included and the donor of the last pair donates to the recipient of the first pair.

3) **Domino Exchange**

Domino exchanges begin with a non-directed donor who donates to the recipient of an incompatible pair. There can be multiple incompatible pairs in a domino exchange as with pairs A, B and C. The last donor donates to a recipient on the transplant deceased donor waitlist who is from the same transplant program as the non-directed donor.

Reference: CBS Website, Organ and Tissue Donation and Transplantation <http://www.organsandtissues.ca/> Oct 10, 2012.

3.2 Non-Directed Anonymous Donor (NDAD) Program

NDAD's are individuals who wish to donate a kidney anonymously.

NDAD

- An NDAD may select to donate through the KPD and initiate a "Domino" paired exchange ([Figure 3](#))
- An NDAD may select to donate through the BC Kidney waitlist (allocation by program to the next appropriate & compatible person)
- An NDAD is not able to set criteria for the recipient selection
- Anonymity must be maintained between donor and recipient

The potential NDAD donor must fulfill the standard assessment criteria described in Section 2 [Donor Assessment](#) with the addition of:

- Be 25 years of age or older.
- Be evaluated by a social worker and/or psychologist or psychiatrist (as needed) to better understand their motivation to donate.
- Have unanimous donor team approval
- Have a mandatory contemplation period from time of approval to surgery.

Additional Resources

[CBS Website - Living Donation](#)

[CBS Professional Education](#)

Ambulatory References (*available on PHSA SHOP*)

- Non-Directed Anonymous Donor Assessment and Eligibility [AMB.02.003]
- Solicitation for Living Kidney Donors [AMB.02.006]

3.3 Shipping of Living Donor Kidneys On Behalf Of KPD

In the KPD program, donors may be matched with recipients in a different province. In some cases an alternative to having the potential donor travel, is to ship the kidney from the Retrieval site to the Transplant Site (CBS Kidney Transplant Advisory Committee (KTAC), Living Donation Advisory Committee (LDAC), and Kidney Surgical Sub-Committee (KSSC).

VGH and SPH acknowledge their sites as Source Establishment for all transplants occurring at their hospitals. See [Responsibility of Transplant Site for Final Donor Assessment](#) for further info on Source Establishment.

The following SOPs and Forms describe the process for both importing and exporting a living donor kidney:

Note: For the context of shipping of living donor kidneys through KPD, the exporting agency is the “Retrieval Establishment”. VGH or SPH is the transplant site (Source establishment), and may be considered the “importer”. This is only for kidneys imported from out of Province from within Canada on behalf of KPD.

CBS Documents (Available on CTR website)

- Shipping of Living Donor Kidneys. Position Statement and Guidance Document, Oct 2020.
- CBS Shipping of a Living Donor Kidney: Guidance for Retrieval Establishments developing SOPs for Shipping to a Transplant (Source) Establishment (Health Canada Living Donation Working Group 2020)
- CBS Acceptance of a Living Donor Kidney: Guidance for Transplant Program (Source Establishments) developing SOPs for Acceptance of a Living Donor Kidney from the Retrieval Establishment (Health Canada Living Donation Working Group 2020).
- CBS Retrieval Establishment - Approval of Living Donors for Shipping of Kidneys Checklist
- CBS Transplant Site / Source Establishment – Approval of Living Donors for Shipping of Kidneys Checklist

Ambulatory SOPs (available on PHSA SHOP)

- *Protocol for a living donor Kidney EXPORTED for transplant in the KPD program [AMB.02.007]*
- *Protocol for a living donor kidney IMPORTED for transplant in the KPD program [AMB.02.008]*

ODHD SOP (available on PHSA SHOP)

- *ODHD Roles and Responsibilities: Living Donation Kidney [ODHD-SRS.02.012]*

4. DOCUMENTATION

All records (paper and electronic) 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 2018](#)).

Records may be maintained in electronic (e.g., PROMIS database, CareConnect, ChartScan; CST Cerner) or paper format as appropriate to the record type. Refer to BCT SOP, Electronic Document Management of Living Donor Charts in CST Cerner [AMB.02.13].

The Donor nurse or designate will complete the QA Patient Chart Review Form ([Appendix I](#)) 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:

CONSENTS
All potential live donors shall sign: <ul style="list-style-type: none">• A two part consent covering Surgical Consent/Blood Product Transfusion Consent prior to OR as per hospital protocol (<i>Note only for donor retrievals occurring in BC hospitals</i>).• Potential Donor Disclosure Form (As found in Full length Med Social Questionnaire)• All out of country live donors shall sign "Consent for Jurisdiction of Treatment (Non-Resident of Canada)" form• Other consent(s) may be required as per specific hospital policies (e.g. Photo consent) or CBS KPD consent.
GENERAL
<ul style="list-style-type: none">• Name, address and current contact information (<i>Note: for KPD all donor names are suppressed/redacted in the recipient chart and records but where applicable the donor's unique BCT or CTR ID number will be documented</i>)• Date of birth• Date of initial contact• Date of interview(s)• Date of approval for donation

GENERAL (Con't)

- Date of transplantation
- Donor's unique BCT identification number (assigned at time of transplant)
- For KPD – Donor's unique KPD Number assigned at the time of registration in the CTR database
- Name and date of the healthcare professional who reviewed the questionnaire(s) and medical records (*See Donor Candidacy Approval Form*)
- Identification of all individuals involved in donor assessment
- Consult letters
- Copies of all correspondence pertaining to the Live Donor during both assessment process and post donation
- Documentation of all significant steps and activities performed by team members from referral to follow-up

TEST RESULTS

Results of all tests, including those that are optional, must be included in the donor record ([Health Canada Guidance 2018](#)). Electronic test records in CareConnect/Cerner are considered part of the donor record.

- Manually transcribed test results and interpretation where applicable
- ABO blood type
- Cross-match and tissue typing results from the Immunology Laboratory
(***Note - not included in donor chart for KPD and NDAD. Retained in Recipient chart and uploaded to PROMIS Recipient section*)
- All laboratory results and tests with dates – At a minimum this includes: CBC (to include at minimum hemoglobin, hematocrit, white blood cell (WBC), platelet counts), levels of serum electrolytes (to include at minimum sodium and potassium), levels of creatinine, urea test, urinalysis and Chest X-Ray.
- Health Canada required serology results See [Table 4](#)
- Height and weight
- Physical examination (e.g., CBS Physical Exam Form) with date and name of qualified person(s) completing the exam(s)

FORMS

- PROMIS Registration - Face sheet (Donor/Recipient Demographics and Identification numbers)
**Note: Recipient name redacted for KPD/NDAD*
- Completed FULL Medical Social History Questionnaire (MSHQ) and date of completion
- Living Donor 30-Day Med-Social Questionnaire
- Donor Candidacy Approval Form
- QA Patient Chart Review Form: Living Donor Programs (See [Appendix I](#))
- Living Donor Transplant FINAL Approval Checklist – Physician (SPH only) (See [Appendix II](#))
(Direct donors copy to CST Cerner Donor & Recipient charts; For KPD copy to recipient chart only)
- Donor assessment worksheet(s)¹
- Donor Nurse Progress Notes (OPD)
- Exceptional Distribution Form (if applicable)
(Direct donors copy to CST Cerner Donor & Recipient charts; For KPD copy to recipient chart only) (Copy to BC Transplant for ALL donors)

¹Worksheets 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].

Other (For Shipped Kidneys – Imported from out of Province)(KPD)

In addition to the above

- All required documentation as per “Transplant Site / Source Establishment - Approval of Living Donors for Shipping of Kidneys Form”

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].

4.1 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. Refer to BCT SOP, Assignment of Donor/Referral Numbers [ODHD-GEN.02.017].

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

Direct Donation

For those transplants involving Direct Donation:

- 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.

KPD

For those transplants involving KPD:

Each potential transplant recipient and donor is provided a unique CTR (Canadian Transplant Registry) ID Number upon registration in the CTR Database.

- The CTR Database tracks all donors and recipients by the unique CTR ID Number.
- KPD Donors may register with a registered incompatible recipient or individually as an NDAD donor.
- CTR records can link registered pairs, proposed matched pairs, or pairs with completed transplants.
- The PROMIS database, as in direct donation, maintains records for BC KPD recipients and donors involved in all BC Living donor transplants.
- The PHN Number, KPD Recipient ID Number, and BCT Recipient ID number of the RECIPIENT are linked to the donor in PROMIS.
- The PHN Number and BCT Donor ID number of the DONOR are linked to the Recipient in PROMIS.

LOCAL NDAD

An NDAD may also choose to donate locally. The recipient's name and records will be suppressed /redacted in the donor chart. The recipient will be identified only by their unique BCT ID #.

For all NDAD records, the PROMIS face sheet will only contain the DONOR demographics, Donor CTR/BCT ID numbers, and Recipient CTR number/BCT Recipient ID number(s) in the "Comments Section". The face sheet may be printed and included in the donor chart.

4.2 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 & 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.

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). The Hospital Health Information Department 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 the specific hospital Health Information Dept.

Additional Resources (*on PHSA SHOP*)

- BCT SOP Assignment of Donor and Referral Numbers [ODHD-GEN.02.017]
- BCT SOP, Document Management Program [RQA.02.001]
- Quality Management and System Requirements of CST Cerner for Living Donor Records [RQA.02.024]
- Electronic Document Management of Living Donor Charts in CST Cerner [AMB.02.013]

5. RECIPIENT ASSESSMENT

For complete details on pre-transplant investigations of recipients, refer to *Clinical Guidelines for Kidney Transplantation* (Available at: [BC Transplant website](#), under Health Professionals).

6. OPERATIVE PROTOCOL

6.1 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 the Donor Nurse in consultation with the Surgeon(s), Physician(s), donor, recipient and the recipient's primary care team. Operating dates for KPD will include careful planning with other transplant centres and CBS.

6.2 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 (*or equivalent*).

6.3 Donor Admission

The admission protocols are determined by the transplanting hospital. Prior to or at time of admission the potential donor is seen by the Anesthesiologist. For some donors, a telephone consult may be done with a nurse designated by the Anesthesiologist.

6.4 Donor Nephrectomy

The donor surgery is carried out according to accepted medical practice. Refer to Patient Handbooks at VGH and SPH. Donor organ packaging and labelling is performed by BCT Organ Donation and Hospital Development (ODHD). Refer to BCT SOP, ODHD Roles and Responsibilities: Living Donation Kidney [ODHD-SRS.02.012].

6.5 Routine Post-operative Care

The post-op care is carried out according to accepted medical practice.

6.6 Recipient Admission and Transplant

For complete information on the admission of living donor recipients, the operation itself and immediate post-transplant care (*Refer to Clinical Guidelines for Kidney Transplantation and Clinical Guidelines for Transplant Medications available at [BCT Website Health Professionals](#)*).

7. POST-OPERATIVE PROTOCOL

7.1 Donor Follow-up

Careful donor follow-up is a requirement of the living donor program to ensure their single kidney is functioning well. To facilitate follow-up, the Donor Nurse provides the donor and family physician with a schedule of recommended testing (*Note specific followup testing may vary between hospital, clinical decision of the nephrologist*).

At 2 weeks:

- Electrolytes, urea, creatinine, eGFR, CBC, urinalysis

At 6 months and then annually:

- creatinine, eGFR, urinalysis, urine ACR, fasting blood sugar, HgbA1c, blood pressure check.

Reminder letters are sent to the donor at the appropriate intervals. Ultimately, the responsibility of ensuring that this follow-up takes place rests with the living donors. In order to maintain contact, donors are advised to inform the transplant program if they move or change family physicians.

Family physicians and donors are advised to notify the transplant centre of any abnormal test results such as elevated blood pressure, change in creatinine or GFR, development of proteinuria, development of diabetes or significant changes to the donor's health.

7.2 Recipient Follow-up

Standard recipient follow-up is described in BCT Clinical Guidelines for Kidney Transplantation and Clinical Guidelines for Transplant Medications (available on website at: [BC Transplant Health 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 Manager, Kidney Medical Director, and the BCT Quality Program bctqualityassurance@bct.phsa.ca

All adverse events and incidents will be fully reviewed, investigated, followed-up, and meet all Health Canada, hospital, and regulatory requirements.

Refer to the following policies:

- BCT SOP, Errors, Accidents and Adverse Reactions [RQA.02.020]
- Health Canada Guidance Document for Source Establishments – [Reporting Adverse Reactions to Human CTO](#) 2010.

8. APPENDICES

List of Appendices ¹	
Appendix I	Example of QA Patient Chart Review Form – Living Donor Kidney (VGH)
Appendix II	Example of Living Donor Transplant FINAL Approval Checklist – Physician (SPH)
Appendix III	Health Canada Frequently Asked Questions – Living Donor Program

¹Note: Appendices may vary depending upon requirements of specific Hospital policies. Please refer to BCT-Quality Assurance for most current form versions and policies.

Example of VGH QA Patient Chart Review Living Donor Kidney

 	PCIS LABEL			
QA PATIENT CHART REVIEW FORM LIVING DONOR KIDNEY				
DONOR NAME: _____ BCT RECIPIENT ID No.: _____ OR Date: _____				
DONOR CHART	COMPLETE	Comments		
	Yes No N/A			
INITIAL EVALUATIONS & FORMS				
Full Medical Social Questionnaire	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Medical Evaluation with Physical Exam (signed and dated) Date of Exam: _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Was the Physical Exam Addendum Form Used? If No: RN has verified with Dr. _____ that the physical exam performed above showed no evidence of needle tracks, lymphadenopathy, palpable masses or blue or purple spots consistent with Kaposi's sarcoma RN Initials: _____ Date: _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Social Worker Evaluation (signed and dated)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Psychologist Evaluation (signed and dated)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Donor Program Candidacy Approval Form - Medical	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Donor Program Candidacy Approval Form - Surgical	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Height: _____	Weight: _____	Date Completed: _____		
Serious Allergy Alert <input type="checkbox"/> Yes <input type="checkbox"/> No RN has communicated to Recipient Program that potential donor has a serious allergy alert Date: _____ Initials: _____ Communicated to: _____				
Hospital Forms				
- Consent for Med or Surgical Care / Admin of Blood Products	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
- Out of Country Consent - Jurisdiction Agreement	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
COMPLETE TESTING WITHIN 1 YEAR PRE-OP				
Chest X Ray or Chest CT (recommended within 30 days of OR)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Electrocardiograph	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
COMPLETE TESTING WITHIN 6 MONTHS PRE-OP				
ABO Blood Group <input type="checkbox"/> Verified completed on 2 separate dates	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
CBC (WBC, RBC, Hgb, HCT, platelets)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Na, K, Cl, Creatinine, Ca, PO ₄ , BUN, eGFR, BNP (>65 y.o.)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Urinalysis	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Pregnancy Testing	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
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QA PATIENT CHART REVIEW FORM LIVING DONOR KIDNEY

THE FOLLOWING MUST BE COMPLETED WITHIN 30 DAYS OF OR DATE				
30-Day Med-Social Questionnaire	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
HEALTH CANADA MANDATORY TESTING	COMPLETE			Comments
	Yes	No	N/A	
anti-HTLV-1 and anti-HTLV-II	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
anti-HIV-1 and anti-HIV-2	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Hepatitis B				
- Hep B Surface Antigen (HBsAg)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
- Total Antibody to Hep B Core Antigen (Anti-HBc Total) (IgG and IgM required)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
- Hep B Surface Antibody (Anti-HBs or HBs Ab)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
anti-HCV (HCV Ab or anti-HCV)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
syphilis (VDRL or RPR)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
CMV IgG	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> Previously reactive
EBV IgG	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> Previously reactive
Other (CSA Recommended Testing)				
- WNV (Seasonal / or based on travel risk)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
RN has communicated all contraindications from 30 day questionnaire to the medical and/or surgical team. Refer to current Clinical Guidelines. RN has verified with Dr. _____ that an additional physical exam				
<input type="checkbox"/> IS <input type="checkbox"/> IS NOT required and the physician has reviewed all available clinical information and donor history as per CTO Regulations / Clinical Guidelines. The potential donor has been assessed as:				
<input type="checkbox"/> SAFE TO PROCEED FOR ORGAN DONATION				
OR				
<input type="checkbox"/> ACCEPTED TO PROCEED FOR ORGAN DONATION UNDER THE PROVISIONS OF EXCEPTIONAL DISTRIBUTION				
RN Initials: _____ Date: _____				
COMPLETE TESTING WITHIN 14 DAYS PRE-OP				
COVID Screening				
Screening Questionnaire + COVID test Date: _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
(list any additional tests in comments)				
Final Cross-Match				
<input type="checkbox"/> KPD/NDAD - cross-match results in Recipient Chart only	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Is this an Exceptional Distribution? <input type="checkbox"/> Yes <input type="checkbox"/> No If Yes - complete an E.D. form prior to OR date.				
<input type="checkbox"/> Copy to BCT QA/ODHD <input type="checkbox"/> Copy to Recipient Chart				
For Shipped Kidneys - Imported (VGH as transplant site/ source establishment) <input type="checkbox"/> N/A				
Complete "Transplant Site/Source Establishment – Approval of Living Donors for Shipping of Kidneys Form"	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
AVAILABLE POST-OR				
PROMIS Summary Sheet (Recipient # / Donor ID #)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
ASSIGNED DONOR ID NUMBER: _____				

COMMENTS

Completed By _____

Date _____

Living Donor Transplant FINAL Approval Checklist – Physician (SPH)



**LIVING DONOR TRANSPLANT
FINAL APPROVAL CHECKLIST - PHYSICIAN**

Planned OR Date: _____

<p>RECIPIENT</p> <p>Name: _____</p> <p>DOB: _____ Blood Type: _____</p> <p><input type="checkbox"/> BCCH Recipient (Review & approval by BCCH team)</p> <p><input type="checkbox"/> Kidney Paired Donor (KPD) CTR # _____</p> <p><input type="checkbox"/> KPD chain number: _____</p>	<p>DONOR</p> <p>Name: _____</p> <p>DOB: _____ Blood Type: _____</p> <p><input type="checkbox"/> Direct Donor</p> <p>DONOR NAME SUPPRESSED</p> <p><input type="checkbox"/> Kidney Paired Donor (KPD) CTD # _____</p> <p><input type="checkbox"/> Non-directed Anonymous Donor (NDAD) BCT I.D. # _____</p>
<p>RECIPIENT VIROLOGY Date: _____</p> <p>HBsAg _____ Anti-HIV(1&2) _____</p> <p>HBcAb (IgG, IgM) _____ CMV _____</p> <p>HBsAb _____ EBV _____</p> <p>Anti-HCV _____</p>	<p>DONOR VIROLOGY Date: _____</p> <p>HBsAg _____ Anti-HIV(1&2) _____</p> <p>HBcAb (IgG, IgM) _____ CMV _____</p> <p>HBsAb _____ EBV _____</p> <p>Anti-HCV _____</p>
<p>Exceptional Distribution</p> <p><input type="checkbox"/> N/A <input type="checkbox"/> YES</p> <p>If Yes, ED form completed Date: _____</p> <p>Severe Donor Allergies</p> <p><input type="checkbox"/> N/A <input type="checkbox"/> YES</p> <p>If Yes: Recipient team informed Date: _____</p>	<p>Exceptional Distribution (ED):</p> <p><input type="checkbox"/> No <input type="checkbox"/> Yes, Reason(s) _____</p> <p>Donor Allergies: (causing anaphylaxis /serious medical concern)</p> <p><input type="checkbox"/> None <input type="checkbox"/> Yes: _____</p> <p>_____</p> <p><input type="checkbox"/> Last Physical Exam Date: _____</p> <p><input type="checkbox"/> Repeat Physical Exam not required</p>
<p>RECIPIENT IMMUNOLOGY Final crossmatch Date: _____ <input type="checkbox"/> Reviewed</p> <p><input type="checkbox"/> Low Risk <input type="checkbox"/> Moderate Risk <input type="checkbox"/> High risk</p> <p>Planned Immunosuppression: _____</p> <p>_____</p>	
<p>RECIPIENT MEDICATIONS: <input type="checkbox"/> Profile reviewed Date: _____</p> <p>Medication considerations: _____</p> <p>_____</p>	
<p>Special planning needs/follow-up (e.g. combined nephrectomy & Living Donor transplant, vaccinations, medications, consults etc.)</p> <p>_____</p> <p>_____</p>	
<p>DONOR APPROVED & SAFE TO PROCEED TO OR <input type="checkbox"/> Yes <input type="checkbox"/> No Date: _____</p> <p>Signature: _____ Printed name: _____ College ID: _____</p>	
<p>RECIPIENT APPROVED & SAFE TO PROCEED TO OR <input type="checkbox"/> Yes <input type="checkbox"/> No Date: _____</p> <p>Signature: _____ Printed name: _____ College ID: _____</p>	



Cells, Tissues & Organs

Frequently Asked Questions - Living Donor Transplant Program

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
- Z900.2.3-03 *Perfusible 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.

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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;

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- 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?

Establishments register with Health Canada by completing and submitting the following form found on Health Canada's Web site: http://www.hc-sc.gc.ca/dhp-mps/compl-conform/licences/frm_0171_tc-tm-eng.php. 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.

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14. Where can one find more information regarding the CTO Regulations?

CTO Regulations:

<http://laws.justice.gc.ca/en/SOR-2007-118>

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/onlinestore/>

Guidance Document:

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

http://www.hc-sc.gc.ca/dhp-mps/brgtherap/reg-init/cell/cto_gd_ld-eng.php

Error/Accident Preliminary Reporting Form:

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

http://www.hc-sc.gc.ca/dhp-mps/alt_formats/pdf/compl-conform/info-prod/cell/frm-0172_doc-eng.pdf

Adverse Reaction Reporting Form:

Canada Vigilance Adverse Reaction Reporting Form

http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/ar-ei_form-eng.php

Regional Inspectorate Programs - Contact information

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Inspectorate Program, Manitoba / Saskatchewan Region

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Provinces: Manitoba and Saskatchewan

Inspectorate Program, Alberta Region

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Province/Territory: British Columbia and Yukon

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