Clinical Process Instruction Manual

Exceptional Distribution Process Instruction

Policy:

Trillium Gift of Life Network (TGLN) is the source establishment for deceased donor, organ assessment, recovery and distribution as per Health Canada. Exceptional Distribution (ExD) is required when organs have not been processed according to a combination of Health Canada's *Safety of Human Cells, Tissues and Organs for Transplantation Regulations (2017)* and to TGLN Clinical Standards. They are distributed to a transplant program based on reasons related to the benefit of the recipient. Organs distributed via ExD are of a known risk, and adverse event reporting and investigation are not necessitated in the event of any reactions due to this known risk.

TGLN is responsible in Ontario for assessing donor suitability and determining which donation cases will require ExD (or a specific advisory otherwise) upon offering organs to the transplant program. In cases for which TGLN accepted "out of province" organs, the Source Establishment documents any ExD conditions and forwards them to TGLN. Determination of whether to accept an offer of organ donation in light of the suitability assessment completed by TGLN is the responsibility of the transplant program.

TGLN will offer the organ to the transplant physician with the reason(s) for ExD. If more than one reason necessitates ExD, TGLN will notify the transplant program(s) of each reason.

TGLN, as source establishment, is permitted to offer exceptionally distributed organs, if the following conditions are met:

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

For out of province and out of country organ imports, TGLN is not the source establishment. If the organ import has not been exceptionally distributed by an out of province source establishment in compliance with Health Canada Regulations, TGLN will contact the source establishment to note the deficiency. Where this occurs for an out of country source establishment, TGLN will apply ExD to the organ and will communicate the reason ExD has been applied to any Ontario transplant program(s) affected.

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If an organ is exceptionally distributed from an out-of-province source establishment, the TGLN Coordinator will use the Organ Procurement Organization (OPO) form. For OPOs like Quebec Transplant, TGLN will request the English version of their EXD form. If an English version cannot be sent, the TGLN Coordinator will use the TGLN form and transcribe the pertinent information from the external OPO form onto the TGLN ExD form. For tissue recovery and release, tissue banks are the acting source establishments.

Process:

1. The Organ and Tissue Donation Coordinator (OTDC) or designate will collect the appropriate donor screening and assessment information and enter it in the donor chart in the TGLN donor management system as soon as possible.

2. Prior to running any organ allocation recommendations, the Clinical Services Coordinator (CSC) will review all pertinent information in the donor chart in the donor management system. If the CSC determines that the information/data collected during the screening and assessment process is not in compliance with either the Health Canada Regulations or to TGLN Clinical Standards, the CSC will identify the case as an ExD circumstance and enter it in the donor chart in the donor management system. See the *Exceptional Distribution Guidelines* in Appendix 1, *Guidelines Related to Organ Donation* and *Excerpt from CSA Standards* in Appendix 2.

3. CSC will consult with TGLN's Chief Medical Officer (CMO) or on-call designate as necessary, when reviewing donor screening and assessment information. If the CSC believes that a case warrants ExD for a reason not listed under the *Exceptional Distribution Guidelines* in Appendix 1 or *Guidelines Related to Organ Donation* and *Excerpt from CSA Standards* in Appendix 2, the CSC may consult the Transplant Support Physician (TSP) on-call to review whether ExD may be applied.

4. Once the reason(s) for ExD are confirmed, the CSC will push the donor information from the donor management system to the TGLN organ allocation and transplant system. The CSC will ensure that the ExD reason(s) are successfully pushed to the TGLN organ allocation and transplant system.

5. The CSC will run the organ specific allocation recommendations in the TGLN organ allocation and transplant system.

6. The CSC will offer the organ(s) in the TGLN organ allocation and transplant system, as per the allocation recommendation. The TGLN organ allocation and transplant system will send system generated notifications to the transplant physician or designate when an offer is made.

7. When making the offer to transplant programs within Ontario, the transplant program will have access to the donor information, including the reason(s) for ExD, if applicable.

8. Upon entering acceptance of an organ in the TGLN organ allocation and transplant system, the transplant physician or designate will be required to enter the justification for accepting the organ as per ExD requirements.

9. The TGLN organ allocation and transplant system will populate the relevant information for the indicated organ in the spaces provided on the *Notice of Exceptional Distribution* form. See Exhibit 1. All information pertaining to the accepting transplant program and the selected recipient will be populated on separate *Notice of Exceptional Distribution* forms for each organ being distributed.

10. If the reason(s) for ExD is/are changed after organ acceptance and prior to the recipient transplantation, the CSC will update the ExD reason(s) in the donor chart in the donor management system. The following steps will occur:

    10.1. The CSC will push the donor information from the donor management system to the TGLN organ allocation and transplant system.

    10.2. The TGLN organ allocation and transplant system will send a notification to any transplant physicians or designates that have accepted an organ from the donor advising that the reason(s) for ExD have been updated, and the organ acceptance will be cancelled and re-offered.

    10.3. The CSC will re-run the allocation, and proceed with steps 6 – 9 above.

11. After organ recovery and recipient transplantation, the TGLN organ allocation and transplant system will send a notification to the transplant physician that accepted the organ(s) under ExD that there is a *Notice of Exceptional Distribution* requiring signature.

12. The transplant physician who accepted the organ will be required to enter their confirmation of acceptance of the ExD in the TGLN organ allocation and transplant system or print the *Notice of Exceptional Distribution*, sign it and return it to TGLN.

13. For organ offers accepted for Out-of-Province (OOP) recipients:

    13.1. The CSC will be responsible for entering all offer acceptance information in the TGLN organ allocation and transplant system on behalf of the accepting OPO. The CSC will ensure that the OPO is aware of the reason(s) for the ExD. The CSC will request and document the OPO transplant physician's justification for accepting the organ as per ExD requirements on

the *Notice of Exceptional Distribution.* See Exhibit 1. The CSC will also document this in the clinical notes in the donor chart.

13.2. The CSC will send a copy of the *Notice of Exceptional Distribution* form to the OOP OPO for signature as early as cross-clamp and up to 48 hours post recovery.

14. Where suitability assessment is not complete at the time of distribution, ongoing suitability assessment will continue and the CSC will inform the transplant programs or OPO of any results still pending. Once the suitability assessment is complete, the CSC will notify the transplant program or OPO of the result. The CSC will document all communication in the donor chart and will update the Post-Release section of the donor profile in the TGLN organ allocation and transplant system, which will populate the *Notice of Exceptional Distribution* with the required information.

14.1. If Post-Release is applied, the TGLN organ allocation and transplant system will send a notification to the transplant physician(s) that accepted the organ(s) that there is a *Notice of Exceptional Distribution* requiring signature after the post-release details and recipient transplant information have been entered in the TGLN organ allocation and transplant system.

15. Once an ExD is signed, the CSC will have the ability to generate a signed *Notice of Exceptional Distribution* form and upload a copy for each recipient to the donor chart in the donor management system.

16. The Surgical Recovery Coordinator (SRC) must check all applicable ExD conditions on the *Organ Donor Surgery Information Form*.

17. When an OPO returns the fully completed *Notice of Exceptional Distribution* back to TGLN, ideally within a period of two weeks after the transplant, complete with the appropriate transplant program approval, the CSC will file the duplicate copy in the donor chart in the donor management system.

ExD Reversal

18. Prior to the recipient transplant, if new information can be provided by the transplant program staff and/or TGLN staff that indicates that ExD is not warranted, he/she can request a reversal of the ExD process already in progress by contacting either the TGLN Chief Medical Officer or their designate. Only these designated TGLN representatives can reverse an ExD process already in progress. Proof of an ExD reversal can be hand-written notes on the ExD Notice signed off by either the CMO or their designate or an email from the same, which will be filed in

the donor chart.

19. If after recipient transplant, evidence is presented to indicate ExD was unwarranted, the transplant program is still obligated to fulfill the ExD process requirements and return the completed/ approved ExD Notice to TGLN.

Records:

Record Name	Form No. (if applicable)	Record Holder	Record Location	Record Retention Time (as a minimum)
Donor Assessment	CSF-9-15	PRC	PRC	16 years
Notice of Exceptional Distribution	CSF-9-24	PRC	PRC	16 years
Recipient Operating Room Data	----------	PRC	PRC	16 years

References:

- Reportable Diseases Listing
- SRC Reporting Tool
- Health Canada. Safety of Human Cells, Tissues, and Organs for Transplantation Regulations. Canada Gazette.
- CAN/CSA-Z900. 1-17: Cells, tissues, and Organs for Transplantation: General Requirements, Canadian Standards Association, 2022.

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Appendix 1: Exceptional Distribution Guidelines

Trillium Gift of Life Network (TGLN) is registered with Health Canada as source establishment for deceased organ donors. As source establishment, TGLN is responsible for determining the safety of deceased organs for transplantation through donor screening, donor testing, donor suitability assessment, labelling and packaging, and storage, per the requirements of the *Safety of Human Cells, Tissues, and Organs for Transplantation Regulations*. If the deceased organ is not processed in accordance to these Regulations, the organ may be offered via Exceptional Distribution (ExD) protocols. ExD requires the transplant physician to authorize use of the organ and obtain informed consent from the recipient.

The following listing includes many conditions that are required to ensure compliance to the Regulations. If not processed in accordance to the regulations, organs are to be offered using ExD protocols. It should be noted that this document is not a comprehensive listing, and other conditions may necessitate offers under Exceptional Distribution. These are to be discussed and confirmed with the Chief Medical Officer or on-call designate.

Donor Suitability Assessment **–**
An ExD is indicated if one or more of these requirements are unknown, not properly conducted or absent from the donor record:

- Hemodilution calculation or no undiluted sample tested or available for required stat and non-stat serology (e.g., diluted toxoplasmosis sample would require ExD for accepting heart transplant program)
- Blood Typing (ABO)
- Physical Examination (to be performed by a qualified person)
- Evidence of lymphoadenopathy, palpable masses, blue or purple spots on the skin or mucous membrane suggestive of Kaposi's sarcoma or needle tracks suggestive of drug abuse
- Pediatric Donor less than or equal to 18 months, or child breastfed within the last 12 months, and birth mother not tested for HIV, HbcAb, HbsAg, HCV, HTLV, Syphilis. Exception: For donors ≥ 29 days old, where NAT testing has already been completed on the pediatric donor, birth mother STAT serology testing is not required.
- Viral PCR of Lower respiratory tract specimen - ETT sample or BAL for SARS CoV-2 (BAL for lung donor; ETT acceptable if BAL not possible) for lung donor[1].
- Donors who are COVID-19 positive, by either NPS or lower respiratory tract specimen PCR[1].

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Medical / Social History **–**
If the below medical/social history is positive, unknown or absent from the donor record, an ExD situation is indicated:

- Any history of sepsis (positive blood culture(s) not considered to be a common contaminant) or contributing factors to sepsis (i.e., endocarditis or suspected endocarditis) since onset of critical illness, and its documentation and resulting treatment
- Persons whose probable cause of death cannot be adequately determined by the Medical Director of the source establishment and there is likelihood of other exclusionary criteria
- Malignancies: i.e., a tumor, growth or mass that has not been documented as being benign by a physician (exceptions: cutaneous basal cell or squamous cell carcinoma that has been treated) OR history of malignancy (except for cutaneous basal cell or squamous cell carcinoma that has been treated)
- History of tuberculosis, hepatitis, HIV infection, Creutzfeldt-Jacob disease (CJD) or other communicable diseases
- Death with neurological disease of an unestablished etiology
- History of dementia or degenerative neurological disorders of viral or unknown etiology: i.e., Parkinson's disease, subacute sclerosing panencephalitis, progressive multifocal leukoencephalopathy and amyotrophic lateral sclerosis (ALS) or Lou Gehrig's disease
- Recipients of human derived pituitary growth hormone within the following time frames:
  - Prior to 1986, if the treatment took place in Canada or the U.S.; or
  - If the treatment took place in a country other than Canada or the U.S, any time that human-derived pituitary growth hormone was available for therapeutic use in that country
- Recipients of human cadaveric (allogeneic) dura mater
- Recipients of organs from EXD donors within a year of transplant[1]
- Prion-related disease: i.e., Creutzfeldt-Jakob disease (CJD), family history of CJD
- Persons with active encephalitis or meningitis of infectious or unknown etiology
- Rabies or within the last 6 months bitten by an animal and treated as if animal was rabid
- Symptoms or exposure to WNV
- Symptoms or exposure to MERS
- Symptoms or exposure to Ebola
- Symptoms or exposure to Zika
- Person with a history of infection with HIV, clinically active HCV, or clinically active HBV
- Persons who are at higher risk for HIV, HBV and HCV. See Appendix 2 for high risk behaviours
- Person with infections that would pose a significant risk to the recipient if transmitted[2]
- Persons, including the birth mother of a donor less than 11 years of age, who test positive for HIV, HbcAb, HbsAg (current or previous HBV infection), HCV, HTLV, Syphilis
- Persons who received treatment for hepatitis C in the last 12 weeks, currently receiving treatment for hepatitis C or persons with a past diagnosis of hepatitis C for which the treatment details are unknown[1]

- Sexual contact with a man who is known to have either: a) A known or suspected medical diagnosis of Zika Virus infection within six months prior to the sexual contact, OR b) Resided in, or travelled to an area with active Zika Virus transmission within the past six months
- Previous residence or travel outside of Canada
  - Rural Mexico and/or Central America and/or South America (for a combined duration of up to 3 months or more)[1]
  - United Kingdom (England, Northern Ireland, Scotland, Wales, Isle of Man or Channel Islands) and/or France (for a combined duration of 3 months or more between January 1, 1980 to December 31, 1996)[1]
  - An area affected by Zika in the past 21 days
  - Travelled in the preceding 56 days to areas where WNV is endemic
  - Recent travel to an area where a travel health notice has been issued[1]

[1] TGLN reasons for exceptional distribution
[2] It is a matter of clinical judgement to determine the significance/level of risk depending on the clinical history, type of transplant, etc.

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Appendix 2: Excerpt from CSA Standards: *Cells, Tissues, and Organs for Transplantation and Assisted Reproduction: General Requirements, Annex E (normative)*

Factors and behaviours associated with a higher risk of human immunodeficiency virus (HIV), hepatitis B virus (HBV), and hepatitis C virus (HCV) E.1

The assessment of donors 11 years of age or older shall include the following risk factors and risk behaviours associated with HIV, HBV, and HCV:

a) persons who report nonmedical intravenous, intramuscular, or subcutaneous injection of drugs in the preceding 12 months;
b) men who have had sex with another man in the preceding 12 months;
c) persons who have engaged in sex in exchange for money or drugs in the preceding 12 months;
d) persons with a history of intranasal drug use for non-medical reasons in the last 6 months, unless HCV NAT is performed and found to be negative;
e) persons who have had sex in the preceding 12 months with any persons described in items a) to d) or with a person known or suspected to have HIV, or clinically active HBV or clinically active HCV;
f) 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, non-intact skin, or mucous membrane;
g) persons who have been in youth correctional facility, jail, or prison for more than 72 consecutive hours in the preceding 12 months;
h) 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
i) persons who have had close contact within 12 months preceding donation with another person having clinically active HBV or clinically active HCV infection (e.g., living in the same household, where sharing of kitchen and bathroom facilities occurs regularly).

** The 12 month period specified in items f) and h) may be reduced to 6 months if nucleic acid testing (NAT) is used for the detection of HIV, HBV, and HCV. See Clause 14.2.6.1 of the CSA Standard: Cells, Tissues and Organs for Transplantation: General Requirements.*

NOTE: Clinically active includes ongoing infections such that there is a risk of transmission through body fluids.

E.2

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

a) persons who have been exposed, in the preceding 12 months*, to known or suspected HIV-, HBV-, and/ or HCV - infected blood through percutaneous inoculation or through contact with an open wound, non-intact skin, or mucous membrane;
b) persons who within 12 months* of donation have undergone tattooing, ear piercing, or body piercing in which sterile procedures were not used (e.g., contaminated instruments and/ or ink were used, or shared instruments that had not been sterilized between uses were used);
c) persons who have had close contact within 12 months preceding donation with another person having clinically active viral hepatitis (e.g., living in the same household, where sharing of kitchen and bathroom facilities occurs regularly);
d) persons who have been breastfed within the past 12 months[+] of donation by women with or at risk for HIV, HBV, HCV; and
e) persons less than 18 months of age who are born to women with or at risk for HIV, HBV, HCV infection

** The 12 month period specified in items E.2 a) and E.2 b) may be reduced to 6 months if NAT is used for the detection of HIV-1, HBV, and HCV. See Clause 14.2.6.1 of the CSA Standard: Cells, Tissues and Organs for Transplantation: General Requirements.*

[+] It is only necessary to assess donors less than eleven years of age against the criteria in item 2 d).

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Exhibit 1: Notice of Exceptional Distribution

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Trillium Gift of Life Network

Trillium Gift of Life Network
483 Bay Street South Tower, 4th Floor
Toronto, Ontario M5G 2C9
Tel (24/7): 1.888.603.1399 Fax: 1.866.557.6100
Website: www.giftoflife.on.ca

CSF-9-24

NOTICE OF EXCEPTIONAL DISTRIBUTION

SECTION 1: Donor Identification (Please submit one form per recipient)			
TGLN Donor #:			
SECTION 2: Reason for Exceptional Distribution (ExD)			
Health Canada Reason:			
☐ Positive Blood Cultures/Active Infections of clinical significance ☐ History of Malignancy ☐ History of dementia/degenerative neuro disease of viral/unknown etiology ☐ Unknown Cause of Death ☐ Unknown on Med/Soc ☐ Unknown Sex History ☐ Risk on Physical Assessment or Incomplete ☐ Risk of CJD or other Prion related disease	☐ Positive Serology ☐ Positive NAT ☐ Diluted Serology sample ☐ Diluted NAT sample ☐ Missing Serology ☐ False positive/repeat reactive/equivocal serology (BC/TQ only) ☐ Missing mandatory organ specific test	Increased Risk for Transmission of Hep B/Hep C/HIV – High Risk Behaviours: ☐ Non-medical injection of drugs in preceding 12 months ☐ Known Sex History Risk ☐ Incarceration > 72h in last 12 months ☐ Tattoo/Piercing with non-sterile procedures < 12 months ☐ Intranasal drug use for non-medical reasons < 6 months ☐ Other:	
Other Reason(s) (Health Canada, TGLN and/or Other Source Establishment with source indicated in brackets): ☐ Travel to/Lived in History with risk for: _____ ☐ Other: _____			
SECTION 3: Post Release ***Only complete if there are outstanding test results/information at time of release that will be available post release***			
Details of outstanding information or test results: _____			
Date/Time of Result Received:	____/____/____ (DD / MM / YYYY)	____:____ (HH : MM)	_____ CSC Name:
Date/Time Post-release Results were sent to Transplant Program:	____/____/____ (DD / MM / YYYY)	____:____ (HH : MM)	_____ CSC Name:
SECTION 4: Confirmation of Transmission of Information			
Recipient # (If known)			
Organ Name	*Please select appropriate organ(s). If other, please specify.* ☐ Heart ☐ Lung ☐ Liver ☐ Pancreas ☐ Kidney(s) ☐ Other:_____		
Transplant Program	*Please select appropriate program. If other, please specify.* ☐ UHN ☐ LHSC ☐ HAM ☐ SMH ☐ HSC ☐ KGH ☐ OHI ☐ OTT ☐ Other:_____		
Reason for ExD Acceptance	*Please select appropriate reason. If other, please specify.* ☐ Benefit Outweighs Risk ☐ Other (Specify): _____		
Date/Time of Acceptance of ExD	**Date:** ____/____/____ (DD / MM / YYYY)	**Time:** ____:____ (HH : MM)	**Name (Role):** _____
SECTION 5: Confirmation of Organ Acceptance – ***To be completed by Transplant Program***			
I (or my authorized designate) have had a conversation with the recipient and/or next of kin/substitute decision maker in which I explained the reason(s) for Exceptional Distribution as defined above, and the risks associated with the reason(s). I have obtained informed consent from the recipient and/or next of kin/substitute decision maker and I authorize the acceptance of the organ(s) described above for Transplant. **Authorizing Physician:** _____ **Authorizing Signature:** _____ **Date:** ____/____/____ (DD / MM / YYYY) **Time:** ____:____ (HH : MM)			

To meet requirements of the Health Canada Regulations, please return signed form within **two weeks of receipt** to TGLN: (416)-214-7797 or 1-866-557-6100 (Toll Free) or #OH-TGLN_csc@ontariohealth.ca

May 30, 2023