Clinical Process Instruction Manual

Donor Assessment - Tissue-Exclusive Process Instruction

Policy:

Criteria for determining donor suitability for recovery have been established by the Trillium Gift of Life Network's (TGLN) Medical Director-Tissue and shall be used to determine eligibility for tissue recovery. Additional criteria have been provided by each processor as approved by each processor's Medical Director. Each donor shall be evaluated using established TGLN and processor criteria for proceeding with recovery, with the ultimate suitability for transplant determined by the receiving processor's Medical Director.

There are several phases to donor assessment, the first of which is an over-the-phone assessment by the Tissue Coordinator (TC). The coordinator receiving the referral obtains a verbal report over the phone from a Health Care Professional (HCP) or other referral sources, such as a coroner, paramedic or funeral director, where the coordinator documents pertinent information into iTransplant. During the second phase, after consent to donate has been documented, the TC performs a donor risk assessment interview with the proxy (e.g. next-of-kin) or the donor (e.g. medical assistance in dying referrals) In the final phase, the ocular Tissue Recovery Coordinator (OTRC) and/or Multi Tissue Recovery Coordinator (MTRC) performs a review of the patient's medical chart (when available) to determine if there are any errors, omissions or additional information not previously documented and performs a physical assessment of the donor and documents all relevant findings as per *CPI-9-510 Physical Examination for Tissue Process Instruction*

Process:

1. This process instruction provides a high-level overview of how donor assessment is conducted, including identification of key responsibilities and processes related to donor assessment for tissue donors.

Requirements for Types of Information Collected for Tissue Donation

2. Specific requirements and procedures for physical assessment, donor risk assessment interview, medical records review, and plasma dilution are outlined in their respective Clinical Process Instructions.

3. Reference the *iTransplant-Tissue Exclusive User Manual* for the specific requirements for each data point collected.

4. All information related to donor assessment and any decisions made regarding donor or tissue suitability and their rationale shall be documented in the donor chart Clinical Notes.

5. TCs shall assess a donor by age criteria, which has been established by TGLN and the processor Medical Director, and can be found in the Tissue Bank Profiles.

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Referral

6. Once the initial referral worksheet is complete, the TC proceeds with donor screening by completing the Tissue Donor Screening page in the Donor Management System.

Donor Suitability

7. The donor shall be screened for evidence of significant active infection as well as indicators for relevant communicable disease agents or diseases.

8. **Disease Screening**

8.1. Initially the TC receives a referral over the phone and documents the verbal report given from the HCP and/or other referral sources, such as a coroner, a paramedic or a funeral director. The TC collects information related to the donor's medical history and current admission and course of events, when applicable. The amount of information the TC is able to obtain at the time of referral will depend on the source of the information (i.e., a funeral director calling in a referral will not have all of the patient's medical history or hospital chart). The TC must attempt to obtain as much information from the source, that is readily available.

8.1.1. If the source of the referral is an HCP within a hospital, a preliminary review of the donor's medical history must be conducted by the TC before recovery coordination can proceed. The TC shall obtain required admission information from the potential donor's hospital medical record (Emergency Medical Services (EMS) forms, physician's notes, Emergency Department (ED) and Intensive Care Unit (ICU) flow sheets), including medications, white blood cell counts (WBCs), temperatures, cultures, and chest x-rays (CXR). The TC shall document if any intravenous (IV) fluids were administered in the past hour or if any blood products were given in the past 48 hours to determine if patient is plasma diluted. Additional information may be required from the attending and/or family physician, coroners, etc.

8.2. The OTRC and/or MTRC performs a secondary review of the patient's medical chart (if one exists and is available) to confirm and document any errors, omissions or additional/new information related to the past medical history and current admission not previously documented in the Donor Management System donor record.

8.2.1. Information includes the potential donor's hospital medical record (EMS forms, physician's notes, ED and ICU flow sheets), including medications, WBCs, temperatures, cultures, and CXRs. The OTRC or MTRC shall document if any IV fluids were administered in the past hour or if any blood products were given in the past 48 hours. Additional information may be required from the attending and/or family physician, coroners, etc.

8.3. Disease screening includes but is not limited to: septicemia; viral disease (e.g. HIV, viral hepatitis, West Nile Virus, rabies, etc.); human transmissible spongiform encephalopathies (CJD, variants); untreated syphilis; clinically active tuberculosis; leprosy (Hansen's disease); and systemic mycosis.

8.4. Disease screening also includes risk factors for relevant communicable disease agents or diseases.

8.5. TCs and OTRCs/MTRCs should refer to *General Tissue Donation Criteria and Contraindications Process Instruction, CPI-9-262* for the exclusion criteria for each tissue bank.

Hemodilution Calculation

9. To determine whether pre-mortem pre-infusion or pre-transfusion blood specimens should be obtained for testing, the TC/OTRC/MTRC will calculate and confirm the hemodilution factor prior to drawing blood specimens for serology testing as per Hemodilution Calculation Process Instruction, CPI-9-210. The TC/OTRC/MTRC will also document if the patient was transferred from another site; this includes date and time, if patient arrived via ambulance (including arrival date and time), plus any fluids administered at admission time. The name of the healthcare professional providing the information relevant for the calculation will be recorded.

Donor Risk Assessment

10. The next-of-kin (NOK) or designate will complete the relevant *Donor Risk Assessment Interview(s)* (DRAI) with the TC as per *CPI-9-261 Medical & Social History – Tissue Process Instruction*.

11. Should more than one person need to be interviewed in order to collect all relevant information, a separate questionnaire must be completed with each additional interviewee.

12. Once completed, the TC evaluates the answers obtained from the relevant DRAI(s) to determine whether any contraindicators exist or if further consultation or clarification is required. The TC evaluates the donor for any exclusions listed in tissue bank specific exclusion criteria. If no exclusions are identified, the case can proceed to coordination and recovery.

Case Coordination

13. If the case requires coroner involvement, the TC will identify the coroner's name and make contact through the OFPS dispatch service. The TC will obtain information from the coroner such as: autopsy time and location, restrictions to donation and any information related to donor suitability.

Outside Contacts:

14. The patient's address and the authorizing persons' information is documented. Additionally, family notification, body refrigeration and initial medical suitability to proceed are all documented.

Clinical Notes

15. All coordinators shall document each conversation with the referring centre, coroner, relevant tissue banks, patient substitute, HCP, together with consultations on donor suitability and any activities relevant to the donation.

16. On acceptance of tissue(s) for transplant by TGLN Coordination and/or tissue banks, all relevant data is forwarded or faxed to the relevant tissue banks and recovery personnel by the TC or designate, as appropriate.

Records:

Record Name	Form No. (if applicable)	Record Holder	Record Location	Record Retention Time (as a minimum)
Donor Medical and Social History Questionnaire	CSF-9-14	PRC	PRC	16 years
Eye-Only Donor Risk Assessment Interview (Donor > 10 years old)	CSF-9-214	PRC	PRC	16 years
Eye-Only Donor Risk Assessment Interview (Child Donor ≤ 10 years old)	CSF-9-215	PRC	PRC	16 years
Eye-Only Donor Risk Assessment Interview Birth Mother	CSF-9-216	PRC	PRC	16 years

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Record Name	Form No. (if applicable)	Record Holder	Record Location	Record Retention Time (as a minimum)
Donor Risk Assessment Interview (Donor > 10 years old)	CSF-9-261	PRC	PRC	16 years
Donor Risk Assessment Interview (Child Donor ≤ 10 years old)	CSF-9-262	PRC	PRC	16 years
Donor Risk Assessment Interview Birth Mother	CSF-9-263	PRC	PRC	16 years

References:

- *Physical Examination for Tissue, CPI-9-510*
- *Medical & Social History – Tissue, CPI-9-261*
- *Standards for Tissue Banking, American Association of Tissue Banks, United States, 14th edition, 2017. D4.000, D4.100, D4.140, D4.200, D4.210, D4.211, D4.220, D4.230, D4.300.*
- *General Tissue Donation Criteria and Contraindications Process Instruction, CPI-9-262*
- *Hemodilution Calculation Process Instruction, CPI-9-210*
- *Physical Examination for Tissue Process Instruction, CPI-9-510*