Ontario Health
Trillium Gift of Life Network

Clinical Process Instruction Manual

On-Site Medical Records Review for Multi-tissue Recovery Process Instruction

Policy:

Trillium Gift of Life Network (TGLN) ensures all pertinent information, with respect to tissue recovery activities, is documented as required by Health Canada's *Safety of Human Cells, Tissues and Organs for Transplantation* (CTO) *Regulations,* current *Canadian Standards Association* (CSA), and *American Association of Tissue Bank* (AATB) *Current Standards for Tissue Banking*.

As part of tissue recovery services, an on-site review of all available and relevant medical records (paper based and/or electronic) is required prior to commencement of recovery activities on all donors.

Relevant medical records are a collection of documents that includes a current donor medical and social history interview, a current report of the physical assessment, laboratory test results (e.g., hospital lab results), medical records, coroner and autopsy findings (e.g., verbal/preliminary), records or other information received from any source pertaining to risk factors for relevant communicable disease.

The review shall include, but may not be limited, to:

- evidence of significant active infection at the time of donation for relevant communicable disease agents or diseases including signs and/or symptoms of viral and fungal infection, bacteremia or sepsis
- risk factors for relevant communicable disease agents or diseases
- additional tissue donor specific criteria as documented in the Clinical Process Instructions (CPI) and compliant with written agreements/contracts

Documentation of case related activities may be completed in paper or electronic format based on the recovery location and timing of case. On multi-tissue cases the Recovery Lead (MTRC) will give the final sign off on the chart review but doesn't necessarily complete the chart review, any individual on the multi tissue team can complete the medical record review and hemodilution review. For ocular cases the TRC performing the ocular recovery will complete the sign off.

Process:

1. The (M)TRC obtains the following materials:
   - *Eye Recovery Form* or *Multi-Tissue Recovery Form* or electronic equivalent

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- indelible ink pen
- patient, donor chart and/or copy of electronic records death certificate/warrant to bury, if available

Record Review

2. Prior to tissue retrieval, the (M)TRC shall conduct a preliminary review of available relevant medical records.

   2.1. The referral information, *Consent Form to Donate Organs and Tissues* and *Medical and Social History Questionnaire* shall be reviewed for completeness, confirmation that the consent is obtained and documented as per AATB D3.300, and to determine the decedent's suitability for tissue donation.

   2.2. The (M)TRC must immediately address any discrepancy or documentation that appears incorrect or incomplete, by using a source record or by direct contact with the person who obtained the information or who can provide the information as appropriate. The (M)TRC (if applicable) will inform the Recovery Lead of the discrepancy.

   2.3. The (M)TRC will review the death certificate/warrant to bury (if available) and document in the donor chart verbatim the cause(s) of death and the full name of the pronouncing physician. If the pronouncing physician's name is not legible, the (M)TRC will indicate in the donor chart that the name was not legible (i.e., indicate by using the following term "sp?" following the spelling of the name).

   2.4. The (M)TRC will determine if the cooling time and the cumulative uncooled time of the donor meets the AATB standards
   For cardiac tissue recovery, the warm ischemic time shall not exceed 24 hours, where the warm ischemic time is defined as time of death to placement of cardiac tissue into cold transport solution at the time of recovery. For donors not refrigerated within 12 hours of death, the warm ischemic time shall not exceed 15 hours. If the donor's body is cooled for a period of time then not cooled for a period of time, the time period the donor's body is not cooled cannot exceed 15 cumulative hours.

   For musculoskeletal, osteochondral and skin recovery, the skin prep shall begin within 24 hours of asystole provided the donor's body was cooled or refrigerated within 12 hours of asystole. The skin prep shall begin within 15 hours of death if the deceased donor's body has not been cooled or refrigerated. If the donor's body is cooled for a period of time then not

cooled for a period of time, the time period the donor's body is not cooled cannot exceed 15 cumulative hours. See D5.400 - Time Limits for Postmortem Tissue Recovery. AATB Standards of Tissue Banking 14th Edition.

3. The (M)TRC will review and document the relevant information on the TGLN Donor Transport Form sent through the refrigeration time email if the donor was cooled in a refrigerated vehicle during transport to a recovery site.

4. A copy of additional relevant and available medical records shall be obtained, reviewed, and included in the donor chart whenever possible prior to tissue donation as per AATB D4.150 Relevant Medical Records Review.

5. The (M)TRC includes additional relevant information, for which there is not a designated location in the electronic records and in the clinical notes. This may include inconsistencies, unusual findings, family requests, and any other pertinent case details or items that may require follow-up. All discrepancies, together with subsequent investigation and any resolution, must be documented in the clinical notes.

6. If the patient's medical record is not available for review prior to the recovery, or time parameters preclude the ability to review the record and recover the tissue within the required amount of time, tissue recovery may proceed.

    6.1 In the case where patient medical records are not available for review, the Recovery Lead or designate shall document in the donor chart that recovery took place without medical record review to flag the chart for retrospective review of pertinent medical records.

    6.2 In the case that time parameters are a concern, the medical record review shall be completed by the Circulator or designate during the multi tissue recovery.

    6.3 Post recovery, the Information Coordinator – Tissue will request the medical records from the hospital and send directly to the Tissue Banks for their review.

Hemodilution Review

7. Upon review of the medical records, it is the (M)TRC's responsibility to ensure that any fluids given in the hour preceding death or sample collection, any blood products or colloids given in the 48 hours preceding death or sample collection, and the weight of the donor correspond with the information listed in any other available record.

8. For combined organ and tissue donors, preliminary hemodilution review documentation may be substituted with hemodilution review documentation from the electronic organ donor record.

9. The (M)TRC verifies that the sample qualifies for hemodilution as per *Hemodilution Calculation Process Instruction CPI-9-210*. If a significant discrepancy in the hemodilution documentation that puts the sample at risk for not meeting hemodilution acceptance is found, or if a sample is not available, a hemodilution worksheet shall be completed.

10. If additional samples are collected for additional tests, a hemodilution assessment must be performed for each sample.

11. Hemodilution calculations must be performed and must be acceptable for all samples tested before proceeding to recovery.

12. If the medical records review uncovers medical issues, or if there are unresolved discrepancies that may impact medical suitability of the donor, the Recovery Lead or Circulator shall confer with Provincial Resource Centre staff, Tissue Manager on-call and/or a consulting physician regarding whether or not to proceed with the recovery.

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Records:

Record Name	Form No. (if applicable)	Record Holder	Record Location	Record Retention Time (as a minimum)
Donor Chart	----------	PRC	PRC	16 Years
Donor Medical & Social History Questionnaire	CSF-9-14	PRC	PRC	16 Years
Eye Recovery Form	CSF-9-80	PRC	PRC	16 Years
Multi-Tissue Recovery Form	CSF-9-146	PRC	PRC	16 Years

References:

- *Standards for Tissue Banking, American Association of Tissue Banks, United States, 14th edition, 2017. D4.100, D4.150, D4.200, D4.210, D4.220, D4.230, D4.240, D3.300, D5.400*
- *Hemodilution Calculation Process Instruction, CPI-9-210*