

Clinical Process Instruction Manual

Physical Assessment for Tissue Process Instruction

Policy:

Donor screening and testing activities are performed to assess donor suitability. As per the Health Canada's *Safety of Human Cells, Tissues, and Organs for Transplantation (CTO) Regulations*, *American Association of Tissue Banks (AATB) Current Standards for Tissue Banking and Eye Bank Association of America Standards (EBAA)*, the Tissue Recovery Coordinator (TRC) or- the Multi Tissue Recovery Coordinator (MTRC) collects and/or verifies comprehensive screening information. The information available in Trillium Gift of Life Network (TGLN) documentation and other relevant medical records will be used to aid determination of donor suitability in order to proceed with tissue recovery.

The physical assessment and documentation are completed by the TRC or MTRC prior to retrieval of tissues intended for transplant. The (M)TRC identifies the staff involved in each significant step of the physical assessment procedure, and documents donor identification and consent verification procedures.

The physical examination consists of an ante-mortem physical examination or post-mortem physical assessment of the donor to identify and assess any physical evidence of relevant communicable disease, high-risk behaviour associated with these diseases, and/or signs of trauma or infection at the sites where tissue recovery is planned. Observations and positive findings shall be documented in the recovery information section of the donor chart. The presence of positive findings of high-risk behaviour, relevant communicable disease(s) or trauma to the retrieval site(s) observed during the physical assessment or indicated in any other available record, shall result in deferral of that donor and/or tissue as applicable as per the tissue deferral criteria. Documentation of the physical assessment may be performed using paper or electronic format based on location and timing of the case. If paper format is used to document the physical assessment, this information must be transcribed to the DMS as soon as possible.

The TRC ensures that established blood borne pathogen precautions are adhered to at all times.

Process:

1. The TRC/MTRC obtains the following materials:
 - indelible ink pen as required
 - *Eye Recovery Form* or equivalent
 - *Tissue Recovery Form* or equivalent

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- relevant donor medical records, including but not limited to: *Consent to Donate Organs and/or Tissue*, completed *Donor Medical and Social History Questionnaire*, and other available relevant medical records
 - pen light
 - examination gloves
 - isolation gown as required (moisture impermeable gown)
 - Mask with face shield or equivalent
 - Cap to cover hair
 - Beard cover if applicable
 - Shoe covers
 - measuring tape
2. The donor shall be removed from the body bag.
 3. Any clothing, jewelry, and any amputated tissue shall be removed. Place these items into a clear plastic bag and set aside in a spot where they will not be mistaken for recovery waste.
 4. If possible, store the jewelry in a separate bag from the other items and place in the custody of Security or another responsible person. Document all jewelry removed on the donor chart if applicable.
 5. For rings and jewelry that cannot be removed, place tape over or around the item and document their appearance and location on the donor chart.
 6. The TRC/MTRC begins the physical assessment anteriorly (supine) at the head and assesses down to the feet.
 7. The TRC/MTRC turns the donor over or rolls the donor on a side, and examines from the posterior surface of the body from head down to the feet.
 8. The TRC/MTRC documents 'unremarkable' if nothing is noted on a total body view (e.g., the posterior view). The TRC does not leave an entire view of the schematic blank.
 9. If it is not possible to visualize an area, the TRC/MTRC documents 'unable to visualize', and provides a rationale (e.g., endotracheal tube blocking the full view of the mouth and Coroner restriction on removing the tube). For larger ocular-exclusive donors, it is unacceptable to document 'unable to visualize' for the posterior aspect of the donor unless the TRC is unable to turn the donor and there is no assistance available.

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10. The TRC/MTRC documents all findings on the donor chart. Relevant findings include, but are not limited to, evidence of communicable disease, high risk behaviour, trauma to the retrieval site, medical interventions, physical abnormalities, or any other positive finding that may potentially impact the safety or quality of the tissue.
11. The TRC/MTRC assesses the donor for the findings listed below. If any of these signs are observed and are deemed to be an indication of either high-risk behaviour or an indication of relevant communicable disease, then the tissue donor should not be accepted as per tissue specific criteria below. A medical consult maybe required to diagnose the findings on the physical exam.
 - physical evidence for risk of or evidence of sexually transmitted diseases such as genital ulcerative disease, herpes simplex, syphilis, chancroid, genital warts, genital lesions, rash, skin lesions (non-genital);
 - for a male donor, physical evidence consistent with anal intercourse including perianal condyloma (insertion trauma, perianal lesions);
 - physical evidence of non-medical percutaneous drug use, such as needle tracks (and/or non-medical injection sites) including assessment of tattoos which may be covering needle tracks;
 - disseminated lymphadenopathy (enlarged lymph nodes);
 - unexplained oral thrush (white spots in the mouth);
 - blue or purple [grey/black] spots or lesions consistent with Kaposi's sarcoma;
 - physical evidence of recent tattooing, ear piercing, or body piercing, or body piercing in the preceding 12 months, in which sterile procedures were not used, or instruments that had not been sterilized between uses were used (tattoos and piercings shall be described).
 - unexplained jaundice, hepatomegaly (enlarged liver) or icterus. Note: Hepatomegaly may not be apparent in a physical assessment if the organ was accepted for transplant or an autopsy was performed);
 - physical evidence of sepsis, such as unexplained generalized rash or generalized petechiae, or fever (rash);
 - large scab consistent with recent history of smallpox (scab);
 - eczema vaccinatum (lesion, scab);
 - generalized vesicular rash, generalized vaccinia (rash);
 - severely necrotic lesion consistent with vaccinia necrosum (lesion); or
 - corneal scarring consistent with vaccinal keratitis (abnormal ocular finding), scarring, and

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- skin sloughing or slippage
12. If the body was rejected for routine autopsy due to infectious criteria or the plan for autopsy includes being done in an infectious disease control room or under any special precautions, the TRC/MTRC documents and explains the reason behind these procedures.
 13. The TRC/MTRC evaluates trauma to tissues to be recovered. The TRC does not recover eye tissue that is severely damaged (i.e., perforated).
 14. On accepted skin donors, the physical assessment shall include documentation of any findings that may affect the quality or quantity of skin recovered.
 15. If the TRC/MTRC has any questions and/or concerns regarding the acceptability of the donor, or an abnormality is found on a donor physical assessment, the TRC/MTRC must consult the Tissue Coordinator (TC), Tissue Program's 24-hour Medical Consultant, Tissue On-Call (TOC) or other suitable knowledgeable medical professional for advice and direction as per the Medical Consult Guidelines and reference CPI-9-557.

Records:

Record Name	Form No. (if applicable)	Record Holder	Record Location	Record Retention Time (as a minimum)
Donor Chart	-----	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
Assessment Form: Tissue Donor	CSF-9-16	PRC	PRC	16 Years

References:

- *Health Canada: Safety of Human Cells, Tissues & Organs for Transplantation Regulations, June 2007*

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- Z900.1-03 Cells, Tissues, and Organs for Transplantation and Assisted Reproduction: General Requirements
- Z900.2.4-03 Ocular Tissues for Transplantation
- Eye Banks Association of America Standards
- Standards for Tissue Banking, American Association of Tissue Banks, United States, 14th edition, 2017. D4.120, D4.210
- American Association of Tissue Banks Guidance Document No. 1