Clinical Process Instruction Manual

Multi-Tissue Recovery Records Process Instruction

Policy:

Each tissue banking organization, including recovery partners, is required to provide detailed documentation of the tissue banking processes for which the organization is responsible. Documentation must be made concurrent with each significant step of the recovery process, and for Trillium Gift of Life Network (TGLN) recovery services. This includes but is not limited to: donor suitability assessment, donor identification, tissue recovery, donor and tissue transport, record review and tissue labelling.

Records shall document the responsible parties and must delineate the dates, times, and locations of procedures, as well as the individuals performing them, in order to facilitate traceability. All records are considered confidential and are kept in a location with controlled access; precautions for the safety and security of records should be in place and self-evident.

The Lead Multi Tissue Recovery Coordinator (MTRC) is responsible for ensuring specific documentation components of the recovery processes are complete, however, all MTRCs involved in documentation are responsible for ensuring correctness and accuracy of the data. The MTRC documenting the tissue recovery is assigned the circulator role during the recovery.

Process:

1. Any trained recovery personnel may complete the tissue recovery documentation. The assigned circulator is accountable for the accuracy and completeness of the information they enter into the tissue recovery form or iTransplant. The Lead MTRC is responsible for reviewing the documentation recorded in the tissue recovery form or iTransplant in the following areas: chart review, physical assessment and deviations for completeness.

2. The circulator is responsible for informing the Lead of any red flags, discrepancies or challenges pertaining to the donor's chart review, donor refrigeration, physical assessment, donor weight, etc.

3. The MTRC shall bring the recovery laptop, scanner and hardcopies of the *Consent Form to Donate Organs and Tissues* and all pertinent donor screening documents from iTransplant to ensure the availability of all records in the event that iTransplant is not accessible due to poor or no internet connection.

4. Documentation of recovery processes shall be completed in iTransplant, the donor management system wherever possible.

5. Only in cases where there is no electronic access to donor records may recovery documentation be documented on the paper backup record (i.e., the *Multi Tissue Recovery Form*). See Exhibit 1.

5.1 If paper documentation is required, the rationale shall be documented in the clinical notes so that any pertinent follow up can be performed.

5.2 Once completed, the paper record shall be scanned into the donor chart and a transcription of the information from the paper record into the electronic record be made.

6. Records for tissue recovery shall include the following:

- name and address of the recovery agency;
- date, time and staff involved in the recovery process;
- location and assessment of the suitability of the recovery site;
- donor, name, age, and sex;
- type, lot number, manufacturer, and expiration date of supplies and reagents used to recover, rinse, and transport tissue;
- specific tissue recovered;
- ABO/Rh if available;
- date and time of asystole;
- date and time of recovery of the heart (time when subjected to cold rinse solution)

For a complete list of every required field, reference the *iTransplant Recovery User Manual*.

7. Additionally, TGLN shall provide a record of the tissue recovered, date of recovery, name and address of the recovery agency, and name of the donor to the recovery site facility by completing the *Multi-Tissue Recovery Note*. See Exhibit 2.

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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
Multi-Tissue Recovery Form	CSF-9-146	Tissue Department	Tissue Department	16 years
Multi-Tissue Recovery Note	CSF-9-147	Tissue Department	Tissue Department	16 years

References:

- Standards for Tissue Banking, American Association of Tissue Banks, United States, 14th edition, 2017. C1.000, C1.100, C2.000, and D5.700
- iTransplant Recovery User Manual

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Exhibit 1: Multi-Tissue Recovery Form

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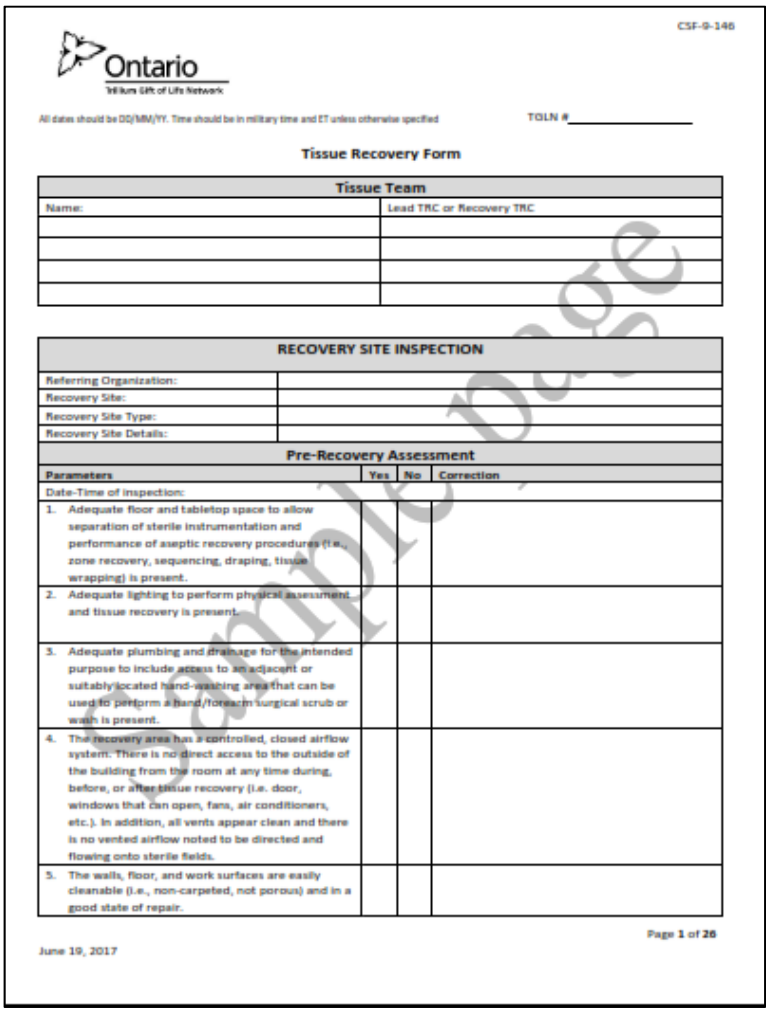

CSF-9-146

Ontario
Trillium Gift of Life Network

All dates should be DD/MM/YY. Time should be in military time and ET unless otherwise specified

TGLN #_____

Tissue Recovery Form

Tissue Team	
Name:	Lead TRC or Recovery TRC

RECOVERY SITE INSPECTION	
Referring Organization:	
Recovery Site:	
Recovery Site Type:	
Recovery Site Details:	

Pre-Recovery Assessment			
Parameters	**Yes**	**No**	**Correction**
Date-Time of inspection:			
1. Adequate floor and tabletop space to allow separation of sterile instrumentation and performance of aseptic recovery procedures (i.e., zone recovery, sequencing, draping, tissue wrapping) is present.			
2. Adequate lighting to perform physical assessment and tissue recovery is present.			
3. Adequate plumbing and drainage for the intended purpose to include access to an adjacent or suitably located hand-washing area that can be used to perform a hand/forearm surgical scrub or wash is present.			
4. The recovery area has a controlled, closed airflow system. There is no direct access to the outside of the building from the room at any time during, before, or after tissue recovery (i.e. door, windows that can open, fans, air conditioners, etc.). In addition, all vents appear clean and there is no vented airflow noted to be directed and flowing onto sterile fields.			
5. The walls, floor, and work surfaces are easily cleanable (i.e., non-carpeted, not porous) and in a good state of repair.			

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Exhibit 2: Multi-Tissue Recovery Note

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Multi Tissue Recovery Note

Hospital: _____ Date: _____ TGLN #: _____

Patient Name: _____ MRN: _____

Recovery Agency: **Trillium Gift of Life Network**

Recovery Personnel (please print):

1. (Lead) _____
2. _____
3. _____
4. _____

The identity of the patient was confirmed along with the consent form. A physical assessment was completed and blood was drawn from the:

☐ subclavian artery, ☐ femoral artery, ☐ jugular vein, ☐ heart, or ☐ N/A (pre-drawn samples available).

All IV lines, defibrillator pads, and tubes, etc. still attached to the patient were removed (in accordance with Coroner's directive, if applicable).

The following tissues were recovered (check all that apply):

☐ Skin, from the: ☐ posterior trunk ☐ posterior legs ☐ abdomen ☐ anterior legs

☐ Heart Valves, ☐ including pericardium and / or ☐ the descending thoracic aorta

☐ Bone and Connective Tissue, including the following:

☐ Humerus	☐R	☐L	☐ Tendons of leg	☐R	☐L	☐ Achilles Tendon	☐R	☐ L
☐ Radius	☐R	☐L	☐ Femur	☐R	☐L	☐ Ilium	☐R	☐ L
☐ Ulna	☐R	☐L	☐ Tibia	☐R	☐L	☐ Hemi-Pelvis	☐R	☐ L
☐ Fascia	☐R	☐L	☐ Fibula	☐R	☐L	☐ Other _____		
☐ Osteochondral Tissue	☐R	☐L						

The recovery of these tissues took place as described in the following pages.

After the recovery, the patient's body was rewrapped in the shroud and returned to the storage location from which it was retrieved.

Lead Multi Tissue Recovery Coordinator Name: _____ **Date:** _____

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