Clinical Process Instruction Manual

Tissue Labelling Controls Process Instruction

Policy:

There shall be appropriate labelling control procedures implemented, with labelling controls incorporated into the Clinical Process Instruction (CPI) Manual for tissue labelling.

Label control includes the review of labels to ensure accuracy. Labels shall be inspected to prevent transcription and other labelling errors. Electronic labelling systems shall possess adequate controls to prevent the erroneous labelling of tissue. Label inspections shall be documented in the donor record as evidence to support label verification was completed and that labels are accurate.

The labelling area shall be inspected prior to the start of labelling activities to ensure that all labels and packaging materials from previous labelling have been removed.

If preprinted or computer-generated labels are used, an example of every label that is utilized shall be kept in the Master Label Log. Dates of use (start and discontinuance) shall be recorded.

Process:

1. Trillium Gift of Life Network (TGLN) shall maintain a Master Label Log. See Exhibit 1. This log will include listing all the labels in the log and a sample of all current labels that are used to identify tissues that are intended for transplant including but not limited to:
   - cardiovascular (CV) tissue labels
   - skin tissue labels
   - musculoskeletal (MS) labels for recovery
   - TGLN number sticker labels
   - package inserts
   - exterior transport labels
2. Nomenclature and units of measurement used to describe tissue shall be described in the CPIs and applied consistently.
3. New labels created must be approved by Quality Authority or designate and the Department Authority or designate prior to use and implementation. Labels will be added to Master Label Log with a printed sample by Clinical Quality Specialist – Tissue or designate only and documented on the Master Label Log Contents List (CSF-9-238).
4. New labels shall be designed to facilitate the use of uniform labelling techniques for each type of tissue.

5. The relevant CPI for each specific tissue label shall be reviewed annually and updated as re-required.

6. The Clinical Specialist or designate shall remove labels from label storage areas once a label has become obsolete, and replace them with the newly implemented label(s) as required. Labels must be replaced in all locations where pre-printed labels are stored, including:

    - Tissue Supply Room at 483 Bay Street, including any pre-packed recovery bags
    - Tissue Supply Storage Room at Forensic Sciences and Coroner's Complex
    - Tissue Recovery Suite at Forensic Sciences and Coroner's Complex

7. The date of discontinuance shall be documented in the Master Label Log Contents List (CSF-9-238).

8. The Master Label Log shall be reviewed annually by Clinical Quality Specialist – Tissue or designate for any new, revised or obsolete labels.

9. A sample of the label shall be kept for archival purposes.

10. The remaining labels shall be discarded.

Records:

Record Name	Form No. (if applicable)	Record Holder	Record Location	Record Retention Time (as a minimum)
Master Label Log Contents List	CSF-9-238	Quality Department	Quality Department	16 years

References:

- Standards for Tissue Banking, American Association of Tissue Banks, United States, 14th edition, 2017. G1.100, G1.200, G2.300, G2.330.

Clinical Process Instruction Manual

Tissue Labelling Controls Process Instruction

Exhibit 1: Master Label Log Contents List

CSF-9-238

Master Label Log
Contents History

Form Number	Form Name	Start of Use	Discontinuance

August 26, 2020