Ontario Health
Trillium Gift of Life Network

Quality System Procedure Manual

Quality Records Procedure

1.0 Purpose:

To establish and maintain a procedure for the identification, storage and maintenance of quality system records.

2.0 Scope:

This procedure applies to:

- Ontario Health - Trillium Gift of Life Network (OH-TGLN)

3.0 Responsibilities:

Director Quality is responsible for:

- ensuring that the required quality system records are filed, stored and maintained in an easily accessible manner and protected against damage, deterioration or loss
- ensuring that records are made available for employees, customers, regulatory authorities and auditors review, when agreed to by OH-TGLN

Managers/Directors are responsible for:

- ensuring that the required quality system records are filed, stored and maintained in an easily accessible manner
- archiving of records beyond their stated retention time, as appropriate

Employees are responsible for:

- creating, filing, storing and maintaining quality system records, as per the quality system documentation

4.0 Procedure:

General

4.1 All records for the quality system are defined in each documented quality system procedure and instruction.

4.2 The retention times for the records detailed in the quality system documentation reflect the minimum time for which records are active within departments.

4.3 Beyond the stated record retention times noted in quality system documentation, some records may be archived.

4.4 Some records are retained until they are superseded, rather than due to elapsed time. As a result, the retention time for records, such as the following, are triggered with a revision to the specified document:

- key suppliers list
- position descriptions

4.5 The department where the record is stored refers to the master copy only. Copies of records can be held by several other employees. However, only the master copy of a record is maintained in a controlled manner.

4.6 Each record provides legible information.

4.7 Each record holder is responsible for collecting, filing, storing and maintaining records which are in use. He/she is also responsible for ensuring that all records are transferred to the designed location for longer-term storage.

4.8 Employees who have the responsibility for storing active quality records must ensure that:

- records are stored in a manner to minimize deterioration or damage
- records are stored in designated areas to prevent loss
- records are filed for ease of retrieval

4.9 Customers, employees, regulatory authorities and auditors are permitted to view quality records, on a case-by-case basis, depending on:

- privacy of information criteria
- customer type
- nature of request

4.10 All electronic records (i.e. scanned charts, scanned and uploaded forms into the donor management system, donor management system database, Organ Allocation System (OAS)database) are maintained by the Information Technology

Department according to the *Business System Data Control Process Instruction, QPI-5-1.*

4.11 All records are stored at a reputable off-site storage and in the offices of Organ and Tissue Donation Coordinators.

4.12 All OH-TGLN records and documentation forms shall use a standardized date and time format as much as possible. The standard date notation is DD-MM-YYYY where DD is the day of the month between 01 and 31, MM is the month of the year between 01 (January) and 12 (December), and YYYY is the year in the usual Gregorian calendar. Similarly, the 24-hour time format shall be used.

Clinical Records

4.13 Records for organs and tissue donors are created and maintained with the following features/inclusions, as a minimum:

- a unique identification number is assigned to each donor. This number becomes the filing reference for each donor file. This number is auto-generated by the donor management system and was arbitrarily started at 200000 for the first donor case entered into the donor management system. This number auto-increments based on referrals entered into the system
- the name of the establishment from which OH-TGLN received organs
- the name of the establishment to which OH-TGLN distributed the tissues and organs
- any shipping documents that were used in the transport of tissues and organs to another establishment
- the donor suitability assessment
- a description of the tissues and organs, recovered from the donor
- the name of any source establishment from which OH-TGLN received an organ referral or to which OH-TGLN made an organ referral
- the name of the retrieval establishment
- the notice of exceptional distribution, if applicable
- documentation of processing activities including donor screening, donor testing, post retrieval testing (when required) and packaging & labelling

- an audit trail for electronic records which includes the altered information, date of the revision and the individual that made the revision
- the OH-TGLN number on all documentation uploaded to the donor chart

4.14 Additionally, records for tissue donors must include:

- record of informed consent
- donor physical assessment
- a copy (image or recreation) of donor identification
- review of medical records, if available

4.15 The quality assurance department maintains the master copy of all records pertaining to accidents, errors and adverse reactions. These records including any investigations that were conducted and corrective actions taken.

4.16 In an establishment role, OH-TGLN will provide the respective source establishment and transplant establishment with information necessary to complete their files.

4.17 The donor chart records are kept for at least sixteen (16) years after transplantation.

4.18 Records of errors, accidents, adverse reactions and internal audits are kept for at least sixteen (16) years after creation.

4.19 Employee qualifications, training and competency records are kept for at least sixteen (16) years after the individual ceases to be an employee of OH-TGLN.

4.20 Copies of all versions of OH-TGLN's quality policies, procedures and instructions are kept for at least sixteen (16) years, after they are superseded by a new version.

4.21 Clinical records are stored in a secure room that is free from damage or destruction.

5.0 Records:

No records.

6.0 References:

- *Business System Data Control Process Instruction, QPI-5-1*
- *Standards for Tissue Banking, American Association of Tissue Banks, United States, 14th edition, 2017. K7.500*