Ontario
Trillium Gift of Life Network

# Clinical Process Instruction Manual

## Organ Recovery Materials Qualification Process Instruction

### Policy:

Trillium Gift of Life Network (TGLN) is committed to ensuring that it maintains appropriate supplies required for recovery of organs and composite tissues. Accordingly, TGLN uses the process described in this procedure for approval of materials and solutions used in recovery and packaging. These are reagents and supplies which could affect the safety and come into direct contact with organs and composite tissues. Surgical recovery supplies are approved based on the *Materials and Solutions Qualification List* that is reviewed annually.

### Process:

1. Materials and solutions to be used for recovery and packaging are selected and approved for use by the Manager, Surgical Recovery Services—Organ or designate.

2. Once approved, the Manager, Surgical Recovery Services—Organ or designate notifies the Quality Department with all relevant information to add the materials and/or solutions to the *Recovery Materials Qualification List*. See Exhibit 1.

3. The Inventory Assistant – Organ (IA - Organ) or designate will flag any received products that are not identical on the *Recovery Materials Qualification List* (either change in supplier and/or manufacturer) and quarantine these products until the relevant information is obtained and approved in accordance with the steps 1 and 2 above.

4. Materials and solutions are generally used in accordance with their manufacturer's intended use. If TGLN's use differs from the manufacturer's intended use, this is documented on the *Recovery Materials Qualification List*.

5. For the supplies which do not affect the safety or come into direct contact with the organs and composite tissues, a formal, rigorous documentation is not required.

6. The Manager, Surgical Recovery Services—Organ or designate will notify the Quality Department when items on the *Recovery Materials Qualification List* change. If an approved item becomes inactive for some reason (e.g., manufacturing issues, recall, etc.) this will be updated in the Notes column on the list. If an item loses its approval, it will be removed from the list.

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7. When deemed necessary, Manager, Surgical Recovery Services—Organ or designate will review the currency of the items listed on the *Recovery Materials Qualification List.*

### Records:

| Record Name | Form No. (if applicable) | Record Holder | Record Location | Record Retention Time (as a minimum) |
|---|---|---|---|---|
| Recovery Materials Qualification List | CSF-9-73 | Quality Assurance Department | Quality Assurance Department | 16 years |

### References:

- None

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### Exhibit 1: Recovery Materials Qualifications List

CSF-9-73

**Recovery Materials Qualification List:** Intended Use & Storage Requirements

| Product | Manufacturer | Manufacturer Product # | Supplier | Supplier Product # | Website or Contact Name, Phone #, Email | Source of Intended Use/Storage Requirements | Manufacturer's/ Supplier's Intended Use | Storage Requirements | Initials (individual who verified information received) | Other Requirements if not already specified (if required) | Notes | Revision Date |
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June 19, 2017