



Clinical Process Instruction Manual

Organ and Tissue Case Sign-Off, Closure and Chart Locking Process Instruction

Policy:

To promote data completeness, Trillium Gift of Life Network (TGLN) requires every case be signed off upon completion. Before sign off, every role involved in the case is accountable for ensuring all aspects of the TGLN chart assigned to their role are complete. The roles involved in this process are: Referral Triage Coordinator (RTC), Organ and Tissue Donation Coordinator (OTDC), OTDC Clinical Responder (OTDC CR), Clinical Services Coordinator (CSC), Surgical Recovery Coordinator (SRC), Tissue Coordinator (TC), Tissue Recovery Coordinator (TRC), Information Coordinator (IC), Quality Department staff, Senior Health Informatics Specialist – Hospital Programs (SHIS-HP), Clinical Specialists and Health Record Reviewers (HRR). For the purposes of this document, the term TGLN coordinator may consist of any of the roles listed above.

To preserve data integrity, charts will be locked 90 days from the date of referral. Locked charts can be viewed, but the ability to change data or upload attachments is restricted.

Process:

Outlined below are process descriptions for both case closure and chart locking for combined organ and tissue (OT) cases, and tissue only (T) cases.

Case Sign-Off and Closure

Charts are signed-off by each function involved in the case. The sign-off activity is performed by first ensuring that the required data elements are completed in the TGLN chart, according to the Role Specific Case Closure Checklist and second by electronically signing off in the chart. See Exhibit 1. Once all required sign-offs for a case are complete, then the case is considered closed. For OT cases that are donors, this occurs when Quality or HRR completes their sign-off and for all other cases it occurs when the IC or HRR completes their sign-off as applicable (in both cases whichever comes last).

For OT Cases, the following occurs:

1. RTC Sign-Off Events
 - After the donor has been declined for no organ recovery potential. In this case the RTC's sign-off closes the case.
 - After consent is obtained
2. CSC Close-Out and Case Closure Events
 - After a referral is ruled out, prior to consent being obtained



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- When consent is obtained (verbal or written), but the case does not proceed to the Operating Room (OR)
 - When consent is obtained (verbal or written), but the case does not proceed to actual transplantation of an organ
 - When an organ is transplanted, after the final cultures are reported and where applicable, Exceptional Distribution forms are returned
3. OTDC/OTDC CR Sign-Off Events
- When the case does not proceed to the OR (includes Family Declines and Consented Not Recovered cases)
 - When the case proceeds to the OR, after any patient transfer
 - When there is a case handover between OTDCs/OTDC CRs
 - When final cultures are obtained
4. SRC Sign-Off Events
- When the case proceeds to the OR (includes Recovered Not Transplanted, Medically Unsuitable in OR, or Unsuccessful DCD cases)
 - After entering data on recoveries where no TGLN SRC was involved
5. QA Sign-Off Events
- After the Organ Donor chart has been reviewed for Health Canada compliance and all organ-related amendments to the chart have been correctly completed

For OT and T Cases, the following occurs:

6. TC Sign-Off Events
- When the ocular and/or multi-tissue has been confirmed as received (Tissue Donors Only)
7. TRC Sign-Off Events
- When the case proceeds to tissue donation and ocular tissue was recovered (GTA TRCs Only)
8. IC Sign-Off Events
- When all of the chart data has been entered
9. HRR Sign-off Events
- After the Health Record Review has been completed



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Chart Locking / Unlocking

The chart locking and unlocking processes follow the steps below:

10. All charts will be locked 90 days from the date of referral.
11. If a chart has already been locked and requires to be unlocked, the following persons will be responsible for unlocking the chart in the following scenarios:
 - 11.1 Quality Department staff is responsible if unlocking is required for an amendment or additional information to be charted or attachments to be uploaded. The reason for unlocking and if applicable the TGLN Coordinator requested to take the action will be documented.
 - 11.2 HRR is responsible if unlocking is required to document information for the Health Record Review Process. The reason for unlocking will be documented as “Unlocked for HRR”.
 - 11.3 SHIS-HP is responsible if data validation checks indicate inconsistencies or missing performance data. The reason for unlocking and if applicable the TGLN Coordinator requested to make the corrections or complete omitted data will be documented.
 - 11.4 IC-Organ or IC-Tissue is responsible if unlocking is requested by a TGLN Coordinator or their manager. The TGLN Coordinator will send an email to the ‘Organ Chart Locking’ inbox for OT cases, or the ‘Tissue Chart Locking’ inbox for T cases, indicating the TGLN chart number and a brief explanation of the reason why. The IC-Organ or IC-Tissue will document this reason when unlocking the chart. Consultation with the Clinical Specialist or Manager prior to changes may be required.
 - 11.5 Clinical Specialists are responsible for unlocking the chart if a TGLN Coordinator or Manager assigns amendments to them. The Clinical Specialists will document the reason for unlocking the chart.
12. Once the amendment is made by a TGLN Coordinator, he/she will notify the person mentioned above who was contacted to unlock the chart. Once notified, the responsible person will lock the chart. In some cases, the information is verified prior to locking the chart. If the information can not be verified or is incomplete the responsible person will perform follow-up to ensure the action is complete prior to re-locking the chart.
13. In emergency cases, if after-hours access to a locked chart is required, the TGLN coordinator will contact ServiceDesk After-Hours Support. In these instances, the ServiceDesk After-Hours Support person will document the reason for unlocking the chart and the name of the TGLN Coordinator who requested it.
14. The IC-Organ or IC-Tissue will review unlocked charts that were opened longer than six months and notify the person(s) who have unlocked the chart to relock the chart.



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Sending Updated Charts to Tissue Banks and Transplant Programs

15. Within five (5) business days of the initial chart locking, the IC-Tissue will send the final TGLN chart for all multi-tissue donors to the appropriate tissue bank(s) unless there are any outstanding amendments. When amendments are complete IC-Tissue will send the updated TGLN chart to all appropriate tissue bank(s).
16. If one of the fields identified in Appendix 1 has been changed for an organ and/or tissue donor after the chart has been locked, the updated information must be sent to the transplant program and/or tissue bank within one (1) business day. Consultation with the Manager or Clinical Specialist prior to sending the updated information may be required.

Records:

- *No records.*

References:

- *No references.*



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Appendix 1: Donor Information

Field	Organ Donor	Tissue Donor
Date of Birth	X	X
Gender	X	X
Death Date-Time	X	
Date of Hospital Admission	X	
Date-Time of Extubation	X	
Absolute Exclusions	X	
Brain Death Declarations	X	
Hospital Name		X
Death Date-Time		X
Absolute Exclusions		X



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Exhibit 1: Sample Role Specific Case Closure Checklist

OTDC TGLN DONOR CASE CLOSURE CHECKLIST
Trillium Gift of Life Network
Documentation table with columns for Item, Documentation, Responsible, Initials, and Comments/Notes. Includes sections for Health Canada Requirements, Donor Information, and Organ Specific Testing.