



Clinical Process Instruction Manual

Tissue Competency and Continuing Education Process Instruction

Policy:

Technical staff must demonstrate competency in the particular operations for which they have received training, including a thorough understanding of the policies, procedures, process controls, and regulatory requirements, and to which they are assigned. As part of maintaining competency, technical staff are required to perform an annual review of Clinical Process Instructions (CPI) for which they have been trained, including safety procedures and annual attendance at hazardous materials training.

Tissue clinical staff shall participate in continuing education, which may include training courses, technical meetings, and any other educational programs pertaining to assigned functions. Such participation shall be documented in the training files.

Process:

General

1. The purpose of this procedure is to describe how Trillium Gift of Life Network (TGLN) manages its competency and continuing education programs
2. It is the responsibility of TGLN to provide and implement a competency and continuing education program. This includes processing requests for continuing education, providing assistance in meeting program requirements, and maintaining all required documentation.

Competency

3. The TGLN preceptor shall assess the staff member for competence prior to independent practice using the appropriate competency assessment tool for the particular job function and recommend approval for independent practice to the manager or designate. See Exhibits 2 - 11. Results of the competency assessment and any opportunities for development shall be shared with the staff member being assessed.
 - 3.1 Using a scale of 1 - 4, each performance element of the task will be rated and assigned the appropriate score in the rating box on the skills checklist.
 - 3.2 A rating of 1 - Limited knowledge or ability to demonstrate required competency (not competent).
 - 3.3 A rating of 2 - Demonstrates partial knowledge or ability to demonstrate competency, but not in all required aspects (basic or novice).
 - 3.4 A rating of 3 - Mostly demonstrates knowledge or ability of competency but needs guidance occasionally (mostly competent).



Clinical Process Instruction Manual

Tissue Competency and Continuing Education Process Instruction

- 3.5 A rating of 4 – No guidance/prompting required to demonstrate knowledge of or ability to perform competency (fully competent).
4. The manager or designate reviews all competency forms submitted by preceptors and approves the staff member for independent practice if their score meets expectations. The manager or designate will complete the appropriate competencies record and date it (See Exhibits 13-15).
5. In cases, where not all performance elements are deemed at a level 4, the trainee may still be deemed competent if there is a minimum of level 3 and they have scored 80% or higher in total.
6. The manager or designate reviews all competency forms, discusses opportunities for development and confirms any need for retraining with the preceptor as required.
7. Education and Professional Practice archives competency assessment records. Results of competency assessments and any follow up shall be maintained in the training file.
8. Competency assessments of technical staff for the in situ recovery procedure are completed by the Eye Bank of Canada (EBC) (See Sample 1) prior to independent practice and henceforth on an annual basis.

Competency Exemption

9. Technical staff may be exempt from the competency assessment for one of the following reasons:
 - 9.1. Technical staff who are trained for an activity that is not a part of their job description or regular activities may receive an exemption from competency assessment on the basis that they will be required to be retrained before conducting the activity again in the future.
 - 9.2. Technical personnel who develop a competency assessment and who provide training for that competency are exempt from the assessment.
10. To record an exemption, complete the Training Qualification and Exemption Form for the applicable staff member. See Exhibit 11. The completed form shall be maintained in the training file.

Annual Competency

11. An annual competency assessment shall be completed for all tissue technical staff for core job functions identified. The manager or designate is responsible for identifying the core job functions to be evaluated. See Appendix 1 and Exhibits 2 - 10.



Clinical Process Instruction Manual

Tissue Competency and Continuing Education Process Instruction

Continuing Education

12. It is the responsibility of each employee to identify gaps in education and/or need for retraining, participate in educational opportunities, once certified to maintain certification as per his/her job requirements.
13. TGLN provides educational opportunities in house regularly for Tissue Coordinators (TCs), Multi-Tissue Recovery Coordinators (MTRCs) and Tissue Recovery Coordinators (TRCs).

TGLN Instructional Personnel

14. Only qualified personnel are to be involved in planning and conducting continuing education sessions.

Certificates of Participation/Completion for TGLN Continuing Education

15. All programs or TGLN departmental designates providing in-house or external continuing education shall issue certificates for participants that have completed the program or session requirements.
16. Education and Professional Practice and/or the tissue administrative team will provide certificates upon completion of the education session and submission of an attendance record.

Maintaining TGLN and Accrediting Agency Generated Continuing Education Units (CEU) Records

17. Education and Professional Practice will archive attendance and completion records of courses held internally and externally.
18. TGLN generated CEUs records shall include:
 - course outline including learning objectives;
 - course handouts and other presentation materials;
 - course evaluation tools;
 - the applicable training packet; and
 - hardcopies or records in a database tracking system.



Clinical Process Instruction Manual

Tissue Competency and Continuing Education Process Instruction

Accrediting Agency CEUs and Recertification

19. CEUs for a Certified Tissue Bank Specialist (CTBS) will be offered when appropriate by the approved provider in accordance with the regulations set forth by the *American Association of Tissue Banks (AATB) Current Standards for Tissue Banking*.
20. Employees must apply for AATB CEUs by submitting the appropriate agency application and all supporting documentation.
21. The AATB website can be referred to for recertification guidelines.
22. It is the employee's responsibility to determine the requirements for recertification, obtain and retain required CEUs, and submit them as required by the applicable agency for recertification.

Records:

Record Name	Form No. (if applicable)	Record Holder	Record Location	Record Retention Time (as a minimum)
Training Attendance Form	CSF-9-176	Tissue Department	Tissue Department	16 years after termination of employment
Tissue Coordinator Competencies Assessment	CSF-9-171	Tissue Department	Tissue Department	16 years after termination of employment
Competency Assessment – Pre-Recovery/Post-Recovery and Safety – Ocular	CSF-9-222	Tissue Department	Tissue Department	16 years after termination of employment
Competency Assessment – In Situ	CSF-9-158	Tissue Department	Tissue Department	16 years after termination of employment



Clinical Process Instruction Manual

Tissue Competency and Continuing Education Process Instruction

Competency Assessment – Enucleation	CSF-9-159	Tissue Department	Tissue Department	16 years after termination of employment
Competency Assessment – Skin Recovery	CSF-9-169	Tissue Department	Tissue Department	16 years after termination of employment
Competency Assessment – Musculoskeletal Recovery	CSF-9-162	Tissue Department	Tissue Department	16 years after termination of employment
Competency Assessment – Osteochondral (En bloc) Recovery	CSF-9-221	Tissue Department	Tissue Department	16 years after termination of employment
Competency Assessment – Heart Valve, Pericardium and Descending Aorta	CSF-9-160	Tissue Department	Tissue Department	16 years after termination of employment
Competency Assessment – Pre-Recovery/Post-Recovery and Safety	CSF-9-164	Tissue Department	Tissue Department	16 years after termination of employment
Competency Assessment - Circulator in Recovery	CSF-9-157	Tissue Department	Tissue Department	16 years after termination of employment
Training Qualification and Exemption Form	CSF-9-180	Tissue Department	Tissue Department	16 years after termination of employment

References:

- Standards for Tissue Banking, American Association of Tissue Banks, United States. J2.200 and J2.300.



Clinical Process Instruction Manual

Tissue Competency and Continuing Education Process Instruction

Appendix 1: List of Competency Assessments

Tissue Coordinator

- Professional Communication / Interaction
- Screening
- Family Approach / Telephone Authorization
- Donor Med/Soc History Questionnaire
- Case Coordination

Tissue Recovery Coordinators

- Pre-recovery
- Post recovery
- Recovery Safety

Ocular

- Enucleation Recovery
- In-situ Ocular Recovery

Multi-Tissue

- Skin Recovery
- Heart Valve, Pericardium and Descending Aorta Recovery
- Musculoskeletal Recovery



Clinical Process Instruction Manual

Tissue Competency and Continuing Education Process Instruction

Exhibit 1: Training Attendance Form



CSF-9-176

TRAINING ATTENDANCE FORM

Title of Session (If CPI, list CPI# and title)	Click or tap here to enter text.	Approximate Length of Session:	Click or tap here to enter text.
Purpose of Session (Mark all that apply)	<input type="checkbox"/> Meeting <input type="checkbox"/> HR Required <input type="checkbox"/> Informational <input type="checkbox"/> Formal Training <input type="checkbox"/> Retraining <input type="checkbox"/> New CPI <input type="checkbox"/> Revised CPI <input type="checkbox"/> Software <input type="checkbox"/> Other (Specify): Click or tap here to enter text.		
Tools/Methods Used (Mark all that apply)	<input type="checkbox"/> CPI <input type="checkbox"/> Discussion <input type="checkbox"/> Observation <input type="checkbox"/> Existing Training Program <input type="checkbox"/> Worksheet <input type="checkbox"/> Demonstration <input type="checkbox"/> Lecture <input type="checkbox"/> Agenda/List of Objectives <input type="checkbox"/> Test <input type="checkbox"/> Practice <input type="checkbox"/> Other (Specify): Click or tap here to enter text.		

*The Trainee's signature indicates that information presented is understood and questions have been answered. Do not sign if further explanation is needed or unanswered questions exist. Do not sign until after training has been completed.

**The Trainer's signature indicates that the Trainer finds that the information presented is understood by the Trainee(s).



Attendee/Trainee Name	Department	Attendee/Trainee Signature*	Date (DD/MM/YYYY)
1. Click or tap here to enter text.	<input checked="" type="checkbox"/> Tissue <input type="checkbox"/> Other (Specify): Click or tap here to enter text.	<input type="checkbox"/> Signature: _____ <input type="checkbox"/> N/A <input type="checkbox"/> See attached document	Click or tap to enter a date.
2. Click or tap here to enter text.	<input type="checkbox"/> Tissue <input type="checkbox"/> Other (Specify): Click or tap here to enter text.	<input type="checkbox"/> Signature: _____ <input type="checkbox"/> N/A <input type="checkbox"/> See attached document	Click or tap to enter a date.
3. Click or tap here to enter text.	<input type="checkbox"/> Tissue <input type="checkbox"/> Other (Specify): Click or tap here to enter text.	<input type="checkbox"/> Signature: _____ <input type="checkbox"/> N/A <input type="checkbox"/> See attached document	Click or tap to enter a date.
4. Click or tap here to enter text.	<input type="checkbox"/> Tissue <input type="checkbox"/> Other (Specify): Click or tap here to enter text.	<input type="checkbox"/> Signature: _____ <input type="checkbox"/> N/A <input type="checkbox"/> See attached document	Click or tap to enter a date.
5. Click or tap here to enter text.	<input type="checkbox"/> Tissue <input type="checkbox"/> Other (Specify): Click or tap here to enter text.	<input type="checkbox"/> Signature: _____ <input type="checkbox"/> N/A <input type="checkbox"/> See attached document	Click or tap to enter a date.
6. Click or tap here to enter text.	<input type="checkbox"/> Tissue <input type="checkbox"/> Other (Specify): Click or tap here to enter text.	<input type="checkbox"/> Signature: _____ <input type="checkbox"/> N/A <input type="checkbox"/> See attached document	Click or tap to enter a date.
7. Click or tap here to enter text.	<input type="checkbox"/> Tissue <input type="checkbox"/> Other (Specify): Click or tap here to enter text.	<input type="checkbox"/> Signature: _____ <input type="checkbox"/> N/A <input type="checkbox"/> See attached document	Click or tap to enter a date.
8. Click or tap here to enter text.	<input type="checkbox"/> Tissue <input type="checkbox"/> Other (Specify): Click or tap here to enter text.	<input type="checkbox"/> Signature: _____ <input type="checkbox"/> N/A <input type="checkbox"/> See attached document	Click or tap to enter a date.
9. Click or tap here to enter text.	<input type="checkbox"/> Tissue <input type="checkbox"/> Other (Specify): Click or tap here to enter text.	<input type="checkbox"/> Signature: _____ <input type="checkbox"/> N/A <input type="checkbox"/> See attached document	Click or tap to enter a date.
10. Click or tap here to enter text.	<input type="checkbox"/> Tissue <input type="checkbox"/> Other (Specify): Click or tap here to enter text.	<input type="checkbox"/> Signature: _____ <input type="checkbox"/> N/A <input type="checkbox"/> See attached document	Click or tap to enter a date.
11. Click or tap here to enter text.	<input type="checkbox"/> Tissue <input type="checkbox"/> Other (Specify): Click or tap here to enter text.	<input type="checkbox"/> Signature: _____ <input type="checkbox"/> N/A <input type="checkbox"/> See attached document	Click or tap to enter a date.



Clinical Process Instruction Manual

Tissue Competency and Continuing Education Process Instruction

Exhibit 2: Tissue Coordinator Competencies Assessment

Page 1



CSF-9-171

Tissue Coordinator Competencies Assessment

Task Assessed	Competency	Completion Signature/Date	
Professional Communication / Interaction	<input type="checkbox"/> Competent <input type="checkbox"/> Needs Retraining <input type="checkbox"/> Not Assessed	_____ Preceptor Signature	_____ Date
Initial Screening	<input type="checkbox"/> Competent <input type="checkbox"/> Needs Retraining <input type="checkbox"/> Not Assessed	_____ Preceptor Signature	_____ Date
Secondary Screening	<input type="checkbox"/> Competent <input type="checkbox"/> Needs Retraining <input type="checkbox"/> Not Assessed	_____ Preceptor Signature	_____ Date
Family or First-Person Approach / Telephone Authorization	<input type="checkbox"/> Competent <input type="checkbox"/> Needs Retraining <input type="checkbox"/> Not Assessed	_____ Preceptor Signature	_____ Date
Donor UDRAI or Med/Soc History Questionnaire	<input type="checkbox"/> Competent <input type="checkbox"/> Needs Retraining <input type="checkbox"/> Not Assessed	_____ Preceptor Signature	_____ Date
Case Coordination	<input type="checkbox"/> Competent <input type="checkbox"/> Needs Retraining <input type="checkbox"/> Not Assessed	_____ Preceptor Signature	_____ Date
Coroner/ Pathologist/MAID Investigator RN	<input type="checkbox"/> Competent <input type="checkbox"/> Needs Retraining <input type="checkbox"/> Not Assessed	_____ Preceptor Signature	_____ Date



Clinical Process Instruction Manual

Tissue Competency and Continuing Education Process Instruction

Exhibit 3: Competency Assessment – Pre-Recovery/Post-Recovery and Safety – Ocular

Page 1



CSF-9-222

Competency Assessment		
Procedure: Pre-Recovery/Post-Recovery and Safety – Ocular		
Employee Name: Click or tap here to enter text.		
Date of Assessment (DD/MM/YYYY): Click or tap here to enter text.		
Assessor Name: Click or tap here to enter text.		Title: Click or tap here to enter text.
Assessment Technique (e.g. case review, test, observed procedure etc.): Click or tap here to enter text.		
Training Type (Initial Training, Annual Competency, Other - Specify): Click or tap here to enter text.		
Case Number: Click or tap here to enter text.		
Task	Score	Comments
Pre-Recovery		
Locates and reviews donor referral case information on DMS	Select Score	Click or tap here to enter text.
Identifies proper authorization and special considerations	Select Score	Click or tap here to enter text.
Assembles supplies and equipment necessary for enucleation and in situ recovery. Documents supply list information appropriately	Select Score	Click or tap here to enter text.
Confirms that all supplies are within expiry dates and that all supply packaging is not damaged	Select Score	Click or tap here to enter text.
Reviews all available donor medical records and documents required details in DMS or other documentation and follows-up where necessary (i.e. contacting Tissue Consultant or EBC consultant)	Select Score	Click or tap here to enter text.
Verifies with donor chart that referral hemodilution calculation is correct or completes a new calculation	Select Score	Click or tap here to enter text.
Evaluates potential recovery site and makes corrections to recovery conditions and/or escalates issues where applicable	Select Score	Click or tap here to enter text.
Documents donor cooled and uncooled times	Select Score	Click or tap here to enter text.



Clinical Process Instruction Manual

Tissue Competency and Continuing Education Process Instruction

Exhibit 4: Competency Assessment – In Situ

Page 1



CSF-9-158

Training and Competency Assessment		
Procedure: In Situ		
Employee Name: Click or tap here to enter text.		
Date of Assessment (DD/MM/YYYY): Click or tap here to enter text.		
Assessor Name: Click or tap here to enter text.		Title: Click or tap here to enter text.
Assessment Technique: (e.g. case review, test, observed procedure etc.): Click or tap here to enter text.		
Training Type (Initial Training, Other - Specify): Click or tap here to enter text.		
Case Number: Click or tap here to enter text.		
Other pertinent assessment info: In Situ in adherence with CPI-9-520		
Task	Score	Comments
Preps orbital area and drapes the donor as per CPI-9-518	Select Score	Click or tap here to enter text.
Inserts speculum so as not to damage epithelium or surrounding ocular structures	Select Score	Click or tap here to enter text.
Performs peritomy and blunt dissection of conjunctiva	Select Score	Click or tap here to enter text.
Scrapes off remaining conjunctiva within 5mm from the limbus	Select Score	Click or tap here to enter text.
Uses trephine to make a partial incision 2-4mm from the limbus, 360° around the globe without penetrating the underlying tissue	Select Score	Click or tap here to enter text.
Uses a scalpel to make an incision through the sclera 2-4mm from the limbus without perforating the choroid	Select Score	Click or tap here to enter text.
Uses scissors to make a 360° incision parallel to limbus around the corneoscleral disc keeping rim size aligned with the trephine marking	Select Score	Click or tap here to enter text.
Uses forceps to carefully remove cornea from remaining eye structure without introducing stress lines to cornea	Select Score	Click or tap here to enter text.
Carefully transfers cornea to storage media container using hand-under-cornea technique in case tissue is dropped	Select Score	Click or tap here to enter text.



Clinical Process Instruction Manual

Tissue Competency and Continuing Education Process Instruction

Exhibit 5: Competency Assessment – Enucleation

Page 1



CSF-9-159

Competency Assessment		
Procedure: Enucleation		
Employee Name: Click or tap here to enter text.		
Date of Assessment (DD/MM/YYYY): Click or tap here to enter text.		
Assessor Name: Click or tap here to enter text.		Title: Click or tap here to enter text.
Assessment Technique: (e.g. case review, test, observed procedure etc.): Click or tap here to enter text.		
Training Type (initial training, Annual Competency, Other - Specify): Click or tap here to enter text.		
Case Number: Click or tap here to enter text.		
Other pertinent assessment info: Enucleation in adherence with CPI-9-512		
Task	Score	Comments
Inserts speculum so as not to damage epithelium or surrounding ocular structures	Select Score	Click or tap here to enter text.
Performs peritomy and blunt dissection of conjunctiva	Select Score	Click or tap here to enter text.
Clamps medial rectus muscle to gain control of eye during removal of whole globe (optional)	Select Score	Click or tap here to enter text.
Uses muscle hook to locate and identify the 4 rectus muscles (medial rectus, superior rectus, lateral rectus and inferior rectus). Severs rectus muscles with scissors	Select Score	Click or tap here to enter text.
Uses enucleation scissors to sever optic nerve leaving ¼ - ½ inch stump	Select Score	Click or tap here to enter text.
Lifts globe using hemostat and cuts any remaining connective tissue if necessary	Select Score	Click or tap here to enter text.
Carefully transfers whole eye to sterile container using hand-under-whole eye technique in case tissue is dropped	Select Score	Click or tap here to enter text.
Segregates contaminated instruments or instrument parts from sterile instruments throughout procedure	Select Score	Click or tap here to enter text.
Performs Donor reconstruction as per CPI-9-512	Select Score	Click or tap here to enter text.



Clinical Process Instruction Manual

Tissue Competency and Continuing Education Process Instruction

Exhibit 6: Competency Assessment – Pre-Recovery/Post-Recovery and Safety – Multi-Tissue

Page 1



CSF-9-164

Training and Competency Assessment		
Procedure: Pre-Recovery/Post-Recovery and Safety - Multi-Tissue		
Employee Name: Click or tap here to enter text.		
Date of Assessment: Click or tap here to enter text.		
Assessor Name/Title: Click or tap here to enter text.		
Assessment Technique: (e.g. case review, test, observed procedure etc...): Click or tap here to enter text.		
<input type="checkbox"/> Initial Training <input type="checkbox"/> Annual Competency <input type="checkbox"/> Other: Click or tap here to enter text.		
Case Number: Click or tap here to enter text.		
Task	Score	Comments
Pre-Recovery		
Appropriate identification of donor	Select Score	Click or tap here to enter text.
Blood draw: determining number of specimens per tissue processor and completing post mortem blood draw, blood labelling and packaging	Select Score	Click or tap here to enter text.
Donor physical assessment	Select Score	Click or tap here to enter text.
Pre-cleaning of recovery room: disinfection process to decrease bioburden on surfaces prior to opening of sterile supplies	Select Score	Click or tap here to enter text.
Recovery Site Inspection	Select Score	Click or tap here to enter text.
Prepares donor by cleansing, wet shaving, and containing possible areas of contamination (pre-surgical wash)	Select Score	Click or tap here to enter text.
Using appropriate aseptic technique, opens sterile supplies, sets-up backtables/mayo stand, labelling, and necessary equipment	Select Score	Click or tap here to enter text.
Open outside packaging of sterile gloves and gown in a manner that avoids contamination	Select Score	Click or tap here to enter text.



Clinical Process Instruction Manual

Tissue Competency and Continuing Education Process Instruction

Exhibit 7: Competency Assessment – Skin Recovery

Page 1



CSF-9-169

Training and Competency Assessment		
Procedure: Skin Recovery		
Employee Name: Click or tap here to enter text.		
Date of Assessment: Click or tap here to enter text.		
Assessor Name/Title: Click or tap here to enter text.		
Assessment Technique: (e.g. case review, test, observed procedure etc....): Click or tap here to enter text.		
<input type="checkbox"/> Initial Training <input type="checkbox"/> Annual Competency <input type="checkbox"/> Other: Click or tap here to enter text.		
Case Number: Click or tap here to enter text.		
Task	Score	Comments
Understands supplies and equipment necessary for a skin recovery	Select Score	Click or tap here to enter text.
Adequately performs initial washing and shaving of donor	Select Score	Click or tap here to enter text.
Set up backtable and amalgatome for skin recovery	Select Score	Click or tap here to enter text.
Perform surgical prepping and draping of donor for skin	Select Score	Click or tap here to enter text.
Assesses and maps tissue of donor in order to maximize yield and recovers skin using amalgatome	Select Score	Click or tap here to enter text.
Aseptically packages skin and passes out of the sterile field to be labelled	Select Score	Click or tap here to enter text.
Correctly disassembles amalgatome and disposes of amalgatome blade safely	Select Score	Click or tap here to enter text.
Ensures that proper reconstruction is performed post recovery and ensured donor ID is replaced on donor	Select Score	Click or tap here to enter text.
Package skin for shipment	Select Score	Click or tap here to enter text.



Clinical Process Instruction Manual

Tissue Competency and Continuing Education Process Instruction

Exhibit 8: Competency Assessment – Musculoskeletal Recovery

Page 1



CSF-9-162

Training and Competency Assessment		
Procedure: Musculoskeletal (MS) Recovery		
Employee Name: Click or tap here to enter text.		
Date of Assessment: Click or tap here to enter text.		
Assessor Name/Title: Click or tap here to enter text.		
Assessment Technique: (e.g. case review, test, observed procedure etc.): Click or tap here to enter text.		
<input type="checkbox"/> Initial Training <input type="checkbox"/> Annual Competency <input type="checkbox"/> Other: Click or tap here to enter text.		
Case Number: Click or tap here to enter text.		
Task	Score	Comments
Understands supplies and equipment necessary for a MS recovery	Select Score	Click or tap here to enter text.
Set up side table and recovery instruments on back table	Select Score	Click or tap here to enter text.
Surgical prepping and draping of donor	Select Score	Click or tap here to enter text.
Recovers Fascia Lata	Select Score	Click or tap here to enter text.
Recovers tendons	Select Score	Click or tap here to enter text.
Recovers long bones of the upper limbs	Select Score	Click or tap here to enter text.
Recovers long bones of the lower limbs	Select Score	Click or tap here to enter text.
Recover Achilles with talus and calcaneus	Select Score	Click or tap here to enter text.
Recover ilium or hemi-pelvis	Select Score	Click or tap here to enter text.
Culture, wrap, package, and label MS grafts in sterile field	Select Score	Click or tap here to enter text.



Clinical Process Instruction Manual

Tissue Competency and Continuing Education Process Instruction

Exhibit 9: Competency Assessment – Osteochondral (En bloc) Recovery

Page 1



CSF-9-221

Training and Competency Assessment		
Procedure: Osteochondral (En bloc) Recovery		
Employee Name: Click or tap here to enter text.		
Date of Assessment: Click or tap here to enter text.		
Assessor Name/Title: Click or tap here to enter text.		
Assessment Technique: (e.g. case review, test, observed procedure etc...): Click or tap here to enter text.		
<input type="checkbox"/> Initial Training <input type="checkbox"/> Annual Competency <input type="checkbox"/> Other: Click or tap here to enter text.		
Case Number: Click or tap here to enter text.		
Task	Score	Comments
Understands supplies and equipment necessary for an Osteochondral recovery	Select Score	Click or tap here to enter text.
Completes appropriate surgical prepping and draping of donor	Select Score	Click or tap here to enter text.
Recovers En Bloc grafts of the upper limbs	Select Score	Click or tap here to enter text.
Recovers En Bloc grafts of the lower limbs	Select Score	Click or tap here to enter text.
Demonstrates safe handling practices when using bone and/or gigli saws	Select Score	Click or tap here to enter text.
Reconstitutes antibiotics and prepares packaging solution	Select Score	Click or tap here to enter text.
Culture, wrap, package, and label En bloc grafts in sterile field	Select Score	Click or tap here to enter text.
Package En bloc tissue and cultures for shipment	Select Score	Click or tap here to enter text.
Clean, spray and package and/or disposes of used recovery instruments for transport	Select Score	Click or tap here to enter text.
Comments: Click or tap here to enter text.		



Clinical Process Instruction Manual

Tissue Competency and Continuing Education Process Instruction

Exhibit 10: Competency Assessment – Heart Valve, Pericardium and Descending Aorta

Page 1



CSF-9-160

Training and Competency Assessment		
Procedure: Heart Valve (HV), Pericardium and Descending Aorta		
Employee Name: Click or tap here to enter text.		
Date of Assessment: Click or tap here to enter text.		
Assessor Name/Title: Click or tap here to enter text.		
Assessment Technique: (e.g. case review, test, observed procedure etc.): Click or tap here to enter text.		
<input type="checkbox"/> Initial Training <input type="checkbox"/> Annual Competency <input type="checkbox"/> Other: Click or tap here to enter text.		
Case Number: Click or tap here to enter text.		
Task	Score	Comments
Understands supplies and equipment necessary for a heart valve, pericardium and descending aorta recovery	Select Score	Click or tap here to enter text.
Set up backtable and OR/recovery suite for heart valve, pericardium and descending aorta recovery	Select Score	Click or tap here to enter text.
Surgical prep & drape donor for heart valve, pericardium and descending aorta recovery	Select Score	Click or tap here to enter text.
Dissects and recovers heart, pericardium and descending aorta	Select Score	Click or tap here to enter text.
Rinse, package & label heart, pericardium and descending aorta in sterile field	Select Score	Click or tap here to enter text.
Packages heart, pericardium and descending aorta for shipment	Select Score	Click or tap here to enter text.
Clean, spray and package used recovery instruments for transport	Select Score	Click or tap here to enter text.



Clinical Process Instruction Manual

Tissue Competency and Continuing Education Process Instruction

Exhibit 11: Competency Assessment - Circulator in Recovery



CSF-9-157

Training and Competency Assessment		
Procedure: Circulator in Recovery		
Employee Name: Click or tap here to enter text.		
Date of Assessment: Click or tap here to enter text.		
Assessor Name/Title: Click or tap here to enter text.		
Assessment Technique: (e.g. case review, test, observed procedure etc.): Click or tap here to enter text.		
<input type="checkbox"/> Initial Training <input type="checkbox"/> Annual Competency <input type="checkbox"/> Other: Click or tap here to enter text.		
Case Number: Click or tap here to enter text.		
Task	Score	Comments
Assist in side table and back table set up	Select Score	Click or tap here to enter text.
Assist prepping and draping of donor	Select Score	Click or tap here to enter text.
Review case paperwork to determine proper authorization and Mshx	Select Score	Click or tap here to enter text.
Complete chart review and verify Hemodilution	Select Score	Click or tap here to enter text.
Demonstrates knowledge of when to appropriately escalate chart and/or physical findings for medical consultation	Select Score	Click or tap here to enter text.
Demonstrates aseptic consciousness to maintain/monitor the sterile field	Select Score	Click or tap here to enter text.
Pass supplies into the surgical field aseptically	Select Score	Click or tap here to enter text.
Set up supply table and pour sterile recovery and transport media	Select Score	Click or tap here to enter text.
Verify recovery staff has obtained appropriate microbiology testing	Select Score	Click or tap here to enter text.
Document all recovery activity in iTransplant or appropriate recovery form	Select Score	Click or tap here to enter text.



Clinical Process Instruction Manual

Tissue Competency and Continuing Education Process Instruction

Exhibit 12: Training Qualification and Exemption Form



CSF-9-180

TRAINING QUALIFICATION AND EXEMPTION FORM

EMPLOYEE NAME: _____

DEPARTMENT: _____

POSITION/TITLE: _____

ORIGINAL HIRE DATE: _____

With respect to the subject(s) listed below, the Employee is (check all that apply):

- Qualified to teach Exempt from training Exempt from Competency Assessment

List applicable subject(s):

Subject(s) qualification verified by (check all that apply):

- Documented initial training on the task (internal or external training)
 Documented competency for performing the task(s)
 Documented training on the applicable CPI(s) (internal or external training)
 Developed the process(es) and/or wrote the CPI(s)
 Validated the process(es)
 Revised the CPI(s)
 Other _____

Quality Approval of Training Qualification/Exemption:

Initial/Date: _____



Clinical Process Instruction Manual

Tissue Competency and Continuing Education Process Instruction

Exhibit 13: Multi-Tissue Recovery Coordinator Competencies Record



CSF-9-256

Multi-Tissue Recovery Coordinator Competencies Record

Name	
Ocular - whole globe	
Ocular - whole globe Clinical Specialist Sign-off	
Ocular - whole globe Clinical Specialist sign-off date	
Ocular - whole globe Manager Sign-off	
Ocular - whole globe Manager sign-off date	
Ocular - in Situ	
Ocular - in Situ Clinical Specialist Sign-off	
Ocular - In Situ Clinical Specialist Sign-off date	
Ocular - In Situ Manager Sign-off	
Ocular - In Situ Manager Sign-Off Date	
MT - Circulator	
MT - Circulator - Clinical Specialist Sign-Off	
MT - Circulator - Clinical Specialist Sign-Off Date	
MT - Circulator - Manager Sign-Off	
MT - Circulator - Manager Sign-Off Date	
Skin	
Skin Clinical Specialist Sign-off	
Skin Clinical Specialist Sign-off Date	
Skin Manager Sign-Off	
Skin Manager Sign-off Date	
Heart Valve	
Heart Valve - Clinical Specialist Sign-Off	
Heart Valve - Clinical Specialist Sign-Off Date	
Heart Valve - Manager Sign-Off	
Heart Valve - Manager Sign-Off Date	
Musculoskeletal	
Musculoskeletal - Clinical Specialist Sign-Off	
Musculoskeletal - Clinical Specialist Sign-Off Date	
Musculoskeletal - Manager Sign-Off	
Musculoskeletal - Manager Sign-Off Date	
Fresh Graft - En bloc bone	
Fresh Graft - En bloc bone - Clinical Specialist Sign-Off	
Fresh Graft - En bloc bone - Clinical Specialist Sign-Off date	
Fresh Graft - En bloc bone - Manager Sign-Off	
Fresh Graft - En bloc bone - Manager Sign-Off date	
Recovery Lead	
Recovery Lead - Clinical Specialist Sign-Off	
Recovery Lead - Clinical Specialist Sign-Off date	
Recovery Lead - Manager Sign-Off	
Recovery Lead - Manager Sign-Off	
Pre-Post Safety	
Pre-Post Safety - Clinical Specialist Sign-Off	

May 24, 2023



Clinical Process Instruction Manual

Tissue Competency and Continuing Education Process Instruction

Exhibit 14: Tissue Coordinator Competencies Record



CSF-9-257

Tissue Coordinator Competencies Record

Employee Name	
Ocular	
Ocular - Clinical Specialist Sign-off	
Ocular - Clinical Specialist Sign-off Date	
Ocular - Manager Sign-off	
Ocular - Manager Sign-off Date	
Multi-tissue	
Multi-tissue Clinical Specialist Sign-off	
Multi-tissue Clinical Specialist Sign-off Date	
Multi-tissue Manager Sign-off	
Multi-tissue Manager Sign-off Date	
Tissue Lead	
Tissue Lead – Clinical Specialist Sign-off	
Tissue Lead – Clinical Specialist Sign-off Date	
Tissue Lead – Manager Sign-off	
Tissue Lead – Manager Sign-off Date	
Inactive	Yes/No



Clinical Process Instruction Manual

Tissue Competency and Continuing Education Process Instruction

Exhibit 15: Tissue Recovery Coordinator Competencies Record



CSF-9-258

Tissue Recovery Coordinator Competencies Record

Employee Name	
Ocular - whole globe	
Ocular - Whole Globe Clinical Specialist Sign-off	
Ocular - Whole Globe Clinical Specialist Sign-off Date	
Ocular - Whole Globe Manager Sign-off	
Ocular - Whole Globe Manager Sign-off Date	
Pre-Post Recovery and Safety	
Pre-Post Recovery and Safety Clinical Specialist Sign-off	
Pre-Post Recovery and Safety Clinical Specialist Sign-off Date	
Pre-Post Recovery and Safety Manager Sign-off	
Pre-Post Recovery and Safety Manager Sign-off Date	
CoVid-19 Swab	
CoVid-19 Swab Clinical Specialist Sign-Off	
CoVid-19 Swab Clinical Specialist Sign-off Date	
CoVid-19 Swab Manager Sign-Off	
CoVid-19 Swab Manager Sign-Off Date	
Ocular - In Situ	
Ocular - In Situ Clinical Specialist Sign-off	
Ocular - In Situ Clinical Specialist Sign-off Date	
Ocular - In Situ Manager Sign-off	
Ocular - In Situ Manager Sign-off Date	
MT - Circulator	
MT - Circulator Clinical Specialist Sign-off	
MT - Circulator Clinical Specialist Sign-off Date	
MT - Circulator Manager Sign-off	
MT - Circulator Manager Sign-off Date	
Inactive	