

SECTION: Clinical
ID NO.: CPI-9-963
PAGE: 1 of 7
ISSUE DATE: June 19, 2017

IOOUE DEVICEN

ISSUE.REVISION: 1.4

REVISION DATE: July 24, 2024 APPROVED BY: Tissue Authority

Clinical Process Instruction Manual

Tissue Program Clinical Training Process Instruction

Policy:

All tissue clinical positions have a training profile that is made up of curricula that, combined with their job description, indicates the functions they perform and the training required.

Trillium Gift of Life Network (TGLN) Tissue Program management and Education and Professional Practice are responsible for maintaining training profiles for each position and putting together a curriculum that supports the functions staff are responsible for performing.

Education and Professional Practice, in conjunction with Tissue Program management, are responsible for the coordination and management of training activities such as:

- new employee orientation
- annual training
- process changes
- continuing education
- effectiveness checks
- facilitate development of training materials / content.
- maintain employee training records (in conjunction with management and employees); and periodically report on training compliance.

The Managers, Tissue and Clinical Specialists are responsible for competency assessments

- collaborating with Education and Professional Practice to develop and maintain training plans and curricula relative to positions under their management
- approving new and revised training plans for employees under their management
- training or assuring training of employees under their management according to this procedure
- ensuring completeness and accuracy of records associated with the training program
- making staff aware of the consequences of the improper performance of their specific jobs
- making personnel who perform verification and validation activities shall be made aware of accidents and errors that may occur and be encountered as part of their job function

Clinical employees are responsible for understanding the requirements of their training plans; participating in training when required; completing training by due date and; managing their documentation for the completion of training.

Training records shall be retained for a minimum of 16 years after termination of employment.



SECTION: Clinical
ID NO.: CPI-9-963
PAGE: **2** of 7

ISSUE DATE: June 19, 2017

ISSUE.REVISION: 1.4

REVISION DATE: July 24, 2024

APPROVED BY: Tissue Authority

Clinical Process Instruction Manual

Tissue Program Clinical Training Process Instruction

Process:

1. The purpose of this process instruction is to describe the Tissue Program employee training system and documentation of training. Employee training is intended to assure all personnel have the necessary education, experience, and training to ensure competent performance of their assigned functions and familiarity with applicable regulations and standards.

Training Overview

- There are three prescribed components of the initial orientation and training of new Tissue Program clinical staff: new employee clinical orientation, Clinical Process Instruction (CPI) training, and onthe-job (OJT) training.
- 3. Training methods and resources may include but are not limited to:
 - didactic/classroom: TGLN has several orientation courses for new employees and conducts other training that is didactic in nature.
 - online courses: self-administered online courses are used to train in various topics.
 - read and understand: procedures performed by employees must be read and employees must sign to indicate comprehension.
 - skills/role specific training: individual training is used to train employees to perform tasks requiring discussion, demonstration, observation, performance under supervision, or similar individual-based training.
 - periodic skills assessment: individual training may be used to periodically assess employees' ability to perform tasks requiring observation / performance under supervision / demonstration of proficiency.
 - quality assurance and electronic systems training
 - other training: other training may include staff meetings, attendance to professional association meetings, ad-hoc training, virtual and in person instructor-led training, etc.
- 4. Training is documented using a combination of electronic and paper records.

TGLN Orientation

5. All Tissue Program staff participate in the TGLN orientation upon hire. Clinical staff attend a role-specific clinical orientation, while non-clinical staff attend a general orientation. The TGLN orientation is coordinated, conducted, and documented by the Education and Professional Practice department. Clinical orientation is conducted during the first week of employment for clinical staff, while a general orientation is usually conducted within the first three months for non-clinical staff.



SECTION: Clinical
ID NO.: CPI-9-963
PAGE: **3** of 7

ISSUE DATE: June 19, 2017

ISSUE REVISION: 1.4

REVISION DATE: July 24, 2024
APPROVED BY: Tissue Authority

Clinical Process Instruction Manual

Tissue Program Clinical Training Process Instruction

Documentation of the completion of the clinical orientation is provided to the manager of the functional area and filed in the employee's training record which is maintained by Education and Professional Practice.

- 6. New employees receive an orientation program that includes meetings with support departments, reading and acknowledging comprehension of procedures, online seminars, TGLN orientation courses, role specific training, and orientation progress checks.
- 7. Documentation at the time of orientation includes the orientation grid for new clinical hires describing the subjects covered during initial orientation, CPI read and understand checklist, and written quizzes and/or competency assessments administered throughout the orientation program on specific topics. These shall be filed in the training records.
- 8. Employees receive continuing education on an ongoing basis in a variety of forms including but are not limited to annual procedure reviews, process changes, TGLN provided training, and external training such as professional association education, etc.
- 9. Periodic skills assessments may be applicable to certain functions to assure proper performance.
- 10. Employees are trained when processes related to their functions change, in addition to the first time they are exposed to a process.

Training Profiles and Plans

- 11. Training profiles are guiding documents that outline the training requirements for Tissue Coordinators, see Exhibit 1, and Multi-Tissue Recovery Coordinators see Exhibit 2 sample. The training profile may include but is not limited to:
 - orientation meetings with support departments such as Finance and Human Resources (HR);
 - reading of applicable controlled documents (e.g., process instructions and forms) and acknowledgement of comprehension;
 - completion of online or other self-guided learning media;
 - attendance to instructor-presented sessions;
 - completion of core competency checklists;
 - progress checks during orientation period;
 - annual skills/competency assessments; and
 - other training tasks.



SECTION: Clinical
ID NO.: CPI-9-963
PAGE: 4 of 7

ISSUE DATE: June 19, 2017

ISSUE.REVISION: 1.4

REVISION DATE: July 24, 2024 APPROVED BY: Tissue Authority

Clinical Process Instruction Manual

Tissue Program Clinical Training Process Instruction

- 12. Training plans are utilized as follows:
 - 12.1. Managers and/or Clinical Specialists and Education and Professional Practice use the training plans, see Exhibit 1 and Exhibit 2, as guiding documents for the respective roles to set the role expectation and requirements to pass competency or orientation. This plan will assist in guiding the employee on what type of activities/components are a requirement of the role.
 - 12.2. Managers and/or Clinical Specialists must approve training plans and changes to training plans. It is the responsibility of the manager and/or Clinical Specialist to make employees aware of their training requirements and coach them as necessary.

New Employees

- 13. HR will notify department leads (i.e., Tissue Program, Education and Professional Practice, Information Services, Payroll etc.) of a new employee upon acceptance of the employment offer.
- 14. The new employee will be assigned a training profile as per the job role.
- 15. For new positions, the new employee's management shall work in conjunction with Education and Professional Practice to develop a customized training profile.
- 16. The new employee is responsible for completing the tasks as indicated on the training profile as well as any additional training that may be assigned on an individual basis.

Initial Training to Clinical Process Instructions

- 17. There are lists of required CPI reading for each of the positions of Tissue Program staff. These lists are maintained by Education and Professional Practice, and reviewed annually by the manager or designate of the specific functional area (donation or recovery). New Tissue Program staff are instructed in the location of all TGLN and Tissue Program's CPIs and the accessing of these CPI's electronically. CPI read and understand sign off coincides with orientation, where staff are expected to have completed the initial review of all applicable policies prior to OJT. Practical training to specific job tasks occurs during OJT, many of the CPIs are required reading for training of specific job tasks and require re-reading.
- 18. For practices and forms related to OJT, please refer to the *On-The-Job Training Clinical Staff Process Instruction, CPI-9-961.*



SECTION: Clinical
ID NO.: CPI-9-963
PAGE: **5** of 7

ISSUE DATE: June 19, 2017

ISSUE REVISION: 1.4

REVISION DATE: July 24, 2024 APPROVED BY: Tissue Authority

Clinical Process Instruction Manual

Tissue Program Clinical Training Process Instruction

Training Records

- 19. Training records shall include the following items:
 - a training checklist for new employees or employees with newly assigned tasks;
 - delineation of functions that employees are authorized and trained to perform;
 - documentation of review and training prior to implementation of new and/or revised CPIs;
 - annual review of policies and procedures for which the employee has been trained, including safety precautions;
 - annual attendance at hazardous materials training; and
 - attendance at workshops, seminars, meetings or other continuing education programs.

Records:

Record Name	Form No. (if applicable)	Record Holder	Record Location	Record Retention Time (as a minimum)
-------------	-----------------------------	---------------	-----------------	--

No records

References:

- Standards for Tissue Banking, American Association of Tissue Banks, United States, 14th edition, 2017. J2.100 and J2.400.
- On-The-Job Training Clinical Staff Process Instruction, CPI-9-961.



SECTION: Clinical
ID NO.: CPI-9-963
PAGE: **6** of 7

ISSUE DATE: June 19, 2017

ISSUE.REVISION: 1.4

REVISION DATE: July 24, 2024

APPROVED BY: Tissue Authority

Clinical Process Instruction Manual

Tissue Program Clinical Training Process Instruction

Exhibit 1: MTRC Training Profile – Sample Page 1



MTRC Training Profile

Position: Mu	ti Tissue Recov	very Coordinator			
Training	☐ Orientation	☐ Orientation-Ocular			
Requirements	☐ Orientation	☐ Orientation-Multi Tissue x 2 weeks			
	o Orient	Orientation-Circulator Training x 1 day			
	o Hands	on training with Clinical Specialist - R&T Skin, HV, MS and			
		chondral recovery when available X 3 days			
		□ Preceptorship: requires –			
		ng shifts with multi tissue team			
		_			
		mum 3 Skin recoveries			
		mum 3 HV recoveries			
		mum 3 MS recoveries			
	4. Mini	mum 3 Osteochondral recoveries			
	*Exc	eptions depending on individual skill level and previous			
	expe	rience			
	☐ Minimum re	equirements for independent practice—Skin and MS recovery sign			
	off				
	☐ Progress Ch	ecks (during preceptorship): requires minimum 1 check-in			
	☐ Retraining (☐ Retraining (requires reason):			
		☐ Annual Competency			
		☐ Circulator in Recovery			
		☐ HV Pericardium Descending Aorta			
		sculoskeletal Recovery			
	_				
		Osteochondral (En bloc) Recovery			
		☐ Pre-Recovery/Post-Recovery and Safety			
		Skin Recovery			
		☐ Team Lead Training (if applicable)			
	☐ Annual Safe	☐ Annual Safety Training			
		☐ Corporate Policies			
	☐ HR and Safe	☐ HR and Safety Videos (Brainshark/Dual Code)			
Required Reading	 Clinical Pro 	ocess Instructions:			
	D	18 totals			
	Donor Referra				
	CPI-9-100 CPI-9-160	Ontario Organ or Combined Organ and Tissue Donation Ontario Tissue Exclusive Referral Donation			
	CPI-9-160	Untario i issue exclusive Referral Donation			
	Donor Assessn	Donor Assessment, Screening, Suitability and Testing			
	CPI-9-203	Coroner's Case			
	CPI-9-207	Donor Medical and Social History - Organ or Combined Organ			
	& Tissue	, ,			
	CPI-9-208	Donor Assessment - Combined Organ and Tissue			
	CPI-9-209	Physical Exam - Organ or Combined Organ and Tissue Donors			
	CPI-9-220	Hospital Profile			
	CPI-9-210	Hemodilution Calculation			
	CPI-9-261	Medical and Social History-Tissue			
	CPI-9-262	General Tissue Donation Criteria and Contraindications			

November 29, 2018 Page 1 of 4



SECTION: Clinical ID NO.: CPI-9-963

PAGE: **7** of 7 ISSUE DATE: June 19, 2017

ISSUE REVISION: 1.4

REVISION DATE: July 24, 2024

APPROVED BY: Tissue Authority

Clinical Process Instruction Manual

Tissue Program Clinical Training Process Instruction

Exhibit 2: Tissue Coordinator Preceptorship Training Plan – Sample Page 1



TISSUE COORDINATOR PERCEPTORSHIP TRAINING PLAN 2024

Orientation/training shifts with assigned preceptor are categorized from Phase 1 to Phase 5: NOTE: plan has been modified to facilitate remote training of new Tissue Coordinators working from he ITRANSPLANT [ITX] ORIENTATION 3 days in Orientation	ome			
ITRANSPLANT (ITX) ORIENTATION	ome			
✓ 3 days in Orientation				
· · · · · · · · · · · · · · · · · · ·				
ITX ORIENTATION Review of all applicable fields as well as entry format as per ITransplant: Tissue Excl	usive			
Manual (SharePoint)				
 Practice entering referrals and completing consent form, coroner permission form, 	DRAIIn			
iTransplant training site				
First shift: OBSERVATION (DAY 1 in PRC)				
PHASE 1 1 st shift trainee observes preceptor − "a day in the life of a Tissue Coordinator"				
, ,	✓ Trainee enters referrals in iTransplant training site in real-time			
Next 5 shifts: REFERRAL INTAKE and SUITABILITY SCREENING (DAY 2, 3, 4, 5, 6)				
 TCs to transfer RNRs to ensure the trainee can practice referral intake for different type 	s of			
referrals; coroner , paramedic, MAID, first person or family				
PHASE 2 Assess medical suitability on taken referrals; MU based on age, MU based on contraind	cators,			
over 80, 76-79 yrs., suitable for multi tissue or eyes only				
✓ 5 th shift – trainee should demonstrate a completed RNR (referral worksheet and donor)	screening			
w/ suitability and faxing the HBF				
1-Day Consent Workshop	1-Day Consent Workshop			
Workshop highlights:				
CONSENT ✓ iTransplant overview				
WORKSHOP - Approach Plan Preparation				
✓ Dual Advocacy with Value Positive Principles				
✓ Scripting Exercises				
Next 6 shifts: APPROACHING, CONSENT, and MED/SOC (DAY 7, 8, 9, 10, 11, 12)				
✓ Day 6 – Trainee will witness any consent from TCs on shift and listen in on any approach	✓ Day 6 – Trainee will witness any consent from TCs on shift and listen in on any approaches taking			
place that same shift; Trainee will approach as of day 7	place that same shift; Trainee will approach as of day 7			
PHASE 3 Once trainee has completed the approach, consent and UDRAI, the preceptor will take	✓ Once trainee has completed the approach, consent and UDRAI, the preceptor will take over to			
show trainee the next steps	show trainee the next steps			
✓ If consent was declined, the preceptor will show trainee the next steps until they determ	nine			
trainee can complete next steps independently				
MULTI-TISSUE 2-Day MT Workshop (with Multi-Tissue Certification issued post completion)				
(MT) Workshop highlights:				
WORKSHOP Medical and Social History Questionnaire				
✓ Multi-Tissue Exclusion Criteria				
✓ Multi-Tissue Assessment (Case Practice)				
✓ Accepting Multi-Tissue and Next Steps				
✓ Screening Checklist (Tissue Cases only)				
✓ iTransplant Documentation				
✓ Tissue-on-Call				
✓ Medical Consults and Tissue Consults				
✓ Recovery Coordination for MT cases				
✓ Shift Report				

JUNE 2024 Page 1 of 2