



## Clinical Process Instruction Manual

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### Telephone Consent and Medical Social History Questionnaire Audit – Tissue Process Instruction

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#### Policy:

As required by the *Gift of Life Act*, informed consent for tissue donation may be obtained by telephone when it is not feasible to obtain informed consent or complete the donor *Medical and Social History Questionnaire* (MSHx), or relevant *Donor Risk Assessment Interview(s)* (DRAI) in person. See *Discussing Donation Opportunities and Obtaining Consent Process Instruction, CPI-9-204, Donor Medical and Social History – Organ or Combined Organ & Tissue Process Instruction, CPI-9-207* and *Medical & Social History – Tissue Process Instruction, CPI-9-261*. In addition, Trillium Gift of Life Network (TGLN) ensures that quality practices are implemented with regards to obtaining consent and completing the appropriate DRAI by verifying documentation of consent and DRAI through the performance of telephone audits. This focused audit is used to evaluate the telephone consent and DRAI process on cases where consent or DRAI are obtained over the phone by Provincial Resource Centre (PRC) staff to ensure it is performed and documented according to Clinical Process Instructions and tissues are recovered only if consent has been obtained.

Telephone audits are conducted semi-annually by the Quality Analyst or designate in a private location to ensure confidentiality. Results of the audit are communicated to relevant management for follow up.

#### Process:

1. Quality Chart Reviewer or Quality Compliance Coordinator or designate obtains a report of all multi-tissue cases for which the PRC obtained telephone consent or DRAI and resulted in recovery.
2. Upon receipt of the tissue donor listing, the Quality Chart Reviewer or Quality Compliance Coordinator or designate randomly selects charts according to the Donor Record Sampling Plan shown in Exhibit 1.
3. A *Tissue Donor Telephone Audit Worksheet* is completed with the information provided in the audio recordings and donor charts. See Exhibit 2.
4. The Quality Chart Reviewer or Quality Compliance Coordinator or designate ensures that all fields of the audit worksheet are complete and documents any errors, omissions and/or inconsistencies.
5. The Quality Chart Reviewer or Quality Compliance Coordinator or designate documents and analyses the final results of the audits and reports findings to the Director Quality and to PRC management.



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#### Records:

Record Name	Form No. (if applicable)	Record Holder	Record Location	Record Retention Time (as a minimum)
Tissue Donor Telephone Audit Worksheet	CSF-9-92	Quality Department	Quality Department	16 years
Donor Medical and Social History Questionnaire	CSF-9-14	PRC	PRC	16 years
Eye-Only Donor Risk Assessment Interview (Donor > 10 years old)	CSF-9-214	PRC	PRC	16 years
Eye-Only Donor Risk Assessment Interview (Child Donor ≤ 10 years old)	CSF-9-215	PRC	PRC	16 years
Eye-Only Donor Risk Assessment Interview Birth Mother	CSF-9-216	PRC	PRC	16 years
Donor Risk Assessment Interview (Donor > 10 years old)	CSF-9-261	PRC	PRC	16 years
Donor Risk Assessment Interview (Child	CSF-9-262	PRC	PRC	16 years



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Donor ≤ 10 years  
old)

Donor Risk  
Assessment  
Interview Birth  
Mother

CSF-9-263

PRC

PRC

16 years

#### References:

- *Discussing Donation Opportunities and Obtaining Consent, CPI-9-204*
- *Donor Medical and Social History – Organ or Combined Organ & Tissue Process Instruction, CPI-9-207*
- *Medical & Social History – Tissue Process Instruction, CPI-9-261*
- Tissue Donor Telephone Audit Worksheet
- *Standards for Tissue Banking, American Association of Tissue Banks, United States, 14th edition, 2017.*
- ISO 2859 Sampling procedures for inspection by attributes
- AATB Bulletin No. 07-36: Changes to AATB Standards for Tissue Banking
- Gift of Life Act



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#### Exhibit 1: Donor Record Sampling Plan Index Values as per ISO 2859

Lot Size	General Inspection Level III Sample Size Code Letter	Sample Size
2-8	B	3
9-15	C	5
16-25	D	8
26-50	E	13
51-90	F	20
91-150	G	32
151-280	H	50
281- 500	J	80
501 – 1200	K	125
1201 – 3200	L	200
3201 - 10000	M	315



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#### Exhibit 2: Tissue Donor Telephone Audit Worksheet

#### Page 1

CSF-9-92

**Tissue Donor Telephone Audit Worksheet**

<b>Auditor:</b>	_____	_____
	Name	Signature
<b>Date:</b>	_____	<b>TGLN Number:</b>
	dd/mmm/yyyy	_____

Required Content:	Yes	No	N/A	Comments
<b>Consent</b>				
Consenting person's name (verification and spelling as needed)				
Consenting person's relationship to donor				
Donor identity				
Consenting person's address				
General types of tissue to be recovered				
General purpose for which the tissue is to be used (Trx/R/T)				
Statement granting permission to have access to donors medical records				
Disclosure of blood testing for transmissible disease and reporting of positives				
Written consent complies with what is in the recording				
Witnessed				
Consenting person's signature (or phone consent)				
Person obtaining consent's signature				
Witness' signature				
Verification that tissues recovered match the consent				
Consent form completed in full and correct?				

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pg. 1 of 2