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Clinical Process Instruction Manual

Medical & Social History – Tissue Process Instruction

Policy:

An inquiry shall be conducted with the donor (medical assistance in death referrals) or the deceased donors next of kin (NOK), the nearest available relative, a member of the donor's household, other individual with an affinity relationship (caretaker, friend, significant life partner) and/or primary treating physician using a standardized questionnaire. The questionnaire should be completed with the individual who can provide the most accurate information.

Questions have been formulated using the Health Canada's Safety of Human Cells, Tissues and Organs for Transplantation (CTO) Regulations and the American Association of Tissue Banks (AATB) Current Standards for Tissue Banking requirements. Questions are included that evaluate past medical history for conditions that could constitute a contraindication release for transplantation as identified in AATB standards Appendix II.

For the purposes of this document, Trillium Gift of Life Network (TGLN) coordinator refers to the Tissue Coordinator (TC), but in some instances the Clinical Services Coordinator (CSC), Specialist - Organ and Tissue Donation (S-OTD), Clinical Responder (CR) or Clinical Specialist (CS) may fill this role.

A TGLN coordinator facilitates the completion of a questionnaire to guide the donor suitability assessment for tissue donation. There are six (6) different Donor Risk Assessment Interview (DRAI) questionnaires to be selected from as outlined in this process instruction.

A complete assessment includes evaluating all potential sources of data such as the potential donor's current hospital medical records, interview of the professionals involved in her/his care at the hospital, NOK and/or others of close relationship to the potential donor. Past medical records may also require review.

For all donors one month (28 days) of age or less, the infant and the birth mother shall be screened for risk of communicable disease agents and diseases and the birth mother must be tested. See *Maternal Serology – SickKids Process Instruction, CPI-9-266.*



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Process:

- The TGLN coordinator will identify the individual(s) who should be interviewed. NOK and/or individuals of close relationship to the potential donor are most likely to be a key source of information about the potential donor's medical and/or social risk factors. Separate questionnaires must be completed for each interview conducted.
- 2. The TGLN coordinator will identify the correct DRAI(s) to be completed by assessing the potential donor's age and other relevant criteria as described below:

Potential Eye-Only Donor

If the potential donor is only suitable for ocular donation at the time of the referral, the TGLN Coordinator chooses to complete one (or more) of the 3 Eye-Only Donor Risk Assessment Interviews:

- 1. Eye-Only Donor Risk Assessment Interview (Donor > 10 years old). See Exhibit 1.
- 2. Eye-Only Donor Risk Assessment Interview (Child Donor ≤ 10 years old). See Exhibit 2.
- 3. Eye-Only Donor Risk Assessment Interview Birth Mother. See Exhibit 3.

If the potential donor is over 10 years old, only the Eye-Only DRAI > 10 years old must be completed. If the potential donor is \leq 10 years old, the Eye- $Only DRAI (Child Donor <math>\leq$ 10 years old) must be completed. If the potential child donor is 18 months of age or under, and/or has been breastfed within the last 12 months the Eye-Only DRAI Birth Mother must also be completed to document maternal risk s. If the child donor has not left the hospital since birth, only the Eye-Only DRAI Birth Mother questionnaire requires completion.

Potential Multi-Tissue Donor

If the potential donor is suitable for multi-tissue donation at the time of the referral, the TGLN Coordinator chooses to complete one (or more) of the three (3) multi-tissue Donor Risk Assessment Interviews:

- 1. CSF-9-252 Donor Risk Assessment Interview (Donor > 10 years old). See Exhibit 4.
- 2. CSF-9-253 Donor Risk Assessment Interview (Child Donor ≤ 10 years old). See Exhibit 5.
- 3. CSF-9-254 Donor Risk Assessment Interview Birth Mother. See Exhibit 6.

If the potential donor is over 10 years old, only the DRAI > 10 years old must be completed. If the potential donor is \leq 10 years old, the DRAI (Child Donor \leq 10 years old) must be completed. If the potential child donor is 18 months of age or under, and/or has been breastfed within the last 12 months the DRAI Birth Mother must also be completed to document maternal risk factor. If the child donor has not left the hospital since birth, only the DRAI Birth Mother questionnaire requires completion. For multitissue donors or if any doubts exist regarding eligibility for ocular exclusive donation, the relevant DRAI(s) are performed in their entirety.



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3. The basic principles that apply when performing the relevant DRAI(s) include the following:

- 3.1. The TGLN coordinator will ensure the NOK will be provided with all the information in a language the proxy is conversant in to provide accurate information. This may include communicating to the proxy using a professional interpreter who is not related to the donor and is conversant in the proxy's language, such as an OTDC or TC, health care provider, hospital's services or TGLN's prescribed translation service.
- 3.2. The TGLN coordinator is responsible for asking all questions and sub-questions, and documenting the respondent's responses on the relevant DRAI(s).
- 3.3. The TGLN coordinator will reasonably endeavor to ask questions as written and may supplement additional explanations using layman's terms as required to aid in understanding. 'Reasonably endeavor' meaning there may be exceptional circumstances where a word may inadvertently be changed, missed or used in a different order but it does mean we will always make reasonable effort. For example, to cover circumstances where a staff may be interrupted and misses a word or the order Further probing questions may be asked by the TC to gather the most comprehensive answer.
- 3.4. The TGLN coordinator documents the responses with sufficient detail and additional clarifying notes as deemed necessary as it relates to the questions.
- 3.5. All documentation of responses to DRAI questions shall be documented real-time, concurrently with the asking of each question on the questionnaires.
 - 3.5.1. If the respondent offers up information related to a different question, the TC is not required to document the response in the current unrelated question and may navigate the questionnaire as needed to complete the corresponding question. Information given that is related to another question can be documented in the Additional Notes section of the questionnaire.
 - 3.5.2. If the respondent provides information not listed in the DRAI being completed, the TC will document this information in the Additional Notes section of the questionnaire.
- 3.6. For positive answers, ensure documentation of timing, diagnosis, treatment, outcome as well as any other pertinent details (like physician or clinic/hospital involved) is included.
- 3.7. If the NOK is unsure how to answer the questions, the coordinator must clarify for the NOK that they must answer the question to the best of their knowledge.



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- 3.8. The TC is responsible for identifying and addressing inconsistencies between the information provided by the person answering the med-soc and the information provided through other sources such as the health care provider (HCP). Any additional information added to the DRAI(s) from a source other than the interviewee, shall be documented in the Additional Notes section of the questionnaire, along with the source of the information, the date and the name of the person documenting the information on the questionnaire if different than the original TGLN coordinator.
- 4. The TGLN coordinator will make every effort to complete the DRAI(s) at the time of consent, and only if the interviewee is physically unable to or insistent that they cannot complete the questionnaire at the time of consent, pick an agreed upon time and phone number in which to connect. If the questionnaire is conducted over the telephone, it must be done on a recorded line.
 - 4.1. The TGLN coordinator is required to document every occurrence when a DRAI is not completed at the time of consent in the clinical notes as well as the agreed upon time, name of the individual and contact number for completion of the questionnaire.
- 5. Prior to commencing a DRAI with the NOK, verify with an HCP that the NOK is in an area where it would be appropriate to proceed with questionnaire (when applicable). Where possible, request that the NOK is seated in a quiet area with privacy as the questions are very personal in nature.
- HCPs are asked to bring the NOK to the phone using acceptable scripting if they are still in the hospital.
- 7. If the NOK is not at the hospital at the time of referral, the TC (or S-OTD in rare instances) confirms the donor family's contact information (name, telephone number, and relationship to the donor) with the HCP.
- 8. The TGLN coordinator uses reasonable efforts in attempt to reach the donor family by telephone. Reasonable Effort is defined as: regular calls up to 12 hours after death if consent has not yet been obtained. For eye-exclusive donors in which consent has been obtained, continue contacting the NOK until confirmed with Eye Bank of Canada (EBC) that the eyes will not be used for transplant. For consented multi-tissue cases, continue contacting the NOK until confirmed with the Tissue Bank(s) that a go ahead is not possible due to time constraints. The TC does not leave any confidential information on voicemails unless requested by the NOK.
- 9. The TGLN coordinator explains to the interviewee(s) that the questions are similar to those asked of blood donors and are intended to help prevent transmission of disease to recipients.
- 10. The TGLN coordinator informs the interviewee that some of the questions asked may be of a sensitive nature, and that even if they seem irrelevant or inappropriate they are standard questions



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as required by the Health Canada and the American Association of Tissue Banks standards. The TGLN coordinator explains that all questions are asked, regardless of age, sex or cultural background of the potential donor.

- 11.The TGLN coordinator informs respondents that the information they share will remain confidential unless required by law or purposes related to organ and tissue donation. The DRAI(s) are not to be left on the patient's chart; any paper copies of the form should be sent to the Provincial Resources Centre (PRC) and uploaded in the donor management system.
- 12. If the person answering the DRAI feels uncomfortable answering questions and/or answers 'unknown', it may be acceptable to ask if there is anyone else who may be able to provide the missing information.
- 13. The TGLN coordinator addresses final details of planning for the donation with the NOK as per *Discussing Donation Opportunities and Obtaining Consent Process Instruction, CPI-9-204.*
- 14. If the TGLN coordinator is unable to obtain a complete DRAI, s/he confirms if consent has been provided for research and/or teaching. If consent for research and/or teaching has been obtained, recovery can take place. If consent for both research and teaching has been declined by NOK, the TGLN coordinator contacts the department responsible for release of body at the donor hospital and inform them that recovery will not be taking place and release of body to the next step is permitted.
- 15. The TGLN coordinator ensures all required information has been obtained and documented, including NOK address information, family physician and funeral arrangements.
- 16. The TGLN coordinator reviews the completed DRAIs for transplant exclusion criteria. The TGLN coordinator should not offer the potential donor to tissue banks where transplant criteria are not met and there is no opportunity and/or consent for research and teaching. If consent has been provided for education and/or research, the TGLN coordinator contacts the tissue bank(s) as applicable to discuss these options as identified on the Tissue Bank Profile.
- 17. The TGLN coordinator ensures the DRAI(s) are reviewed in their entirety, and any errors or omissions corrected prior to providing copies to the receiving tissue bank (where applicable).
- 18. The TGLN coordinator sends a copy of the completed DRAI(s) to the tissue bank(s) being offered tissues (where applicable). Should any changes be made to the questionnaire after the initial offer, any new additional information shall be added in the comments section, along with the date and source of the information and a revised version of the questionnaire shall be sent to each of the tissue banks being offered or having accepted the donor (where applicable).



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Records:

Record Name	Form No. (if applicable)	Record Holder	Record Location	Record Retention Time (as a minimum)
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 Donor ≤ 10 years old)	CSF-9-262	PRC	PRC	16 years
Donor Risk Assessment Interview Birth Mother	CSF-9-263	PRC	PRC	16 years

References:

- Ontario Tissue Exclusive Referral Donation Process Instruction, CPI-9-160
- Discussing Donation Opportunities and Obtaining Consent fProcess Instruction, CPI-9-204
- Maternal Serology SickKids Process Instruction, CPI-9-266.

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• Standards for Tissue Banking, American Association of Tissue Banks, United States, 14th edition, 2017. D4.140



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Exhibit 1: Eye-Only Donor Risk Assessment Interview (Donor > 10 yrs old)

Trillium Gift of Life Network

Eye-Only Donor Risk Assessment Interview (Donor >10 yrs old)

483 Bay Street South Tower, 4th Floor Toronto, Ontario M5G2C9 Tel (24/7): 1.888.603.1399 Fax: 1.866.557.6100 Website: www.eifbfife.on.ca

CSF-9-214

Donor Name:				
First	Middl	e	Last	
Person Interviewed:				
	Name	Re	lationship	
Contact Information:()	Add	Cit.	Chaha	
Phone	Address	City	State	Zip
The interview was conducted:	by telephone in person	n 🗖		
Person Interviewed:	Name	Po	elationship	
	Name	Ke	iauorisriip	
Contact Information:() Phone	Address	City	State	Zip
The interview was conducted:	by telephone ☐ in pers	on 🗖		
Person conducting interview and	completing this form:			
reison conducting interview and	Completing this form.			
those asked when someo	ne sensitive and personal na ne donates blood. We ask th onation. I will read each que	ese questions for the h	ealth of those wh	e similar (
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^{*} The interviewer should mix the appropriate pronoun with other terms with which the historian can relate: the donor's given name; their nickname; inserting "your" father, mother, husband, wife, sister, brother, daughter, son, or child (as indicated).



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Exhibit 2: Eye-Only Donor Risk Assessment Interview Child Donor ≤10 years old



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Eye-Only Donor Risk Assessment Interview Child Donor ≤10 years old

CSF-9-215 483 Bay Street South Tower, 4th Floor Toronto, Ontario M5G2C9 Tel (24/7): 1.888.603.1399 Fax: 1.866.557.6100

				Website:	www.giftoflife.
Donor Name:					
First	S N	Middle		Last	
Person Interviewed:					
	Name		Relatio	onship	
Contact Information:()_			_		
Phone		Address	City	State	Zip
The interview was conducted: by	y telephone 🗆	in person 🗆			
Person Interviewed:					
CISON INCOVICUO.	Name		Relatio	onship	
Contact Information: ()					
Phone		Address	City	State	Zip
The interview was conducted:	by telephone	in person 🗆			
	l annualation this f				
Person conducting interview and	completing this is	orm:			
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Exhibit 3: Eye-Only Donor Risk Assessment Interview Birth Mother

Gift of Life Network	Eye-Only Don	Only Donor Risk Assessment Interview Birth Mother				
Child Donor's Name:	First	Midd	tle	Last		2
Birth Mother's Name:	First	Midd	dle	Last		1720
Person Interviewed: _	Name		-	Relationship to	Birth Mother	
Contact Information:	()Phone	Δ	ddress	City	State	Zip
	ducted: by telephone erview and completing this	in	person 🗆			
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Exhibit 4: Donor Risk Assessment Interview Child Donor >10 years old



TGLN Donor Risk Assessment Interview (Donor >10 years old)

Trillium Gift of Life Network 483 Bay Street South Tower, 4th Floor Toront Outzrio M5G2C9

CSF-9-261

Donor Name:	First		Middle	Last		Donor Da	ate of Birth:	DD/MM/YYYY
Place of Interview:	□ Phone	□ Hospital	□ Other	D	ate-Time I	nterview	DD/MM/YYYY	: EDT
Person Conducting I	nterview	and Comp	leting For	n:				
								: EDT
Name (First a	nd Last)			Signature			DD/MM/YYYY	hh:mm
Person Interviewed:								
		Name (Fi	rst and Last)			Rel	ationship	
Contact Information	:							Canada
		Address		City	Province		Postal Code	Country
	_()Phone		Phone Type:	☐ Home	□ Cell	□ Work	
		Phone						
Complete this section is	f an additi	ional person	was intervie	wed 🗆 N/A				
Person Interviewed:		Name (First ar	nd Last)			Re	lationship	
Contact Information: _		Address		City	Provin		Postal Cod	Canada e Country
				•				
-	_()_	Phone		Phone Type:	□ Home	□ Cell	□ Work	
I want to advise you	of the s	ensitive an	d persona	I nature of some	of these o	mestions.	They are si	milar to those
asked when someon	ne donat	es blood. W	e ask thes	e questions for	the health	of those	who may rec	eive her/his*
gift of donation. I	will read	l each ques		ou will need to a Yes" or "No."	answer to t	he best o	f your know	edge with a
SECTION A: Pers	on Inte	rviowad		10.				
		1						
A1. How long have you	ı known h	ner/him*?						
A2. Do you know her/			□No		ovide the fol	llowing info	ormation of the	e best person(s)
be able to answer her/his medical his			to contact: A2a. Name:					
relationship lifesty								
				A2b. Relationshi	•			
				A2c. Phone Nun	nber:			
SECTION B: Infe	ction &	Commun	icable Il	lness				
B1. In the past 12 mg			□No	B1a. What type	of infection?	?		
investigated, diagr any type of infecti		reated for	□Yes	B1b. Date and o	luration?			

January 30, 2024 Page 1 of 21 Donor ID #_____

^{*} The interviewer should mix the appropriate pronoun with other terms with which the historian can relate: the donor's given name; their nickname; inserting "your" father, mother, husband, wife, sister, brother, daughter, son, or child (as indicated).



SECTION: Clinical ID NO.: CPI-9-261 PAGE: **11** of 13

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Exhibit 5: Donor Risk Assessment Interview Child Donor ≤10 years old

January 30, 2024

Gift of Life Network	TGLI	l Donor Ris Child Don	k Assessme nor ≤10 yea		riew and	em Gift of Life Network lay Street South Tower, loor Toronto rio MSCIDC9 CSF-9-262
Donor Name:				D	onor Date of Birth:	
	First	Middle	Last			DD/MM/YYYY
Place of Interview:				ate-Time Int	erviewed:/_/_ DD/MM/YYY	:_E
erson Conducting Int		on piecing rom	Signature		DD/MN/YY	- <u>÷</u> ED
Marine (Final area			agrature		DOJ/MY111	
Person Interviewed:	No	me (First and <u>test)</u>			Relationship	
ontact Information:						Canada
	Addr		City	Province	Postal Code	Country
	()Pho	ne	Phone Type:	☐ Home	□ Cell □ Work	
omplete this section if a	ın additional pe	erson was interviev	wed 🗆 N/A			
erson Interviewed:						
	Name (First and Leat			Relationship	
ontact Information:						Canada
	Addr	ess	City	Province	Postal Co	de Country
_±) Pho	ne	Phone Type:	□ Home □	Cell	
I want to advise you o	donates blo	od. We ask these	e questions for	the health of	those who may re	ceive her/his
gift of donation. I w	nust also be con nors who have \$18 months of	mpleted in the follo been breastfed wild	fes" or "No." owing scenarios: thin the last 12 n		•	vieuge with a
gift of donation. I w Reminders: The DRAI Birth Mother m a) \$10 year-old don b) Donors who are: c) ONLY the DRAI B	nust also be con nors who have \$18 months of Birth Mother is	mpleted in the follo been breastfed wid d needed for pediati	fes" or "No." owing scenarios: thin the last 12 n		•	ricuye with a
gift of donation. I w Reminders: The DRAI Birth Mother m a) \$10 year old don b) Danars who are c c) ONLY the DRAI B SECTION A: Person	nust also be con nors who have ≤18 months of Birth Mother is n Interview	mpleted in the follo been breastfed wid d needed for pediab red	fes" or "No." owing scenarios: thin the last 12 n		•	ricuye with a
Reminders: The DRAI Birth Mother m a) \$10 year old don b) Donors who are:	nust also be con cos who have \$18 monther is in Interview (nown her/him in well enough in uestions about ry or social and	mpleted in the follower breastfed with needed for pediables and needed for needed for needed for	fes" or "No." owing scenarios: thin the last 12 n ric donors who ne	ever left the ho wide the follow p:	•	

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Donor ID # ____



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Exhibit 6: Donor Risk Assessment Interview Birth Mother



TGLN Donor Risk Assessment Interview Birth Mother

Trillium Gift of Life Network 483 Bay Street South Tower 4th Floor Toronto, Ontario M5G2C9

CSF-9-263

Donor Name:	First		Middle	Last				DD/MM/YYYY	
Place of Interview:	□ Phone	☐ Hospital	Other .	D	ate-Time I	nterviewe	ed:// DD/MM/YYYY	: EDT	
Person Conducting I	nterview	and Comp	leting Form	n:					
Name (First a	and Last)			Signature			DD/MM/YYYY	: EDT	
Person Interviewed:		Name (Fi	rst and Last)			Rel	ationship		
_						-			
Contact Information		Address		City	Province		Postal Code	Canada Country	
						"		,	
	_(Phone		Phone Type:	□ Home	□ Cell	□ Work		
Complete this section is	6 an additi	anal naman	a intania	wad D N/A					
Complete this section is	i ari auuru	onai person	was intervie	wed u N/A					
Person Interviewed:		Name (First ar				D-I	ationship		
		Name (First ar	iú Lest)			Rei	auonsnip		
Contact Information: _		Address		City	Province		Postal Code	Canada Country	
		Audiess		•				Country	
-	_()_	Phone		Phone Type:	☐ Home	□ Cell	■ Work		
					6.1				
I want to advise yo asked when someo gift of donation. I	ne donat	es blood. W	e ask thes	e questions for	the health	of those	who may rece	ive her/his*	
gire of donacioni 1	Will redu	cuen ques		Yes" or "No."	unswer to t	iic best o	i your known	age With a	
The DRAI Birth Moti a) ≤10 year old of									
b) Donors who ar			Dreastieu w	nunn une nast 12 n	nonuis				
c) Pediatric donoi	rs who net	ver left the h	ospital since	e birth. See Quest	ion #27				
Only Birth Moth	er DRAI c	ompleted	□ Additio	onal DRAI Comple	ted				
SECTION A: Pers	SECTION A: Person Interviewed								
A1. Is the person bein			□No	Ala. If no,					
potential donor's b	oirth moth	er?	□Yes	What is th	e birth moth	er's name	?		
A2. Do you know the			□No	If no, please pr	ovide the fol	lowing info	rmation of the	best person(s)	
birth mother well of answer questions			□Yes	to contact:					
history or social ar			■ res	A2a. Name:					
lifestyle?				A2b. Relationsh	ip:				

January 30, 2024 Page 1 of 21 Donor ID #_____

^{*} The interviewer should mix the appropriate pronoun with other terms with which the interviewee can relate: the mother's given name; her nickname; inserting "you," mother, sister, or wife (as indicated).