



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:

1. 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 ≤ 10 years old, the *Eye-Only DRAI (Child Donor ≤ 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 ≤ 10 years old, the *DRAI (Child Donor ≤ 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 multi-tissue 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.
6. 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 DRAs 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 Process 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)



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

CSF-9-214

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.on.ca

Donor Name: _____		
First	Middle	Last
Person Interviewed: _____		
Name	Relationship	
Contact Information: (____) _____		
Phone	Address	City State Zip
The interview was conducted: by telephone <input type="checkbox"/> in person <input type="checkbox"/>		
Person Interviewed: _____		
Name	Relationship	
Contact Information: (____) _____		
Phone	Address	City State Zip
The interview was conducted: by telephone <input type="checkbox"/> in person <input type="checkbox"/>		
Person conducting interview and completing this form:		
_____	_____	_____
Print Name	Signature	Date/Time
<p>I want to advise you of the sensitive and personal nature of some of these questions. They are similar to those asked when someone donates blood. We ask these questions for the health of those who may receive her/his* gift of donation. I will read each question and you will need to answer to the best of your knowledge with a "Yes" or "No."</p>		
<p>A1. How long have you known him/her?</p>		<p>(blank field to enter in period of time)</p>

* 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**



**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.on.ca

Donor Name: _____					
First	Middle	Last			
Person Interviewed: _____					
Name			Relationship		
Contact Information: _____					
(____)	Address	City	State	Zip	
The interview was conducted: by telephone <input type="checkbox"/> in person <input type="checkbox"/>					
Person Interviewed: _____					
Name			Relationship		
Contact Information: _____					
(____)	Address	City	State	Zip	
The interview was conducted: by telephone <input type="checkbox"/> in person <input type="checkbox"/>					
Person conducting interview and completing this form:					
Print Name		Signature		Date/Time	

I want to advise you of the sensitive and personal nature of some of these questions. They are similar to those asked when someone donates blood. We ask these questions for the health of those who may receive her/his* gift of donation. I will read each question and you will need to answer to the best of your knowledge with a "Yes" or "No."

A1. How long have you know him/her?

(blank field to enter in period of time)

* The interviewer should mix the appropriate pronoun with other terms with which the interviewee can relate: the donor's given name; their nickname; inserting son, daughter, or child (as indicated).



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Exhibit 3: Eye-Only Donor Risk Assessment Interview Birth Mother



Eye-Only Donor Risk Assessment Interview Birth Mother

CSF-9-216

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.on.ca

Child Donor's Name: _____
First Middle Last

Birth Mother's Name: _____
First Middle Last

Person Interviewed: _____
Name Relationship to Birth Mother

Contact Information: _____
Phone Address City State Zip

The interview was conducted: by telephone in person

Person conducting interview and completing this form:

Print Name Signature Date/Time

I want to advise you of the sensitive and personal nature of some of these questions. They are similar to those asked when someone donates blood. We ask these questions for the health of those who may receive her/his* gift of donation. I will read each question and you will need to answer to the best of your knowledge with a "Yes" or "No."

Check if the DRAI for the Birth Mother is the only DRAI that will be completed. This circumstance occurs only when the child donor has not left the hospital since birth. See Question #27.

A1. Have you/she EVER been quarantined, investigated, diagnosed, or treated for a potentially communicable illness (e.g. Influenza A, SARS, or Ebola)?	<input type="checkbox"/> No <input type="checkbox"/> Yes	(i). Please explain and include date(s): (ii) Treatment?
A2. Have you/she EVER had direct contact or exposure to a place or person who is known or suspected to have a potentially communicable illness (e.g. Influenza A, SARS, Ebola)?	<input type="checkbox"/> No <input type="checkbox"/> Yes	Please explain:
2a. Did you (she*) have a family physician or a specialist?	<input type="checkbox"/> No <input type="checkbox"/> Yes	2a(i). When was your/her* last visit? 2a(ii). Why? 2a(iii). Provide any contact information (e.g., name, group, facility, phone number, etc.):

* 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).



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

		TGLN Donor Risk Assessment Interview Child Donor ≤10 years old		<small>Trillium Gift of Life Network 683 Bay Street South Tower, 4th Floor Toronto Ontario M5G 2C9</small>	
Donor Name: _____ <small>First Middle Last</small>		Donor Date of Birth: ____/____/____ <small>DD/MM/YYYY</small>		<small>CSF-9-262</small>	
Place of Interview: <input type="checkbox"/> Phone <input type="checkbox"/> Hospital <input type="checkbox"/> Other _____		Date-Time Interviewed: ____/____/____ ____:____ EDT <small>DD/MM/YYYY</small>			
Person Conducting Interview and Completing Form:					
Name (First and last): _____		Signature: _____		____/____/____ ____:____ EDT <small>DD/MM/YYYY</small>	
Person Interviewed: _____ <small>Name (First and last) Relationship</small>					
Contact Information: _____ <small>Address City Province Postal Code Country</small>					
Phone: ____ (____) _____ Phone Type: <input type="checkbox"/> Home <input type="checkbox"/> Cell <input type="checkbox"/> Work					
<i>Complete this section if an additional person was interviewed</i> <input type="checkbox"/> N/A					
Person Interviewed: _____ <small>Name (First and last) Relationship</small>					
Contact Information: _____ <small>Address City Province Postal Code Country</small>					
Phone: ____ (____) _____ Phone Type: <input type="checkbox"/> Home <input type="checkbox"/> Cell <input type="checkbox"/> Work					
<p>I want to advise you of the sensitive and personal nature of some of these questions. They are similar to those asked when someone donates blood. We ask these questions for the health of those who may receive her/his* gift of donation. I will read each question and you will need to answer to the best of your knowledge with a "Yes" or "No."</p>					
Reminders: <small>The DRAI Birth Mother must also be completed in the following scenarios:</small> a) <u>≤10-year-old</u> donors who have been breastfed within the last 12 months b) Donors who are ≤18 months old c) ONLY the DRAI Birth Mother is needed for pediatric donors who never left the hospital since birth					
SECTION A: Person Interviewed					
A1. How long have you known her/him*?					
A2. Do you know her/him well enough to be able to answer questions about her/his medical history or social and relationship lifestyle?		<input type="checkbox"/> No <input type="checkbox"/> Yes		<i>If no, please provide the following information of the best person(s) to contact:</i> A2a. Name: A2b. Relationship: A2c. Phone Number:	

* The interviewer should mix the appropriate pronoun with other terms with which the interviewee can relate: the donor's given name; their nickname; inserting son, daughter, or child (as indicated).



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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:		Donor Date of Birth:	
First	Middle	Last	DD/MM/YYYY
Place of Interview: <input type="checkbox"/> Phone <input type="checkbox"/> Hospital <input type="checkbox"/> Other _____		Date-Time Interviewed: DD/MM/YYYY - hh:mm EDT	
Person Conducting Interview and Completing Form:			
Name (First and Last)		Signature	
		DD/MM/YYYY - hh:mm EDT	
Person Interviewed: _____			
Name (First and Last)		Relationship	
Contact Information: _____			
Address		City	Province
		Postal Code	Canada
		Country	
_() _____		Phone Type: <input type="checkbox"/> Home <input type="checkbox"/> Cell <input type="checkbox"/> Work	
Phone			
Complete this section if an additional person was interviewed <input type="checkbox"/> N/A			
Person Interviewed: _____			
Name (First and Last)		Relationship	
Contact Information: _____			
Address		City	Province
		Postal Code	Canada
		Country	
_() _____		Phone Type: <input type="checkbox"/> Home <input type="checkbox"/> Cell <input type="checkbox"/> Work	
Phone			
I want to advise you of the sensitive and personal nature of some of these questions. They are similar to those asked when someone donates blood. We ask these questions for the health of those who may receive her/his* gift of donation. I will read each question and you will need to answer to the best of your knowledge with a "Yes" or "No."			
The DRAI Birth Mother must be completed in the following scenarios:			
a) ≤10 year old donors who have been breastfed within the last 12 months			
b) Donors who are ≤18 months old			
c) Pediatric donors who never left the hospital since birth. See Question #27			
<input type="checkbox"/> Only Birth Mother DRAI completed		<input type="checkbox"/> Additional DRAI Completed	
SECTION A: Person Interviewed			
A1. Is the person being interviewed the potential donor's birth mother?	<input type="checkbox"/> No <input type="checkbox"/> Yes	A1a. If no, What is the birth mother's name?	
A2. Do you know the potential donor's birth mother well enough to be able to answer questions about her medical history or social and relationship lifestyle?	<input type="checkbox"/> No <input type="checkbox"/> Yes	If no, please provide the following information of the best person(s) to contact: A2a. Name: A2b. Relationship:	

* 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).