



Clinical Process Instruction Manual

Donor Medical and Social History – Organ or Combined Organ & Tissue Process Instruction

Policy:

An inquiry shall be conducted with the donor (medical assistance in death referrals) or the deceased donor's next of kin, 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 to the release of tissue for transplantation as identified in AATB standards Appendix II.

In the event of an emerging diseases, endemics or pandemics new/revised questions may be developed to address specific concerns in a supplemental medical social history questionnaire (MSHx). This supplemental MSHx may exist as a separate document and be in place until the questions can be added/revised in iTransplant.

A Trillium Gift of Life Network (TGLN) coordinator conducts the MSHx and any supplemental MSHx in effect (henceforth collectively referred to as the MSHx). The interview may be conducted in-person or by telephone. In all cases, respondents are informed that the information they share remains confidential to the extent permitted by law. The MSHx is not to be left on the patient's chart; all copies of the form should be uploaded into the donor management system.

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.

In the case of organ(s) offered to Ontario by other provinces or the U.S., the offering program completes a MSHx and a copy is faxed to TGLN's PRC.

For the purposes of this document, the TGLN coordinator may be the Referral Triage Coordinator (RTC), Clinical Services Coordinator (CSC), Clinical Responder (CR), and/or Specialist - Organ and Tissue Donation (S-OTD). For cases where MSHX is being completed by the Tissue Coordinator (TC), refer to CPI-9-261.



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Process:

1. The TGLN coordinator or healthcare professional will identify the individual(s) who should be interviewed. If the potential donor is 18 months of age or under, and/or has been breastfed within the last 12 months, a separate questionnaire is used to document maternal risk factors. Next-of-kin (NOK) and/or other 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 MSHx must be completed for each interview conducted. See Exhibit 1 and Exhibit 2 for a sample of the MSHx.
2. The basic principles that apply when performing the MSHx include the following:
 - 2.1 The TGLN coordinator is responsible for asking all questions and sub-questions, and documenting the respondent's answers on a full MSHx.
 - 2.2 The TGLN coordinator asks all questions as written and may supplement additional explanations using layman's terms as required to aid in understanding. Further probing questions may be asked by the coordinator to gather the most comprehensive answer.
 - 2.3 The TGLN coordinator documents all comments made by the interviewee(s).
 - 2.4 All documentation of responses to MSHx questions shall be documented real-time, concurrently with the asking of each question on the MSHx.
 - 2.5 If the respondent offers up information related to a different question, the coordinator is not required to document the response in the current unrelated question and shall indicate to the respondent that they will be asked about this in a subsequent question later on in the MSHx.
 - 2.6 If the respondent provides information not listed in the MSHx, the coordinator documents this information in the comments box on the MSHx.
 - 2.7 For positive answers, ensure documentation of timing, diagnosis, treatment, and outcome, as well as any other pertinent details (like physician or clinic/hospital involved), is included.
 - 2.8 If the NOK is unsure how to answer the questions, the coordinator clarifies for the respondent that they must answer the question to the best of their knowledge.
 - 2.9 The TGLN coordinator is responsible for identifying and addressing inconsistencies between the information provided by the person answering the MSHx and the information provided through other sources, such as the health care professional. Any additional information added to the MSHx from a source other than the interviewee shall be documented in the comments section of the MSHx, along with the source of



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the information and the date and the name of the person documenting the information on the MSHx if different than the original TGLN coordinator.

3. The TGLN coordinator will make every effort to complete the MSHx at the time of consent. If the interviewee is physically unable to or is insistent that they can't complete the MSHx at the time of consent, obtain agreement on a time and place or phone number when the MSHx can be done. This may include the use of a professional interpreter who should not be related to the donor and is conversant in the interviewee's language, such as an S-OTD, health care provider, hospital's services or TGLN's prescribed translation service.
 - 3.1 The TGLN coordinator is required to document every occurrence when a MSHx 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 MSHx.
 - 3.2 In situations where the person to be interviewed is experiencing fatigue or there are communication challenges, e.g. patients eligible for MAID provision or bereaved spouse:
 - 3.2.1 Provide an advanced copy of the questions to the donor and/or person donor has provided permission to be involved in donor process and interview donor or family member to ensure the asked questions are completed, stating any written answers and asking clarifying questions as needed.
 - 3.2.2 Interview a person the donor has provided permission to be involved in donor process or obtain a second med social history if MAID patient/bereaved spouse is unable to provide questions in person due to inability to communicate/fatigue.
 - 3.3 An incomplete questionnaire would require notice of exceptional distribution.
4. The TGLN coordinator selects an appropriate, private setting for the in-person interview.
5. Prior to conducting the interview, 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 and assess medical suitability of organs and tissues for transplant. See *Medical & Social History Questionnaire Description and Rationale, CSF-9-13* reference document on the On-line Resource Centre (ORC) for the detailed rationale for each question. See Exhibit 3.
6. The TGLN coordinator informs the interviewee that some of the questions asked may be of a sensitive nature, including questions on sexual activity and social alcohol and drug use, and that even if they seem irrelevant or inappropriate they are standard questions as required by Health Canada and the American Association of Tissue Banks. The interviewer explains that



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all questions are asked, regardless of age, sex or cultural background of the potential donor. For further tips on conducting interviews, see the *Donor Medical & Social History Questionnaire – Description & Rationale, CSF-9-13*.

7. The TGLN coordinator asks all questions to obtain a complete assessment and documents all comments to each question made by the interviewee(s).
8. 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*.
9. When the MSHx is complete, the TGLN coordinator signs and enters the completed questionnaire into iTransplant. Prior to signing the MSHx, the TGLN coordinator ensures that all required information has been obtained and documented, including the name of the healthcare professional who reviewed the potential donor’s medical records, if applicable. In the event a supplemental MSHx is used it will also be uploaded to the donor chart.
10. The TGLN coordinator ensures the MSHx is reviewed in its entirety, and any errors or omissions are corrected immediately to ensure any copies distributed are up to date.
11. The TC/CSC is responsible for sending any required copies of the completed MSHx to the tissue bank(s) and OPOs. Should any changes be made to the MSHx after the initial offer, any new additional information shall be added in the comments section, along with the date and source of the information. A revised version of the MSHx shall be sent to each of the organizations that have been offered or have accepted tissue or organs from the donor.

Records:

Record Name	Form No. (if applicable)	Record Holder	Record Location	Record Retention Time (as a minimum)
Donor Medical & Social History Questionnaire	CSF-9-14	PRC	PRC	16 years
Donor Medical & Social History Questionnaire French	CSF-9-259	PRC	PRC	16 years



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References:

- *Ontario Organ or Combined Organ and Tissue Donation Process Instruction, CPI-9-100*
- *Non-Ontario Organ Donor Process Instruction, CPI-9-101*
- *Ontario Tissue Exclusive Referral Donation Process Instruction, CPI-9-160*
- *Discussing Donation Opportunities and Obtaining Consent Process Instruction, CPI-9-204*
- *Infectious Disease Testing – STAT Process Instruction, CPI-9-211*
- *Exceptional Distribution Process Instruction, CPI-9-217*
- *Medical & Social History Questionnaire Description and Rationale, CSF-9-13*
- *Standards for Tissue Banking, American Association of Tissue Banks, United States, 14th edition, 2017. D4.140, D4.220*



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Exhibit 1: Donor Medical & Social History Questionnaire

Sample Page 1

CSF-9-14

TGLN ID #: _____ Complete this box for Paediatric Donors ONLY: Donor Maternal



Trillium Gift of Life Network
483 Bay Street South Tower, 4th Floor Toronto, Ontario M5G2C9
Telephone (24/7): 1.877.363.8456 Facsimile: 1.866.557.6100
Website: www.giftoflife.on.ca

Donor Medical and Social History Questionnaire

Donor Name: _____ TGLN ID #: _____

Name of Interviewee(s): _____

Relationship(s): _____

Address: _____

Donor's Address: Same as above, or: _____

Phone Number: _____

How long have you known him/her? _____

Before proceeding with organ and tissue donation, we need to ask you some questions (similar to those asked of blood donors) to gather information about any health or social risk factors that may be present. Certain parts of the questionnaire are sensitive, but the information is necessary to help determine whether there are diseases present that may be transmitted to the recipient. We ask that you answer all questions to the best of your knowledge. Answers will be kept strictly confidential (see Privacy Note).

Do you know him/her well enough to be able to answer questions about his/her medical history or social and relationship lifestyle? Yes No

If no, please provide the following information of the best person(s) to contact:

Name: _____ Relationship: _____

Phone Number: _____

Healthcare Professional who reviewed the donor's hospital medical record: N/A

Name: _____ Title: _____

Healthcare Professional who conducted the interview and completed the questionnaire:

Name: _____

Title: _____

Date of Interview: _____ Signature of Interviewer: _____

If the donation occurring is for Ocular Tissue only, it is necessary to complete the highlighted questions only.

Privacy Note: The personal information collected through this form is collected under the authority of Gift of Life Act, 2000. Trillium Gift of Life Network will use it for the purpose of determining suitability and other purposes related to organ and/or tissue donation and transplantation. If you have any questions regarding this collection, please contact: Trillium Gift of Life Network – Provincial Resource Centre: GTA: 416.363.4438, outside GTA: 1.877.363.8456.



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Exhibit 2: Donor Medical & Social History Questionnaire French

Sample Page 1

CSF-9-259

N° Identification attribué par le RTDV : _____

Cochez convenablement pour les donneurs pédiatriques seulement :

Donneur Mère naturelle



Réseau Trillium pour le don de vie
483 rue Bay, tour Sud, 4^e étage, Toronto, Ontario M5G2C9
Télé (24/7) : 1.877.363.8456 Téléc. : 1.866.557.6100
Site Web: www.giftoflife.on.ca/fr

Questionnaire sur les antécédents médicaux et sociaux du (de la) donneur(e)

Nom du (de la) donneur(e) : _____ N° Identification attribué par le RTDV : _____

Nom de la (des) personne(s) enquêtée(s) : _____

Lien avec le (la) donneur(e) : _____

Adresse : _____

Adresse du (de la) donneur(e) : comme ci-dessus, ou : _____

Numéro de téléphone : _____

Depuis quand connaissez-vous le (la) donneur(e)? _____

Avant de procéder à un don d'organes et de tissus, nous devons vous poser quelques questions (similaires à celles posées aux donneurs de sang) pour recueillir des renseignements en regard de la présence des facteurs de risques médicaux et sociaux. Certaines questions sont de nature délicate, mais ces renseignements sont nécessaires pour déterminer le dépistage de certaines maladies susceptibles d'être transmises aux receveurs. Nous vous demandons de répondre à toutes les questions au meilleur de votre connaissance. Les réponses resteront strictement confidentielles (voir l'avis de confidentialité).

Pensez - vous connaître suffisamment le (la) donneur(e) pour pouvoir répondre aux questions concernant ses antécédents médicaux ou sociaux, ses relations et son mode de vie? Oui Non

Si non, veuillez nous indiquer les coordonnées de la (des) personne(s) convenable(s) à contacter :

Nom : _____ Lien avec le (la) donneur(e) : _____

Numéro de téléphone : _____

Nom du professionnel de la santé qui a examiné le dossier médical hospitalier du (de la) donneur(e) : S/O

Nom : _____, Titre : _____

Nom du professionnel de la santé qui a mené l'entrevue et complété l'enquête :

Nom : _____

Titre : _____

Date de l'entrevue : _____ Signature du professionnel qui a mené l'entrevue : _____



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Exhibit 3: Donor Medical & Social History Questionnaire: Description and Rationale

Sample Page 1



CSF-9-13

Donor Medical & Social History Questionnaire: Description and Rationale

Purpose of the Questionnaire

Information obtained from the *Donor Medical and Social History Questionnaire* provides valuable information regarding donor suitability for the purposes of exceptional distribution, and factors into the decision about whether to accept organs and/or tissue for transplantation. Donor history is critical to identifying the risk versus benefit for a potential transplant recipient. The final decision regarding eligibility to donate is made by the tissue bank medical director and/or the transplant physician(s). Consultation with TGLN's Chief Medical Officer may provide guidance on whether exceptional distribution protocols are necessary.

Approach

The interviewer's comfort level with the questions in the *Donor Medical and Social History Questionnaire* (MSHx) impacts the tone of the interview. Comfort and familiarity with the questions is beneficial and helps to place everyone at ease.

One option for starting the interview is to ask the interviewee if she/he has ever donated blood, and to draw similarities between the questions used in the process. The interviewer should explain the purpose of the MSHx and explain that the purpose of the questionnaire is to learn if the potential donor had any previous illnesses or conditions that might prevent donation of certain organs and tissues, and to prevent the transmission of any disease through transplantation.

It is important to ask all the same questions in the same way. Do not apologize for having to ask the questions. Although an apology is well meant, it may imply the interviewer does not believe questions are appropriate to the situation or that the interviewer is not comfortable with the questions or answers. It may discourage the interviewee from answering the questions to the fullest extent of their knowledge.

Responses of 'yes' or 'unknown' to questions may require further investigation. It is the responsibility of the interviewer to exercise clinical judgement and critical thinking to prompt interviewee for elaboration on responses. Information gathered from the interviewee could provide insight on severity and treatment of condition identified, or could provide direction to a source where more information could be discovered about the condition, such as past medical records.

Responsibilities of the Person Conducting Interview & Completing Form

Ethical Considerations

The medical and social history of the donor directly affects the future health of transplant recipients. The questions are an important way to ensure recipients receive the best possible chance for future good health and quality of life. Further, families donate organs and tissue with the belief that another person will benefit. To honour the donor families' intentions and provide the best outcome for all involved, interviewers must *consistently ask ALL questions* in the questionnaire without fail. Failure to do so deviates from the requirements of the Health Canada Regulations and CSA Standards.