Human Cells, Tissues and Organs for Transplantation Adverse Reaction Reporting Form

An unexpected, serious adverse reaction (AR) that is thought to involve the transmission of an infectious disease or disease agent and is suspected to be derived from the donor must be investigated and reported to Health Canada by Source Establishments. Preliminary (initial) reports must be submitted within 24 hours after the start of the investigation. For further information, refer to the Guidance Document for Cell, Tissue and Organ Establishments and the *Safety of Human Cells, Tissues and Organs for Transplantation Regulations* (CTO Regulations).

A) Information Related to the Source Establishment Reporting to Health Canada

A.1	Name of the Source Establishment:		
A.2	Name/Title of the person reporting:		
A.3	Establishment registration number:		
A.4	Address of Source Establishment : City: Province/Territory/State : Postal/Zip code: Country:		
A.5	Phone number:	A.6	Fax number:
A.7	Contact person (if different than A.2):		
A.8	Email address:		
A.9	Type of report: ☐ Preliminary ☐ 15-day Follow-up ☐ Final		
A.10	Date of this report: (yyyy/mm/dd)		
A.11	Date AR reported to Source Establishment: (yyyy/mm/dd)		
A.12	Date investigation initiated by Source Establishment: (yyyy/mm/dd)		
A.13	Source Establishment report number:		

A) Information Related to the Source Establishment Reporting to Health Canada (continued)	
A.14	All implicated CTO in the Source Establishment's possession have been quarantined: ○ Yes – please complete Part D.6 ○ Not applicable (N/A) ○ No If no, please explain:
A.15	Required notifications have been issued to all other implicated establishments: ○ Yes (yyyy/mm/dd) ○ N/A ○ No If no, please explain:
B) Information Related to the Recipient	
B.1	Recipient number:
B.2	Age at Time of AR: ○ Years ○ Months
B.3	Sex: ○ Female ○ Male
B.4	Indication for transplant:
B.5	Type of CTO transplanted:
B.6	Lot number of the transplanted CTO, if applicable:
B.7	Date of transplant: (yyyy/mm/dd)
B.8	Date of AR occurrence: (yyyy/mm/dd)
B.9	Country in which AR occurred:

C) Information Related to the Recipient's AR	
C.1	Describe the AR (include identification of the infectious agent and relevant clinical information):
C.2	Select the consequence for the recipient (check all seriousness criteria that apply): ☐ death (yyyy/mm/dd) ☐ a life-threatening condition ☐ persistent or significant disability or incapacity ☐ medical, dental or surgical intervention to preclude a persistent or significant disability or incapacity ☐ their in-patient hospitalization or its prolongation
C.3	Investigations/laboratory data applicable to the AR are included? ○ Yes ○ No ○ No and Pending
C.4	Is the AR suspected to be due to a deviation(s) in processing? ○ Yes ○ No If Yes, has an Error or Accident Report (FRM-0172) been submitted to Health Canada's Regulatory Operations and Enforcement Branch ○ Yes ○ No If no, please explain:
C.5	Treatment of the AR (include relevant clinical course information):
C.6	Outcome of recipient's AR: ○ Recovered ○ Not Recovered ○ Recovering ○ Fatal ○ Recovered with Sequelae ○ Unknown

D) Information Related to the Donor	
D.1	Donor identification code:
D.2	Living donor? ○ Yes ○ No
D.3	How the donor died (e.g. motor vehicle accident): ☐ N/A Please provide detailed clinical information if relevant:
D.4	Donor investigations/laboratory data are included? ○ Yes ○ Pending
D.5	Date of retrieval of CTO from donor: (yyyy/mm/dd)
D.6	Description of other CTO retrieved from donor, including dates when transplanted or quarantined: ☐ N/A
D.7	Any other unexpected, serious AR reports associated with other CTO retrieved from the same donor? ○ Yes ○ No If Yes, AR report(s) submitted to Health Canada? ☐ Yes (yyyy/mm/dd)
D.8	Description of the status of all other recipients of donor CTO: ☐ N/A
D.9	Is this a case of Exceptional Distribution? ○ Yes ○ No If yes, why?

Note: An update must be submitted within 15 days after the start of the investigation and every 15 days thereafter, until the final report is submitted. A final report describing the results of the investigation, final disposition of implicated CTO, reasons for the disposition, and any corrective actions taken, must be submitted upon completion of the investigation.

Please complete section E or provide a separate report.

E) Final Report Information	
E.1	Describe the results of the investigation:
E.2	Describe the final disposition of implicated CTO and reasons for the disposition: ☐N/A
E.3	Describe any corrective actions taken:

Submit Report to:

Reports should be submitted by facsimile to the Canada Vigilance Program, Marketed Health Products Directorate:

Facsimile: 613-957-0335

Email for enquiries: Marketed Health Products Directorate (hc.canada.vigilance.cto.sc@canada.ca)

Privacy Notice Statement:
For the purposes of the Canada Vigilance Program, information related to the identity of the donor, recipient and/or reporter will be protected as personal information under the Privacy Act, including in cases of an access to information request. For details with regard to personal information collected under this Program, visit the Personal Information Bank; Health Canada; Health Products and Food Branch; Branch Incident Reporting System; PIB# PPU 088 at:
https://www.canada.ca/en/health-canada/corporate/about-health-canada/activities-responsibilities/access-information-privacy/info-source-federal-government-employee-information.html.