Health Canada Santé Canada

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Human Cells, Tissues and Organs for transplantation – Error or Accident investigation reporting form (FRM-0172)

Suspected Errors or Accidents (E/A) identified after distribution of Cells, Tissues and Organs (CTO), that could lead to a serious adverse reaction involving the transmission of an infectious disease or disease agent, are to be reported to Health Canada. A preliminary report must be issued within 24 hours after the start of the investigation. An update (follow-up report) is required to be submitted within 15 calendar days after the start of the investigation and every 15 calendar days after, until the final report is submitted. A final report describing the results of the investigation, final disposition of implicated CTO, reason for disposition, and any corrective actions taken, must be submitted upon completion 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.

A) Information related to the source establishment reporting to Health Canada

A.1	Type of report: ☐ Preliminary ☐ Follow-up ☐ Final	
A.2	Date of this report: (yyyy/mm/dd)	
A.3	Establishment's E/A reference number (optional):	
A.4	Name of the source establishment:	
A.5	Name/title of the person reporting:	
A.6	Establishment registration number:	
A.7	Address of source establishment (street, city, province/state, postal code):	
A.8	Phone number:	A.9: Fax number:
A.10	Contact person:	

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A.11	Email address:	
A.12	Actual date of E/A occurrence: (yyyy/mm/dd)	A.13 Date E/A reported to source establishment: (yyyy/mm/dd)
A.14	Date E/A awareness date: (yyyy/mm/dd)	A.15 Date investigation initiated by Source Establishment: (yyyy/mm/dd)
A.16	All implicated CTO, in source establishment's possession, have been quarantined: ○ Yes ○ No If No, please explain:	
A.17	Required notifications have been issued to all other implicated establishments: ○ Yes - Please complete Part D.4 ○ No If No, please explain:	
A.18	Signature/title of person submitting the report:	

B) Information related to the establishment that originally reported the E/A to the source establishment (if applicable)

B.1	Name of reporting establishment: ☐ Not applicable, suspected E/A discovered by source establishment

B.2	Type of establishment who reported the E/A to the source establishment: ☐ Importer ☐ Another source establishment ☐ Distributor ☐ Transplant establishment ☐ Other If "Other", please explain:
B.3	Address of reporting establishment (street, city, province/state, postal code):
B.4	Name/title of the person who reported the E/A to source establishment:
B.5	Phone number:
B.6	Fax number:
B.7	Contact person:
B.8	Email address:
B.9	Date of E/A occurrence: (yyyy/mm/dd)
B.10	Date E/A awareness date: (yyyy/mm/dd)

C) Information Related to Cells, Tissues and Organs (CTO)

C.1	Description of implicated CTO:

C.2	Description of other CTO recovered from same donor(s):
C.3	CTO donor identification code(s):
C.4	Product number, product barcode, if applicable:
C.5	Lot number(s), if applicable:
C.6	Expiry date(s) of implicated CTO: (yyyy/mm/dd)
C.7	Was the product labelled as sterile? ○ Yes ○ No
C.8	A copy of the original report is attached? ○ Yes ○ No If No, please explain:

D) Investigation description	
D.1	Detailed description of the E/A and investigation:
D.2	Name(s) of any suspected transmissible disease(s) or disease agents(s):
D.3	Corrective actions taken to date:

D.4	List other establishments involved and date they were notified:
D.5	Additional information:

Submit report to:

Regulatory Operations and Enforcement Branch (ROEB)

Email: hc.bpcp-pcpb.sc@canada.ca

Facsimile: 613-960-2156

Privacy notice: The personal information you provide to Health Canada is governed in accordance with the *Privacy Act*. We only collect the information we need to administer the *Safety of Human Cells, Tissues and Organs for Transplantation Regulations* under the *Drugs and Food Act*.

Purpose of collection: We require your personal information to administer the *Safety of Human Cells, Tissues and Organs for Transplantation Regulations* under the *Drugs and Food Act*.

Other uses or disclosures: In limited and specific situations, your personal information may be disclosed without your consent in accordance with subsection 8(2) of the *Privacy Act*.

Refusal to provide the information: The information you provide will help you meet the investigation and reporting requirements of the *Safety of Human Cells, Tissues and Organs for Transplantation Regulations*. Failure to provide this information may result in not meeting all of the requirements of the *Safety of Human Cells, Tissues and Organs for Transplantation Regulations*.

For more information: This personal information collection is described in Info Source, available online at https://www.canada.ca/en/health-canada/corporate/about-health-canada/activities-responsibilities/access-information-privacy/info-source-federal-government-employee-information.html. A Personal Information Bank is under development and will be included on Info Source.

Your rights under the *Privacy Act*: In addition to protecting your personal information, the Privacy Act gives you the right to request access to and correction of your personal information. For more information about these rights, or about our privacy practices, please contact the Privacy Management Division at hc.privacy-vie.privee.sc@canada.ca. You also have the right to file a complaint with the Privacy Commissioner of Canada if you think your personal information has been handled improperly.