Protected A
when completed

Sperm and ova error or accident investigation report form (FRM-0447)

This form is to be used for the submission of error or accident (E/A) investigation reports to Health Canada as required by section 67 and 68 of the Safety of Sperm and Ova Regulations (Safety Regulations).

	**Important:** key or cautionary information you want people to know
	**Information:** supplementary information such as quotes and legal references

An establishment or health professional conducting an investigation into a suspected error or accident must send a preliminary error or accident report to Health Canada within 72 hours after the start of the investigation, if **both** of the following criteria are met:

- The error or accident is thought to have occurred during an activity they conducted.
- The error or accident could lead to an adverse reaction and was identified after the sperm/ova was released from quarantine and made available for use or distribution.

It is acknowledged that all information may not be available at the time of initial reporting, however the preliminary report must be submitted with initial information.

Canada

An interim report must be submitted within 15 days after the start of the investigation and every 15 days after that. An interim report must contain:

- The progress of the investigation.
- Any new information with respect to the suspected E/A.
- Any measures taken during those 15 days to mitigate further risk.

A final report using this form containing the results of the investigation, details concerning the disposition of implicated sperm and ova including the reasons for that disposition, and any corrective actions taken, must be submitted within 72 hours of completing the investigation.

For further information, please refer to Health Canada's *Guidance Document: Safety of Sperm and Ova Regulations* at: https://www.canada.ca/en/health-canada/programs/consultation-safety-sperm-ova-regulations/document.html.

Important: Please complete all applicable sections of the form. Once completed, please submit the form to the Biological Product Compliance Program at hc.bpcp-pcpb.sc@canada.ca or by facsimile at 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 Sperm and Ova Regulations under the Assisted Human Reproduction Act.

Purpose of collection: We require your personal information to administer the Safety of Sperm and Ova Regulations under the Assisted Human Reproduction 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 Sperm and Ova Regulations. Failure to provide this information may result in not meeting all of the requirements of the Safety of Sperm and Ova 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 Health Canada's Privacy Coordinator 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.

PART A: Information related to the establishment or health professional reporting the suspected E/A to Health Canada	
Name of the reporting establishment or health professional:	
Name/Title of person reporting the E/A to Health Canada:	
Registration Number:	☐ Not applicable
Address (street, city, province/state, postal code):	
Phone number:	Fax number:
Contact person, if different from above:	
Email address:	

PART B: Is this investigation the result of a notification received by another establishment or health		
○ Yes. Complete section B with information on the establishment or health professional that sent the notice regarding the suspected E/A. ○ No. The suspected E/A was discovered by the reporting establishment or health professional. Proceed to section C.		
Name of establishment that sent the notice regarding the suspected E/A:		
Name/Title of person who communicated the suspected E/A to the reporting establishment :		
Registration number:	○ Unknown	○ Not applicable
Address (street, city, province/state, postal code):		
Phone number :		Fax number :
Contact person, if different from above :		
Email address :		

PART C: Error or accident summary ☐ Summary provided in attached documentation
Date E/A was discovered: (yyyy/mm/dd)
Date the investigation was initiated by the reporting establishment or health professional: (yyyy/mm/dd)
Establishment specific E/A number, if applicable:
E/A detailed description (including number of donors or samples implicated, number of establishments or health professionals implicated, if known):
Description of adverse reaction that could occur and the respective infectious agent:

Immediate and planned corrective actions with anticipated timelines (e.g. risk assessment, quarantine, dates of notifications sent to other establishments, etc):
List of other establishments or health professionals involved and date they were notified:
Investigation results (if applicable):
Was Health Canada verbally notified of the E/A? ○ Yes; indicate when verbal notification was given: (yyyy/mm/dd) ○ No

PART D: Signature

Signature of person submitting the preliminary report:	Date (yyyy /mm /dd):

Submit report to:

The Biological Product Compliance Program at: hc.bpcp-pcpb.sc@canada.ca