FRM-0446: Sperm and ova primary establishment registration application

When to use this form

This application is to be used by primary establishments who wish to register under the *Safety of Sperm and Ova Regulations* (Safety Regulations). Primary establishment refers to an establishment that conducts all processing activities in respect of sperm or ova, whether it conducts them itself or another establishment conducts any of the activities on its behalf.

You will find Instructions on how to complete the sperm and ova primary establishment registration application at the end of this application. For any questions or clarifications, please email the Biological Product Compliance Program at ahrregistration-enregistrementpa@hc-sc.gc.ca.

Privacy notice

The personal information you provide to Health Canada will be used by the Biological Product Compliance Program under the Safety of Sperm and Ova Regulations under the *Assisted Human Reproduction Act* and handled in accordance with the *Privacy Act* (https://laws-lois.justice.gc.ca/ENG/ACTS/P-21/index.html).

Why are we collecting your personal information? We require your personal information to administer the Safety of Sperm and Ova Regulations under the *Assisted Human Reproduction Act*

Will we use or share your personal information for any other reason? In limited and specific situations, your personal information may be disclosed without your consent in accordance with subsection 8(2) of the *Privacy Act*

What happens if you don't want to provide your personal information? Failure to provide the requested information will result in delays in processing your request and may result in the refusal of your application.

What are your rights? You have the right to access and request a correction and/or notation to your personal information. You also have a right to complain to the Privacy Commissioner of Canada if you feel your personal information has been handled improperly. For more information about these rights, or about how we handle your personal information, please contact the Biological Product Compliance Program.

For more information: The collection of your personal information is described in Info Source at infosource.gc.ca. A Personal Information Bank is under development and will be included on Info Source.

Pub: 210657

Canada

Depending on the type of application, fields indicated with an asterisk (*) may be mandatory.

Part 1: Type of application *

Registration (complete parts 2 and 3)

☐ **Application for registration**: Select this if your primary establishment is submitting a registration application for the first time (refer to section 5 of the Safety Regulations for more information).

☐ **Application for amendment:** Select this if you are already registered to process either sperm or ova (but not both) and wish to amend your existing registration and add the other gamete (refer to section 8 of the Safety Regulations for more information). This application must be submitted prior to performing activities subject to the amendment.

☐ **Change of information**: Select this if you have an existing primary establishment registration number and wish to change any information on your registration application that does not require an application for amendment. This change must be submitted within 30 days of the change (refer to section 11 of the Safety Regulations for more information).

Notice of cessation (complete parts 2A and 4)

☐ **Cessation of activities**: Select this if you have ceased all registered activities at your establishment. This form must be competed and submitted within 30 days of the change (refer to section 11 of the Safety Regulations for more information).

Part 2: Registration *

A) Primary establishment information

Primary establishment registration number (if applicable):		
Primary establishment name:		
Previous name(s) of the establishment (if applicable):		
Civic address		
Building name (if applicable):		
Street number:	Street name:	Suite:
City:	Province/State:	Postal/Zip Code:
Country:		
Mailing address ☐ same as above		
Street number/ P.O. box:	Street name:	Suite:
City:	Province/State:	Postal/Zip code:
Country:		
Primary contact information		
Contact's first name, last name and title:		Language: ☐ English ☐ French
Telephone:	E-mail:	
Emergency contact information (if different from primary contact)		
Contact's first name, last name and title:		Language: ☐ English ☐ French
Telephone:	E-mail:	

B) Activities and building information

Select all activities that your establishment conducts. Please submit a separate entry for parts B and C for each building where activities are conducted.

Address where activities are conducted

☐ same as above

Building name (if applicable):		
Street number:	Street name:	Suite:
City:	Province/State:	Postal/Zip Code:
Country:		

Activities *Numbers 1-3 are the processing activities conducted on the donor, including the required infectious disease testing of the donor (i.e. donor testing). Numbers 4-12 are the activities and testing that are conducted on the gamete(s).	Gamete	
	Sperm	Ova
1. Donor suitability assessment - donor screening	☐	☐
2. Donor suitability assessment - physical examination	☐	☐
3. Donor suitability assessment - donor testing	☐	☐
4. Obtaining	☐	☐
5. Preparing	☐	☐
6. Identifying	☐	☐
7. Testing	☐	☐
8. Preserving	☐	☐
9. Assessing quality	☐	☐
10. Labelling	☐	☐
11. Quarantining	☐	☐
12. Storing	☐	☐

C) Type of process (optional)

☐ Regular process ☐ Directed donation process

Additional information (optional)

D) Establishments conducting activities on your behalf

Please submit a separate part D for each establishment conducting activities on your behalf.

Establishment name:		Registration number (if applicable):	
Street number:	Street name:		Suite:
City:	Province/State:	Country:	Postal/Zip Code:

Activities *Numbers 1-3 are the processing activities conducted on the donor, including the required infectious disease testing of the donor (i.e. donor testing). Numbers 4-12 are the activities and testing that are conducted on the gamete(s).	Gamete	
	Sperm	Ova
1. Donor suitability assessment - donor screening	☐	☐
2. Donor suitability assessment - physical examination	☐	☐
3. Donor suitability assessment - donor testing	☐	☐
4. Obtaining	☐	☐
5. Preparing	☐	☐
6. Identifying	☐	☐
7. Testing	☐	☐
8. Preserving	☐	☐
9. Assessing quality	☐	☐
10. Labelling	☐	☐
11. Quarantining	☐	☐
12. Storing	☐	☐

Additional information (optional)

Part 3: Signature and attestation *

This section must be completed by your establishment's senior executive officer before submitting the form to Health Canada.

I, _____ (print), as the senior executive officer,
(Name and Title)

hereby certify that

(i) the primary establishment named in this application has evidence demonstrating that it is able to meet the requirements of the *Safety of Sperm and Ova Regulations*,

(ii) any other establishment that is proposed to process sperm or ova on behalf of the primary establishment is able to meet the requirements of the *Safety of Sperm and Ova Regulations*,

(iii) all information submitted in support of the application is accurate and complete, and

(iv) I have the authority to bind the establishment.

Signature: _____ Date: _____
(yyyy-mm-dd)

E-mail:	Telephone:

Part 4: Notice of cessation *

Gamete	☐ Sperm	☐ Ova
Cessation date (yyyy-mm-dd)		

Details of the disposition of the sperm or ova in the possession or control of the primary establishment:

Signature and attestation for notice of cessation

I, _____ (print) as the senior executive officer,
(Name and Title)

hereby certify that

(i) that if the primary establishment has not ceased all of its activities, it has evidence demonstrating that it meets the requirements of the *Safety of Sperm and Ova Regulations*,

(ii) that if the primary establishment has not ceased all of its activities, any other establishment that processes sperm or ova or is proposed to process sperm or ova on its behalf meets the requirements of the *Safety of Sperm and Ova Regulations*,

(iii) all information submitted in support of the notice is accurate and complete, and

(iv) I have the authority to bind the establishment.

Signature: _____ Date: _____
(yyyy-mm-dd)

E-mail:	Telephone:

Instructions on how to complete the sperm and ova primary establishment registration application (FRM-0446)

Before completing this form, we recommend that you read the relevant sections of the:

- *Safety of Sperm and Ova Regulations* (https://laws-lois.justice.gc.ca/eng/regulations/SOR-2019-192/index.html)
- *Guidance Document – Safety of Sperm and Ova Regulations* (https://www.canada.ca/en/health-canada/programs/consultation-safety-sperm-ova-regulations/document.html)
- Registration and notification guide for sperm and ova establishments under the *Safety of Sperm and Ova Regulations* (https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/registration-notification-guide-donor-sperm-ova-establishments-gui -0128.html)

The following legend shows the three types of icons used in this document, and the way they are intended to be used.

Important: Key or cautionary information for people to know.

Information: Supplementary information like quotes and legal references.

Tip: Things for people to do or understand.

Establishments that intend to distribute or import sperm or ova for the purpose of Assisted Human Reproduction (AHR) are subject to notification requirements under section 18 of the Safety Regulations.

Establishments that intend to begin importing or distributing sperm or ova for the purpose of AHR must submit their notification using the Sperm and ova establishment notification form (FRM-0448).

Registration checklist (optional) – FRM-0446

It is not mandatory to complete the checklist, however it is provided for your convenience and it is recommended that you complete it to ensure that all fields have been filled out as required.

Type of application	To be completed
☐ Application for registration	☐ Cover letter (recommended) ☐ Registration checklist (recommended) ☐ Part 1 ☐ Part 2 ☐ Part 3
☐ Application for amendment	☐ Cover letter (recommended) ☐ Registration checklist (recommended) ☐ Part 1 ☐ Part 2 ☐ Part 3
☐ Change of information	☐ Cover letter (recommended) ☐ Registration checklist (recommended) ☐ Part 1 ☐ Part 2 ☐ Part 3
☐ Cessation of activities	☐ Cover letter (recommended) ☐ Registration checklist (recommended) ☐ Part 1 ☐ Part 2A ☐ Part 4

General Instructions

A primary establishment is the entity responsible for ensuring that, prior to distribution or use in Canada, donor sperm and ova are processed in accordance with the Safety Regulations. Primary establishments must register with Health Canada and are responsible for all processing activities, whether they conduct them themselves or another establishment does any of the processing activities on their behalf.

Foreign establishments that process sperm or ova may register with Health Canada as a primary establishment to facilitate the distribution in Canada of sperm or ova that they process, or be listed on the registration of a primary establishment as an establishment that is conducting processing activities on behalf of the primary establishment.

When you are completing the tables in Part 2B and 2D, it is important to note that not all processing activities are activities conducted on the sperm and ova. Therefore, please ensure if you have an establishment conducting activities on your behalf that the activities in Part 2D are accurately represented. For example, a laboratory conducting infectious disease testing for the donor on your behalf should have #3 Donor suitability assessment - donor testing selected.

The processing activities listed in Parts 2B and 2D of the registration application form (FRM-0446) categorized under numbers 1-3 “Donor Suitability Assessment (donor screening, physical exam and donor testing)” are the processing activities conducted on the donor, including the required infectious disease testing of the donor (i.e. donor testing). However, the remaining processing activities under numbers 4-12 (obtaining, preparing, identifying, testing, preserving, assessing quality, labelling, quarantining & storing) are the activities and testing that are conducted on the sperm or ova.

For any questions, please send your inquiries by email to the Biological Product Compliance Program at ahrregistration-enregistrementpa@hc-sc.gc.ca.

How to submit your form

Before submitting this form, please ensure that the senior executive officer has signed part 3 Signature and Attestation. In the case of notice of cessation, the senior executive officer must sign part 4. Only signed and dated applications will be accepted.

You may submit your application using an e-signature if applicable.

When ready to submit your form the preferred method of submission is to email the Biological Product Compliance Program with your completed application form attached at ahrregistration-enregistrementpa@hc-sc.gc.ca. If you are unable to submit by email, you may submit using the following:

Fax: (613)-960-2156

Mail: Biological Product Compliance Program
Regulatory Operations and Enforcement Branch
3rd floor Jeanne Mance Building
200 Eglantine Driveway, Tunney's Pasture
Address Locator 1903D
Ottawa, Ontario
K1A 0K9

In order to facilitate processing of your application, we recommend:

- that you include your establishment name as it appears on the registration form in the subject line of the email
- that you inform us if you are submitting by fax or mail by sending an e-mail to ahrregistration-enregistrementpa@hc-sc.gc.ca

As per section 20 of the *Safety of Sperm and Ova Regulations*, a primary establishment and any other establishment that distributes or imports sperm or ova must send to the Minister, in the form established by the Minister, an annual attestation

(a) on or before April 1 of the calendar year following the year in which the notice of distribution or importation is sent; and

(b) on or before April 1 of each subsequent calendar year.

The annual attestation can be submitted using the Sperm and ova establishment annual attestation form (FRM-0449).