FRM-0171: Human cells, tissues and organs (CTO) for transplantation - establishment registration application form

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 readers to do or understand.

Please read **Annex 3: Instructions on how to complete FRM-0171** before completing this application form.

For any questions or clarifications, please email the Biological Product Compliance Program at roeb.cto-dgoral@hc-sc.gc.ca.

You must inform Health Canada in writing of any required changes to the information provided in your most recent application within 30 calendar days after the change is made.

You should submit the form FRM-0171 along with a cover letter describing the reason for your submission.

Examples of amendments include:

- changing contact information
- changing the medical or scientific director
- changing your establishment's name or address
- adding or removing an activity
- adding or modifying any CTO information

All applicants must complete **Part 1: Type of application** and **Part 2: Establishment information** of the registration application.

Part 1: Type of application

☐ **Initial application**: Select this if your establishment is submitting a CTO registration application for the first time.

☑ **Change of information**: Select this if your establishment has a CTO registration number.

Reason for submission: ○ Information update ◉ Renewal ○ Cancellation of registration

Part 2: Establishment information

CTO establishment registration number (if applicable): 100230

Establishment name (this name will be displayed on the registration certificate):

DCI Donor Services dba Sierra Donor Services Eye Bank

Pub: 200241

Canada

For hospital programs, the establishment name should include both the hospital and program names.

Previous name(s) of establishment (if applicable):
DCI Donor Services dba Sierra Donor Services Eye Bank, Sierra Donor Services and Tennessee Donor Services

Note that the contacts provided below should have a direct involvement within your program.

Primary contact information (for correspondence with Health Canada)

Contact's first name, last name and title: Faith Spann, Manager of Quality and Compliance

Language preference: ◉ English ○ French

Telephone #1: 615-564-3639

Telephone #2:

Email: faith.spann@dcids.org

Generic email:

Secondary contact information (may also be used for correspondence, particularly in situations where Health Canada has been unable to reach the primary contact)

Contact's first name, last name and title: Stephanie Cottrell, Ocular Quality Compliance Coordinator

Language preference: ◉ English ○ French

Telephone #1: 916-567-1600

Telephone #2:

Email: stephanie.cottrell@dcids.org

Generic email:

Civic address (where the registered activities will occur)

Building name (if applicable): Sierra Donor Services Eye Bank

Street number: 3940

Street name: Industrial Blvd

Suite:

City: West Sacramento

Province/State: CA

Postal/Zip code: 95691

Country: United States of America

Mailing address (where correspondence is to be sent)

☑ same as above

Street number/P.O. box:

Street name:

Suite:

City:

Province/State:

Postal/Zip code:

Country:

Establishment's additional address(es)

Does your establishment have additional addresses where regulated activities are conducted?

◉ Yes

- Annex 1: Establishment's additional address(es) must be completed in this application.
- For each additional address, complete a separate Annex 1: Establishment's additional address(es) and attach the additional annex(es) to your submission.

○ No

- Annex 1: Establishment's additional address(es) is not applicable for your establishment.

If you are the source establishment, complete:

- [x] Part 3
- [ ] Part 4 (if applicable)
- [x] Part 5
- [x] Part 6

If you are importing and distributing or only distributing CTO, complete:

- [ ] Part 4
- [ ] Part 5
- [ ] Part 6

If you are cancelling your registration, complete:

- [ ] Part 7

Part 3: If you are the source establishment

A **source establishment** is responsible for the processing of cells, tissues and organs, whether the processing is carried out by the source establishment itself or by another establishment, and for determining whether the cells, tissues and organs are safe for transplantation.

Under the *Safety of human cells, tissues and organs for transplantation Regulations* (CTO Regulations), the activity of processing is described as donor screening; donor testing; donor suitability assessment; retrieval, except for organs and islet cells; testing and measurements performed on the cells, tissues or organs after they are retrieved; preparation for use in transplantation, except for organs; preservation; quarantine; banking; packaging and labelling. **Therefore, your registration application will include all the required activities defined under processing.**

Based on the CTO Regulations, **source establishment** includes:

(a) in the case of an organ from a deceased donor, the relevant organ donation organization;
(b) in the case of adjunct vessels that are retrieved with an organ and not used immediately in the organ transplantation, the relevant tissue bank;
(c) in the case of an organ from a living donor or lymphohematopoietic cells that are not banked, the relevant transplant establishment;
(d) in the case of tissues or banked lymphohematopoietic cells, the relevant cell or tissue bank; and
(e) in the case of islet cells, the establishment that prepares the cells for use in transplantation.

Select all types of CTO your establishment is processing, even if part of the processing is conducted on your behalf.

Note: If part of the processing activities are conducted on your behalf, you must complete Annex 2: Other entity information (activities conducted on applicant's behalf) in your registration application.

Part 3: If you are the source establishment (continued)

Please indicate which CTO you are responsible for as the source establishment

A) Tissues, including ocular tissues

Type of CTO	Deceased donor	Living donor	Proprietary name (if applicable)
1. Amniotic membrane	---	☐	
2. Aortic/Pulmonary conduits	☐	---	
3. Arteries	☐	---	
4. Bone	☐	☐	
5. Cartilage	☐	---	
6. Composite tissue	☐	---	
7. Fascia	☐	---	
8. Heart valves	☐	---	
9. Ligament	☐	---	
10. Pericardium	☐	---	
11. Peripheral nerve	☐	☐	
12. Peritoneal membrane	☐	☐	
13. Skin	☐	☐	
14. Tendon	☐	---	
15. Veins	☐	---	
16. Cornea	☑	☐	
17. Sclera	☑	☐	
18. Whole globes	☑	☐	
19. Other:	☐	☐	
20. Other:	☐	☐	

B) Cells			
Type of CTO	Deceased donor	Living donor	Retrieved in a foreign country and imported to be transplanted in your establishment
1. Cells derived from bone marrow	---	☐	☐
2. Cells derived from cord blood	---	☐	☐
3. Cells derived from peripheral blood	---	☐	☐
4. Other:	☐	☐	☐
5. Other:	☐	☐	☐

C) Organs		
Type of CTO	Deceased donor	Living donor
1. Adjunct vessels	☐	☐
2. Composite tissue	☐	---
3. Gastrointestinal	☐	---
4. Islet cells	☐	☐
5. Kidney	☐	☐
6. Liver	☐	☐
7. Lung	☐	☐
8. Pancreas	☐	☐
9. Whole Heart	☐	---
10. Other:	☐	☐
11. Other:	☐	☐

D) Additional information (optional)
Additional comments, clarifications, or description of activities or products

Are you importing CTO from a foreign country into Canada?

Yes:

☐ Continue to Part 4

No:

☑ Continue to Part 5

Are you distributing CTO received from a Canadian establishment (for which you are **not** the source establishment) to other Canadian establishments?

Yes:

☐ Continue to Part 4

No:

☑ Continue to Part 5

Part 4: If you are importing and distributing or only distributing CTO

This section applies **only** to **Canadian** establishments that:

- Import CTO from a foreign country and distribute them to establishments within Canada including within their own health authority. Part 4 only applies to CTO imported and distributed for which you are **not** the source establishment.
  - **Note 1:** If you are a source establishment for lymphohematopoietic cells not banked, and are importing cells retrieved from a foreign country to be transplanted in your program, indicate the type of cells that you are importing under Part 3.
  - **Note 2:** With regards to imported organs from deceased donors, the source establishment would be the foreign Organ Donation Organization (ODO). In some cases, the foreign ODO may deal directly with the Canadian transplant establishment, who would not have to register as an importer since the transplant establishment is only importing for use in its own establishment. In some cases, a Canadian ODO may be involved in the process, but acting on behalf of the transplant establishment as a facilitator. If you are an ODO and act as a facilitator for the Canadian transplant establishment, Part 4 does not apply to you. If you are a Canadian transplant establishment of imported organs from deceased donors, Part 4 does not apply to you.
- Distribute CTO received from a Canadian establishment (for which you are **not** the source establishment) to other Canadian establishments (distribution within Canada).

Select all CTO that apply to your establishment and indicate if your establishment is storing tissues and cells (even if the storage is conducted by another establishment on your behalf).

A) Tissues, including ocular tissues

If you are entering information in Part 4 A), please also complete Part 4 B).

Type of CTO	Deceased donor	Storage	Living donor	Storage
1. Amniotic membrane	---	---	☐	☐
2. Aortic/Pulmonary conduits	☐	☐	---	---

A) Tissues, including ocular tissues (continued)				
Type of CTO	Deceased donor	Storage	Living donor	Storage
3. Arteries	☐	☐	---	---
4. Bone	☐	☐	☐	☐
5. Cartilage	☐	☐	---	---
6. Composite tissue	☐	☐	---	---
7. Fascia	☐	☐	---	---
8. Heart valves	☐	☐	---	---
9. Ligament	☐	☐	---	---
10. Pericardium	☐	☐	---	---
11. Peripheral nerve	☐	☐	☐	☐
12. Peritoneal membrane	☐	☐	☐	☐
13. Skin	☐	☐	☐	☐
14. Tendon	☐	☐	---	---
15. Veins	☐	☐	---	---
16. Cornea	☐	☐	☐	☐
17. Sclera	☐	☐	☐	☐
18. Whole globes	☐	☐	☐	☐
19. Other:	☐	☐	☐	☐
20. Other:	☐	☐	☐	☐

B) Information on imported and distributed or only distributed tissue

If additional space is needed, please submit an attached document with the relevant information.

Source establishment processing CTO				Establishment from which CTO is received (if different from the source establishment)	
Name of source establishment	CTO registra-tion number	CTO proprietary name (if applicable)	CTO type	Name of establishment	CTO registration number (if applicable)

B) Information on imported and distributed or only distributed tissue (continued)					
Name of source establishment	CTO registra-tion number	CTO proprietary name (if applicable)	CTO type	Name of establishment	CTO registration number (if applicable)

C) Cells

Type of CTO	Deceased donor	Storage	Living donor	Storage
1. Cells derived from bone marrow	---	---	☐	☐
2. Cells derived from cord blood	---	---	☐	☐
3. Cells derived from peripheral blood	---	---	☐	☐
4. Other:	☐	☐	☐	☐
5. Other:	☐	☐	☐	☐

D) Organs

Type of CTO	Deceased donor	Living donor
1. Adjunct vessels	☐	☐
2. Composite tissue	☐	---
3. Gastrointestinal	☐	---
4. Islet cells	☐	☐
5. Kidney	☐	☐
6. Liver	☐	☐
7. Lung	☐	☐
8. Pancreas	☐	☐
9. Whole Heart	☐	---
10. Other:	☐	☐
11. Other:	☐	☐

D) Additional information (optional)

Additional comments, clarifications, or description of activities or products

Part 5: Other entity information

Other entity refers to an establishment that is not part of the applicant's organization, but performs regulated activities on behalf of the applicant.

Do other entities perform regulated activities on your behalf?

Yes

- Annex 2: Other entity information must be completed in this application.
- For each additional other entity, complete a separate Annex 2: Other entity information and attach the additional annex(es) to your submission.

No

- Annex 2: Other entity information is not applicable for your establishment.

If you are submitting an initial registration, an information update, or a registration renewal, complete:

☑ Part 6

If you are cancelling your registration, complete:

☐ Part 7

Part 6: Statement of compliance

In order for your application to be processed, this section must be completed, unless you are notifying Health Canada of a cancellation (see Part 7).

I hereby certify that the establishment named in this application is in compliance with the *Safety of Human Cells, Tissues and Organs for Transplantation Regulations.*

AND

I attest that the information in this application, including any identified changes, is accurate and complete as required under section 6(1) Application of the *Safety of Human Cells, Tissues and Organs for Transplantation Regulations*.

Name of medical or scientific director:		Title:
Jennifer Li, MD		Ocular Medical Director
Signature:  Digitally signed by Jennifer Li Date: 2023.09.08 10:37:51 -07'00'		Date (yyyy-mm-dd):
Telephone: 916-734-6602	E-mail: jyli@ucdavis.edu	Fax (optional):

Part 7: Notice of cancellation

This section must be completed if you are notifying Health Canada that registered activities have ceased at your establishment.

Effective date of cessation (yyyy-mm-dd):
(Example: 2018-07-23)

Reason for cessation of the activities:

Details on the disposition of the cells, tissues and organs in your establishment's possession:

As per section 13(2) Cessation of activity of the *Safety of Human Cells, Tissues and Organs for Transplantation Regulations*, I hereby confirm that activities requiring a Health Canada CTO Registration have ceased at the establishment named in this application.

Name of medical or scientific director:		Title:
Signature: Electronic signature accepted		Date (yyyy-mm-dd): (Example: 2018-07-23)
Telephone:	E-mail:	Fax (optional):

Privacy Notice

The personal information you provide to Health Canada will be used by the Biological Product Compliance Program under the *Safety of Human Cells, Tissues and Organs for Transplantation Regulations* authorized under the *Food and Drugs Act* and handled in accordance with the *Privacy Act*.

Why are we collecting your personal information? We require your personal information to administer the *Safety of Human Cells, Tissues and Organs for Transplantation Regulations* under the *Food and Drugs 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 Health Canada Privacy Coordinator at privacy-vie.privee@hc-sc.gc.ca.

For more information: The collection of your personal information is described in Info Source at infosource.gc.ca. Refer to the personal information bank (PIB) HC PPU 408 - Compliance and Enforcement - Biologics & Radiopharmaceuticals.

Annex 1: Establishment's additional address(es)

Establishment's additional address(es) 1 of 2		
Street number: 566	Street name: Mainstream Drive	Suite: 300
City: Nashville	Province/State: Tennessee	Postal/Zip code: 37228
Country: United States of America		

Establishment's additional address(es) 2 of 2		
Street number: 1609	Street name: University Blvd NE	Suite:
City: Albuquerque	Province/State: NM	Postal/Zip code: 87102
Country: United States of America		

Establishment's additional address(es) ___ of ___		
Street number:	Street name:	Suite:
City:	Province/State:	Postal/Zip code:
Country:		

Establishment's additional address(es) ___ of ___		
Street number:	Street name:	Suite:
City:	Province/State:	Postal/Zip code:
Country:		

If you require additional Annex 1 tables, please **click here** if accessing the form on the Health Canada website. If accessing the form in MS Word format, please copy this table as many times as required. When submitting your registration application form to Health Canada, please ensure that all required additional Annex 1 attachments are present.

Annex 2: Other entity information (activities conducted on applicant's behalf)

Other entity refers to an establishment that is **not part** of the applicant's organization, but performs regulated activities on behalf of the applicant. For example, if your infectious disease testing is done by a laboratory not associated with your organization, the name of this laboratory needs to be included as an other entity.
**Establishments such as hospitals and end users may be storing CTO but if that storage is not being done on behalf of the registrant then they should not be included as an other entity. An establishment that is storing on behalf of the registrant and for which the registrant takes responsibility should be included in this section.

Establishment's other entity														1 of 1
Establishment name: Creative Testing Solutions														
Street number: 2424		Street name: West Erie Drive												Suite:
City: Tempe		Province/State: AZ										Postal/Zip code: 85282		
Country: United States of America														
Activities		Donor screening	Donor testing	Donor suitability assessment	Retrieval	Testing and measurement after retrieval	Preparation for use in transplantation	Preservation	Quarantine	Banking	Labelling and packaging	Importation	Distribution	Storage **
Organs	Deceased donor	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
	Living donor	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Tissues	Deceased donor	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
	Living donor	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Ocular tissues	Deceased donor	☐	☑	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
	Living donor	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Lympho-hemato-poietic cells	Deceased donor	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
	Living donor	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

If you require additional Annex 2 tables, please **click here** if accessing the form on the Health Canada website. If accessing the form in MS Word format, please copy this table as many times as required. When submitting your registration application form to Health Canada, please ensure that all required additional Annex 2 attachments are present.

Annex 3: Instructions on how to complete FRM-0171

Part 1: Type of application

1. **Initial application:**
   Select this option if this is the first time your establishment is applying for a CTO establishment registration number.

2. **Change of information:**
   Select this option if you are submitting any change to your existing CTO registration. You must select this option only if you already have a CTO establishment registration number. The change of information should be submitted by the contact or medical/scientific director included in the current registration.

   Reason for submission:

   a) **Information update:** Select this option if there has been a change to your establishment's information. If the change is related to an additional address or other entity, attach Annex 1 and/or 2 (as applicable) with changes clearly indicated. Examples of changes to your establishment that would require an information update are:
   - changing contacts' information
   - changing the medical or scientific director
   - changing your establishment's name
   - changing your establishment's civic and/or mailing address
   - changing your establishment's additional address(es)
   - changing your establishment's other entities
   - adding or removing an activity
   - adding or removing any CTO information

   b) **Renewal:** Select this option if you are renewing your CTO registration. Make sure to include your establishment's most current information. **Your CTO registration expiry date is found on your CTO registration certificate.** Note that your CTO registration is valid until December 31 in the year after the year in which the registration number is issued.

   c) **Cancellation of registration:** Select this option if you wish to cancel your CTO registration with Health Canada. Proceed to complete Parts 2 and 7 only.

Part 2: Establishment information

As per section 13(1) of the CTO Regulations: Ongoing requirements to notify the Minister, your establishment is required to keep the information provided in your CTO registration application up to date, and to submit a change of information application within 30 calendar days of making a change.

1. **CTO establishment registration number (if applicable):**
   - Indicate your CTO registration number. This number can be found on your registration certificate.

2. **Establishment name (this name will be displayed on the registration certificate):**
   - The establishment name is the legal name of your establishment.
   - For hospital programs, establishment names should include both the hospital and program names.

3. Previous name(s) of establishment (if applicable):
   - Provide the establishment name indicated on your previous CTO registration certificate.

4. Primary contact information and secondary contact information:
   - Provide your establishment's primary and secondary contact information:
     - This information must be current and must include two contacts that Health Canada can use in both urgent and non-urgent situations where your establishment must be contacted via email or telephone.
     - The names provided must have a direct involvement within your establishment to act on requests from Health Canada.

5. Civic address:
   - Provide the building and program name if applicable.
   - Provide the address where your registered activities will occur.

6. Mailing address:
   - Provide the mailing address if different from your establishment's civic address.
   - Select the box "same as above" if this address is the same as the civic address.

7. Establishment's additional address(es):
   - Complete this section if your establishment has multiple addresses.
   - Complete a separate Annex 1: Establishment's additional address(es) for each additional address.
   - Select the box "Yes" to indicate that Annex 1 is submitted with this application. Otherwise, select the box "No".

Part 3: If you are the source establishment

- Source establishment (defined in section 1 of the CTO Regulations) includes:
  (a) In the case of an organ from a deceased donor, the relevant organ donation organization;
  (b) In the case of adjunct vessels that are retrieved with an organ and not used immediately in the organ transplantation, the relevant tissue bank;
  (c) In the case of an organ from a living donor or lymphohematopoietic cells that are not banked, the relevant transplant establishment;
  (d) In the case of tissues or banked lymphohematopoietic cells, the relevant cell or tissue bank; and
  (e) In the case of islet cells, the establishment that prepares the cells for use in transplantation.

- Processing, in respect of cells, tissues and organs, means any of the following activities (defined in section 1 of the CTO Regulations):
  (a) donor screening;
  (b) donor testing;
  (c) donor suitability assessment;
  (d) retrieval, except for organs and islet cells;
  (e) testing and measurements performed on the cells, tissues or organs after they are retrieved;
  (f) preparation for use in transplantation, except for organs;
  (g) preservation;
  (h) quarantine;
  (i) banking; and
  (j) packaging and labelling.

- Complete Parts 3, 4 (if applicable), 5 (if applicable) and 6.
- Select all types of CTO your establishment is processing, even if part of the processing is conducted on your establishment's behalf.

- Complete Annex 1 if you have an additional establishment address(es).
- Complete Annex 2 if another entity performs activities on your establishment's behalf.

A) Tissues, including ocular tissues

- Select the type of tissues (including ocular tissues) that your establishment is processing by indicating whether they are from deceased and/or living donors.
- It is important to note that composite tissues, which are vascularized composite allografts consisting of multiple tissue types (e.g., a full face or hand transplant), can meet the definition of a tissue or an organ under the CTO Regulations. It is up to the source establishment to determine which set of regulatory provisions is most appropriate for their circumstances. This decision should be reflected in the registration application.
- Enter the proprietary name of the product, if applicable, as shown in the example below:

A) Tissues, including ocular tissues			
Type of CTO	Deceased donor	Living donor	Proprietary name (if applicable)
1. Amniotic membrane	–––	☑	Product Y

B) Cells

- Select the type of lymphohematopoietic cells your establishment is processing as shown in the example below:

B) Cells			
Type of CTO	Deceased donor	Living donor	Retrieved in a foreign country and imported to be transplanted in your establishment
1. Cells derived from bone marrow	–––	☑	☐

- If you are a source establishment for lymphohematopoietic cells not banked, and are importing cells retrieved from a foreign country to be transplanted in your program, please indicate the type of cells that you are importing under Part 3.

C) Organs

- Select the type of organs your establishment is processing by indicating whether they are from deceased and/or living donors. Islet cells and adjunct vessels are included in the options since they are regulated as organs.
- It is important to note that composite tissues, which are vascularized composite allografts consisting of multiple tissue types (e.g., a full face or hand transplant), can meet the definition of a tissue or an organ under the CTO Regulations. It is up to the source establishment to determine which set of regulatory provisions is most appropriate for their circumstances. This decision should be reflected in the registration application.
- An example of a source establishment processing whole heart from a deceased donor is shown below:

C) Organs		
Type of CTO	Deceased donor	Living donor
9. Whole Heart	☑	–––

D) Additional information (optional)

- Provide further information to clarify what types of activities are conducted and/or products processed by your establishment.

Part 4: If you are importing and distributing or only distributing CTO

- This section applies **only** to **Canadian** establishments that:

  - Import and distribute CTO from a foreign country into Canada (including in your own health authority). Part 4 only applies to CTO imported and distributed for which you are **not** the source establishment.
    - **Note 1:** If you are a source establishment for lymphohematopoietic cells not banked, and are importing cells to be transplanted in your program, Part 4 does not apply to you. In that case, please indicate the type of cells that you are importing under Part 3.
    - **Note 2:** With regards to imported organs from deceased donor, the source establishment would be the foreign Organ Donation Organization (ODO). In some cases, the foreign ODO may deal directly with the Canadian transplant establishment, who would not have to register as an importer since the transplant establishment is only importing for use in its own establishment. In some cases, a Canadian ODO may be involved in the process, but acting on behalf of the transplant establishment as a facilitator. If you are an ODO and act as a facilitator for the Canadian transplant establishment, Part 4 does not apply to you. If you are a Canadian transplant establishment of imported organs from deceased donors, Part 4 does not apply to you.
    - **Note 3:** If you are importing, your registration will automatically include the activities of importation and distribution.

  - Are located in Canada and distribute CTO received from a **Canadian** establishment (for which you are **not** the source establishment) to other **Canadian** establishments (distribution within Canada).
    - **Note:** If you are distributing, your registration will automatically include the activity of distribution.

A) Tissues, including ocular tissues

- Select the type of tissues (including ocular tissues) that your establishment is importing and distributing or distributing only by indicating whether they are from deceased and/or living donors.
- Select if your establishment is storing products as shown in the example below (even if storage is conducted on your establishment's behalf). If storage is conducted on your establishment's behalf, also complete Annex 2.

A) Tissues, including ocular tissues				
If you are entering information in Part A), please also complete Part B).				
Type of CTO	Deceased donor	Storage	Living donor	Storage
1. Amniotic membrane	---	---	☑	☑

- It is important to note that composite tissues, which are vascularized composite allografts consisting of multiple tissue types (e.g., a full face or hand transplant), can meet the definition of a tissue or an organ under the CTO Regulations. It is up to the source establishment to determine which set of regulatory provisions is most appropriate for their circumstances. This decision should be reflected in the registration application.

B) Information on imported and distributed or only distributed tissue

- Provide details on the source establishment that process the tissues and describe the general CTO type obtained from that source establishment.
- If the CTO is not received directly from the source establishment, provide details on the establishment from which the CTO is received.
- If additional space is needed, submit an attached document with the relevant information.

C) Cells

- Select the type of lymphohematopoietic cells your establishment is importing and distributing or only distributing. If you are a source establishment for lymphohematopoietic cells not banked, and are importing cells to be transplanted in your program, Part 4 does not apply to you. In that case, please indicate the type of cells that you are importing under Part 3.
- Select if your establishment is storing products even if storage is conducted on your establishment's behalf. If storage is conducted on your establishment's behalf, also complete Annex 2.

D) Organs

- Select the type of organs your establishment is importing and distributing or only distributing by indicating whether they are from deceased and/or living donors. Islet cells and adjunct vessels are included in the options since they are regulated as organs.
- With regards to imported organs from deceased donors, the source establishment would be the foreign Organ Donation Organization (ODO). In some cases, the foreign ODO may deal directly with the Canadian transplant establishment, who would not have to register as an importer since the transplant establishment is only importing for use in its own establishment. In some cases, a Canadian ODO may be involved in the process, but acting on behalf of the transplant establishment as a facilitator. If you are an ODO and act as a facilitator for the Canadian transplant establishment, Part 4 does not apply to you. If you are a Canadian transplant establishment of imported organs from deceased donors, Part 4 does not apply to you.
- It is important to note that composite tissues, which are vascularized composite allografts consisting of multiple tissue types (e.g., a full face or hand transplant), can meet the definition of a tissue or an organ under the CTO Regulations. It is up to the source establishment to determine which set of regulatory provisions is most appropriate for their circumstances. This decision must be reflected in the registration application.

E) Additional information (optional)

- Provide further information to clarify what types of activities are conducted and/or products are processed by your establishment.

Part 5: Other entity information

- Select the box "Yes" if you have other entities. Otherwise, select the box "No".
- All establishments are required to complete Part 5 and Annex 2 if they have other entities.
- For example, if a laboratory is performing donor testing on your behalf, list the laboratory as an other entity.

Part 6: Statement of compliance

- Complete Part 6 only if you are submitting an initial registration, an information update or a registration renewal.
- Provide the name, title, signature (electronic signature is accepted), including date of signature, telephone number and e-mail of the medical or scientific director.

- If a new medical or scientific director is appointed for your establishment, a new declaration of compliance must be signed and sent to Health Canada.
- If you are notifying Health Canada of cancellation, complete Part 7.

In order for your application to be processed, the medical or scientific director must sign and date the declaration. In signing the declaration, the signatory is attesting to the compliance of your establishment with the CTO Regulations. Making false, misleading, inaccurate or incomplete statements may be grounds for refusal to issue a CTO registration number, as per section 8 Refusal of the CTO Regulations.

The declaration of compliance signed by a medical or scientific director assures Health Canada that your establishment acknowledges its responsibilities under the CTO Regulations. This provides a level of assurance that the CTO processed, imported and distributed or only distributed in Canada meet the safety requirements set out in the CTO Regulations, and that procedures are in place to protect the public should a problem be identified. This declaration of compliance does not preclude Health Canada from conducting inspections in order to verify compliance with the CTO Regulations.

Part 7: Notice of cancellation

- Complete Part 7 only if you are notifying Health Canada of a cancellation of your CTO registration.
- For your application to be processed, provide the name, title, signature (electronic signature is accepted), including date of signature, telephone number and e-mail of the medical or scientific director.
- Include the effective date of cessation of all regulated activities under the CTO Regulations. Note that your registered CTO activities can no longer be performed at your establishment after this date.
- Provide the reason for cessation of the activities and the details on the disposition of all CTO in your establishment's possession.

The medical or scientific director must sign and date the declaration in order for the application to be processed. In signing the declaration, the signatory is attesting that this establishment will no longer perform activities that requires a CTO Registration after the cessation date indicated on the form. The disposition of all CTO in your establishment's possession must also be provided.

Annex 1: Establishment's additional address(es)

- Complete Annex 1 if your establishment has multiple addresses.
- Select the box "Yes" in Part 2 if Annex 1 is submitted with your application.
- If additional Annex 1 tables are required:
    - If accessing the form on the Health Canada website, press on the "click here" found at the bottom of the page of Annex 1 which will bring you to another Annex 1 page with additional tables.
    - If accessing the form in MS Word format, please copy this table as many times as required.
    - When submitting your completed registration application form to Health Canada, ensure that all required additional Annex 1 attachments are present.
- Within the title, number the additional addresses in order of appearance by using "_____ of _____". For example, "2 of 5" would indicate that this address is the second of five additional addresses submitted.

Annex 2: Other entity information (activities conducted on applicant's behalf)

- Indicate any other entities that perform activities on your establishment's behalf in Annex 2.
- Select the box "Yes" in Part 5 if Annex 2 is submitted with your application.
- If additional Annex 2 tables are required:
    - If accessing the form on the Health Canada website, press on the "click here" found at the bottom of the page of Annex 2 which will bring you to another Annex 2 page with additional tables.
    - If accessing the form in MS Word format, please copy this table as many times as required.
    - When submitting your completed registration application form to Health Canada, ensure that all required additional Annex 2 attachments are present.
- Indicate the name of the other entities used by your establishment, their address, and CTO activities in this annex. For example:
    - The laboratory that performs the infectious diseases testing, the microbial testing or the Human Leukocyte Antigen typing when required.
    - Storage where the records are kept.
    - Third party logistics businesses who only transport CTO on behalf of an establishment and do not have ownership of the CTO.
- Within the title, please number the other entities in order of appearance by using "_____ of _____". For example, "10 of 15" would indicate that this address is the tenth of fifteen other entities submitted.

How to submit your form

Before you submit your form, please ensure that the following has been completed:

- All parts of the application that apply to your establishment have been completed.
- The medical or scientific director signed the statement of compliance in Part 6 if you have submitted an initial registration, an information update or a registration renewal.
- The medical or scientific director signed the notice of cancellation in Part 7 if you have notified Health Canada of a cancellation.
- Annex 1 and Annex 2 have been completed and are included (if applicable).

Submit your form:

The preferred method for submitting your form is by **e-mail**. When submitting by e-mail, ensure to include the following in the subject line:

- Registration number of your establishment (if previously registered)
- Name of your establishment
- Type of application submission (Part 1) (Example: Renewal)

E-mail: roeb.cto-dgoral@hc-sc.gc.ca

Fax: (613) 960-2156

Mail: Biological Products Compliance Program
Regulatory Operations and Enforcement Branch
3rd floor, Jeanne Mance Building
200 Eglantine Driveway, Tunney's Pasture
A.L. 1903C
Ottawa, Ontario
K1A 0K9

For any questions, please send your inquiries to roeb.cto-dgoral@hc-sc.gc.ca.