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Importation or Export of Human Products

Homoclave of the format
FF-COFEPRIS-04
RUPA Number

For COFEPRIS use only

Entry number

Before filling out this form, carefully read the instructions and the filling guide.
Fill in using legible block letters or type or computer.
The form will not be valid if it contains erasures or alterations to the information.

1. Homoclave and name of the procedure

Homoclave:	Name:

If you are applying for a **permit to import or export cells and tissues, including blood, its components and derivatives, as well as other products of human beings,** please select an option:

- ☐ Internment
- ☐ Exit

2. Owner details

Natural person
RFC:
CURP:
Name(s):
First surname:
Second surname:
Telephone:
Extension:
Email:

Legal entity
RFC:
Company name or business name:
Legal representative
RFC:
CURP:
Name(s):
First surname:
Second surname:
Telephone:
Extension:
Email:

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Tax address of the owner

Postal code:	Locality:
Type and name of road: (For example: Avenue, boulevard, street, highway, road, private road, dirt road, among others.)	Municipality or mayor's office: Federal Entity:
Exterior number: / Interior number:	Between roads (type and name): And road infrastructure (type and name):
Type and name of the colony or human settlement: (Type of human settlement, for example: Condominium, estate, ranch, subdivision, among others.)	Rear roadway (type and name): Telephone: Extension:

3. Establishment details

RFC:	Company name or business name:
Indicate the code and description of the business activity that corresponds to the establishment according to the Industrial Classification System of North America:	
Clave SCIAN	Description of the SCIAN key
Health license number or operating notice:	

Note: If there is insufficient space for the SCIAN keys, add the necessary lines.

Health Officer

RFC:
CURP:
Name(s):
First surname:
Second surname:
Health Officer Notice Number:

Establishment address

Postal code:	Locality:
Type and name of road:	Municipality or mayor's office: Federal Entity:

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(For example: Avenue, boulevard, street, highway, road, private road, dirt road, among others.)	Between roads (type and name):
Exterior number: / Interior number:	And road infrastructure (type and name):
Type and name of the colony or human settlement:	Rear roadway (type and name):
(Type of human settlement, for example: Condominium, estate, ranch, subdivision, among others.)	Telephone:
	Extension:

Legal representative(s) and/or authorized person(s)	
Legal representative	**Authorized person**
CURP:	CURP:
Name(s):	Name(s):
First surname:	First surname:
Second surname:	Second surname:
Telephone:	Telephone:
Exemption:	Exemption:
Email:	Email:

Note: Reproduce the boxes of legal representative(s) and/or authorized person(s) as many times as necessary.

4. Type and use of the product

Select the product type:

- ○ Cells
- ○ Tissue (includes corneas)
- ○ Blood
- ○ Blood components
- ○ Blood derivatives
- ○ Other products of human origin (please specify): _____

Type of import regime:

- ○ Temporary regime
- ○ Definitive regime

Select the product use:

- ○ Investigation
- ○ Teaching
- ○ Treatment for therapeutic purposes
- ○ Cryopreservation
- ○ Diagnosis

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5. Modification to the entry or exit permit

Document number to be modified:

Statement of reasons for the modification to the entry or exit permit

Already
ccio
is
in
this way
be fruitful

action(s) or update(s) you wish to perform.
In the "Dice" table, enter the complete current data.
In the "Should say" table, place the complete, modified data.

Type of modification	Dice	It should say
☐ Product		
☐ Presentation		
☐ Amount		
☐ Regime		
☐ Customs		

Type of modification	Dice		It should say	
☐ Recipient's address	Postal code:		Postal code:	
	Type and name of road: (For example: Avenue, boulevard, street, highway, road, private road, dirt road, among others)		Type and name of road: (For example: Avenue, boulevard, street, highway, road, private road, dirt road, among others)	
	Number exterior:	Number interior:	Exterior number:	Interior number:
	Type and name of the colony or human settlement: (Type of human settlement, for example: Condominium, estate, ranch, subdivision, among others.)		Type and name of the colony or human settlement: (Type of human settlement, for example: Condominium, estate, ranch, subdivision, among others.)	
	Locality:		Locality:	
	Municipality or mayor's office:		Municipality or mayor's office:	
	Federal Entity:		Federal Entity:	
	Between roads (type and		Between roads (type and	

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	name):	name):
	And road infrastructure (type and name):	And road infrastructure (type and name):
	Rear roadway (type and name):	Rear roadway (type and name):
	Telephone:	Telephone:
	Extension:	Extension:

(a) Only when the establishment is national.

Type of modification		Dice		It should say	
☐	Address of origin	Postal code:		Postal code:	
		Type and name of road: (For example: Avenue, boulevard, street, highway, road, private road, dirt road, among others)		Type and name of road: (For example: Avenue, boulevard, street, highway, road, private road, dirt road, among others)	
		Exterior number:	Interior number:	Exterior number:	Interior number:
		Type and name of the colony or human settlement: (Type of human settlement, for example: Condominium, estate, ranch, subdivision, among others.)		Type and name of the colony or human settlement: (Type of human settlement, for example: Condominium, estate, ranch, subdivision, among others.)	
		Locality:		Locality:	
		Municipality or mayor's office:		Municipality or mayor's office:	
		Federal Entity:		Federal Entity:	
		Between roads (type and name):		Between roads (type and name):	
		And road infrastructure (type and name):		And road infrastructure (type and name):	
		Rear roadway (type and name):		Rear roadway (type and name):	
		Telephone:		Telephone:	
		Extension:		Extension:	

(a) Only when the establishment is national.

6. Recipient details (final destination)

Natural person
RFC(a):
CURP:
Name(s):
First surname:
Second surname:
Telephone:

Legal entity
RFC(a):
Company name or business name:

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Extension:
Email:

(a) Only when the recipient is located in national territory.

Recipient's address (final destination)

Postal code:	Locality:
Type and name of road: (For example: Avenue, boulevard, street, highway, road, private road, dirt road, among others)	Municipality or mayor's office:
Exterior number: / Interior number:	Federal Entity(ies):
Type and name of the colony or human settlement: (Type of human settlement, for example: Condominium, estate, ranch, subdivision, among others.)	Between roads (type and name): And road name): (type and Rear roadway (type and name):

(a) Only when the establishment is national.

7. Origin information

Natural person	Legal entity
RFC(b):	RFC(b):
CURP:	Company name or business name:
Name(s):	
First surname:	
Second surname:	
Telephone:	
Extension:	
Email:	

(b) Only when the natural or legal person is located in national territory.

Address of origin

Postal code:	Locality:
Type and name of road: (For example: Avenue, boulevard, street, highway, road, private road, dirt road, among others)	Municipality or mayor's office(b):
Exterior number: / Interior number:	Federal Entity(b):
	Between roads (type and name):
	And road infrastructure (type and

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Type and name of the colony or human settlement: (Type of human settlement, for example: Condominium, estate, ranch, subdivision, among others.)	name): Rear roadway (type and name):

(b) Only when the natural or legal person is located in national territory.

8. Product details

Specific name:	Quantity or Volume:
Unit of Measurement:	Presentation:
Unit of Measurement for the application of the TIGIE (UMT):	Quantity of unit of measure for application of the TIGER:
Storage and transport conditions:	Use:
Tariff Classification:	Customs office of entry or exit (Specify only one):
Scientific research protocol number:	Number of the last sanitary registration document and related certificates:

If you require more than one customs office, you must submit an application for each one.

I declare, under oath, that the establishment from which the cells, tissues, blood, its components, derivatives and other products of human origin originate, has the necessary operating conditions, infrastructure and sanitary control to guarantee the quality, safety and traceability of said products, and therefore they do not represent a risk to the health of the population.

I declare that this statement makes me responsible for the truthfulness and accuracy of the information declared, and I acknowledge that the falsity, alteration or omission of data will result in the imposition of the corresponding sanctions and security measures in accordance with current legislation.

It is the responsibility of both the facility that provides and the facility that receives cells, tissues, blood and its derivatives, or other products from human beings covered by the corresponding import permit, to analyze and verify that they are free of any pathology before their final destination and depending on their use. This information must be available to the Ministry of Health upon request. This is in accordance with Articles 283, 284, and 313, Section I of the General Health Law. To this end, they must have proof that the products are free of pathologies and the technical procedures used to obtain them.

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In accordance with the provisions of section II of article 35 of the Federal Law of Administrative Procedure, I agree to receive all types of notifications related to this procedure via email:

Email address to receive notifications:

(MANDATORY)

_____

Under penalty of perjury, the undersigned declares that the information provided and accompanying this form are true and verifiable. This application is currently undergoing document review by the relevant department and is subject to applicable health control and surveillance measures, in accordance with Article 17 bis, section VI, of the General Health Law, and Articles 1, 2, sections II and XI, of the Regulations of the Federal Commission for Protection against Sanitary Risks.

The data or attachments may contain confidential information; do you agree to make them public? ○ Yeah ○ **No**

_____

Full name and signature of the owner or
Legal representative

For any clarification, doubt and/or comment regarding this procedure, the COFEPRIS Telephone Assistance Center number **800-033-5050** is available , and in case you require follow-up on the procedure, the Processing area. sent al Foranea, request information al mail **tramitacion_foranea@cofepris.gob.mx,** as well as the contact line of the Government of Mexico *079 of the Center for Attention for Well-being.