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Registration, modification or deregistration of Biosafety Committee

Homoclave of the format
FF-COFEPRIS-09
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:

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 requesting the procedure
RFC:
CURP:
Name(s):
First surname:
Second surname:
Telephone:
Extension:
Email:

Tax address of the owner

Postal code:	
Type and name of road: (For example: Avenue, boulevard, street, highway, road, private road, dirt road, among others.)	
Exterior number:	Interior number:
Type and name of the colony or human settlement:	

Location (if applicable):
Municipality or mayor's office:
Federal Entity:
Between roads (type and name):
And road infrastructure (type and name):
Rear roadway (type and name):
Telephone:
Extension:

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(Type of human settlement, for example: Condominium, estate, ranch, subdivision, among others.)

3. Establishment details

RFC:	Name or name social:

Health Service Establishment Sanitary License Number (Case H) In which surgical and/or obstetric procedures are performed or Notice of operation, modification or deregistration of the health officer responsible for the health service establishment:

Establishment address

Postal code:	Location (if applicable):
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:
	Between roads (type and name):
Exterior number: / Interior number:	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:

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:
Exemption:	Exemption:
Email:	Email:

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

4. Members of the new Committee, to be modified or removed

Committee registration number

Biosecurity to be modified or reduced:

○ Appointment of members ○ Member resignation of ○ Member replacement of ○ Change of address of the establishment

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4.A Chairman of the Committee

In case of appointment or resignation of the committee chair, use the first column.

If you need to modify the details of the committee chairperson, use the first column to record the current data and the second column for the modified data.

First column		Second column	
Only fill in this section if: ○ Designation ○ To modify ○ Resignation		Only fill in this section if: ○ Already modified	
RFC:		RFC:	
CURP:		CURP:	
Name(s):		Name(s):	
First surname:		First surname:	
Second surname:		Second surname:	
Telephone:		Telephone:	
Extension:		Extension:	
Email:		Email:	
Profession:		Profession:	
Experience in Biosafety:		Experience in Biosafety:	
Scientific ○ Yeah ○ No		Scientific ○ Yeah ○ No	
1	Title of Scientific Publication:	1	Title of Scientific Publication:
	Number of TWO:		Number of TWO:
	Electronic League:		Electronic League:
2	Title of Scientific Publication:	2	Title of Scientific Publication:
	Number of TWO:		Number of TWO:
	Electronic League:		Electronic League:
3	Title of Scientific Publication:	3	Title of Scientific Publication:
	Number of TWO:		Number of TWO:
	Electronic League:		Electronic League:

4.B Secretary of the Committee

In case of appointment or resignation of the committee secretary, use the first column.

If you need to modify the details of the committee secretary, use the first column to record the current data and the second column for the data that has already been modified.

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First column		Second column	
Only fill in this section if: ( ) Designation ( ) To modify ( ) Resignation		Only fill in this section if: ( ) Already modified	
RFC:		RFC:	
CURP:		CURP:	
Name(s):		Name(s):	
First surname:		First surname:	
Second surname:		Second surname:	
Telephone:		Telephone:	
Extension:		Extension:	
Email:		Email:	
Profession:		Profession:	
Experience in Biosafety:		Experience in Biosafety:	
Scientific ( ) Yeah ( ) No		Scientific ( ) Yeah ( ) No	
1	Title of Scientific Publication:	1	Title of Scientific Publication:
	Number of TWO:		Number of TWO:
	Electronic League:		Electronic League:
2	Title of Scientific Publication:	2	Title of Scientific Publication:
	Number of TWO:		Number of TWO:
	Electronic League:		Electronic League:
3	Title of Scientific Publication:	3	Title of Scientific Publication:
	Number of TWO:		Number of TWO:
	Electronic League:		Electronic League:

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4.C Members of the Committee

In case of appointment or resignation of the committee member(s), use the first and second columns.

If you need to modify the information for the committee member(s), use the first column to record the current information and the second column for the modified information.

First column	Second column
Only fill in this section if: ○ Designation ○ To modify ○ Resignation	Only fill in this section if: ○ Designation ○ Already modified ○ Resignation
RFC:	RFC:
CURP:	CURP:
Name(s):	Name(s):
First surname:	First surname:
Second surname:	Second surname:
Telephone:	Telephone:
Extension:	Extension:
Email:	Email:
Profession:	Profession:
Experience in Biosafety:	Experience in Biosafety:
Scientific ○ Yeah ○ No	Scientific ○ Yeah ○ No
○ Internal ○ External	○ Internal ○ External
Institution:	Institution:
1 Title of Scientific Publication:	1 Title of Scientific Publication:
1 Number of TWO:	1 Number of TWO:
1 Electronic League:	1 Electronic League:
2 Title of Scientific Publication:	2 Title of Scientific Publication:
2 Number of TWO:	2 Number of TWO:
2 Electronic League:	2 Electronic League:
3 Title of Scientific Publication:	3 Title of Scientific Publication:
3 Number of TWO:	3 Number of TWO:
3 Electronic League:	3 Electronic League:

If more vowels are required, you can reproduce this box as many times as necessary.

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4.D Users of health services and/or members of civil society who are part of the Committee:

In case of appointment or resignation of the committee member(s), use the first and second columns.
If you need to modify the data of the committee member(s), use the first column to record the current data and the second column for the modified data.

First column	Second column
Only fill in this section if: ○ Designation ○ To modify ○ Resignation	Only fill in this section if: ○ Designation ○ Already modified ○ Resignation
RFC:	RFC:
CURP:	CURP:
Name(s):	Name(s):
First surname:	First surname:
Second surname:	Second surname:
Telephone:	Telephone:
Extension:	Extension:
Email:	Email:
Function performed:	Function what performed:
○ Health services ○ Civil society	○ Health services ○ Civil society

If you need to enter more user data, you can reproduce this box as many times as necessary.

4.E Change of address

Type of modification	Dice	It should say
☐ Home establishment of the	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.)
	Location (if applicable):	Location (if applicable):
	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):

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	Telephone:	Telephone:
	Extension:	Extension:

In accordance with the provisions of section II of article 35 of the Law Federal Administrative Procedure I agree to receive all types of notifications regarding 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 requesting the procedure

For any clarification, doubt and/or comment regarding this procedure, the number **800-033-5050** of the COFEPRIS Telephone Assistance Center is available , and if you require follow-up on the procedure sent to the Foreign Processing area, request information by email to **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.

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Annex 1.

NOTE: It is mandatory to submit this annex attached to the application form FF-COFEPRIS-09.

Functions and Responsibilities of the members of the Biosafety Committee		
Function	Activities and responsibilities	Signature of each one of the members
President		
Secretary		
Vocal		
Vocal		
Vocal		
Vocal		
User of health services and/or members of civil society		

You can add as many rows as necessary, according to the members of the Biosafety Committee.

Note.- Users of health services and/or members of civil society are included as members in the Committee Registry because it is the figure considered in the “Official Mexican Standard NOM-012-SSA3-2012, Which establishes the criteria for the execution of health research projects in human beings”.