

Comisión Federal para la Protección contra Riesgos Sanitarios

Instructions for completing the Committee Registration Application form

RUPA: The Single Registry of Accredited Persons (RUPA) is the interconnection and computer systematization of the Registries of Persons

Accredited entities are registered to allow individuals (both natural and legal persons) to conduct business with government agencies and decentralized bodies using a unique identification number based on the Federal Taxpayer Registry (RFC). The RUPA (Single Registry of Accredited Entities) aims to integrate government information on the incorporation and operation of businesses. The required documents are submitted only once, and a single registration number is issued, which can be used for various procedures across all federal government agencies. You can request this registration at <http://www.rupa.gob.mx>, where you will find all the necessary information to complete the process.

1. Homoclave, name and type of procedure

Write the HOMOCLAVE, NAME and MODALITY OF THE PROCEDURE as described below:

Committee registration application by:

New or registered

COFEPRIS-05-038-B Committee Registration Application.
Option B - Research Committee

COFEPRIS-05-038-C Committee Registration Application.
Option C - Biosafety Committee

Modification

COFEPRIS-05-085 Amendment to Committee Registration.

Procedures with the Character of a Notice:

COFEPRIS-05-086 Annual Committee Activity Report.

COFEPRIS-05-088 Notice of Removal from Committee Registry.

2. Owner details

Natural person

Natural person: An individual with the capacity to enter into obligations and exercise rights.

RFC: Federal Taxpayer Registry as registered by the owner to the Ministry of Finance and Public Credit (SHyCP).

CURP (optional): Unique Population Registry Code, only for individuals.

Name(s): Full name, without abbreviations, as registered by the owner to the Ministry of Finance and Public Credit (SHyCP).

First surname: Full first surname, without abbreviations, as registered by the owner to the Ministry of Finance and Public Credit (SHyCP).

Second surname: Full second surname, without abbreviations, as registered by the owner with the Ministry of Finance and Public Credit (SHyCP).

Area Code, Telephone and Extension: Telephone number(s), including area code. Example: Area Code:

01 (55)

Local phone number: 57 31 49 52

Extension (when applicable): 1494

Email: The owner's email address, in lowercase and without spaces.

Legal entity

Legal entity: It is a group of people who come together for a specific purpose, for example, a commercial company, a civil association.

RFC: Federal Taxpayer Registry as registered by the company to the Ministry of Finance and Public Credit (SHyCP).

Name or Business Name: Full name, without abbreviations, of the Name or Business Name of the establishment, this data must be as it is registered with the Ministry of Finance and Public Credit (SHyCP).

Contacto:

Calle Oklahoma No. 14, Colonia Nápoles; Delegación Benito Juárez, Ciudad de México, C.P. 03810.

Teléfono 01-800-033-5050

contacto@cofepris.gob.mx

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Legal representative or agent requesting the procedure

RFC: Federal Taxpayer Registry of the Legal Representative under which he is registered with the Ministry of Finance and Public Credit (SHyCP).

CURP (optional): Unique Population Registry Code, only for individuals.

Name(s): Full name, without abbreviations, of the legal representative or agent requesting the procedure.

First surname: Full first surname, without abbreviations, of the legal representative or agent requesting the procedure.

Second surname: Full second surname, without abbreviations, of the legal representative or agent requesting the procedure.

Area Code, Telephone and Extension: Telephone number(s), including area code. Example:

Area Code: 01 (55)

Local phone number: 57 31 49 52

Extension (when applicable): 1494

Email address: Email address, in lowercase and without spaces, of the legal representative or agent requesting the procedure.

Tax address of the owner

Note: Address under which the taxpayer is registered with the Ministry of Finance and Public Credit (SHCP)

Postal code: Full postal code number corresponding to the company's tax address.

Type and name of road: Type and full name without abbreviations of the Avenue, Boulevard, Street, Highway, Road, Private, Unpaved, among others where the company's tax domicile is located, for example: Periférico Avenue, Cerrada de San Ignacio, Picacho Ajusco Highway.

Exterior number: Indicate the exterior number of the company's tax address.

Interior number: If the company's tax address has an interior number or letter, please also note it down.

Type and name of the colony or human settlement: Type and full name without abbreviations of the colony, condominium, hacienda, ranch, subdivision, section, sector, among others where the company's tax domicile is located, For example: Naples, Rancho Las Américas.

Location: Location where the company's tax domicile is located (when applicable).

Municipality or mayor's office: Full name without abbreviations of the mayor's office or municipality where the company's tax domicile is located.

Federal Entity: The federal entity where the company's tax domicile is located. For example: Mexico City, Baja California, State of Mexico.

Between road and road (type and name): Between which Avenue, Boulevard, Street, Highway, Road, Private, Unpaved, among others is the company's tax domicile located, for example: Periférico Avenue, Cerrada de San Ignacio, Picacho Ajusco Highway.

Rear roadway (type and name): Avenue, Boulevard, Street, Highway, Road, Private, Unpaved, among others rear to where the company's tax domicile is located.

Area Code, Telephone and Extension: Telephone number(s), including area code. Example:

Area Code: 01 (55)

Local phone number: 57 31 49 52

Extension (when applicable): 1494

3. Establishment details

RFC: Federal Taxpayer Registry as registered with the Ministry of Finance and Public Credit (SHyCP).

Company Name or Business Name: Full name without abbreviations of the establishment (Example: Farmacia Lupita, Laboratorios Terra, SA de CV, Procesadora de Alimentos S. de RL de CV, etc.).

Establishment address

Postal code: Full postal code number corresponding to the address where the establishment is located.

Type and name of road: Type and full name without abbreviations of the Avenue, Boulevard, Street, Highway, Road, Private, Unpaved, among others where the address of the establishment is located, for example: Periférico Avenue, Cerrada de San Ignacio, Picacho Ajusco Highway.

Exterior number: Indicate the exterior number of the address where the establishment is located.

Interior number: If the address where the establishment is located has an interior number or letter, please also note it down.

Type and name of the colony or human settlement: Type and full name without abbreviations of the colony, condominium, hacienda, ranch, subdivision, section, sector, among others where the address of the establishment is located, For example: Naples, Rancho Las Américas.

Location: Location of the address where the establishment is located (when applicable).

Municipality or mayor's office: Full name without abbreviations of the mayor's office or municipality where the establishment's address is located.

Federal Entity: The federal entity where the establishment's address is located. For example: Mexico City, Baja California, State of Mexico.

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Between road and road (type and name): Between which Avenue, Boulevard, Street, Highway, Road, Private, Unpaved, among others is the address of the establishment located, for example: Periférico Avenue, Cerrada de San Ignacio, Picacho Ajusco Highway.

Rear roadway (type and name): Avenue, Boulevard, Street, Highway, Road, Private, Unpaved, among others behind where the establishment's address is located.

Area Code, Telephone and Extension: Telephone number(s), including area code. Example:

Area Code: 01 (55)

Local phone number: 57 31 49 52

Extension (when applicable): 1494

4. Members of the Committee to be New or Removed

Select the option according to the procedure to be carried out.

- ☐ Appointment of members
- ☐ Replacement of members
- ☐ Resignation of members
- ☐ Change of address of the establishment

Document Number or Committee Registration: Enter the number of the document to be modified.

4.A Chairman of the Committee

Only fill in this section if:

- To notify a new member, mark the "APPOINTMENT" circle.
- To modify a member, previously notified, mark the "TO BE MODIFIED" circle in the first column and fill in the information exactly as you notified the member. In the second column, mark the "ALREADY MODIFIED" circle and fill in the member's current information.
- To report the departure of a member, mark the "RESIGNATION" circle and fill in the information provided by the member.

RFC: Federal Taxpayer Registry under which the Secretary of the Committee is registered with the Ministry of Finance and Public Credit (SHyCP).

CURP (optional): Unique Population Registry Code of the Committee Secretary.

Name(s): Full name without abbreviations of the Committee Chair.

First surname: Full first surname without abbreviations of the Committee Chairman.

Second surname: Full second surname without abbreviations of the Committee Chairman.

Area Code, Telephone and Extension: Telephone number(s), including area code. Example:

Area Code: 01 (55)

Local phone number: 57 31 49 52

Extension (when applicable): 1494

Email: Email address, in lowercase and without spaces, of the committee chair.

Profession: Note the profession of the Committee Chair.

Scientist: Check if the Committee Chair is a professional with a scientific background.

Note: In case of replacement, you must indicate the details of the member to be replaced and mark "TO BE MODIFIED", then the details of the new member and mark "ALREADY MODIFIED".

4.B Committee Secretary

Only fill in this section if:

- To notify a new member, mark the "APPOINTMENT" circle.
- To modify a member, previously notified, mark the "TO BE MODIFIED" circle in the first column and fill in the information exactly as you notified the member. In the second column, mark the "ALREADY MODIFIED" circle and fill in the member's current information.
- To report the departure of a member, mark the "RESIGNATION" circle and fill in the information provided by the member.

RFC: Federal Taxpayer Registry under which the Secretary of the Committee is registered with the Ministry of Finance and Public Credit (SHyCP).

CURP (optional): Unique Population Registry Code of the Committee Secretary.

Name(s): Full name, without abbreviations, of the Committee Secretary.

First surname: Full first surname, without abbreviations, of the Committee Secretary.

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Second surname: Full second surname, without abbreviations, of the Committee Secretary.

Area Code, Telephone and Extension: Telephone number(s), including area code. Example: Area

Code: 01 (55)

Local phone number: 57 31 49 52

Extension (when applicable): 1494

Email: Email address, in lowercase and without spaces, of the Committee Secretary.

Profession: Enter the profession of the Committee Secretary.

Scientist: Check " " if the Committee Secretary is a professional with a scientific background.

Note: In case of replacement, you must indicate the details of the member to be replaced and mark "TO BE MODIFIED", then the details of the new member and mark "ALREADY MODIFIED".

4.C Members of the Committee

Only fill in this section if: • To notify a new

member, mark the "APPOINTMENT" circle.

- To modify a member, previously notified, mark the "TO BE MODIFIED" circle in the first column and fill in the information exactly as you notified the member. In the second column, mark the "ALREADY MODIFIED" circle and fill in the member's current information.

- To report the departure of a member, mark the "RESIGNATION" circle and fill in the information provided by the member.

RFC: Federal Taxpayer Registry under which the member is registered with the Ministry of Finance and Public Credit (SHyCP).

CURP (optional): Unique Population Registry Code.

Name(s): Full name, without abbreviations, of the member in question.

First surname: Full first surname, without abbreviations of the member in question.

Second surname: Full second surname, without abbreviations of the member in question.

Area Code, Telephone and Extension: Telephone number(s), including area code. Example: Area

Code: 01 (55)

Local phone number: 57 31 49 52

Extension (when applicable): 1494

Email address: Email address, in lowercase and without spaces, of the Member in question.

Profession: List the profession of the Committee Member.

Scientist: Check if the Committee Secretary is a professional with a scientific background.

Internal: Check if the Committee member belongs to the Institution.

External: Check if the Committee member does not belong to the Institution.

Institution (if external is selected): Write the full name without abbreviations of the institution to which you belong.

Note: In case of replacement, you must indicate the details of the member to be replaced and mark "TO BE MODIFIED", then the details of the new member and mark "ALREADY MODIFIED".

4.D Users of Health Services and/or Members of Civil Society Members of the Committee

Only fill in this section if:

- To notify a new member, mark the "APPOINTMENT" circle.

To modify a member, previously notified, mark the "TO BE MODIFIED" circle in the first column and fill in the information exactly as it was provided to the member. In the second column, mark the "ALREADY MODIFIED" circle and fill in the member's current information.

- To report the departure of a member, mark the "RESIGNATION" circle and fill in the information provided by the member.

RFC: Federal Taxpayer Registry under which the Users and/or Committee Members are registered with the Ministry of Finance and Public Credit (SHyCP).

CURP (optional): Unique Population Registry Code.

Name(s): Full name, without abbreviations, of the Users and/or Committee Members.

First surname: Full first surname, without abbreviations, of the Users and/or Committee Members.

Second surname: Full second surname, without abbreviations, of the Users and/or Committee Members.

Area Code, Telephone Number and Extension: Telephone number(s), including area code. Example:

Lada: 01 (55)

Local phone number: 57 31 49 52

Extension (when applicable): 1494

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Email: Email address in lowercase and without spaces.

Function performed: Indicate the function performed by the Users and/or Committee Members.

Health Services: Check if the Committee member belongs to the Health Services that chairs it.

Civil Society: Check if the Committee member belongs to civil society.

Note: In case of replacement, you must indicate the details of the member to be replaced and mark "TO BE MODIFIED", then the details of the new member and mark "ALREADY MODIFIED".

4.E Modification of address

It says / authorized condition: Enter the data exactly as it appears in the already authorized permit.

It should say / requested condition: Enter the complete data, exactly as you want it to be modified.

To modify the address, the fields must be filled in according to the following: **Postal code:** Complete postal code number that corresponds to the address where the establishment is located.

Type and name of road: Type and full name without abbreviations of the Avenue, Boulevard, Street, Highway, Road, Private, Unpaved, among others where the address of the establishment is located, for example: Periférico Avenue, Cerrada de San Ignacio, Picacho Ajusco Highway.

Exterior number: Indicate the exterior number of the address where the establishment is located.

Interior number: If the address where the establishment is located has an interior number or letter, please also note it down.

Type and name of the colony or human settlement: Type and full name without abbreviations of the colony, condominium, hacienda, ranch, subdivision, section, sector, among others where the address of the establishment is located, For example: Naples, Rancho Las Americas.

Location: Location of the address where the establishment is located (when applicable).

Municipality or mayor's office: Full name without abbreviations of the mayor's office or municipality where the establishment's address is located.

Federal Entity: The federal entity where the establishment's address is located. For example: Mexico City, Baja California, State from Mexico.

Between road and road (type and name): Between which Avenue, Boulevard, Street, Highway, Road, Private, Unpaved, among others is the address of the establishment located, for example: Periférico Avenue, Cerrada de San Ignacio, Picacho Ajusco Highway.

Rear roadway (type and name): Avenue, Boulevard, Street, Highway, Road, Private, Unpaved, among others behind where the establishment's address is located.

Area Code, Telephone and Extension: Telephone number(s), including area code. Example:

Area Code: 01 (55)

Local phone number: 57 31 49 52

Extension (when applicable): 1494

5. Reporting

Chairman of the Committee presenting the annual report

RFC: Federal Taxpayer Registry under which the Committee President is registered with the Ministry of Finance and Public Credit (SHyCP).

CURP (optional): Unique Population Registry Code, only for individuals.

Name(s): Full name, without abbreviations, of the Chair of the Committee submitting the Report.

First surname: Full first surname, without abbreviations, of the Chairman of the Committee presenting the Report.

Second surname: Full second surname, without abbreviations, of the Chairman of the Committee presenting the Report.

Area Code, Telephone and Extension: Telephone number(s), including area code. Example:

Area Code: 01 (55)

Local phone number: 57 31 49 52

Extension (when applicable): 1494

Email: Email address, in lowercase and without spaces, of the Committee Chair.

Full name and handwritten signature of the Committee Chair: Write the full name without abbreviations and handwritten signature of the Chair of the Committee Submitting the Report (notified to the Federal Commission for Protection against Sanitary Risks).

Note: A separate format must be used for each Committee for which the Annual Report is submitted.

I declare under oath that I comply with the applicable requirements and regulations, without prejudice to any sanctions I may incur for making false statements to an authority. I also accept that notification of this procedure will be carried out through the Comprehensive Services Center or offices in the states corresponding to the Federal Health System. (Article 35, Section II of the Federal Law of Administrative Procedure)

In accordance with the Federal Law on Transparency and Access to Public Government Information, the data or annexes may contain confidential information; you must indicate whether you agree to make them public.

Contacto:

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The data or attachments may contain confidential information; do you agree to make them public?

" Yeah

" No

Full name and handwritten signature of the Head of the Institution or Establishment: Write the full name without abbreviations and handwritten signature of the Head of the Institution or Establishment, notified to the Federal Commission for Protection against Sanitary Risks.

Note: A separate format must be used for each Committee for which the Annual Report is submitted.

Location: Specify the location where the procedure is presented.

Date: Indicate the date the procedure is submitted, starting with the day, month, and year. Example:

21	/	07	/	2017
DD		MM		AAAA

For any clarification, doubt and/or comment regarding this procedure, please call the COFEPRIS Telephone Assistance Center, in Mexico City or from anywhere in the country dial toll-free **01-800-033-5050** and if you require the entry number and/or tracking of your procedure sent to the Foreign Processing area dial toll-free **01-800-420-4224**.

Contacto:

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Comisión Federal para la Protección contra Riesgos Sanitarios

Instructions for completing and document requirements for the Committee Registration Application form

In this document, you will find the guide for completing the form and the documentary requirements that you must submit along with your corresponding application.

For each procedure you carry out, you must submit a separate "Committee Registration Application" form duly completed according to the Quick Fill Guide below.

NOTE 1: You may not be required to submit more documents than those indicated in the requirements, except as provided in article 15 of the Federal Law of Administrative Procedure, regarding the accreditation of legal personality.

NOTE 2: The documentation must be submitted by the interested party, legal representative or authorized person, in accordance with the provisions of **article 19 of the Federal Law of Administrative Procedure**.

1. Registration Application by:

1.1. New or registered

Homoclave

Name, type and quick filling guide

COFEPRIS-05-038-B

Committee Registration Application.
Option B.- Research Committee

1 ÿ 2 ÿ 3 ÿ 4 ÿ 4.A ÿ 4.B ÿ 4.C ÿ 4.D

For the minutes of the Committee's installation, please refer to the technical guide for the submission of supporting documents, which can be found on the COFEPRIS website.

Documentary requirements

ÿ Completed "Committee Registration Application" form. ÿ Minutes of the Research Committee's installation meeting.

ÿ *Curriculum Vitae* of the person who chairs the Committee.

ÿ From the scientists who make up the Committee (at least 3), documentation that proves their experience in research.

NOTE: For public institutions, please attach the documentation as follows:

- » Document that proves the legal personality of the Legal Representative of the institution (indicating their powers and duties).
- » Legible copy of the appointment, official gazette, or internal regulations of the institution you represent
- » Legible copy of official identification of the legal representative (National Electoral Institute (INE) credential or valid passport or military service card) national military service or driver's license).
- » Legible copy of official identification of authorized persons (National Electoral Institute (INE) credential or valid passport or military service card) national military service or driver's license).

Contacto:

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Comisión Federal para la Protección contra Riesgos Sanitarios

Homoclave

Name, type and quick filling guide

COFEPRIS-05-038-C

Committee Registration Application.
Option C - Biosafety Committee

1 2 3 4 4.A 4.B 4.C 4.D

For the minutes of the Committee's installation, please refer to the technical guide for the submission of supporting documents, which can be found on the COFEPRIS website.

Documentary requirements

• Completed "Committee Registration Application" form. • Minutes of the Biosafety Committee's installation meeting. • *Curriculum Vitae* of the Committee Chair.

• From the scientists who make up the Committee (at least 3), documentation that proves their experience in research.

NOTE: For public institutions, please attach the documentation as follows:

- » Document that proves the legal personality of the Legal Representative of the institution (indicating their powers and duties).
- » Legible copy of the appointment, official gazette, or internal regulations of the institution you represent
- » Legible copy of official identification of the legal representative (National Electoral Institute (INE) credential or valid passport or military service card) national military service or driver's license).
- » Legible copy of official identification of authorized persons (National Electoral Institute (INE) credential or valid passport or military service card) national military service or driver's license).

1.2. Modification

Homoclave

Name and quick fill guide

COFEPRIS-05-085 Modification of Committee Registration.

1 2 3 4 4.A 4.B 4.C 4.D 4.E

For proof of appointment of Committee members, please refer to the technical guide for submitting supporting documents found on the website.
 COFEPRIS internet.

Documentary requirements

• "Committee Registration Application" form duly completed.

• For each of the new members of the Committee, a certificate of appointment signed by the person who chairs the Committee.

• Original of the Committee record to be modified.

• In case of a change in the Committee President, attach the *Curriculum Vitae* of the new president.

NOTE: For public institutions, please attach the documentation as follows:

- » Document that proves the legal personality of the Legal Representative of the institution (indicating their powers and duties).
- » Legible copy of the appointment, official gazette, or internal regulations of the institution you represent
- » Legible copy of official identification of the legal representative (National Electoral Institute (INE) credential or valid passport or military service card) national military service or driver's license).
- » Legible copy of official identification of authorized persons (National Electoral Institute (INE) credential or valid passport or military service card) national military service or driver's license).

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2. Procedures with the character of a notice

Homoclave

COFEPRIS-05-086

Name and quick fill guide

Annual Committee Activity Report.

1 2 3 4 5

For the annual report, please refer to the auxiliary format for submitting attached documents, which can be found on the COFEPRIS website.

Documentary requirements

- "Committee Registration Application" form, duly completed, and if acknowledgment is required, a legible copy must be submitted.
- Annual report on the integration of the Committee and activities related to the evaluation of projects according to the objective and scope of application of the standard NOM-012-SSA3-2012 containing the following data:
 - » Project identification data (name and objective of each protocol submitted to the Committee)
 - » Number of protocols approved and rejected.
 - » Percentage of progress of approved protocols

NOTE: This report must be submitted during the first 10 business days of June each year.

Homoclave

COFEPRIS-05-088

Name and quick fill guide

Notice of Removal from Committee Registry.

1 2 3 4 4.A 4.B 4.C 4.D

Documentary requirements

- "Committee Registration Application" form, duly completed, and if acknowledgment is required, a legible copy must be submitted.
- Original of the Committee Registration that you wish to cancel.

Contacto:

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