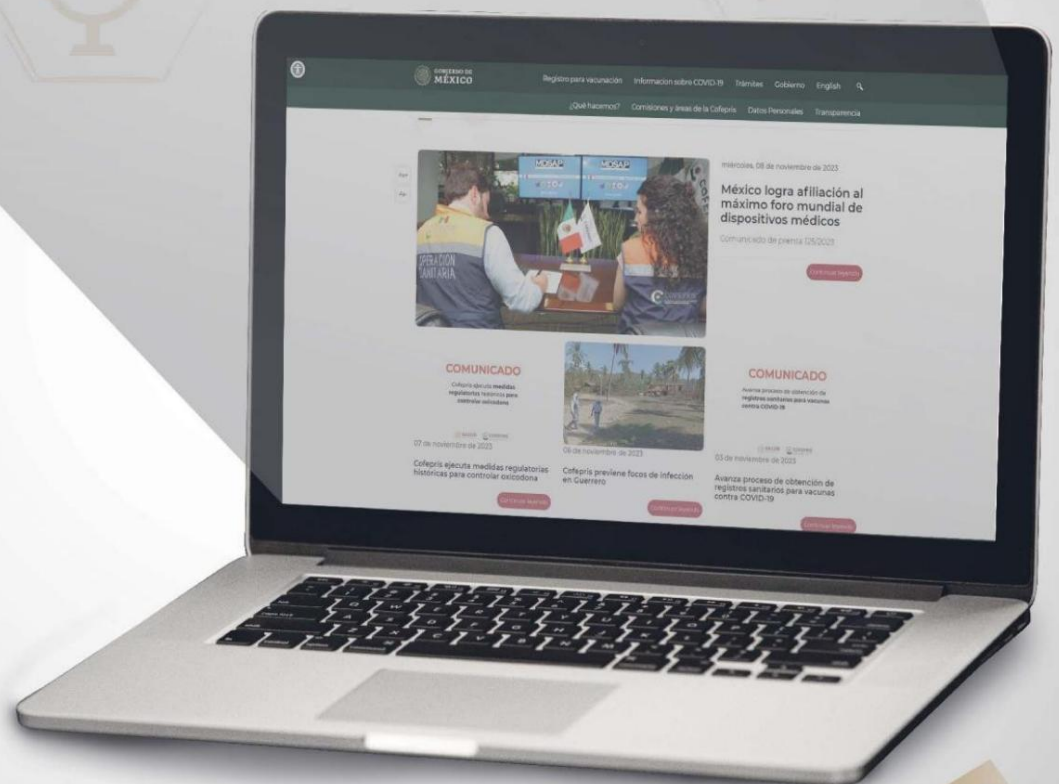


May 19, 2025

DIGIPRIS: Online Regulation

Clinical Trials



User Manual:

Access to the platform,
profiles and roles



Salud
Secretaría de Salud



Access to the platform, profiles and roles

DIGIPRIS: Online Regulation is the platform for procedures and services of the Federal Commission for the Protection against Sanitary Risks (Cofepris), where you can request authorizations for Clinical Trials (research protocols involving human subjects) in all their forms, as well as modifications or amendments to the protocol authorization.

Homoclaves of procedures:

COFEPRIS-04-010: Request for Authorization of Research Protocol on Human Beings, in all its modalities:

- Modality A: Medicines, Biological or Biotechnological
- Modality B: Medications (Bioequivalence Studies)
- Modality C: New resources (Studies of materials, grafts, transplants, prostheses, physical, chemical and surgical procedures) and other methods of prevention, diagnosis, treatment and rehabilitation carried out on human beings, except for pharmacological ones)
- Modality D: Risk-free research (observational studies that use documentary research techniques and methods, and those in which no intentional intervention or modification is made to the physiological, psychological, and social variables of the research subjects)

COFEPRIS-09-012 Request for Modification or Amendment to the Research Protocol Authorization.

Through this Manual, the user will learn about the different types of roles and profiles through which the request for homoclave procedures COFEPRIS-04-010 and COFEPRIS-09-012 can be made.



Content

Accessing the system and creating a profile.....	4
Logout.....	7
Roles and Permissions.....	7
Assign roles and permissions to individuals	9
Revoke roles and permissions from individuals	13
Review previously assigned roles and permissions, active and/or revoked	15



Salud
Secretaría de Salud

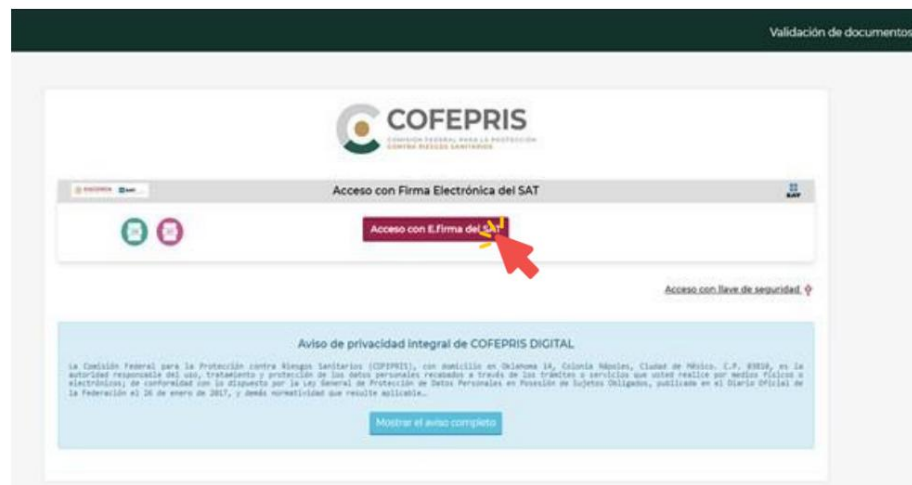


Accessing the system and creating a profile

1. To access the DIGIPRIS: Online Regulation platform, go to www.gob.mx/cofepris, go to the "Links of Interest" section, click on "DIGIPRIS: Online Regulation," go to the "Clinical Trials Research" section, and click on the "Access here" button.
2. Once on the site, click the "Enter DIGIPRIS: Online Regulation" button. As the account holder, you must log in to the system with your e-signature, or that of the company you represent, and the platform will automatically detect your information and create your profile. The platform's full privacy notice is also available in this section. You can view it by clicking "Show full notice."



3. In the next window, select "Access with SAT e-signature."



Update Date: May 19, 2025



Salud
Secretaría de Salud



- The platform will display the button to enter the “e.signature Certificate”, click and upload the corresponding file (certificate, .cer).

The platform will immediately begin validating the data. Once the validation is complete, the certificate's original data string will appear, along with the date and time the system requested entry.

- Next, click the “Upload private key .key” button and select the file corresponding (private key .key).



- [illegible]

- You will be able to:

- 



Salud
Secretaría de Salud

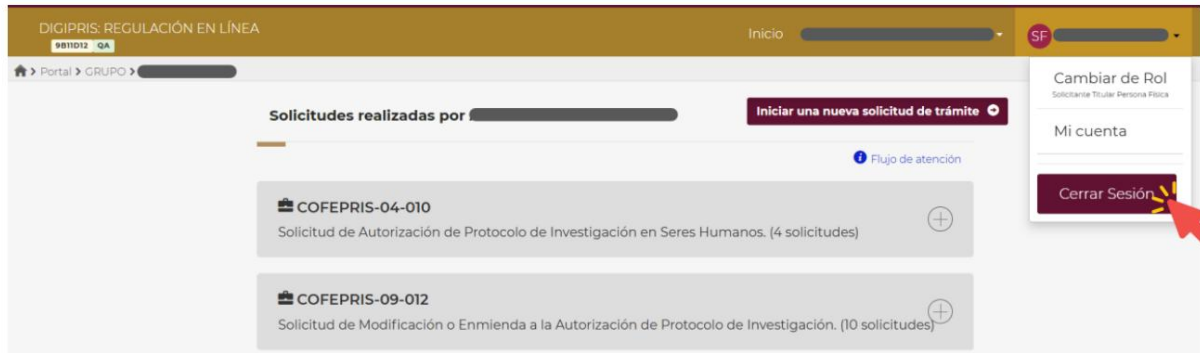


COFEPRIS
COMISIÓN FEDERAL PARA LA PROTECCIÓN
CONTRA RIESGOS SANITARIOS



Log out

1. From the “Start” menu, click on the organization name to display the menu corresponding.
2. To finish, click “Log out.”



Roles and permissions

Any adult with a valid e-signature and active status may be an applicant within the platform. The applicant is the account holder, who will have control over all information and can activate access to the other roles permitted within the platform.

Two types of applicant user profiles can be created:

- **Individual Applicant:** This is a person with a CURP (Tax Identification Number), RFC (Registered Taxpayer Identification Number), and an electronic signature from the SAT (Tax Administration Service), who completes the process in their own name as the account holder. For individuals, the first account entry and subsequent review, assignment, or revocation of roles must be made with the electronic signature corresponding to the account holder.
- **Legal Entity Applicant:** An organization with a Taxpayer Registration Number (RFC) and an electronic signature from the SAT, which is considered the owner of the transaction. For legal entities, the first account entry and subsequent review, assignment, or revocation of roles must be made with the electronic signature corresponding to the legal representative of the electronic signature with the SAT.



Salud
Secretaría de Salud



COFEPRIS
COMISIÓN FEDERAL PARA LA PROTECCIÓN
CONTRA RIESGOS SANITARIOS



The **roles and permissions** that the **applicant (individual or legal entity)** can assign to other people within their account, to be part of the **group** are:

- **Authorizer:** In the case of an individual, this is the account holder (the applicant). In the case of accounts belonging to legal entities, this role will be assigned to the individual identified as the legal representative in the SAT electronic signature certificate. Therefore, the procedures signed by this person will be done on behalf of and as the owner of the legal entity.
- **Editor:** A natural person authorized by the applicant to complete or delete applications, view the status of procedures, read resolutions, and download resolution letters.
- **Viewer:** A natural person authorized by the applicant who has the power to access information and documents related to the procedures in "read" mode only.

All these roles form a **group**, which can be made up of:

- **Legal person applicant:** the authorizer (natural person, legal representative of the person) moral before the SAT), the individuals authorized as editors and viewers
- **Natural person applicant:** the authorizer (the natural person who owns the RFC with which the started the session), the natural persons authorized as editors and viewers.

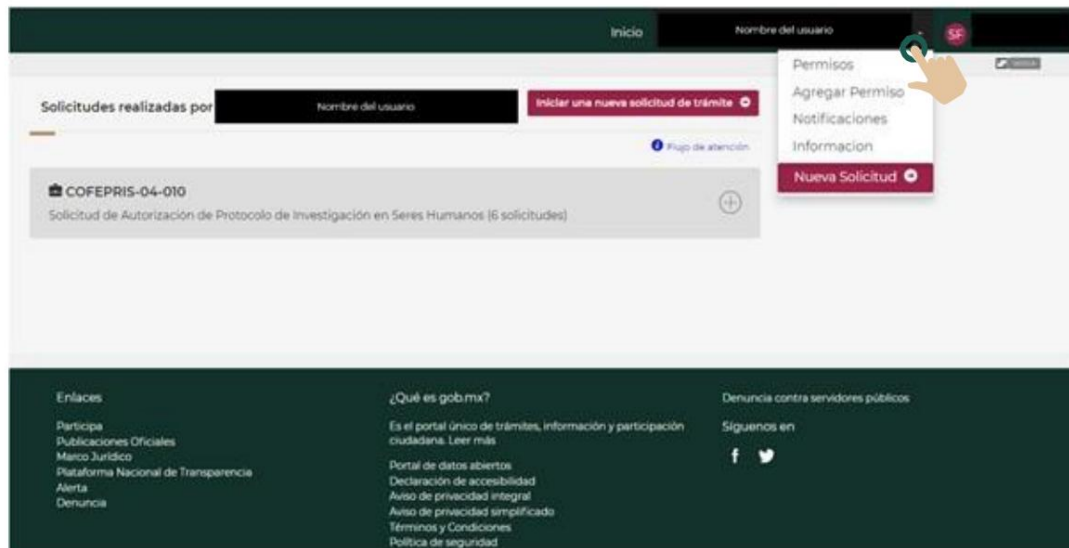


Salud
Secretaría de Salud



Assign roles and permissions to individuals

1. From the **"Home"** screen, click on your **"Username"** in the top right corner to open the corresponding menu. In the corresponding menu, click the **"Add Permissions"** button to open the screen that allows you to add the corresponding permissions to the **group**.



2. Click on the **"E.Signature Certificate"** button and upload the certificate file (.cer) of the natural person you want to add.





Salud
Secretaría de Salud



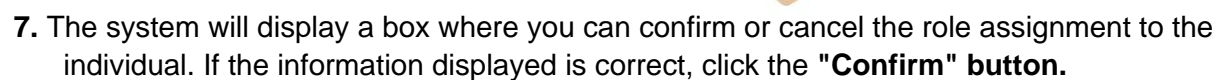
- The platform will display the **certificate's identification information**: certificate number, expiration date, certificate holder's name, CURP (Customer Registration Number), RFC (Registered Citizenship and Immigration Code) with homoclave, and email address registered with the SAT (Tax Administration Service). Review this information before adding a new user to the **group**.

- Below the RFC identification data you will be able to identify the menu to select the role of the person within the **group**.

Select the desired **"User Role"** : editor or viewer.

- Once you've selected the role, you'll see a summary of the permissions granted by this role. Next to **"Access Role,"** select the **"Access Time"** you want to assign to this individual within the group.

Note: Please note that all roles will be deactivated if the corresponding e.signature becomes invalid.





Salud
Secretaría de Salud



8. Once you confirm the action, the platform will direct you to the **“Granted Operational Permissions”** section where you can see all active users within the group.



9. To return to the main section, click the **“Home”** button.

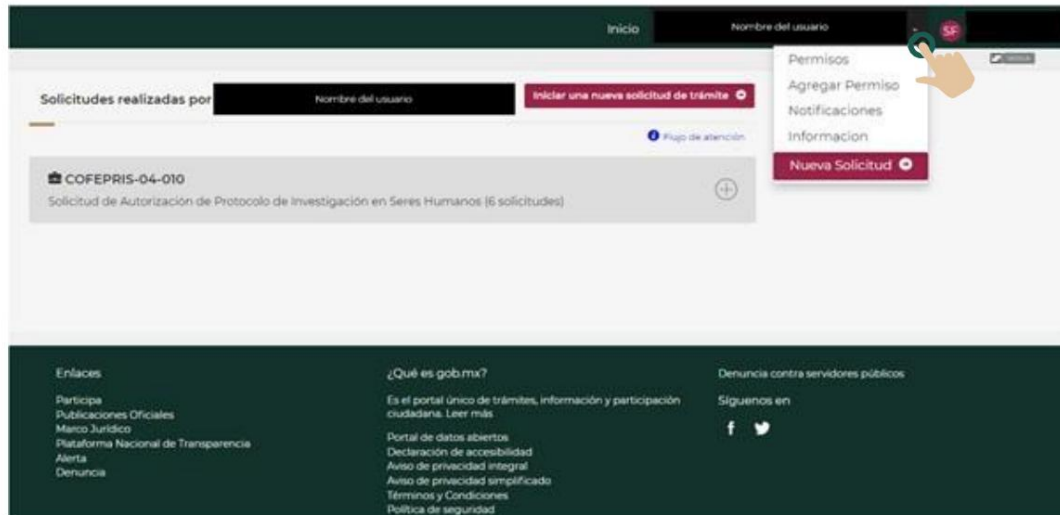


Salud
Secretaría de Salud



Revoke roles and permissions from individuals

1. From the **"Home"** screen, click on your **"Username"** in the top right corner to display the corresponding menu. Click on the **"Permissions"** button to display the **"Operational Permissions Granted"** screen.



2. In this section you can view the name of the active users, the role within the group, start and end dates of the assigned role.

USUARIO	ROL	RECURSO	RUCIO	FIN	STATUS	REVOCAR
[Redacted]	Solicitante Titular Persona Física	[Redacted]	19/7/2023 17:15:27	17/10/2026 16:05:30	ACTIVE	
[Redacted]	Editor	[Redacted]	26/Octubre/2023 19:11:45	24/Octubre/2024 19:11:45	ACTIVE	REVOCAR



Salud
Secretaría de Salud



- On the far right of the table, click the **“REVOKE”** button in the row corresponding to the individual whose previously granted permissions you want to remove.



- Immediately the platform will display a pop-up window where you can confirm the selected action. Select **“REVOKE”** to proceed with this action.



- Once you confirm the action, the platform will direct you to the **“Granted Operational Permissions”** section where you can see all active users within the group.



- To continue with your procedures, click the **“Start”** button.



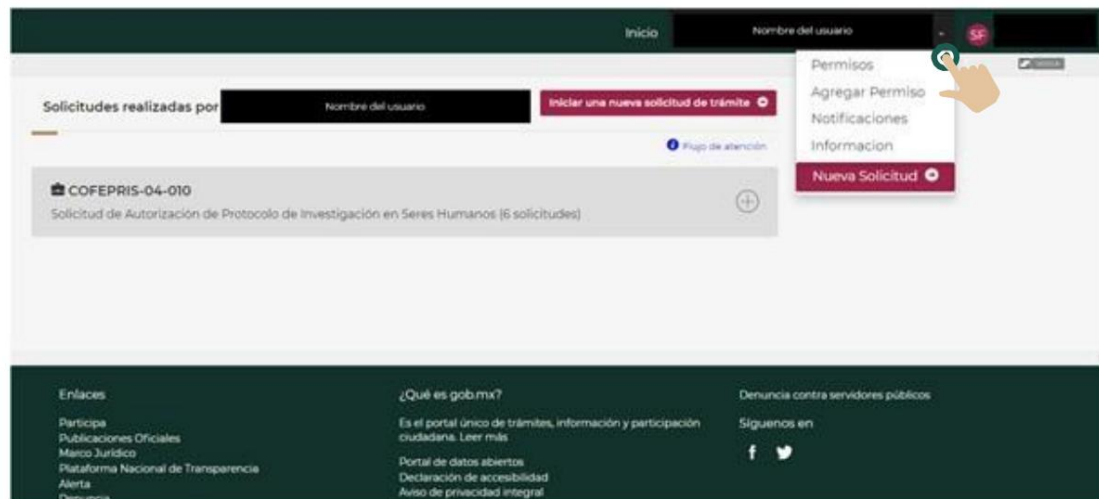
Salud
Secretaría de Salud



Review previously assigned roles and permissions, active and/or revoked

1. From the “**Home**” screen, click on the top right section where your account appears. “**Username**” to display the corresponding menu.

Click the “**Permissions**” button to display the “Operational Permissions Granted” screen . In this section, you can view the user's name, role within the group, start and end dates for the assigned role, and the role's status.



2. To see the details about the functions that each role can perform, click on “**Role details**” of each of the users added to the group.

Note: The “Granted Operational Permissions” screen allows you to view the users and permissions that are active within a group, when this option is selected in the control in the upper right corner.





Salud
Secretaría de Salud



3. To hide this information, click on **“Role Details”** again.

Note: To view all revoked users and permissions, on the **“Granted Operational Permissions”** screen, click the control in the upper right corner of the table of granted permissions.

4. Once you click the **control**, the information will change from **"Active"** to **"All,"** and you'll be able to view the history of users who have or have had permissions within the group. Users who are no longer active in the group will appear with **"REVOKED"** in the status section.



5. To continue with your procedures, click the **“Start”** button.



Update Date: May 19, 2025