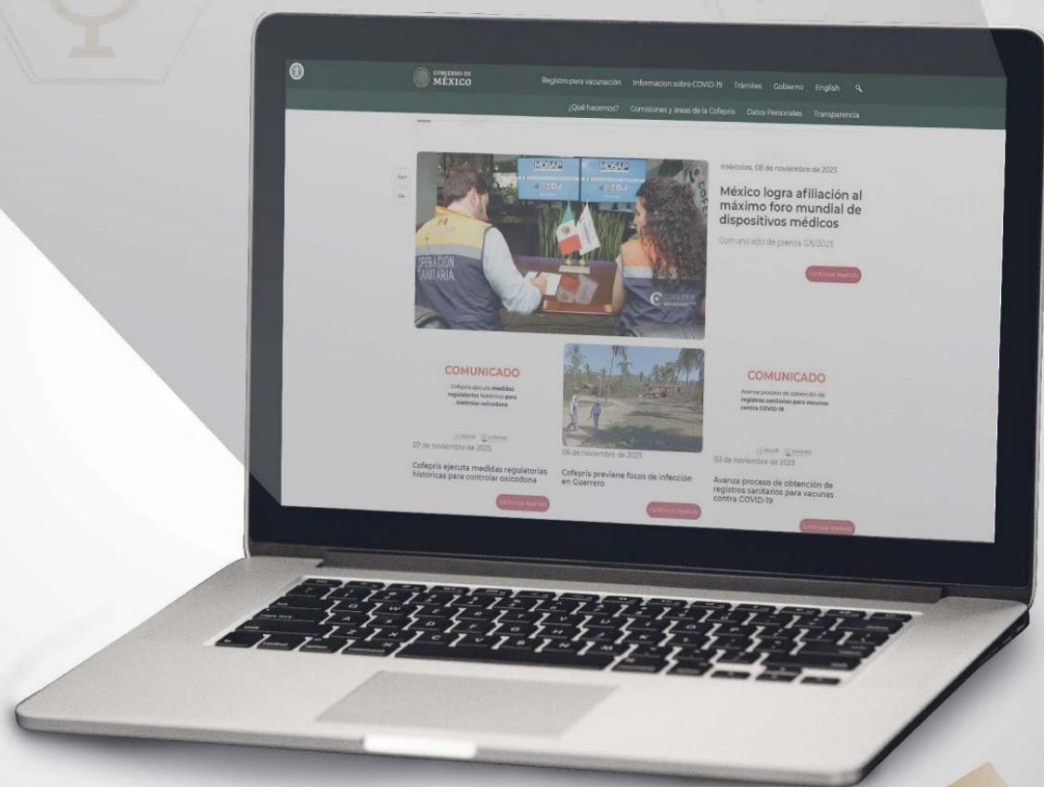


DIGIPRIS: Research and Clinical Trials



User manual: System access, profile creation and roles



Introduction

DIGIPRiS: Research and Clinical Trials is the platform for procedures and services of the Federal Commission for the Protection against Health Risks (Cofepris), where authorizations for research protocols in human beings (in all their modalities) and modifications or modifications can be requested. amendments to protocol authorization.

Procedures homoclaves:

- COFEPRIS-04-010 Request for Authorization of Research Protocol in Human Beings, in all its modalities: Modality A.- Medications, Biological or Biotechnological
Modality B.- Medications (Bioequivalence Studies)

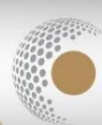
Modality C.- New resources (Studies of materials, grafts, transplants, prostheses, physical, chemical and surgical procedures) and other methods of prevention, diagnosis, treatment and rehabilitation carried out in human beings, except pharmacological ones)

Modality D.- Risk-free research (observational studies that use techniques, documentary research methods and those in which no intervention or intentional modification is carried out in the physiological, psychological and social variables of the research subjects)
- COFEPRIS-09-012 Request for Modification or Amendment to the Research Protocol Authorization.

On our platform you can consult all the procedures that your organization has requested regarding the homoclaves previously listed; You will be able to observe both those previously authorized and those that are in process; as well as view the status of the process from the application, evaluation, verification, signature and resolution.

Remember that you can have several applications and procedures in process simultaneously. You will be able to enter as many times as necessary and your data, as well as requests and procedures, will be uploaded.

The steps for using the platform are listed below.





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Access to the system and profile creation

1. To enter the **DIGIPRiS platform: Online Regulation**, go to the page www.gob.mx/cofepris, Go to the “**Leagues of interest**” section and click on “**DIGIPRiS: Online Regulation**”.

You can also enter directly through the league:

[https:// digiprisregulationenlinea.cofepris.gob.mx](https://digiprisregulationenlinea.cofepris.gob.mx)

The **comprehensive Privacy Notice** will be available prior to entry. **of DIGIPRiS: Research and Clinical Trials** and the terms and conditions with the title **DIGIPRiS: Online Regulation. TERMS OF USE**. Read these sections by clicking “*Show the full notice*” and “*Show full terms of use*”.

It is very important to read and understand the **TERMS OF USE** since by entering the platform you will be simultaneously signing and accepting them.



2. Once you have read the **TERMS OF USE**, click on the “**Enter DIGIPRiS: Online Regulation**” button. As owner, You must enter the system with your e.signature, or that of the company you represent, and the platform will automatically detect your data and your profile will be created.
3. In the next window select “**Access with SAT e-signature**”.

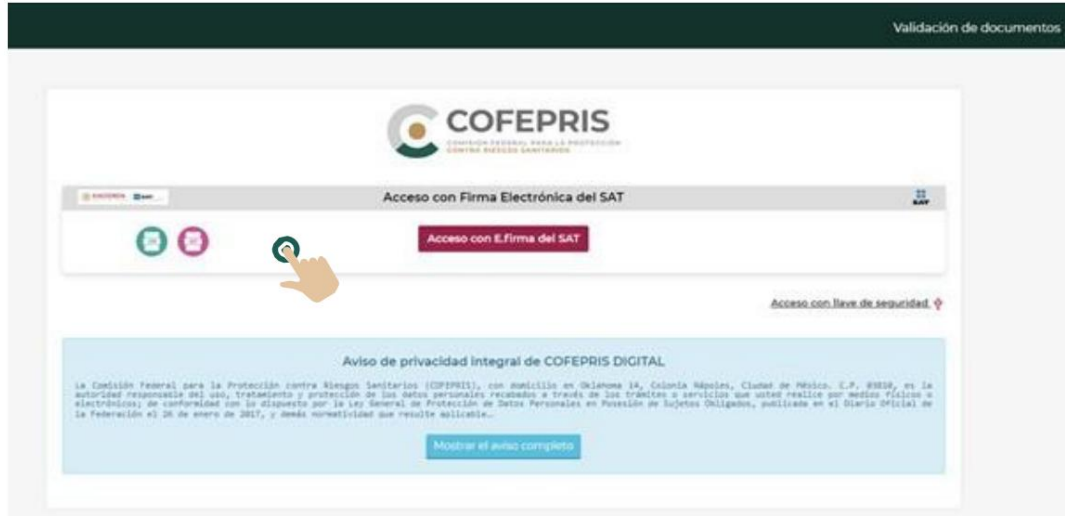




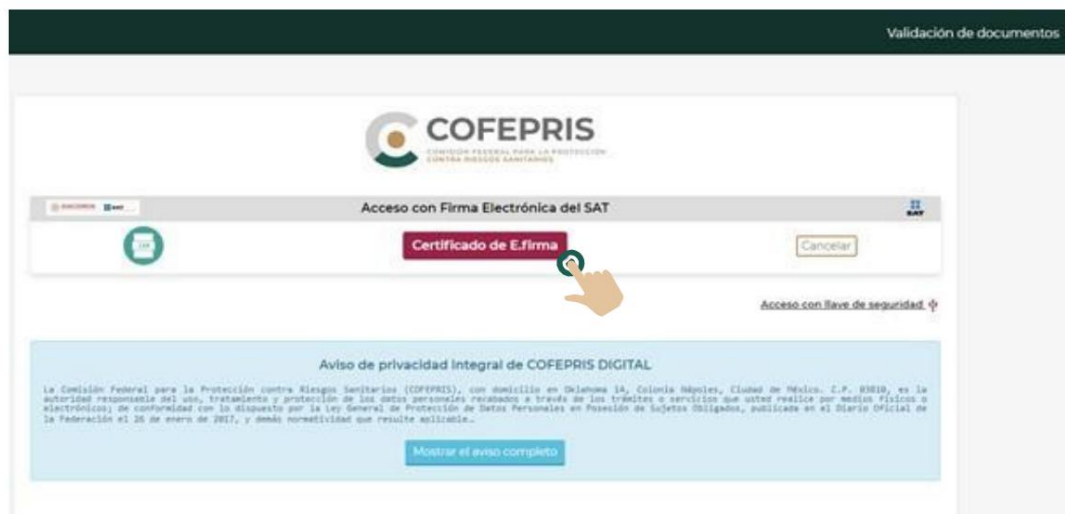
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4. The platform will display the button to enter the “**e.firma Certificate**”, click and load the corresponding file (certificate, .cer).

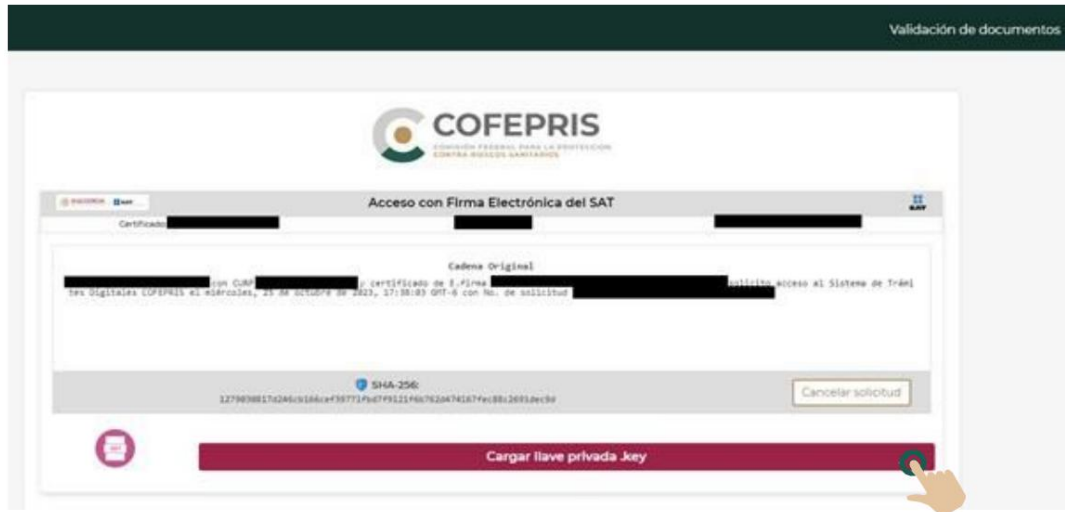


The platform will immediately begin validating the data. A
Once the validation is completed, the original data string of the certificate
will appear, accompanied by the date and time in which the system is requesting
entry.

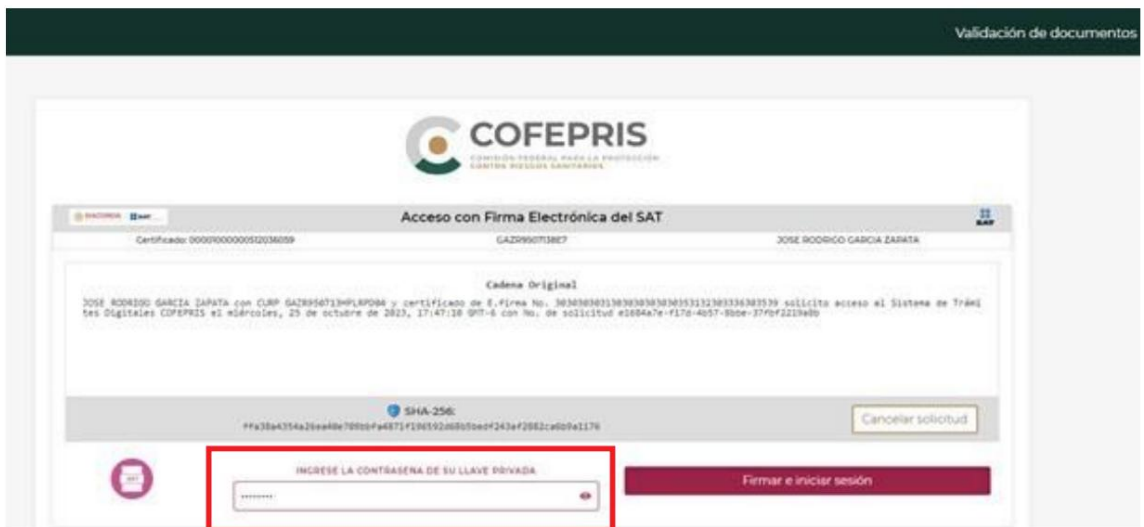




5. Then click the **“Load private key .key”** button and select the corresponding file (private key .key).

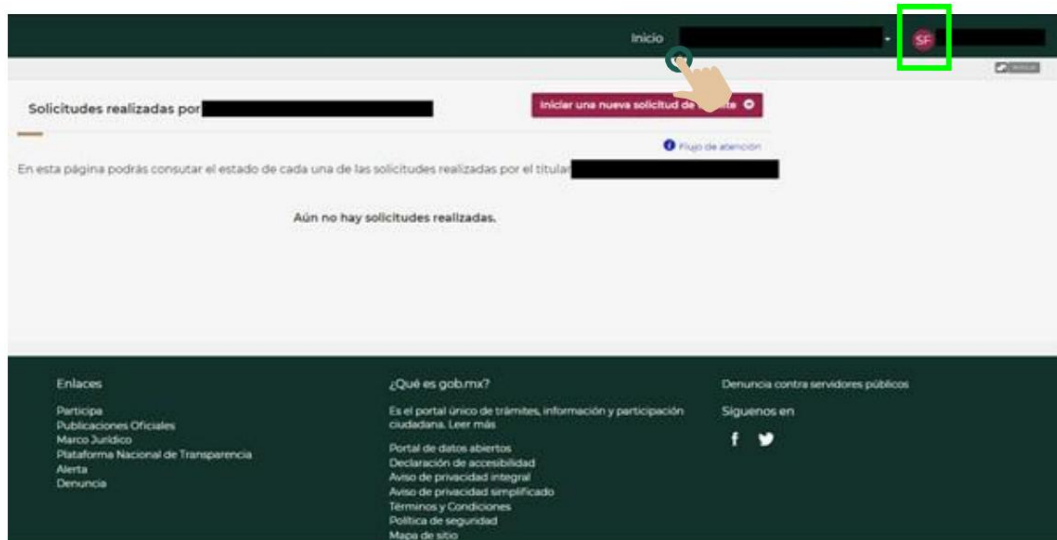


6. Next click on the **“Load private key .key”** button and select the corresponding file (private key .key).



7. Subsequently, the platform will display the “Home” screen of the user. On this screen you can:

- Confirm whether access was given in the name of a natural person (“SF” applicant natural person) or legal entity (“SM” applicant legal entity).
- Consult your profile and register the email to which you wish to receive the notices generated by the platform.
- Assign roles and permissions.
- Access the menu to review who has permission to enter this account, the assigned roles, and the details of each role.
- Revoke previously assigned roles.
- Access the information menu.
- Make a new request.
- Review the requests and procedures previously carried out.





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Logout

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



Roles and permissions

Any person of legal age 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 of all the information and will be able to activate access to the other roles that are allowed within the platform.

According to the RFC used to enter the platform, there are two types of profiles requesting users :

- **Natural Person Applicant:** This is a person who has a CURP registration, RFC and electronic signature from the SAT, who carries out the procedure in his or her name as the owner. In the case of natural persons, the first entry into the account and the subsequent review, assignment or Revocation of roles must be done with the e-signature corresponding to the account holder.
- **Moral Person Applicant:** It is an organization that has an RFC and an electronic signature from the SAT, which is considered the owner of the procedure. For legal entities, the first entry into the account and the subsequent review, assignment or revocation of roles must be done with the e.signature corresponding to the legal entity.





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

- **Authorizer:** in the case of a natural person, it is the same account holder (the applicant). In the case of accounts that correspond to legal entities, the legal representative registered in the E.firma certificate is automatically assigned as authorizer. In both cases (natural person or legal entity), once inside the account, the role of authorizer can be granted to other people.

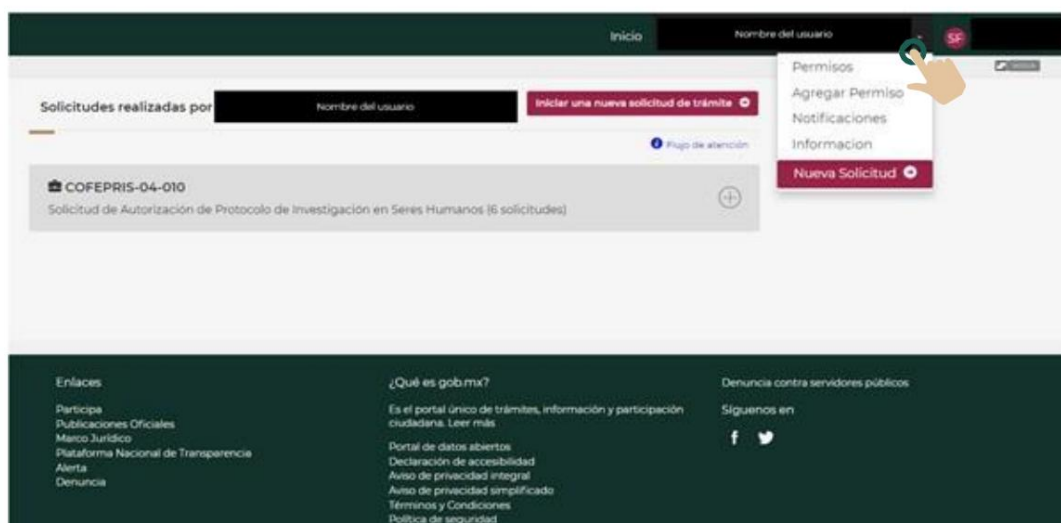
physical entities, take into account that the procedures signed by all the authorizers will be carried out in representation and ownership of the applicant (natural or legal person who owns the account).
- **Editor:** Natural person authorized by the applicant who has the power to fill out or delete applications, view the status of the procedures, read resolutions and download resolution letters.
- **Viewer:** Natural person authorized by the applicant who has the power to access only in “read” mode the information and documents related to the procedures.

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

- **Applicant legal entity:** the legal representative as authorizer (natural person legal representative of the legal entity before the SAT), the natural persons authorized as “authorizers” to sign procedures on behalf of the legal entity, the “editors” and “viewers”.
- **Natural person applicant:** the owner of the RFC as authorizer (the person owner of the RFC with which the session was started), the natural persons authorized as “authorizers” to sign procedures in the name of the natural person, the “editors” and “viewers”.

Assign roles and permissions to individuals

1. From the **“Home”** screen, click on the upper right section where your **“Username”** appears to display the corresponding menu. In the corresponding menu, click on the **“Add permissions”** button to display the screen that allows you to add the corresponding permissions to the **group**.



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

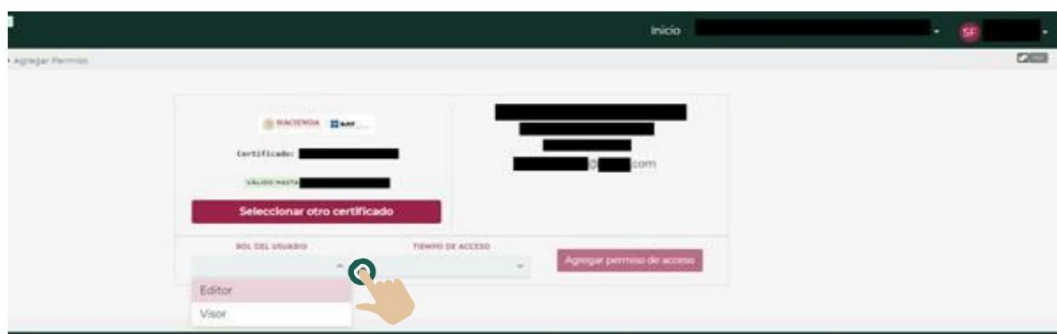




- The platform will indicate the **identification data of the certificate**: certificate number, validity date, name of the certificate owner, CURP, RFC with homoclave and email registered with the SAT. Review the data before adding a new user to the **group**.



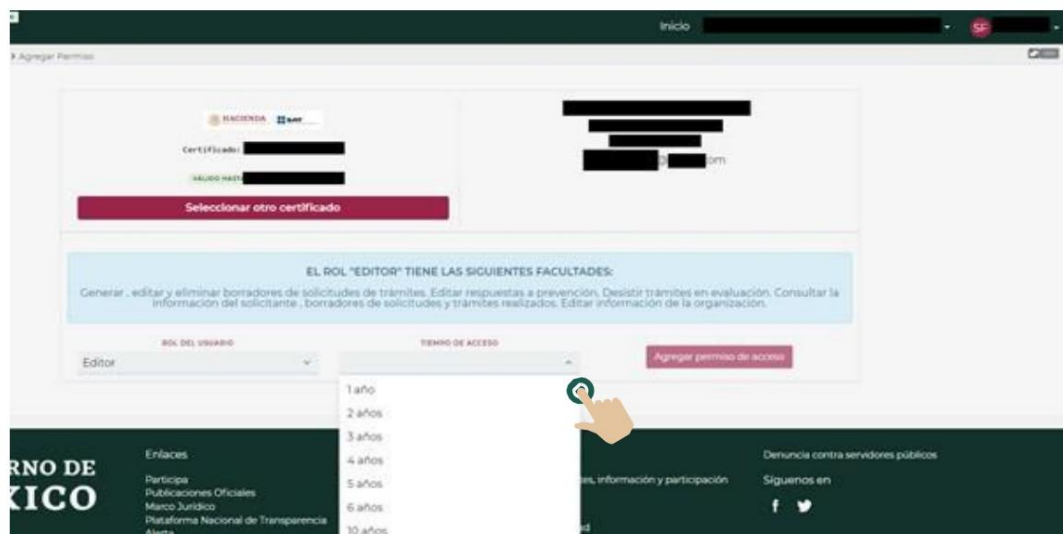
- Below the RFC identification data you can identify the menu to select the person's role within the **group**.
Select the desired **“User Role”** : authorizer, editor, or viewer.



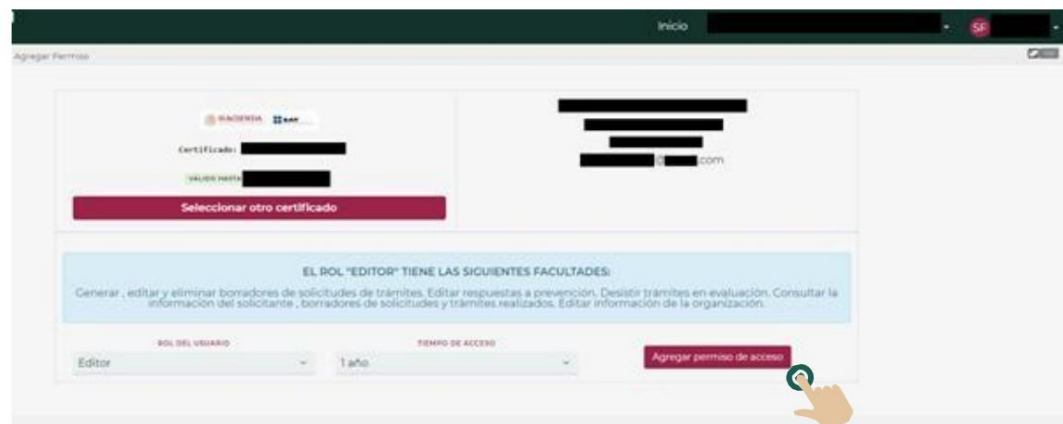


5. Once the role is selected, you can view a summary of the permissions granted by this role. Next to the “**Access Role**”, select the “**Access Time**” that you want to assign to this individual within the group.

Note: Please note that all roles will be disabled if the e.corresponding signature loses validity.



6. Subsequently, click on the “**Add access permission**” button





- The system will display a box in which you can confirm or cancel the assignment of the role to the natural person. If the information displayed is correct, click the **“Confirm”** button.



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



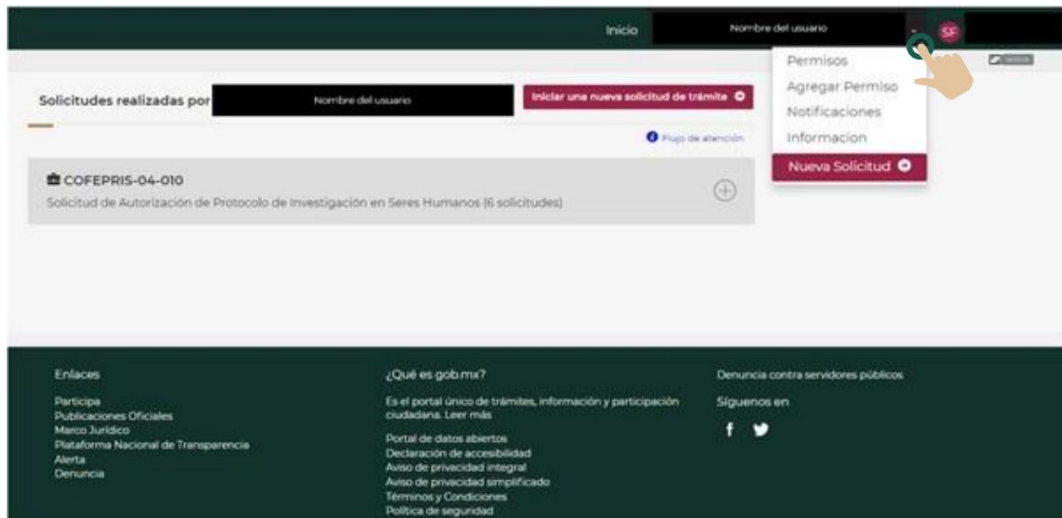
- To return to the main section, click the **“Home”** button.





Revoke roles and permissions from individuals

1. From the **“Home”** screen, click on the upper right section where your **“Username”** appears to display the corresponding menu. Click on the **“Permissions”** button to display the **“Operating 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.



- At the far right of the table, click the **“REVOCATE”** button in the row corresponding to the individual to whom you wish to remove the permissions previously granted.



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



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



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



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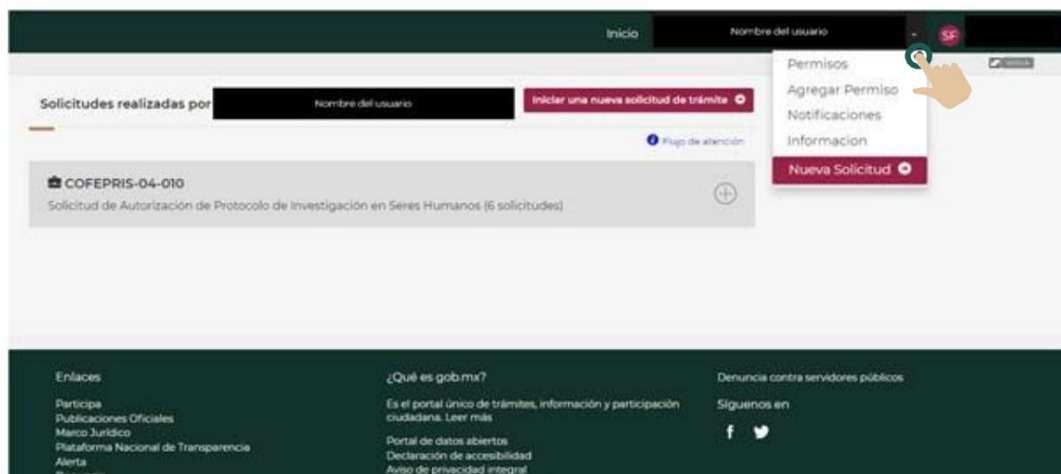


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Review previously assigned active and/or revoked roles and permissions

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

Click on the “**Permissions**” button to display the “**Operating Permissions Granted**” screen . In this section you can view the name of the users, role within the group, start and end dates of the assigned role and the status of the role.



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

Note: The “*Operating Permissions Granted*” 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.





Permisos Operativos Otorgados

USUARIO	ROL	RECURSO	INICIO	FIN	STATUS	REVOCAR
[Redacted]	Solicitante Titular Persona Fisica	GRUPO [Redacted]	18/Julio/2023 17:53:57	13/Febrero/2026 16:05:30	Activo	

Detalles del rol

- Acceso a los trámites e información del grupo solicitante en el sistema
- Editar solicitudes e información de grupo solicitante en el sistema
- Agregar permisos de acceso a personas en el grupo solicitante
- Revocar permisos otorgados a personas en el grupo solicitante
- Crear nuevas solicitudes
- Editar formulaciones de solicitudes
- Eliminar formulaciones de solicitudes
- Firmar y enviar solicitudes
- Declarar de un trámite que se encuentra en proceso de evaluación
- Editar la información que será enviada como respuesta a una prevención

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

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

4. Once you click **the control**, the information will change **“Active”** to **“All”** and you can 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 the legend **“REVOCED”** in the status section.

Permisos Operativos Otorgados

MARIA DE LOS ANGELES TOVAR VARGAS
TOVA901007EN?

Todos

USUARIO	ROL	RECURSO	INICIO	FIN	STATUS	REVOCAR
[Redacted]	Solicitante Titular Persona Fisica	GRUPO [Redacted]	18/Julio/2023 17:53:57	13/Febrero/2026 16:05:30	Activo	
[Redacted]	Editor	GRUPO [Redacted]	24/Octubre/2023 09:43	24/Octubre/2024 09:43	Activo	REVOCAR
[Redacted]	Editor	GRUPO [Redacted]	18/Julio/2023 17:19:34	18/Julio/2024 17:19:34	Revocado	

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

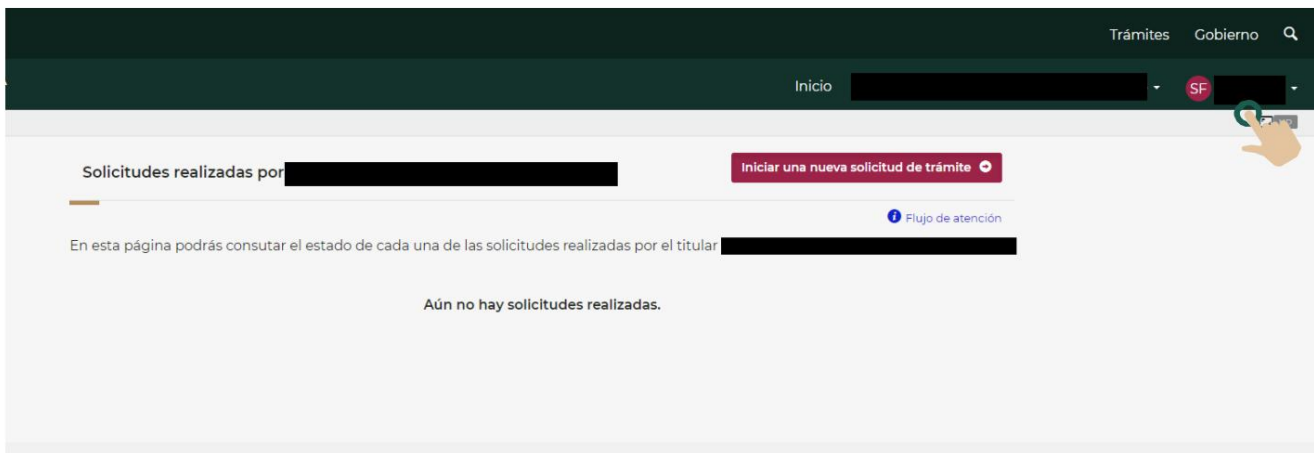




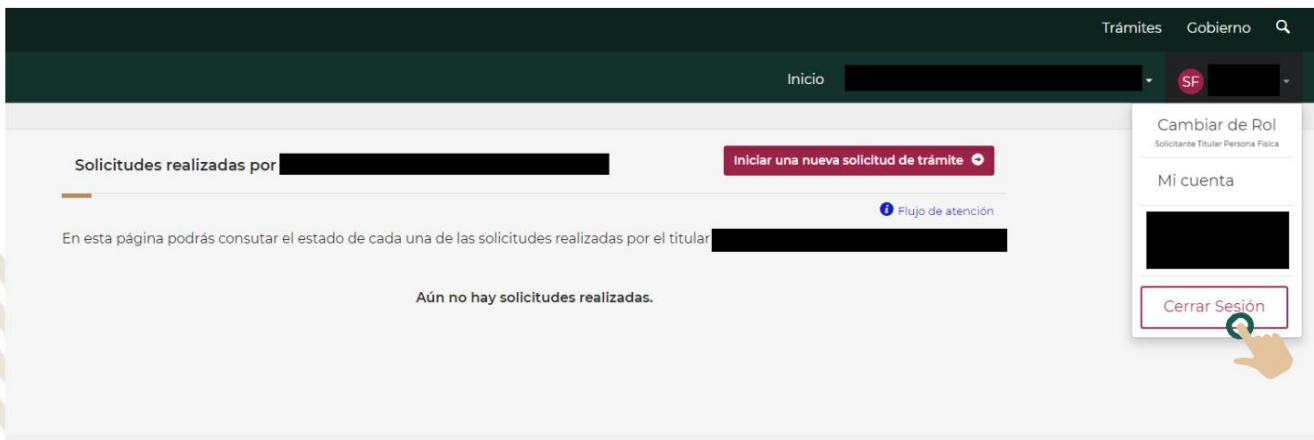
Register an email to receive notices from the platform

Automatically, the platform will register the email that is linked to the E.firma with which you make the deposit. It will be possible to have an email for each individual or legal entity that is part of the group. The email registered on the platform will be used to send the notices corresponding to the procedures carried out. You can change this email to the one you consider relevant by following these steps:

1. From the home screen, click on the name of the individual you are in the upper right corner, to display the corresponding menu.

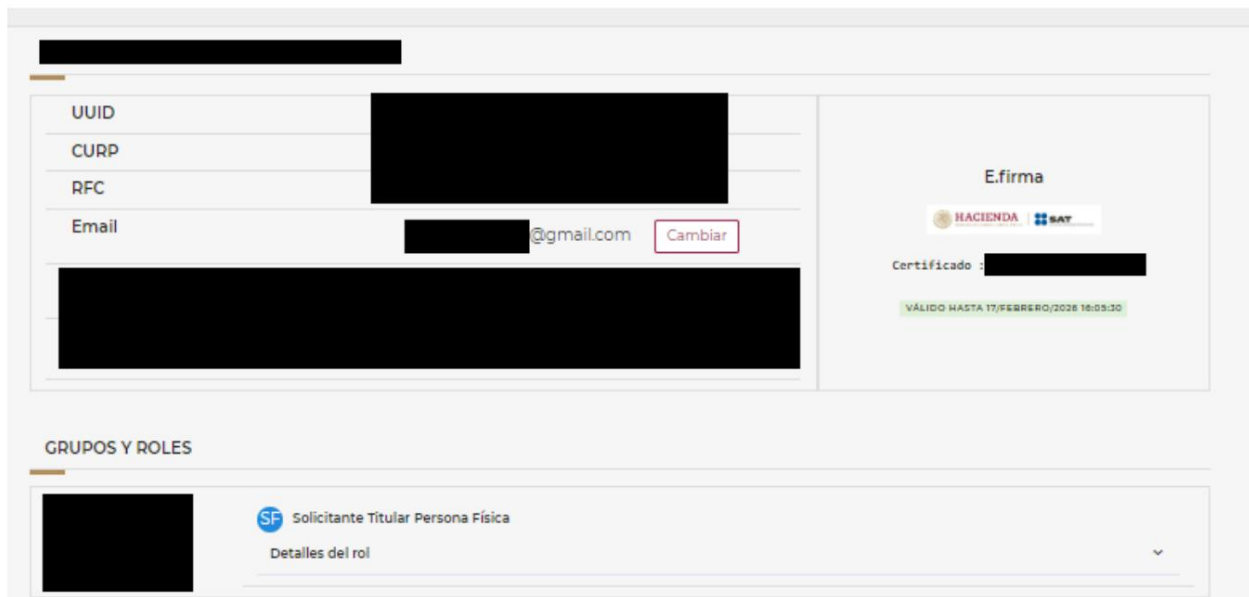


2. Once the corresponding menu is displayed, click on “My account”.

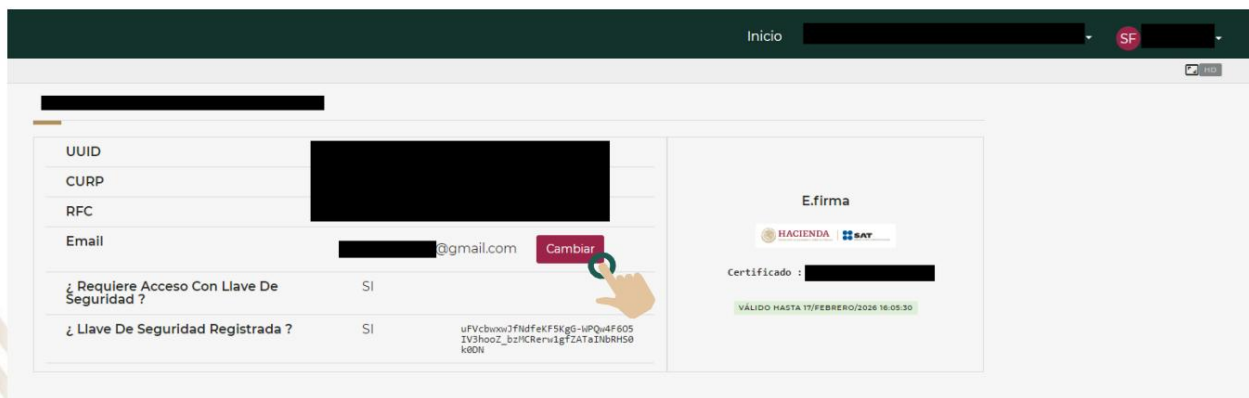




3. In this section you can view the data corresponding to the E.firma with which you entered the platform, such as CURP, RFC, email, validity date of the E.firma, the **groups** to which it belongs and the **roles** in which it is authorized in each of them.



4. Click the “**Change**” button located on the right side of the email address registered.





- Once you click, the text fields to capture the email will be displayed email in which you wish to receive the notices.

Inicio [redacted] SF [redacted]

UUID [redacted]
CURP [redacted]
RFC [redacted]
Email [redacted]

Email actual: [redacted]@gmail.com
Al cambiarla dirección de correo electrónico se cerrará su sesión actual y deberá iniciar sesión nuevamente.

Ingrese nuevo email [redacted]

Confirme nuevo email [redacted]

Ingrese un email válido

Confirmar Cancelar

E.firma
HACIENDA SAT
Certificado : [redacted]
VÁLIDO HASTA 17/FEBRERO/2026 16:05:30

- Capture the email to which the notices generated by the platform for your procedures will be sent. Confirm this email by entering it again in the text field below.

Inicio [redacted] SF [redacted]

UUID [redacted]
CURP [redacted]
RFC [redacted]
Email [redacted]

Email actual: [redacted]@gmail.com
Al cambiarla dirección de correo electrónico se cerrará su sesión actual y deberá iniciar sesión nuevamente.

[redacted]@gmail.com

[redacted]@gmail.com

Confirmar Cancelar

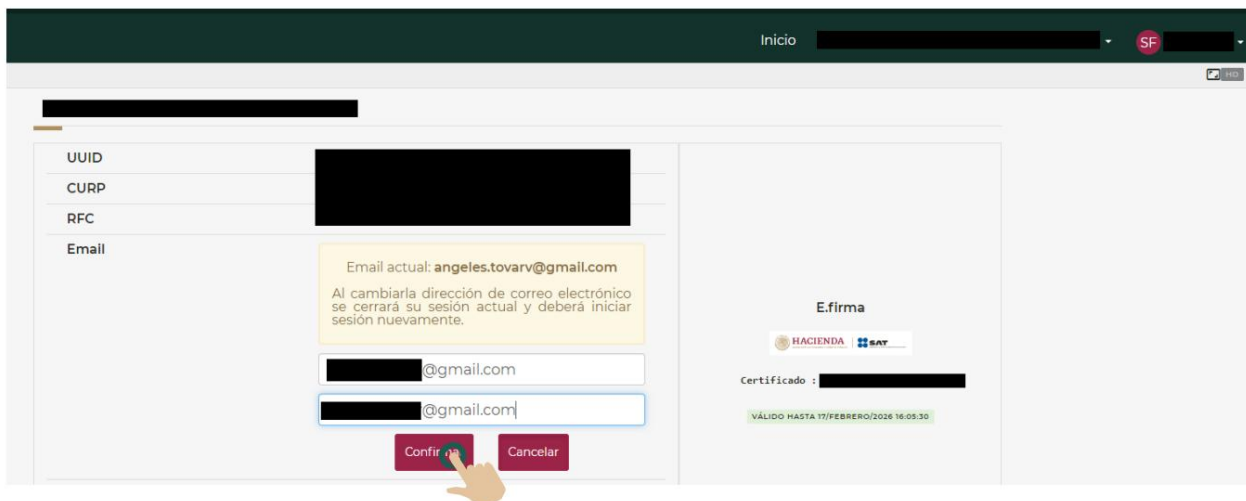
E.firma
HACIENDA SAT
Certificado : 00001000000511475311
VÁLIDO HASTA 17/FEBRERO/2026 16:05:30



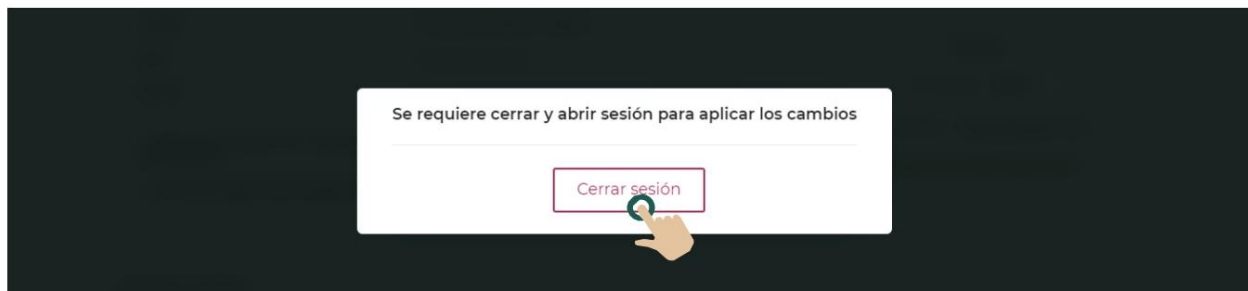


7. Once the email capture and confirmation has been completed, click the button **“Confirm”** is located just below the text fields.

Please note that changing your email address will log you out. and you will need to log in again.



8. Once you click the **“Confirm”** button, the platform will tell you that it is required log out and log in to apply the changes. Click **“Sign Out”** to finish.



From this moment you will receive the notices corresponding to your procedures at the registered email address. In case you want to confirm the change, you can enter again and follow the route described previously.





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Data classification and access to information

During the capture of information and uploading documents to the platform, you will be able to identify the information classification labels under each of the requirements:

ESCRITO LIBRE DE SOLICITUD:*

Adjuntar archivo WORD ↕

*Este campo no debe estar vacío

These labels will help you know the use, treatment and controls that the information from Cofepris.

Label	Classification	Description
PÚBLICO	Public	Information in the public domain, without any particular treatment
INTERNO	Internal	Information accessible to all Cofepris staff
RESTRINGIDO	Restricted	Information accessible only to specific Cofepris personnel as it is essential for the performance of their activities.

If during the use of the platform you have doubts regarding the **classification label**, Click on the label and the platform will display the necessary information.

PATROCINADOR:*

TRDS

Este campo no debe estar vacío

PÚBLICO

Puede ser accedido en cualquier ambito, incluida su divulgación pública.





Abbreviations

COFEPRIS: Federal Commission for the Protection against Health Risks

CURP: Unique Population Registry Code

RFC: Federal Taxpayer Registry

SAT: Tax Administration System

