May 19, 2025

DIGIPRiS: Online Regulation

Clinical Trials

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User Manual: Access to the platform, profiles and roles





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:

- ÿ Modality A: Medicines, Biological or Biotechnological
- ÿ Modality B: Medications (Bioequivalence Studies)
- ÿ 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)
- ÿ 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.







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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."

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	COFEPRIS DIGITAL
DFEPRIS DIGITAL es la plataf nitaria en México.	orma en linea diseñada para facilitar y agilizar el proceso de gestión de tramites relacionados con la regulación
rsona en una oficina de COR	uarios realizar trámites desde cualquier lugar con acceso a internet, eliminando la necesidad de presentarse en EPRIS, Los usuarios pueden realizar diferentes tipos de trámites, como la solicitud de autorización de protocolos s autorizadas de errotocolos, entre etros.
na vez que se presenta un t visión y aprobación. Los usu alquier actualización o camb	rámite en linea, el sistema automáticamente lo enruta al departamento correspondiente de COFEPRIS para su arios pueden monitorear el estado de sus trámites en linea y recibir notificaciones por correo electrónico sobre o en su estado.
digitalización refrenda nues ls. De esta forma, se optimiza	tro compromiso como agencia de regulación sanitaria innovadora, que protege la salud de las personas en nuestro y garantiza la conflanza, certeza y seguridad en nuestros trámites y servicios
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3. In the next window, select "Access with SAT e-signature."







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

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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.

5. Next, click the "Upload private key .key" button and select the file corresponding (private key .key).

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6. Next, click the "Upload private key .key" button and select the file corresponding (private key .key).

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- 7. The platform will then display the user's "Home" screen. On this screen
 - ÿ Verify whether access was granted in the name of a natural person ("SF" natural person applicant) or a legal entity ("SM" legal entity applicant).
 - ÿ Assign roles and permissions.
 - ÿ Access the menu to review who has permission to access this account, the assigned roles, and the details of each role.
 - ÿ Revoke previously assigned roles. Access the notifications menu.
 - ÿ Access the information menu. Make a new request.
 - ÿ Review previously completed applications and procedures.



You will be able to:





Log out

- **1.** From the "Start" menu, click on the organization name to display the menu corresponding.
- 2. To finish, click "Log out."

DIGIPRIS: REGULACIÓN EN LÍNEA 9811012 - 94		nicio 🗨 🔶	5
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	COFEPRIS-04-010 Solicitud de Autorización de Protocolo de Investigación en Seres Humanc	os. (4 solicitudes)	
	COFEPRIS-09-012 Solicitud de Modificación o Enmienda a la Autorización de Protocolo de Ir	nvestigación. (10 solicitudes)	

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:

- ÿ **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.
- ÿ 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.







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:

- ÿ 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.
- ÿ Editor: A natural person authorized by the applicant to complete or delete applications, view the status of procedures, read resolutions, and download resolution letters.
- ÿ 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:

- ÿ Legal person applicant: the authorizer (natural person, legal representative of the person) moral before the SAT), the individuals authorized as editors and viewers
- ÿ **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.







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.

	Inicio	Nombre del usuario
olicitudes realizadas por	Nombre del usuario	Anrepar Permiso
• P	O rup d	extension Information
COFEPRIS-04-010		Nueva Solicitud •
Solicitud de Autorización de Protocolo de Inve	sogación en seres Humanos (e solicitudes)	
Enlaces	sugación en seres Humanos (e solicitudes) ¿Qué es gob.ms?	Denuncia contra servidores públicos

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

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Agregai Fermisis			CHEM
	Carge el certificado de elfirma del usuario al que desea agregar permisos en el grupo		
	Certificado de E.firma		
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3. 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.

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4. 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.

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	Editor Visor				

5. 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.









6. Then, click on the "Add access permission" button.

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7. The system will display a box where you can confirm or cancel the role assignment to the individual. If the information displayed is correct, click the "Confirm" button.

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	El usuario tendra las siguientes facultades:
	¿ Esta seguro que desea agregar permisos de acceso como EDITOR al usuario por un periodo de 1 ANO ?





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.

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9. To return to the main section, click the "Home" button.







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.

Solicitudes realizadas por	Inicio Nombre del usuano	Notificaciones
COFEPRIS-04-010 Solicitud de Autorización de Protocolo de Im	Page a vestigación en Seres Humanos (6 solicitudes)	de atenden Informacion Nuevo Solicitud
Enlaces	¿Qué es gob.mx?	Denuncia contra servidores públicos

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.

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3. 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.

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

¿ Esta seguro de que desea revocar el permiso de Editor a P REVOCAR CANCELAR	

5. 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.



6. To continue with your procedures, click the "Start" button.







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.

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COFEPRIS-04-010			0	Nueva Solicitud 💿	
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Enlaces Participa Publicaciones Oficiales Marco Jurístico	¿Qué es gob.mx? Es el portal único de trámiter ciudadana. Leer más	, información y participación	Denunci Siguenc	sen	

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.





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.

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5. To continue with your procedures, click the "Start" button.

