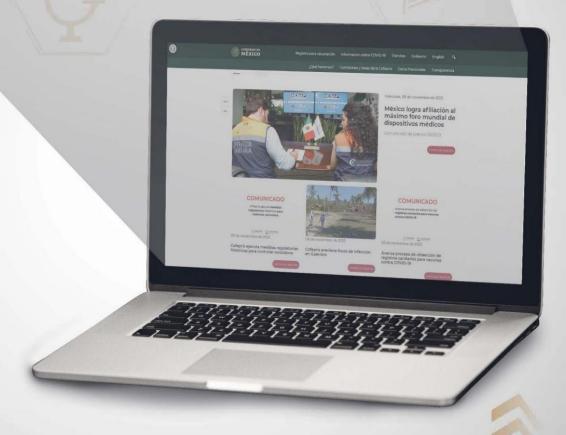
DIGIPRIS: Research and Clinical Trials



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.

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The steps for using the platform are listed below.



Content:

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Access to the system and creation of the profile	3
Logout	7
Roles and permissions	7
Assign roles and permissions to individuals	9
Revoke roles and permissions from natural persons	13
Review previously assigned active and/or revoked roles and permissions15	
Register an email to receive notices from the platform17	
Classification of data and access to information	21
Abbreviations	



Access to the system and profile creation

 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

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.

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	DIGIPRIS: Regulación en Línea		
	DICIPRIS: Regulación en Línea es la plataforma en línea diseñada para facilitar y agilizar el proceso de gestión de trámites relacionados con la regulación sanitaria en México.		
	Este sistema permite a los usuarios realizar trámites desde cualquier lugar con acceso a internet, eliminando la necesidad de presentarse en persona en una oficina de COFEPRIS. Los usuarios pueden realizar diferentes tipos de trámites, como la solicitud de autorización de protocolos clinicos, enmiendas a solicitudes autorizadas de protocolos, entre otros,		
	Una vez que se presenta un trámite en línea, el sistema automáticamente lo enruita al departamento correspondiente de COFEPRIS para su revisión y aprobación. Los usuarios pueden monitorear el estado de sus trámites en línea y recibir notificaciones por correo electrónico sobre cualquier actualización o cambio en su estado.		
	La digitalización refrenda nuestro compromiso como agencia de regulación sanitaria innovadora, que protege la salud de las personas en nuestro país. De esta forma, se optimiza y garantiza la confianza, certeza y seguridad en nuestros trámites y servicios		
	Ingresar a DICIPRIS: Regulación en Línea		
	DICIPRIS: Regulación en Linea. TÉRMINOS DE USO		
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	Aviso de privacidad integral de DIGIPRIS: Regulación en Linea		
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	Mostrar el aviso completo:		

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.

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



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00 0	Acceso con E.firma del SAT	
		Acceso con llave de seguridad. 🕈
	Aviso de privacidad integral de COFEPRIS DIGITAL	

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

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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.

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

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

ancient Bar	Acceso con Firma Electrónica del SAT	
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JOSE RODRIGO GARCIA DAPATA con 1 Ses Olgitales COMEMPIS el múérico	Cadess Griginal CADP GLI285607309(LDDGM) y certificano ne frires No. 305080801303003030 oles, 25 de octubre de 2013, 17(47:10 097-6 com No. 68 solicitud el064a7e	UNMS11121001350005500 salicita sciesa el Siatema de Trámi -+176-4657-800e-37/brizi3edo

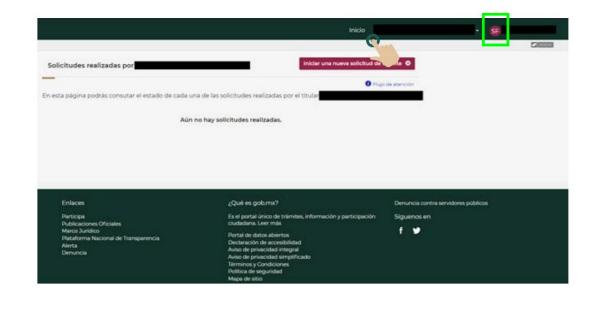
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7. Subsequently, the platform will display the "Home" screen of the user. On this screen you can:

- 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".

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COFEPRIS-04-010 Solicitud de Autorización de Protocolo de Investigación en Seres Humanos (6 solicitudes)	Cerrar Sesiór

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".







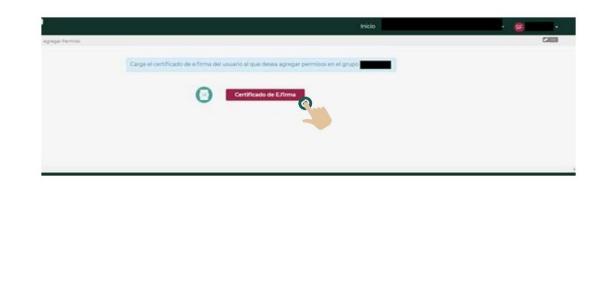


Assign roles and permissions to individuals

 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.

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iolicitudes realizadas por	Nombre del usuario	Acrecar Dermiss	
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2. Click on the "**E.Signature Certificate**" button and upload the file certificate (.cer) of the natural person you want to add.





3. 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.**

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4. 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.



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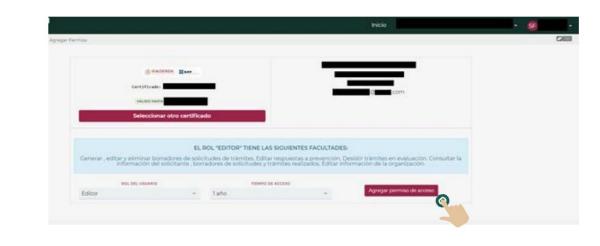


5. Once the role is selected, you can view a summary of the permissions granted by this role. Next to the "Access Role", select the "Access Time" that you want to assign to this individual within the group.

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

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	Alerta	10 años	14	

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







7. 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.

El usuario tendra las siguientes facultades: Generar y editar y elisinar borradores de solicitudes de trásites. Editar responstas a provención. Cessitir trásites en evaluación. Consoltar la información del solicitante ; borradores de solicitudes y trásites realizados. Editar información de la organización. Concelar Confirmar	¿ Esta ser	suro que desea agregar permisos de acceso como EDITOR al usuario
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		Cancelar Confirmar

8. 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.

				Inici	-		-	 - 6
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9. To return to the main section, click the **"Home" button.**







Revoke roles and permissions from individuals

 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.

	Inicia	Nombre del usuario	
olicitudes realizadas por	Nombre del usuario	Antenar Dermiso	
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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.

							CHE
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3. 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.

				Inicio			8	-
	Permisos O	perativos	Otorgad	os				
					Activos			
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	Solicitante Titular Persona Fricca Detalles del rol v	Reuno	* 75%.499/2023 777327	109w0rw102026 16:05:50	Active			
	() Editor Detalles dal rol v	JORUPOI	100000002003 10040	24/0ctubre/2004 1311.49	HITHE REVOCAR)		

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



5. 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.



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





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Review previously assigned active and/or revoked roles and permissions

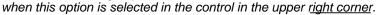
1. From the "Home" screen, click on the upper right section where your "Username" appears to display the corresponding menu.

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.

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olicitudes realizadas por	Nombre del usuario	Iniciar una nueva solicitud de	etrámite O	Agregar Permis		
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COFEPRIS-04-010			Ð	Nueva Solicitur	10	
Solicitud de Autorización de Protocolo	de Investigación en Seres Humanos I6 s	olicitudes)	0			
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	¿Qué es gobrmx?	olicitudes) imites, intornación y participación	Denund		cos	

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,







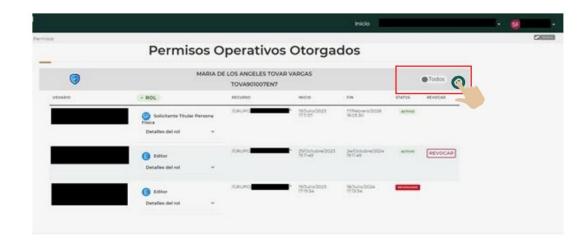


3. To hide this information, click again on "Role Detail"

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.



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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.

	Trámites	Gobierno	q
Inicio	÷	SF	÷
		Ct.	34.5
Solicitudes realizadas por			
Flujo de atención			
En esta página podrás consutar el estado de cada una de las solicitudes realizadas por el titular			
Aún no hay solicitudes realizadas.			

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

		Trámites Gobierno
	Inicio	• SF
		Cambiar de P Solicitante Titular Persona
Solicitudes realizadas por	Iniciar una nueva solicitud de trámite 오	Mi cuenta
_	Elujo de atención	2 2 2
En esta página podrás consutar el estado de cada una de las solicitudes realizadas por	el titular	
Aún no hay solicitudes realizadas		Cerrar Se <u>si</u> ó





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

RFC		E.firma
imail	@gmail.com Cambiar	HACIENDA SAT
		Certificado :
		VÁLIDO HASTA 17/FEBRERO/2028 16:05:30
IPOS Y ROLES		

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

			Inicio	- SF
UUID				
CURP				
RFC			E.firma	
Email		@gmail.com Cambiar	HACIENDA SAT	
¿ Requiere Acceso Con Llave De Seguridad ?	SI		Certificado : VÁLIDO HASTA 17/FEBRERO/2026 16:05:30	
¿ Llave De Seguridad Registrada ?	SI	uFVcbwxwJfNdfeKF5KgG-WPQw4F605 IV3hooZ_bzMCRerw1gfZATaINbRH50 k0DN		

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

		Inicio	• <u>SF</u> •
UUID			
RFC			
Email	Email actual: © @gmail.com Al cambiarla dirección de correo electrónico se cerrará su sesión actual y deberá iniciar sesión nuevamente.	E.firma	
	Ingrese nuevo email	Certificado :	
	Confirme nuevo email Ingrese un email válido Confirmar Cancelar	VÁLIDO HASTA 17/FEBRERO/2026 16:05:30	

6. 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.

UUID CURP RFC Email Confirmar Confirmar Confirmar Confirmar Confirmar			Inicio	· <u>SF</u>
CURP RFC Email Email Al cambiarla dirección de correo electrónicos se certará su sesión actual y deberá iniciar sesión nuevamente. @gmail.com @gmail.com Certificado : 00001000000511475311 @gmail.com	_			
RFC Email Email actual: Ogmail.com Al cambiarla dirección de correo electrónico se certará su sesión actual y deberá iniciár sesión nuevamente. E.firma Ogmail.com @ HACILINDA #ser Ogmail.com Certificado : 00001000000511475311 Ogmail.com VALIDO HASTA 17/FEBRERO/2026 16:0530	UUID			
Email Email actual: Comparing a dirección de correo electrónico se certar a su sesión nuevamente. Comparing amail.com Certificado : 00001000000511475311 Comparing amail.com Valido HASTA 17/2EBERD/2036 16.0330	CURP			
Email actual: @gmail.com Al cambiaria dirección de correo electrónico se cerrará su sesión nuevamente. E.firma @gmail.com @ HACIENDA @gmail.com Certificado : 00001000000511475311 @gmail.com VALIDO HASTA 17/FEBRERO/2018 16.03.30	RFC			
	Email	Al cambiarla dirección de correo electrónico se cerrará su sesión actual y deberá iniciar @gmail.com	HACIENDA HACIENDA Certificado : 00001000000511475311	



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.

		Inicio	• SF
UUID			
CURP			
RFC			
Email	Email actual: angeles.tovarv@gmail.com Al cambiarla dirección de correo electrónico se cerrará su sesión actual y deberá iniciar sesión nuevamente.	E.firma	
	@gmail.com	Certificado :	
	@gmail.com	VÁLIDO HASTA 17/FEBRERO/2026 16:05:30	
	Confir Cancelar		

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.

Se requiere cerrar y abrir sesión para aplicar los cambios	
Cerrar sesión	

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.



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:



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
	Internal	Information accessible to all Cofepris staff
	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.

	A
Este campo no debe estar vacio	
Puede ser accedido en cualquier ambito, incluida su divulgación pública.	



Abbreviations

COFEPRIS: Federal Commission for the Protection against Health Risks

DIGIPRIS

CURP: Unique Population Registry Code

RFC: Federal Taxpayer Registry

SAT: Tax Administration System



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