DIGIPRIS: Investigación y Ensayos Clínicos

NUEVOS PROTOCOLOS Y ENMIENDAS

MEXICO

- COFEPRIS-04-010 Solicitud de Autorización de Protocolo de Investigación en Seres Humanos, en todas sus modalidades
- COFEPRIS-09-012 Solicitud de Modificación o Enmienda a la Autorización de Protocolo de Investigación.



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:

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• **COFEPRIS-04-010** Request for Authorization of Research Protocol on 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.

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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 digital entry of the aforementioned procedures are listed below.



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Data classification and access to information

Remember that 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 will have by 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 while using the platform you have questions regarding the **classification label**, click on it and the platform will display the necessary information.

Public data will be part of the information that will be disseminated in RNEC once your request is authorized, so we suggest not sharing addresses, emails or personal contact telephone numbers. These data also have the TRDS label in reference to the fact that they are requested in accordance with that recommended by the World Health Organization (WHO).



General information about applications

Before starting an application consider the following:

- Any applicant, natural person, legal entity or natural person with The authorizer or editor role may initiate and modify the data of a "Request".
- In the upper portion of the window you will be able to see the following panel of the status of the procedure during the entire process of capturing data and uploading documents of the "Request".

🚯 Solicitud 🍪 Evaluación	- O Verificación	- 😰 Firma	🔞 Resolución
Cuando su solicitud este completa y guardada, de Autorizador si el solicitante Titular es una Persona N	be ser firmada por el rol de Solicitan Moral.	te Titular Persona Física o r	por el Rol de

- Whenever you want, you can save a request to continue editing later. Only changes that have been saved before ending the session will be retained, so it is recommended to "SAVE" regularly.
- The data captured and the documents uploaded will be available within the "**Request**" for reading and/or downloading by all individuals who are part of the group.
- The information captured and the digitized documentation will remain in the system for 90 calendar days as part of the "**Request**".

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To each "Request" the platform assigns an alphanumeric identification string or "Request Number" which, for security reasons, will not be a consecutive sequence.



- The "**Request**" must be signed and sent, using the current and active signature of the "**Applicant**", to be considered a "**Procedure**". At this time the platform will assign a "**Procedure Number**" that will be consecutive according to the homoclave, modality, date and time of signing.
- Once the "**Request**" is considered a "**Procedure**", the information and documents will continue to be available for consultation by the user, but cannot be modified. You can identify it in the process status panel as "**Evaluation**":

🚯 Solicitud 😂 Evaluación	O Verificación	– 😰 Firma ——— 🛞 Resolución
Fecha de Ingreso 24/Octubre/2023 00:29:03	Solicitud Descargar	Acuse de Recepción

• Throughout the sections that make up the "**Application**" you will be able to view the progress in the boxes on the right side: you will see a "check" for completed sections and "warning triangles" where information is missing.

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D DEPRESENTANTE LEGAL	× .	PERSONA FISICA O MORAL	
DOMICILIO FISCAL DEL PROPIETARIO	~	NOMBRE O RAZÓN SOCIAL:*	
DATOS DEL ESTABLECIMIENTO DEL TITULAR		Nombre del solicitante	
DATOS DEL ESTABLECIMIENTI DEL TITULAR		B PÓBLICO	
RESPONSABLE SANITARIO		PRIMER APELLIDO:	SEGUNDO APELLIDO:
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To navigate between the different sections of the application, click on the boxes on the right side of the screen, which indicate the name of the corresponding section and the titles of the forms that make up the set of requirements.

		Inicio	• 😆
OCLAVE > COFEPRIS-04-010 > M	ODALIDAD >	A > SOUCITUD > F2508/R5-5801-8089-we95-588544aa8e83	200
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BERSONA FISICA O MORAL	2		
BEPRESENTANTE LEGAL		COMPROBANTE DE PROD Y CABTA DE SOUDITUD	
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INFORMACIÓN SOBRE EL			

Actions allowed for a request or procedure

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As already mentioned in the "**Application**" process, it is a stage prior to the evaluation of the "**Procedure**". Due to this, the actions allowed and the documents available from the platform vary according to the stage of the "**application**" or "**processing**". For greater clarity we provide the following information tables:

		Application	
Stage	Edition	Consultation and download of documents	Other permitted actions
AII	Yeah	Yeah	Delete request Sign and Send



	Procedure										
Stage	Edition	Consultation and download of documents	Other permitted actions								
initial evaluation	No	Yeah	Download Application Form Download Acknowledgment of Receipt Desist process								
Verification or Signature	No	Yeah	Download Application Form Download Acknowledgment of Receipt Desist process								
Resolution (authorized or discarded)	No	Yeah	Download Application Form Download Acknowledgment of Receipt Download resolution letter								
Resolution in case of Prevention	Yeah*	Yeah	Download Application Form Download Acknowledgment of Receipt Download resolution letter Desist process								

In the case of procedures in which the meaning of the resolution is prevention, you will be able to edit only the information and text fields marked as prevented. For more information, see the title **Respond to prevention**.

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Edit or delete a previously saved request

- 1. From the **"Home"** screen you can view all the requests made by the **group** and their status organized by Homoclave.
- 2.

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To locate a specific request, click the "(+)" button located in the corresponding homokey row.

Inicio	•	8	-
Solicitudes realizadas por Index solicitud de triemba •			
Plujo de atención			
COFEPRIS-04-010 Solicitud de Autorización de Protocolo de Investigación en Seres Humanos (8 solicitudes)			
COFEPRIS-09-012 Solicitud de Modificacion o Enmienda a la Autorización de Protocolo de Investigación (3 solicitudes)			

3. By clicking you will be able to view all the requests and their status, organized by modality. In this section you can see the "Application Number", applicant, date of last saved modification and stage.

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									-
Se Modalidad A: Medicamentos, Biológio	os o Biotecnológico	s.							
Solicitud	No. Trámite			🏴 Etapa					
Solicitud	reg. (ramine	Solicitud	Evaluación	Verificación	Firma	Resolución			
F2506595-5585-8089-8595-586544AA8593 Selicitante 260cm/sel22316/0103		0					Consultar >		
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8854AA55-2A81-825C-8409-FA853E38A312 Solicitume	23330041040000 24/0:54/m 2022 00:29-05			0			Consultar >		



4. To edit, review the data or download the documents of an application, click on the "**Consult**" button in the corresponding row.

🖀 Modalidad A: Medicamentos, Biológ	icos o Biotecnológico	4							
				P Etapa					
Solicitud	No. Trámite	Solicitud	Evaluación	Verificación	Firma	Resolución			
F2506485-5585-8089-8295-586544AA8293 Sellejtante 2600suleve202211-01-03		o					Consultar		
80482046-81C3-F528-C546-4878A528588 Solicitaria	233300010400004 2710mulow20231310.34		0				Consultar >		
8054AA55F-2A83-825C-8409-FA853K38A352 Solicitante	23330041040002 24/0/54/4/2023-00/29/03			0			Consultar >		

Note: In the case of a "**Request**", after pressing the "**Consult**" button, the editing window will be displayed.

To properly enter information and documents, we recommend that you review the following titles of the manual:

- Sections that make up an Application
- Capture information in a Request
- Upload files in a Request
- 5. Remember to always save the information before leaving the procedure, or signing and sending it. For more information on how to save the information, see the title Saving changes made to a Request within this manual.

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In case you decide to delete the request:

1. At the bottom portion of the request editing window, you will find the **"DELETE REQUEST" button.** Click the button.

Inicio	•	9	•
HOMOCLAVE & COFERIS-04-010 & MODALIDAD & D & SOLICITUD & SIN44MIN-BRITORSI-4625-STREEMINSORES			
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2. The platform will display a screen to confirm the action. Click the "YES, DELETE" button to confirm the deletion.

Note: Please note that deleting a request cannot be undone and you will lose the data and/ or documents associated with this request.



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3. Click "Home" to return to the main section.



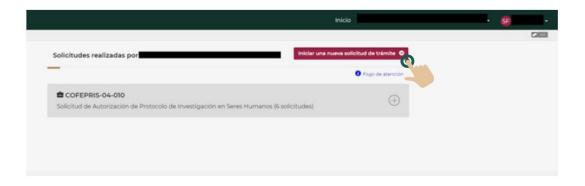
Request for Authorization of Research Protocol on Human Beings (COFEPRIS-04-010)

The following section will indicate the general procedure for requesting Authorization of a **Research Protocol** in human beings, amendments or modifications to it. For more information about each modality, the variations in requirements and their legal bases, it is suggested to consult the **specific guides**. The following example will be carried out with the Authorization of Research Protocol on Human Beings (COFEPRIS-04-010).

To start the request:

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1. Once you have entered the platform, from the "Home" menu, click on the "Start a new processing request" button.



2. A window will appear to select the procedure you wish to carry out. Click on the "(+)" button located on the side of the COFEPRIS-04-010 Homoclave to view the different modalities of the procedure.

HOMOCLAVE	Inick	0	• 5	-
	Selecciona una Homoclave y modalidad para iniciar una nueva	solicitud		
	COFEPRIS-04-010 Solicitud de Autorización de Protocolo de Investigación en Seres Humanos	0		
	COFEPRIS-09-012 Solicitud de Modificación o Enmienda a la Autorización de Protocolo de Investigación	÷		



3. Identify the relevant modality for the request you wish to make and click on the "**Continue**" button that appears at the far right of the modality.



4. You will be directed to the section where the data of the procedure and the formats that will be required are briefly indicated. If you agree and wish to continue, click on the **"START A COFEPRIS-04-010 REQUEST" button.**

COFEPRIS Solicitud de	Autorización	de Protocolo de Investigación en Seres Humanos		
Modalidad / Versión 20230	A : Medicament	os, Biológicos o Biotecnológicos.		
_				
		er la autorización para iniciar un estudio, protocolo o ensayo clínico en seres humanos, para probar un		
medicamento	, biológico o bi	otecnológico		
Homoclave	Modalidad	Formatos requeridos		
Homoclave COFEPRIS- 04-010	Modalidad	Formatos requeridos Datos del Propietario - Datos del Establecimiento del Titular - Comprobante de Pago y Carta de Solicitud - Patrocinador - Documentos de la Investigación - Producto de Investigación - Centro de Investigación - Centro de Atención a Urgencias - Investigación - Comité de Elics en Investigación - Comité de Bioseguridad - Importador - Información Complementaria - Otros Documentos -		
COFEPRIS-		Datos del Propietario - Datos del Establecimiento del Titular - Comprobante de Pago y Carta de Solicitud - Patrocinador - Documentos de la Investigación - Producto de Investigación - Centro de Investigación - Centro de Azención a Urgencias - Investigación Principal - Equipo de Investigación - Comite de Elica en Investigación - Comité de Investigación - Centro de elica en Investigación -		

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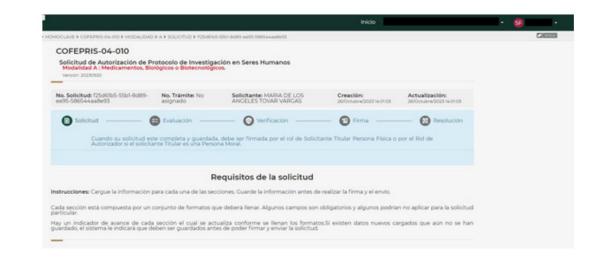


5. While the request is being generated, the platform will display a pop-up window. Please wait.



- 6. Subsequently, a window will appear where you can:
 - View the status of the request.
 - View general application data: application number, process number (not yet assigned), applicant name, creation and update date.
 - Review the Instructions for filling out the application.
 - Enter the information and documents required for the application.

To begin capturing information and uploading documents go to the lower region of the window.



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To properly enter information and documents, we recommend that you review the following titles of the manual:

- Sections that make up an Application
- Capture information in a Request
- Upload files in a Request

Note: You should always save information before signing and shipping. For more information on how to save the information, see the title **Saving changes made to a Request**

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within this manual.





Sections that make up an Application

With slight variations, each of the requests for the **COFEPRIS-04-010** homoclave It is made up of the following sections:

- **Owner data:** form with the applicant's information, the information provided in this section will be used for the electronic capture of the "Authorizations, Certificates and Visits Form, FF-COFEPRIS-01".
- Data from the owner establishment: this information is very important, since it will be used for the electronic capture of the "Authorizations, Certificates and Visits Form, FF-COFEPRIS-01".
- Proof of payment and request letter.
- Sponsor.
- **Research documents:** this section requests general research data and documents (research protocol, study schedule, researcher manual and informed consent).
- Research product.
- Research Center.
- Emergency care center.
- Principal investigator.
- Research team.
- Research ethics committee.
- Investigation committee.
- Biosafety committee.
- Importer.
- **Complementary information:** this section requests general data about the research and also others that are necessary to contact the people who could provide information about the research.



 Other documents: if you have other documents that you consider important for the evaluation of your application that have not been required in other sections, you can enter them here (materials for research subjects, addendums to the protocol, annexes, etc.). These documents will not be authorized, only "acknowledgment of receipt" will be made. It is allowed to add up to 15 documents.

In the case of amendments and modifications (COFEPRIS-09-012), the requirements follow the same order, however, only the sections in which data or documents need to be updated according to each type of procedure are requested. For protocols that were updated prior to the start of the digital platform, it will be necessary to capture an additional "Complementary Information" form. This will allow information about the protocol to be published in the new version of the RNEC.

For more information about each modality, the variations in requirements and their legal bases, it is suggested to consult the **specific guides.**





Classification of Amendments and Modifications within the platform

For the purposes of order in the attention of the procedures and clarity within the requirements, on the platform the **Amendments and Modifications** are classified according to the following table. To review the details of each one and the specific requirements, it is suggested that you consult the **corresponding guide**.

Modality (Internal)	Type of Amendment or Modification
то.	Amendment to base documents: research protocol, researcher manual or informed consent/assent
b.	Inclusion of research centers
с.	Changes to the research center: address and/or name
d.	Principal Investigator Changes
AND.	Change or integration to the research team
F.	Changes to the emergency center: address and/or name
g.	Changes to the Evaluation Committees: Research Ethics Committee, Research Committee or Biosafety Committee
Н.	Security amendment
YO.	Changes to the owner: address and/or name
J.	Sponsor changes: address and/or name
К.	Change or addition of importer
17 ^{L.}	Other modifications



Capture information in a Request

Before starting, take the following into account:

- Each section is made up of a set of forms that you must fill out. Some fields are required and some may not apply to the particular "**Request**".
- Each form will tell you whether the data is required (red filled boxes, warning triangle, and *"This field must not be empty"*) or optional (white filled boxes).

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- There is a progress indicator for each section which is updated as the forms are filled out. If any requirement does not apply to your application, it is not necessary to complete it to advance.
- If there is new data uploaded that has not yet been saved, the system will prompt you that it must be saved before you can sign and submit the application.
- Throughout the application, you can find some "*tips*" that will give you greater clarity about the different requirements, just click on the information button ("i") located on the side of the requirement.





Upload files in a Request

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- For this title the same considerations apply as in Capturing information in a Request_
- For the format of the documents, you will be indicated the format they must have (.pdf or word), as indicated in the following images.

Example PDF document (.pdf):

		Inicio	· 💡 · ·
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	LICENCIA SANITARIA.pdf		
	Adjuntar archivo PDF 1		

Example WORD file (.doc or .doxc):

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Note: Take into account that documents with passwords, extensions, macros or formats other than those indicated cannot be entered.

- To upload files, click the "Attach PDF file" button or "Attach WORD file" as appropriate to each requirement and select the document(s) you want to add and click the "Open" button in the pop-up window.
 - You can add documents one by one or select multiple documents at the same time.



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III (to mit)	Este equipo	Consentimiento informado adultos	26/10/2023 0458 p.m.	Chrome HTML Do.,	184 KB	
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	🐠 Red	Consentimiento informado en padres o L	26/75/2023 04:59 p.m.	Chrome HTML Do	164 KB	
	Nombre	"Consentimiento informado en padres o tutores" "Asent	imiento informado" "Con	Documento Adobe /	Acrobat ~ Cancelar	

2. Once you click on the "**Open**" button, a "**File Upload**" pop-up window will be displayed where you must confirm the upload of the selected file(s) by clicking on the "**Upload**" button.

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X Descartar Cargar		

Note: In case you do not want to upload any of the previously selected documents, click on the red button (**Trash Can with X**) to remove that document from those that will be uploaded. It is also possible to select "Discard" to cancel the upload of all files visible in the "**File Upload**" **pop-up window**.





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Nombre de archive: Consentimiento informado adultos.pdf (#869.985.996) (#10.986.996.996) (#10.986.996.996.996.996.996.996.996.996.997.995.996.996.996.996.996.996.996.996.996	
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3. When you begin uploading the files, you can view its progress in the lower right corner of each document.

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4. When the files are uploaded you will be directed to the "**Application**" section in which the documents were uploaded. If necessary, you can download the documents to view them by clicking on the green rounded box where the weight of the file is indicated.





5. Afterwards, you can continue filling out the different forms, uploading documents or proceed to save the fields. To know how to save the changes, go to the section on Saving the changes made in the "Request for Authorization of Research Protocol in Human Beings" or the "Request for Modification or Amendment of Research Protocol" of this manual.

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Save changes made to a Request

To save changes made to a "**Request**", go to the bottom of the page within.

1. On this screen you will be able to see the different elements that you have modified and are available to save. To complete the saving process click on the **"SAVE" button.**

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Note: You should always **"SAVE"** changes to information and documents before signing and submitting.

It is very important to verify that the information presented in the forms is correct, since some sections will be part of the resolution letter issued by the Health Authorization Commission (such as name of the titular establishment, address of the establishment, name of the sponsor, scientific title of the protocol, etc). For more information, consult the guide corresponding to each homoclave and modality.

Remember that some of this data will be part of the information that will be published in RNEC once your application is authorized (such as public protocol title, inclusion criteria, exclusion criteria). For more information, consult the specific section of this manual Data classification and access to information.

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Sign and send an application or Generate a procedure

To finalize your request, it must be sent and signed, so you must follow the following steps:

- 1. In this section, capture the requested information, upload the documents and save the changes made to your "Application". For more information consult these manual titles:
 - General information about applications
 - Capture information in a Request
 - <u>Upload files in a Request</u>
 - Save changes made to a Request
- 2. Go to the bottom section of the application window and click the "SIGN AND SUBMIT" button.

	Inicio	- 8
IOMOCLAVE > COFERRIS-04-010 > MODALIDAD > A > SOLICITUD > F25	06/05-5501-8089-ee95-580564aa8e93	CARDIN
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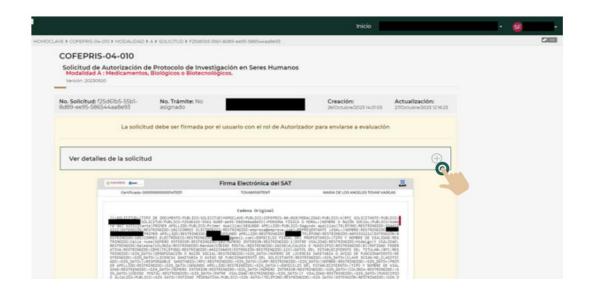
3. The platform will display a window where you can view the application number, applicant, creation date and update date.

If necessary, you can review the details of the request by clicking on the "(+)" button at the far right of the "View request details" box.

DIGIPRIS

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To hide the information click on the "(-)" button at the far right of the "View request details" box.

			Inicio		· 😆
IVE > COFEPRIS-04-010 > MODALIDAD	A > SOUCITUD > F25d6/b5-	-5501-0-009-ee95-500544aade93			
COFEPRIS-04-010					
Solicitud de Autorización o Modalidad A : Medicamento Versión 20230920	le Protocolo de Inves , Biológicos o Biotecno	stigación en Seres Humanos ológicos			
No. Solicitud: f25d61b5-55b1- 8d89-ee95-586544aa8e93	No. Trámite: No asignado		Creación: 26/0ctubre/2023 14-01-05	Actualización: 23/0ctubre/2023/12/16/23	
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- 4. To sign the request, go to the bottom portion of the window and click on the **"Upload private key .key"** button and upload the corresponding file.
- 5. Once the platform verifies the validity of your electronic key, a text field will open in which you must enter the password for your private key. When finished, click "**Sign.**"

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Desist or consult a procedure

From the "Home" screen you can view all the requests made by the group and their status organized by Homoclave.

1. To locate a specific request, click the "(+)" button located in the corresponding homokey row.

Inicio		•	9	
Solicitudes realizadas por tolciar una nueva solicitud o	se trámite O		C	
	jo de atención			
COFEPRIS-04-010 Solicitud de Autorización de Protocolo de Investigación en Seres Humanos (8 solicitudes)	C			
COFEPRIS-09-012 Solicitud de Modificación o Enmienda a la Autorización de Protocolo de Investigación (3 solicitudes)	Ð			

- 2. By pressing the button you will be able to view all the requests and their status, organized by modality.
 - In this section you can see the application number, process number if it has been signed and stage, as well as the applicant and date of last saved modification.

DIGIPRIS

Modalidad A: Medicamentos, Biológ	isos o Biotecnológico							
				🏴 Etapa			1	
Solicitud	No. Trámite	Solicitud	Evaluación	Verificación	Firma	Resolución		
F2506585-5582-8089-8295-586546448293 Selected 26/24569622231x/2/03	•	0					Consultar >	
BD48204E-B1CS-F528-C54E-4078A520E580 Solutione	23330041040004 21005-0-e201313/024		0				Consultar >	
84544455-2481-8252-8409-FA853E384312 Solicitante	23330041048002 24/0ctub-e/2025-00-25/05			0			Consultar >	





3. To consult the details of a "**Procedure**", click on the "**Consult**" button in the corresponding row.

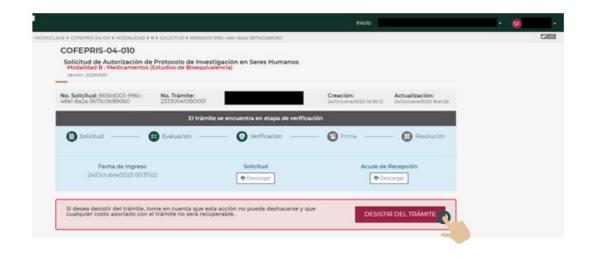
					Inici	•		•	SF	
										0
Modalidad A: Medicamentos, Biológi	cos o Blotecnológicos									
Solicitud	No. Trámite			🏴 Etapa						
soucida	NO. Tramite	Solicitud	Evaluación	Verificación	Firma	Resolución				
F2506185-5581-8089-EE95-5865444A8E93 Selectante: HARA DE LOS ANGELES TOVARHARGAS 26/Detubin/202314/01/03		٥					Consultar >			
RD48204E-85C1-F528-C54E-40784520E580 Selekterter WARM DE LOS ANGELES TOVARVARGAS	23330045040004 29/0ctubre/2023/03/0/24		0				Consultar >			
B054AA5F-2881-821C-B4D9-FA853E36A312 Seletante: Haltia DE LOS ANDELES TOVID VARDAS	233300458A0002 24/0ctubre/2023002903			o			Consult			

4. Within the **"Consult"** section of each procedure, you will find the different actions you can perform.

(E) COFEPRIS-G4-(TO) MODALIDAD) A) SOL			Inicio	· 9
Información de la solicitud Origin		e 0 (C + C), D + C) 48 - 40 DBSJ, MEDOU	Θ	
CATOS DEL PROPIETARIO				
E PERSONA FISICA O MOBAL				
NOMBRE O RAZÓN SOCIAL		VALOB		
· minutes	13	+539_8872+		
PRIMER APELLIDO	8	+529,5670+		
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EXTENSIÓN		-site_mitte-		
COBREO ELECTRÓNICO		«SIN_BAID»		

- 5. In case you decide to withdraw from a procedure: at the bottom of the window to consult the procedure, you will find the "DESIST FROM THE PROCEDURE" button. Click the button. Take into account that:
 - Withdrawal cannot be undone.
 - Any costs associated with the procedure cannot be recovered.





6. A pop-up window will immediately appear in which you must sign this action. To sign the action, click the "**Upload private key .key**" button and upload the corresponding file.

Si desea desistir del y que cualq	trámite, tome en cuenta que esta acción no p uler costo asociado con el trámite no será reci	uede deshacerse uperable.	
Centrals	Firma Electrónica del SAT	<u></u>	
040-PUBLICO-BIRPC SOLI composed(TRAPGTE)PUBLI derecto y por así com to piero que esta acci UTA no será recuparado	(D:10)NOM#10000017-DECLARACIONES-IDECLARACION: PUBLICO (Pec) and/ a mis intervess como solicitante, desisto del trafett de as definitiva, so puesto destantes y oue cultorio del trafetto.	994c-48e1-8a2a-3473	
 16#85142#29398821	9 544.256 bc4eb6ca5479c2ac23597c1a7x39415254ac36899437482	Cancelar Firma	
0	Cargar Ilave privada .key		

7. Once the validity of your electronic key has been verified, a text field will open in which you must enter the password for your private key. When finished, click "Sign."

DIGIPRIS

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Concercion Base	Firma Electrónica del SAT	
CertiFicado: 00001000000571475311	10vA901007EN/7	MARIA DE LOS ANCELES TOVAR VARC AS
<pre>cdp89868[TRAMITE:PuBLICD:233] derecho y por asi convenir a to pieno que esta acción es o</pre>	I-PULICO-TOXHBIARTENT [SOLICITAD FRE Bealingeoli-Collaboration=[Solicitants esi intereuse como sullicitante, desi efficience, so guerde desianterse y que t texto de desistimiento es de prueba recento]	N:PUBLECO:Deciaro que por propio sto del trámite con el conocimien cualquier costo asociado al trám
Alabid 1 a 20 Mind 2 Inc dashi	SHA-256: x5479c3dc23587c1a7x38d1528dacb008443	Cancelar Firma

8. When you finish withdrawing the process, the platform will send it to the **Process Status Panel.** Where you can download the withdrawal receipt by clicking on the "**Download**" button located under the text "**Resolution document**".





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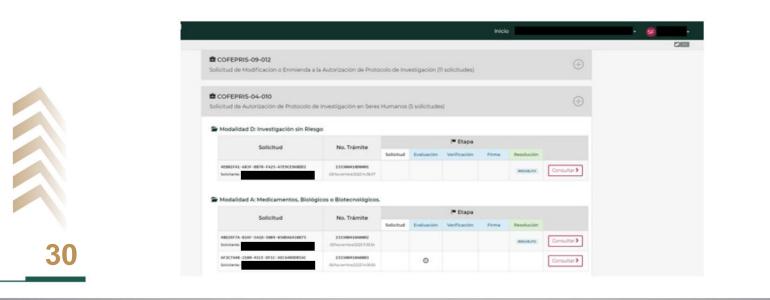
Download documents associated with a procedure

From the **"Home"** screen you can view all the requests made by the **group** and their status organized by Homoclave.

1. To locate a specific request, click the "(+)" button located in the corresponding homokey row.

Inicia	200
Solicitudes realizadas por Iniciar una nueva solicitud de trámite O	
O Physic de atlención	
COFEPRIS-09-012 Solicitud de Modificación o Enmienda a la Autorización de Protocolo de Investigación (II solicitudes)	
COFEPRIS-04-010 Solicitud de Autorización de Protocolo de Investigación en Seres Humanos (4 solicitudes)	

- 2. By pressing the button you will be able to view all the requests and their status, organized by modality.
 - In this section you can see the application number, process number if it has been signed and stage, as well as the applicant and date of last saved modification.



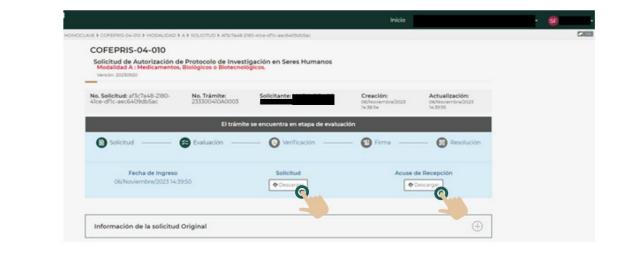


3. To review the documents generated by the platform and associated with a procedure, click on the "**Consult**" button in the corresponding row.

COFEPRIS-09-012							0	
Solicitud de Modificación o Enmienda a l	a Autorización de Proto	colo de Inv	estigación (l'	solicitudes)			\oplus	
COFEPRIS-04-010							0	
Solicitud de Autorización de Protocolo de	Investigación en Seres	Humanos	(5 solicitudes	a.			\oplus	
🖀 Modalidad D: Investigación sin Riesç	20							
Solicitud	No. Trámite			P Etapa				
Junchud	THE TRANSPORT	Solicitud	Evaluación	Verificación	Firma	Resolución		
4EB03FA1-683F-8878-FA25-A7E9CE968002 Subcitante	23330045000005 03550-07570/2023 % 30/07					88546478	Consultar >	
🖀 Modalidad A: Medicamentos, Biológ	icos o Biotecnológicos							
				P Etapa				
Solicitud	No. Trámite	Solicitud	Evaluación	Verificación	Firma	Resolución		
48029F7A-82AF-5A3D-5089-8580A6438875 Solicitante	23339845848892 05%sole=rene2022.0.3334					*******	Consultar >	
AF3C78A8-2180-45CE-0F1C-AEC6409085AC Solicitaria	23330041040003 05/hove=mtre/202314/39/50		0				Consultar 3	

4. Within the **"Consult"** section of each procedure, you will find the different actions you can perform.

In all "**Procedures**" you can download the "**Application Form**" or the "**Acknowledgment of Receipt**" by clicking on the "**Download**" button under each item.



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5. In the case of "**Procedures**" in the "**Evaluation**" stage, under the **Process Status Panel** you will find the "**Original Application Information**" resource. To display the captured information and uploaded documents, click the "(+)" button at the far right of the box.

			Inicio		• 😫
CLAVE > COFEPRIS-04-010 > MODALIDAD >	A > SOLICITUD > A73c7648-21	80-4/ce-offic-aeo6409db5ac			c
COFEPRIS-04-010					
Solicitud de Autorización d Modalidad A : Medicamentos Versión: 2023/0920	e Protocolo de Investi Biológicos o Biotecnolo	igación en Seres Humanos gicos.			
No. Solicitud: af3c7a48-2180- 41ce-dflc-aec6409db5ac	No. Trámite: 233300410A0003	Solicitante: MARIA DE LOS ANGELES TOMAD VADICAS	Creación: 06/Novembre/2023 343854	Actualización: 06/Noviembre/2023 14:39:55	
	El trámite	se encuentra en etapa de evaluar	slón		
Solicitud	🔁 Evaluación		— 📵 Firma —	- 🙆 Resolución	
Fecha de Ingreso 06/Noviembre/202314/3		Solicitud	Acuse d	le Recepción	
Ognoviembre/2023 I4-3	930	◆ Descargar	(* :	Xescargar	
Información de la solicitud	Original				

6. By clicking you will be able to see a summary of all the information of the original request. To hide the information click on the "(-)" button in the upper right corner of the box.

			Inicio	· 9 · ·
LAVE > COPEPRIS-04-010 > MODALIDAD > A > SOL	CITUD > 8548254	4e-b1c1-f52b-c54e-4d7ba520e5b0		2003
Información de la solicitud Origin	al			
DATOS DEL PROPIETABIO				
PERSONA FISICA O MORAL				
CAMPO		VALDE		
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PRIMER APELLIDO		v\$28_5610v		
SECUNDO APELLIDO	13	+525_3610+		
TELÉFONO	13	*SIN_5410+		
EXTENSIÓN	13	+513,5613+		
	13	-318_5830+		

7

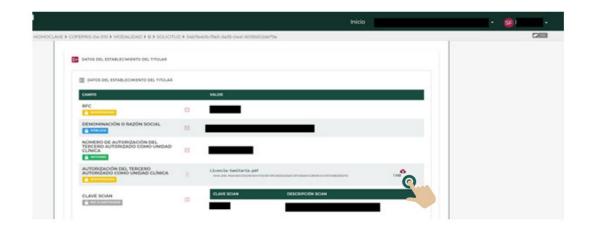
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7. To download any of the documents that are part of the procedure, locate the requirement within the drop-down list.

Then, click on the "**cloud**" icon at the far right of the row corresponding to the document. The download will start immediately, please wait.

0





8. In the case of procedures in the resolution stage, click on "**consult**" to view: the "**Application number**", applicant, date of last saved modification, stage and "**Procedure number**".

					Inici	•		• 9	E
Solicitudes realizadas por					Iniciar ur	na nueva solicit	ud de trámite O		
_			_				O Plujo de atención		
COFEPRIS-09-012 Solicitud de Modificación o Enmienda a l	a Autorización de Proto	colo de Inv	estigación (Il	solicitudes)			\oplus		
COFEPRIS-04-010 Solicitud de Autorización de Protocolo de	Investigación en Seres	Humanos	(5 solicitudes	ġ.			\oplus		
🖀 Modalidad D: Investigación sin Riesg	0								
Solicitud	No. Trámite			I* Etapa					
Junchity	The second	Solicitud	Evaluación	Verificación	Firma	Resolución			
4EINOFA3-683F-8878-FA25-A7E9CE968002 Solotanae Holita DE LOS ANCELES YOUNE UNIGAS	233380414008091 05%shamana/2003%-38.07						Consultar >		
							0		

9. As in the procedures in other stages, you can download the "**Application Form**" or the "**Acknowledgment of Receipt**" by clicking on the "**Download**" button under each item.

You will also be able to see the meaning of your resolution and the date of issue of the resolution (see below).

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To download the corresponding letter, click on the "**Download**" button that appears under "**Resolution Letter.**" The download will begin in a few moments, please wait.

8.

•



Authorized Procedure:



Prevented Procedure:

No. Solicitud: cce09d99-1e08- 06bc-b2a3-33ed397d6277	No. Trámite: 233300912H0001		Creación: 03/Noviembre/2023 17:45:23	Actualización: 05/Noviembre/2023 15:44:40
	El trá	imite se encuentra prevenido		
Prevención	Evaluación	— 💿 Verificación —	- E Firma	- 🔞 Resolución
El solicitante debe automáticamente p	responder con las observa por falta de seguimiento.	aciones atendidas antes del pa	ara evitar que el trámite se	a desechado
El solicitante debe automáticamente p Fecha de Ingreso	por falta de seguimiento.	aciones atendidas antes del pa		a desechado de Recepción
automáticamente p	por falta de seguimiento.		Acuse d	
automáticamente p Fecha de Ingreso	por falta de seguimiento.)4:05	Solicitud	Acuse d	de Recepción

Dismissed Procedure:

No. Solicitud: 4eb02fa1-683f- bb78-fa25-a7e9ce96bdd2	No. Trámite: 233300410D0001		Creaclón: 03/Noviembre/2023 13/24/17	Actualización: 05/Noviembre/2023 16:41:06
	9	El trámite fue desechado		
Solicitud	🔁 Evaluación	— 🗿 Verificación ——	😰 Firma	- 🔞 Resolución
		i i i i i i i i i i i i i i i i i i i		
Fecha de Ingreso		Solicitud	Acuse d	e Recepción
Fecha de Ingreso 03/Noviembre/2023 14:3	8:07	Solicitud		le Recepción Descargar
			•	

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

Remember that the legal times to respond to notifications of the resolution of the procedures will begin from their review on the platform.

0



Respond to a prevented procedure

From the "Home" screen you can view all the requests and procedures carried out by the group and their status organized by Homoclave.

	solicitude e trámite O	
Solicitudes realizadas por	Fluge de atención	
COFEPRIS-09-012 Solicitud de Modificación o Enmienda a la Autorización de Protocolo de Investigación (II solicitudes		
COFEPRIS-04-010 Solicitud de Autorización de Protocolo de Investigación en Seres Humanos (S solicitudes)	Œ	

^{1.} To locate a specific request, click the "(+)" button located in the corresponding homokey row.

	Inicio		89	20
Solicitudes realizadas por	Iniciar una nueva solicitud de trán	nite O		
-	O Physic de a	sención		
COFEPRIS-09-012 Solicitud de Modificación o Enmienda a la Autorización de Protocolo de Investigaci	ión (11 solicitudes)	0	·	
COFEPRIS-04-010 Solicitud de Autorización de Protocolo de Investigación en Seres Humanos (5 solici	tudes)	Ð		

2. To review the procedure, click on the "**Consult**" button in the corresponding row.



					j,	nicio			• 😵
olicitudes realizadas por				1	iniciar una	nueva solicitu	d de trámite O		
							Flujo de atención		
COFEPRIS-09-012							\oplus		
Solicitud de Modificación o Enmienda	a la Autorización d	Protocolo	de Investig	pación (11 solie	itudes)		Đ		
S Modalidad K: Cambio o adición de	Importador								
Solicitud	No. Trámite			🏴 Etapa					
		Solicitud	Evaluación	Verificación.	Firma	Resolución			
SECENCE - 2452 - 9977 - 0146 - FE23MACE41CB Selectede MARIX D2 LOS ANDELES FONBLY/MICAS D3/November/2025 16 5+33		0					Consultar >		
Modalidad 3: Cambios de patrocin	ador (domicilio y/k	razón soc	ial)						
Solicitud	No. Trámite			I# Etapa					
		Solicitud	Evaluación	Verificación	Firma	Resolución			
758E865E-DE62-B8D7-38EA-381E56662DEE Selectaritie HADIX DE LOS ANCELES TOURD VARCAS	23330091230001 05%ovember/2023/0.3v/					NEULTO	Consultar>		

3. For procedures in the resolution stage you can download the "Application Form", "Acknowledgment of Receipt" and the "Resolution Letter"

by clicking on the "Download" button below each of the documents. The download will begin in a few moments, please wait.

 Solicitud: cce09d99-le08- ibc-b2a3-33ed397d6277 	No. Trámite: 233300912H0001	Solicitante:	Creación: 03/Noviembre/2023 17:45:23	Actualización: 05/Noviembre/2023 15:44:40
	EIt	rámite se encuentra prevenido	l.	
Prevención	Evaluación		- 🕲 Firma	- 🔞 Resolución
	responder con las obser or falta de seguimiento.	vaciones atendidas antes del p	bara evitar que el trámite se	a desechado
				a desechado le Recepción
automáticamente p	oor falta de seguimiento.		Acuse d	
automáticamente p Fecha de Ingreso	oor falta de seguimiento. 14:05	Solicitud	Acuse d	le Recepción

4. In the lower region of the window you will find the box to

Consult the **"Information of the original application"**, **"Observations of the first evaluation"** and the sections corresponding to prevention to capture the data or upload the necessary documents.

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nformación de la solicitud Origi	nal 🕂
bservaciones de la primera evi	aluación 🕀
	COMBROBANTE DE RACO Y CARTA DE SOLICITUD
INFORMACIÓN SOBRE LA EXMERICIA SOLOTIADA AL REOTOCOLO	COMPROBANTE OF FRCO
ANTECEDENTES DEL PROTOCOLO	COMPROBANTE DE PAGO DEL TRÁMITE*
CENTROS DE INVESTIGACIÓN	llave de paga.pdf sold and the sold and the
TENNENDA A NODILICACIONES	Adjuntar archivo t
	Campo marcado como advertido por el dictaminador

5. To view the **"Original Application Information"** or **"First Evaluation Observations,"** click the **"(+)"** button at the far right of the corresponding box. To hide the information click on the "(-)" button at the far right of the box.

Information about the original request:

COMPROBANTE DE PAGO Y CARTA DE SOUCITU	0		
COMPROBANTE DE PACO			
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COMPROBANTE DE PAGO DEL TRÁMITE		Line de page-pér tes de la contractamente contracta	24.42
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ESCRITO LIBRE DE SOLICITUD		CHETA DE ACEPTACIÓN IP, decx Des DR. Machatación/instantación/instantación/internet-incorran	140

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Observations from the first evaluation:

formación de la solicito	ud Original			\oplus
bservaciones de la prin	nera evaluación			0
COMPROBANTE DE PAGO Y C	NITA DE SOLICITUD			-
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6. **To Respond to Prevention,** go to the bottom of the window. You will find the different sections of the procedure that require capturing new information or uploading documents.

Please note that only the fields that have been requested by the Authorization Commission will be available to modify. Cofepris Sanitary; In these sections you can:

- Modify or delete and replace data.
- Delete and replace or add documents.

To properly enter information and documents, we recommend that you review the following titles of the manual:

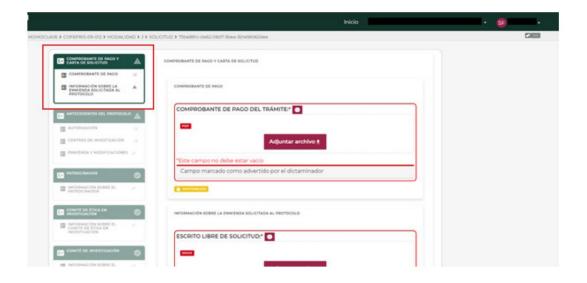
- Sections that make up an Application
- <u>Capture information in a Request</u>

DIGIPRIS

<u>Upload files in a Request</u>







Remember to save the information before signing and sending. For more information, see the title **Saving changes made to a Request** within this manual.

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7. Once you have finished and saved your changes, proceed to "SIGN AND SEND RESPONSE TO PREVENTION". For more information, consult the Sign and send an application or Generate a procedure section within this manual.

VE > COFEPRIS-09-012 > MODALIDAD	> 3 > SOLICITUD > 75be861c-de62-68d7-3be	a-3ble56062dee		
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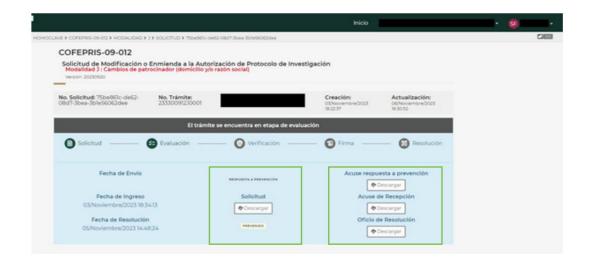
8. During the signing process, a pop-up window will be displayed. Please wait.



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9. Once the **Prevention Response is signed**, the platform will display a window where you can download the corresponding documents. For more information, go to the **Download documents associated with a procedure** section of this manual.





10. While the **Prevention Response** is in the "**Evaluation**" **stage**, in the lower region of the window you will be able to see the "Information of the original request", the "Observations of the first evaluation", the "information of the first response to prevention" or "**DESIST FROM THE PROCEDURE**".

For more information see the Withdraw or consult a procedure section.

Note: Remember that the COFEPRIS-04-010 and COFEPRIS-09-012 procedures in all their modalities only have the opportunity for prevention and, therefore, a response to prevention.

	Inicio	· 9
VE & COFERRIS-09-012 & MODALIDAD & 3 & SOLICITUD & 15bee80c-de82-08d7-3bea-3ble86062dee		0
Información de la solicitud Original	\oplus	
Observaciones de la primera evaluación	÷	
Información de la primera respuesta a prevención	\oplus	
Si desea desistir del trámite, tome en cuenta que esta acción no puede deshacerse y que cualquier costo asociado con el trámite no serà recuperable.	DESISTIR DEL TRÁMITE	

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



Abbreviations

COFEPRIS: Federal Commission for the Protection against Health Risks CURP: Unique Population Registry Code WHO: World Health Organization RFC: Federal Taxpayer Registry RNEC: National Registry of Clinical Trials SAT: Tax Administration System TRDS: Trial Registration Data Set



