DIGIPRiS:
Investigación y Ensayos Clínicos

NUEVOS PROTOCOLOS Y ENMIENDAS

- 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:

- **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.

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.

Content:

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
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 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".**
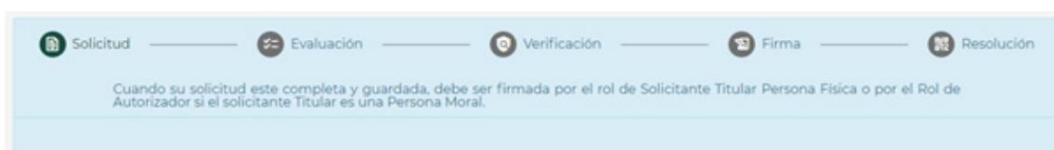
- Whenever you want, you can save a request to continue editing later. Only changes that have been saved before ending the session will be retained, so it is recommended **to "SAVE"** regularly.

- 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".**

- 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":**

- 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.

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.
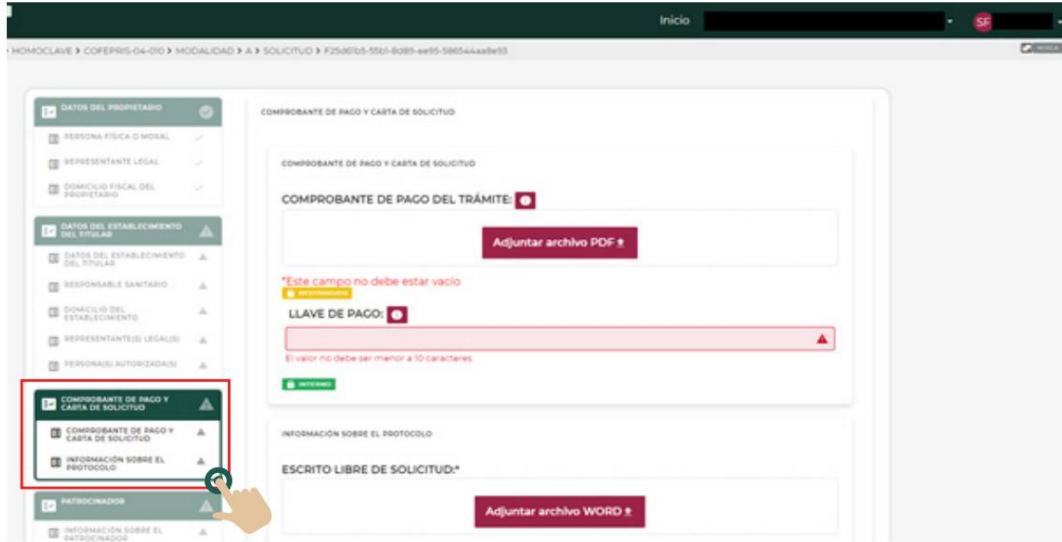
Actions allowed for a request or procedure

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**
All	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.**

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

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.

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

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.
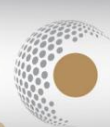
In case you decide to delete the request:

1.   At the bottom portion of the request editing window, you will find the **"DELETE REQUEST" button.** Click the button.
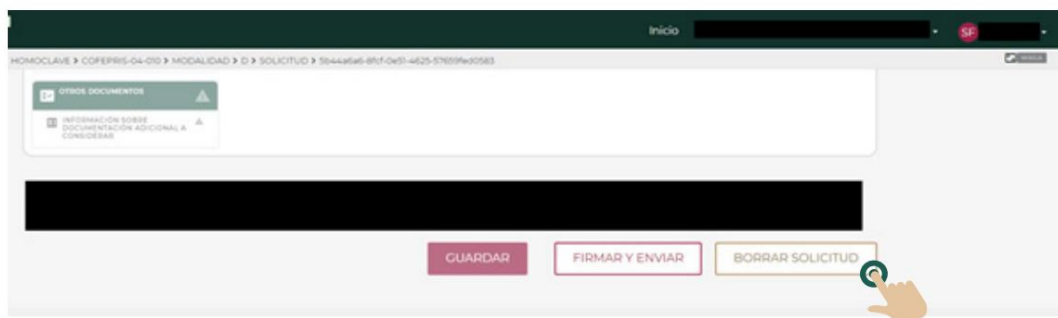
2.   The platform will display a screen to confirm the action. Click the **"YES, DELETE"** button to confirm the deletion.

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

3.   Click "Home" to return to the main section.
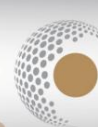
**Request for Authorization of Research Protocol on Human Beings
(COFEPRIS-04-010)**

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:

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.

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.**

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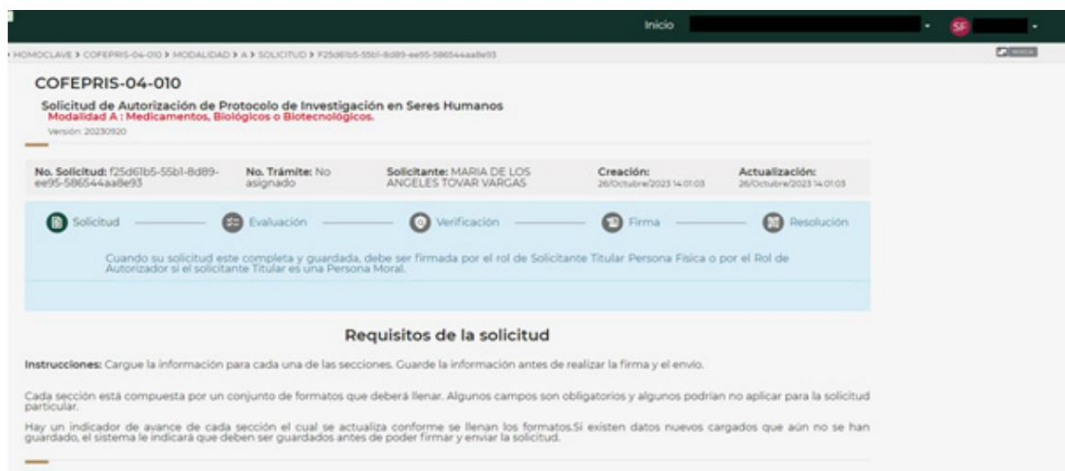
To properly enter information and documents, we recommend that you review the following titles of the manual:

- 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**

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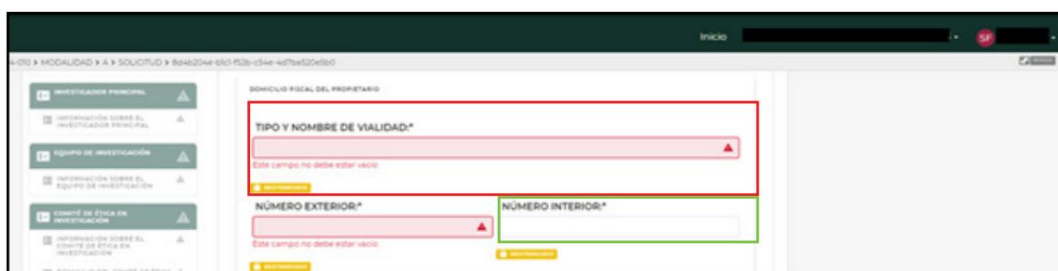
For the purposes of order in the attention of the procedures and clarity within the requirements, on the platform the **Amendments and Modifications** are classified according to the following table. To review the details of each one and the specific requirements, it is suggested that you consult the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

_____

Modality (Internal)	Type of Amendment or Modification
TO.	Amendment to base documents: research protocol, researcher manual or informed consent/assent
b.	Inclusion of research centers
c.	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
H.	Security amendment
YO.	Changes to the owner: address and/or name
J.	Sponsor changes: address and/or name
K.	Change or addition of importer
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).

- 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

- 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):

Example WORD file (.doc or .doxc):

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

1. **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.

DIGIPRIS
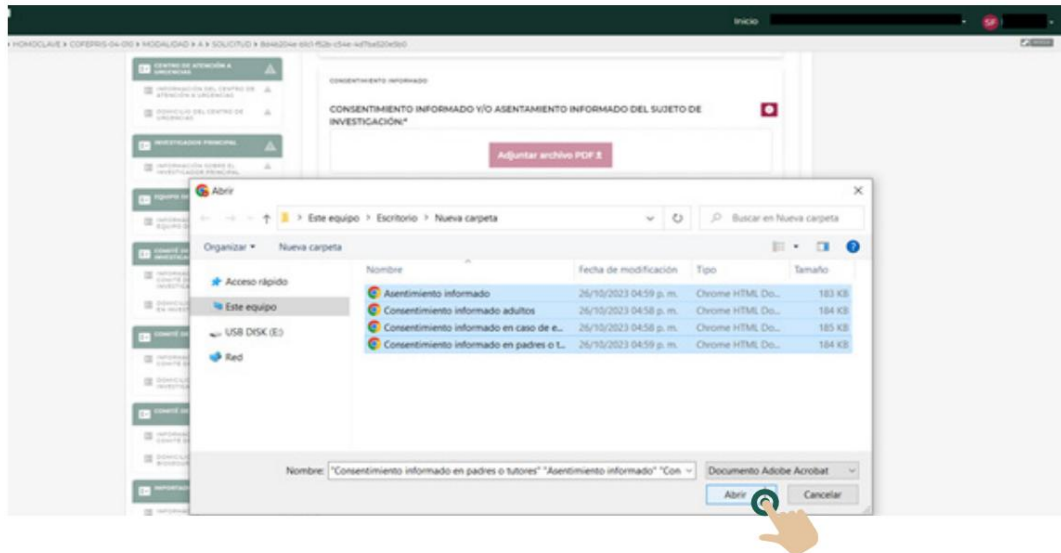
2. Once you click on the **"Open"** button, a **"File Upload"** pop-up window will be displayed where you must confirm the upload of the selected file(s) by clicking on the **"Upload" button.**
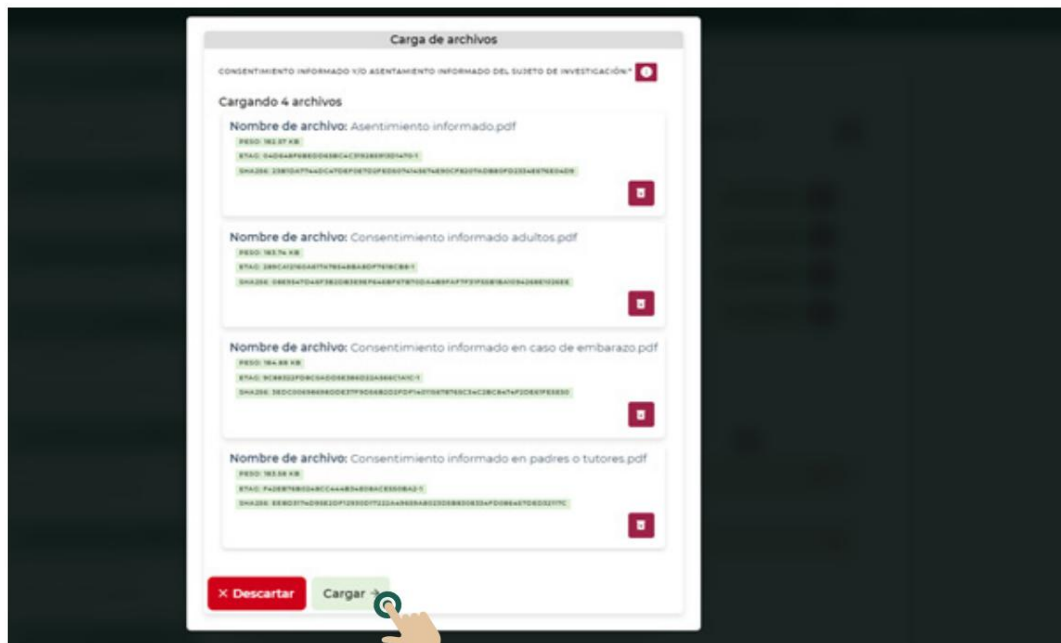
Note: *In case you do not want to upload any of the previously selected documents, click on the red button (Trash Can with X) to remove that document from those that will be uploaded. It is also possible to select "Discard" to cancel the upload of all files visible in the* ***"File Upload" pop-up window.***
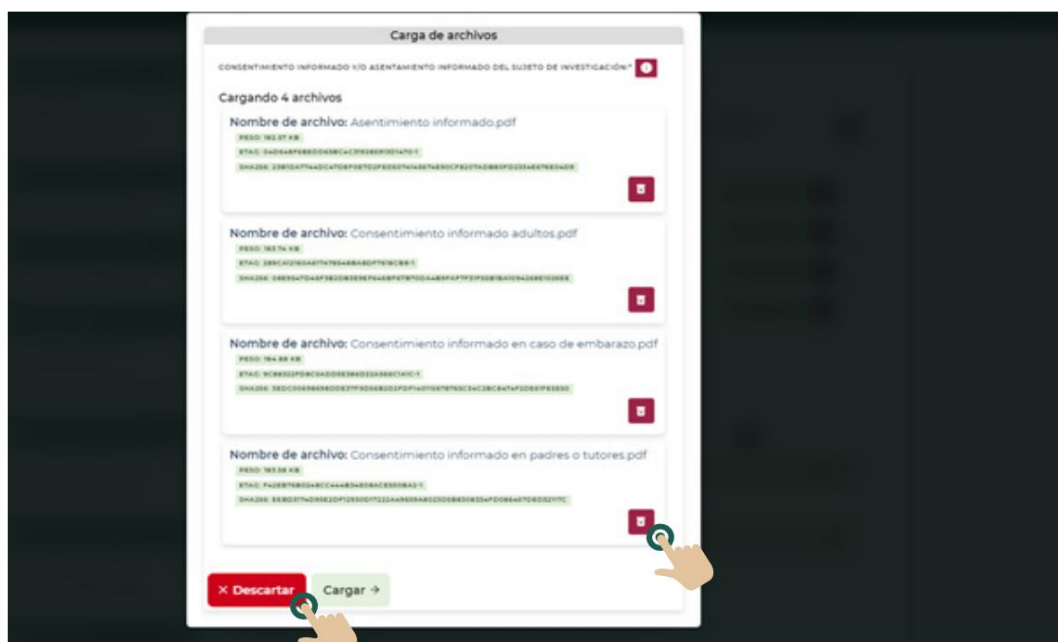
3.   When you begin uploading the files, you can view its progress in the lower right corner of each document.
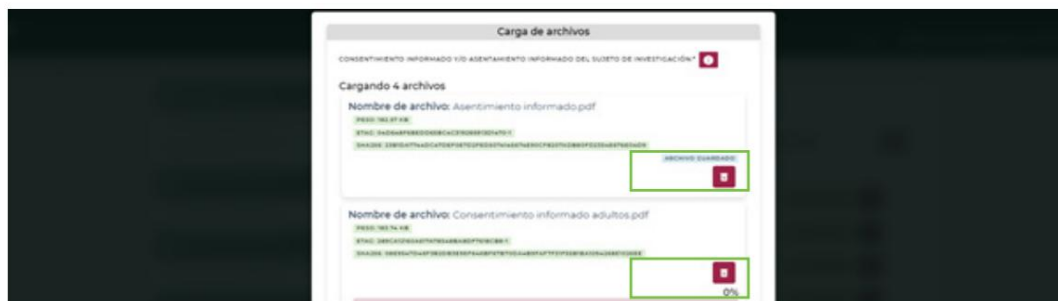
4. When the files are uploaded you will be directed to the **"Application"** section in which the documents were uploaded. If necessary, you can download the documents to view them by clicking on the green rounded box where the weight of the file is indicated.
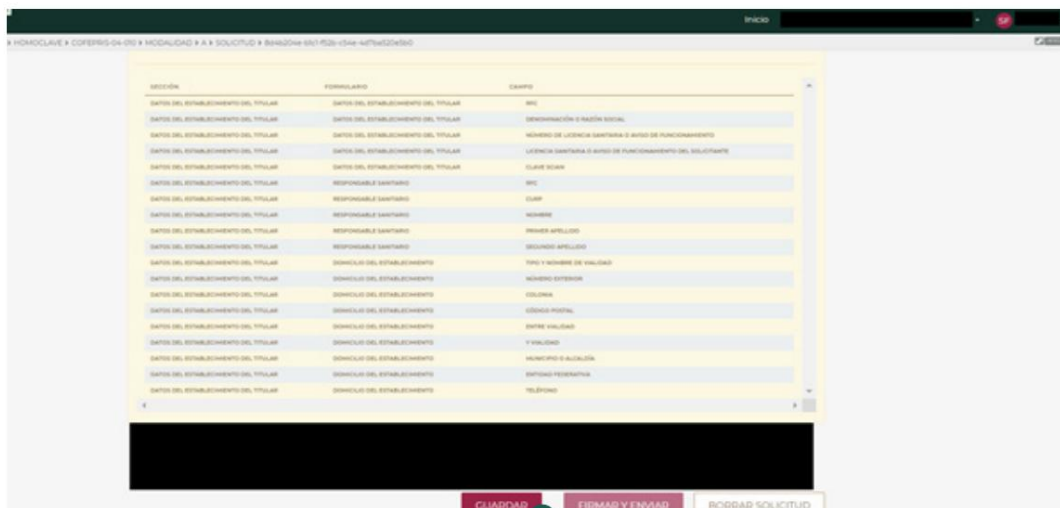
5.   Afterwards, you can continue filling out the different forms, uploading documents or proceed to save the fields. To know how to save the changes, go to the section on **Saving the changes** made in the **"Request for Authorization of Research Protocol in Human Beings"** or the **"Request for Modification or Amendment of Research Protocol"** of this manual.

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.**

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.**

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
- Upload files in a Request
- Save changes made to a Request

2. Go to the bottom section of the application window and click the **"SIGN AND SUBMIT"** button.
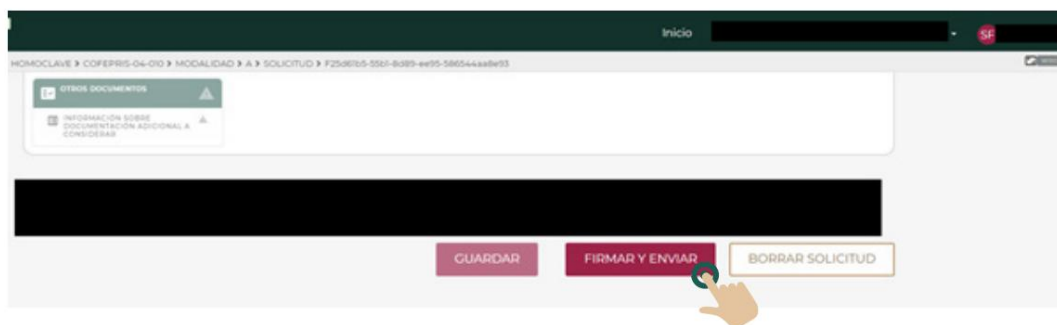
3. The platform will display a window where you can view the application number, applicant, creation date and update date.
If necessary, you can review the details of the request by clicking on the "(+)" button at the far right of the **"View request details" box.**
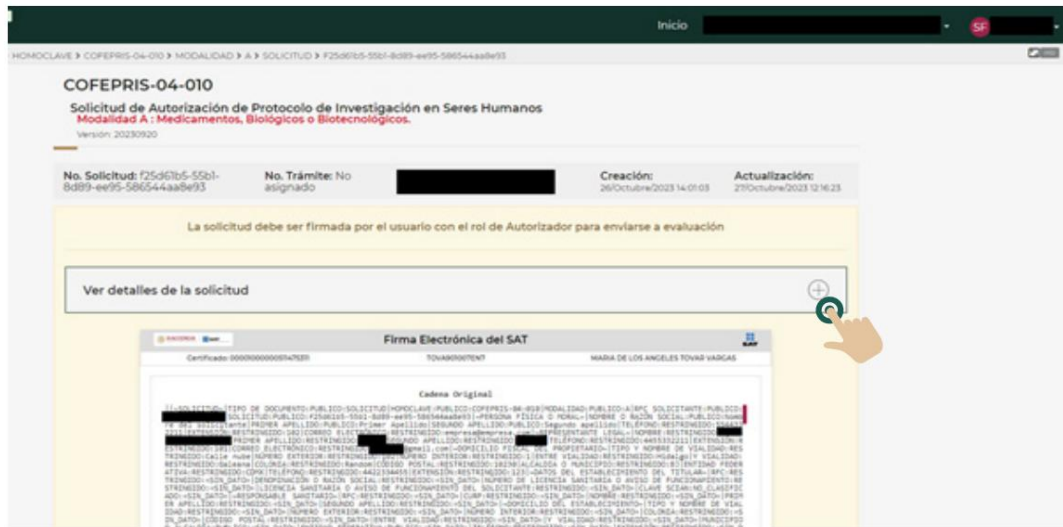
To hide the information click on the "(-)" button at the far right of the **"View request details" box.**
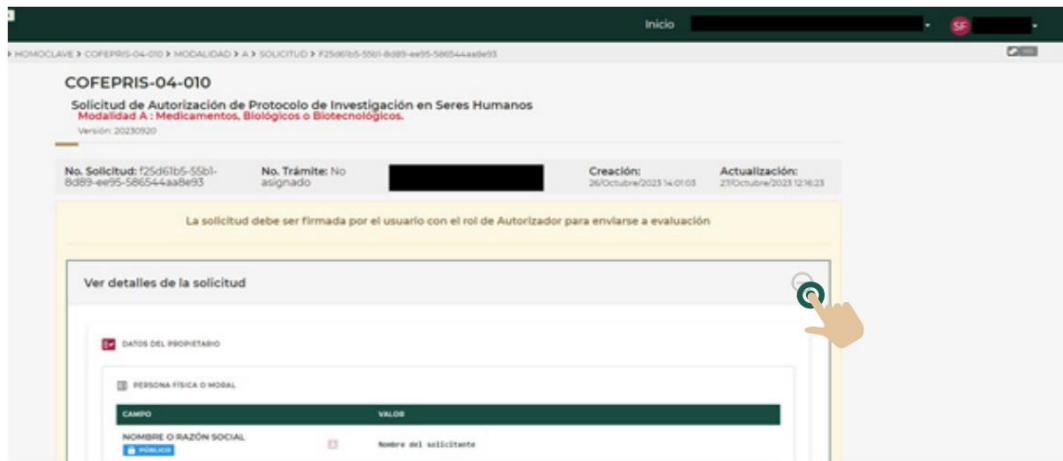
4. To sign the request, go to the bottom portion of the window and click on the **"Upload private key .key"** button and upload the corresponding file.

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."**
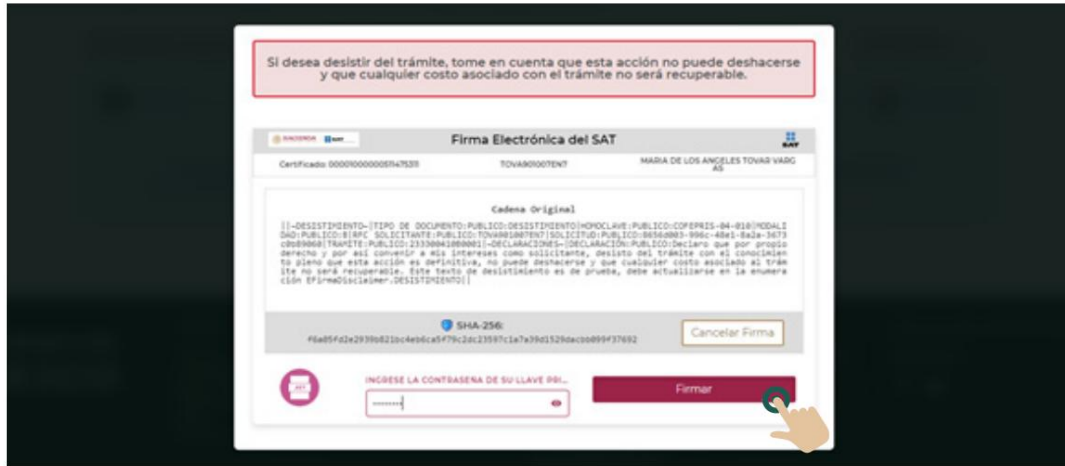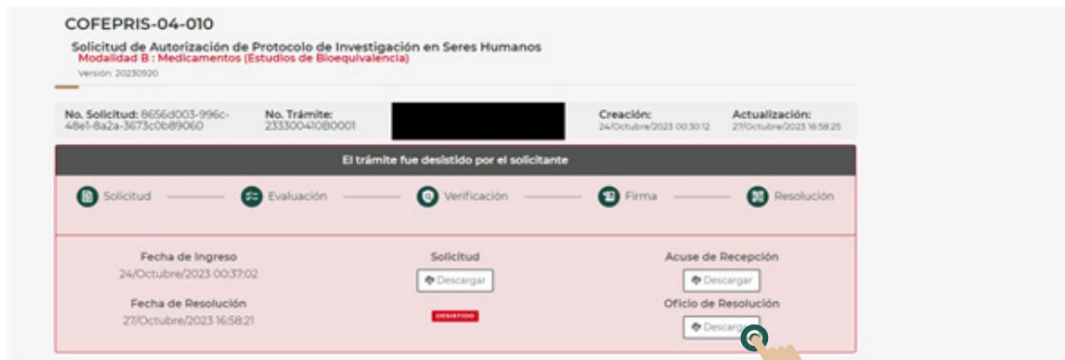
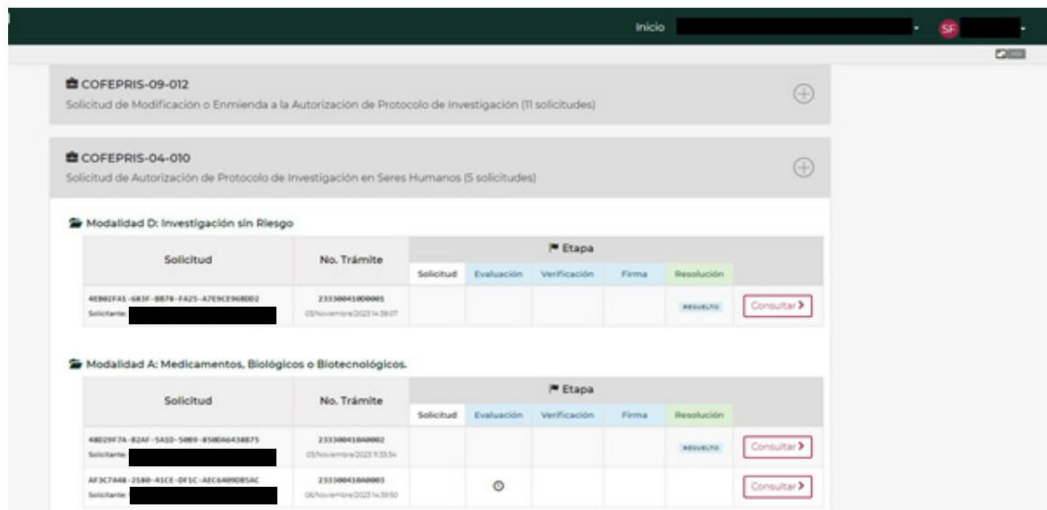## Desist or consult a procedure

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.

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

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

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.

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."**

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".**

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.
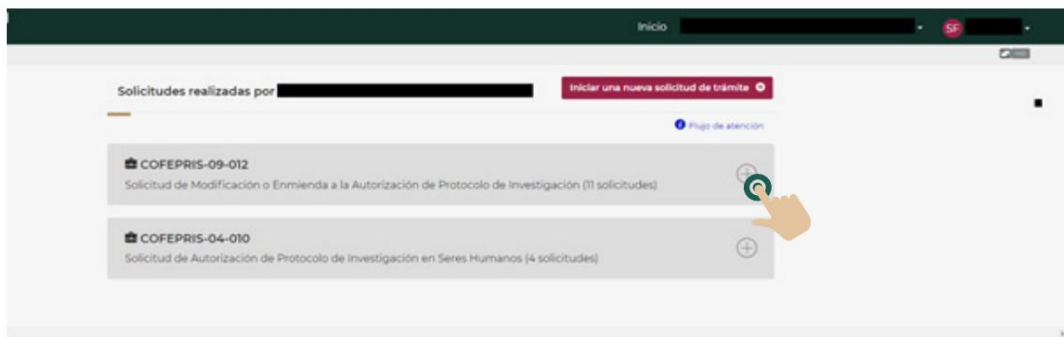
2. By pressing the button you will be able to view all the requests and their status, organized by modality.

- 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.

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.

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.

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.

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.

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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".**

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).

    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.

Authorized Procedure:

Prevented Procedure:

Dismissed Procedure:

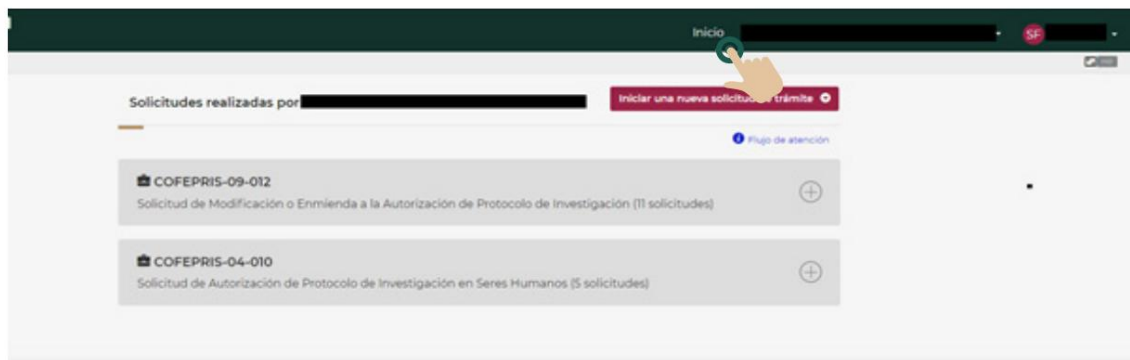10.   To continue with your procedures, click the "Start" button

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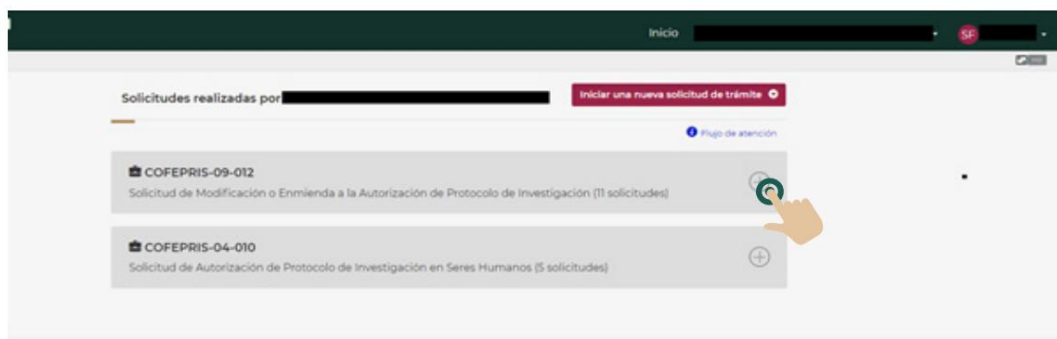
Respond to a prevented procedure

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

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

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

3. For procedures in the resolution stage you can download the **"Application Form", "Acknowledgment of Receipt"** and the **"Resolution Letter"**
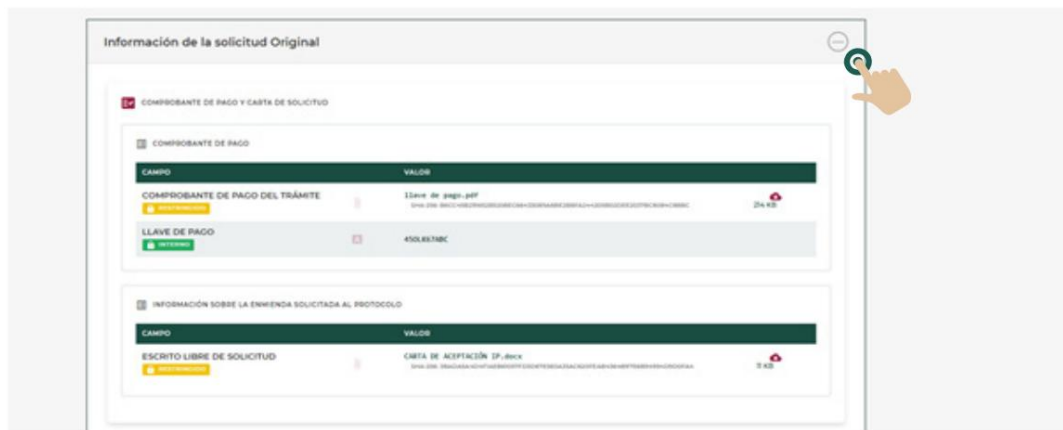by clicking on the "Download" button below each of the documents. The download will begin in a few moments, please wait.

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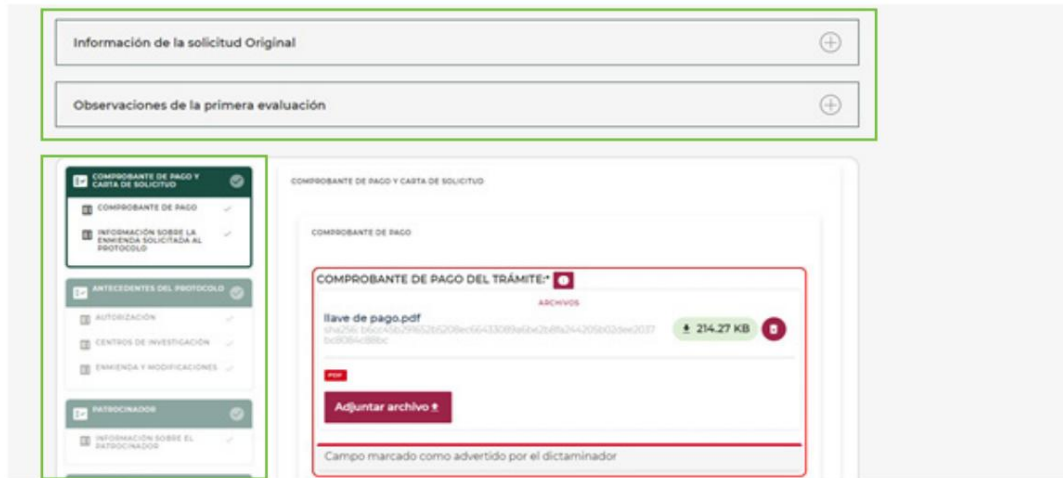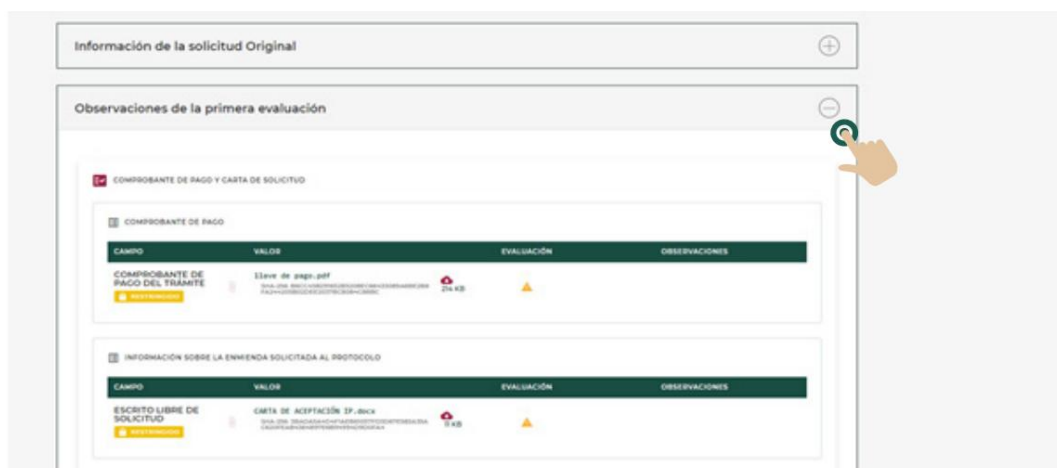
5.   To view the **"Original Application Information"** or **"First Evaluation Observations,"** click the **"(+)"** button at the far right of the corresponding box. To hide the information click on the "(-)" button at the far right of the box.

Information about the original request:

SALUD | **COFEPRIS**
SECRETARÍA DE SALUD | COMISIÓN FEDERAL PARA LA PROTECCIÓN CONTRA RIESGOS SANITARIOS

Observations from the first evaluation:

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:
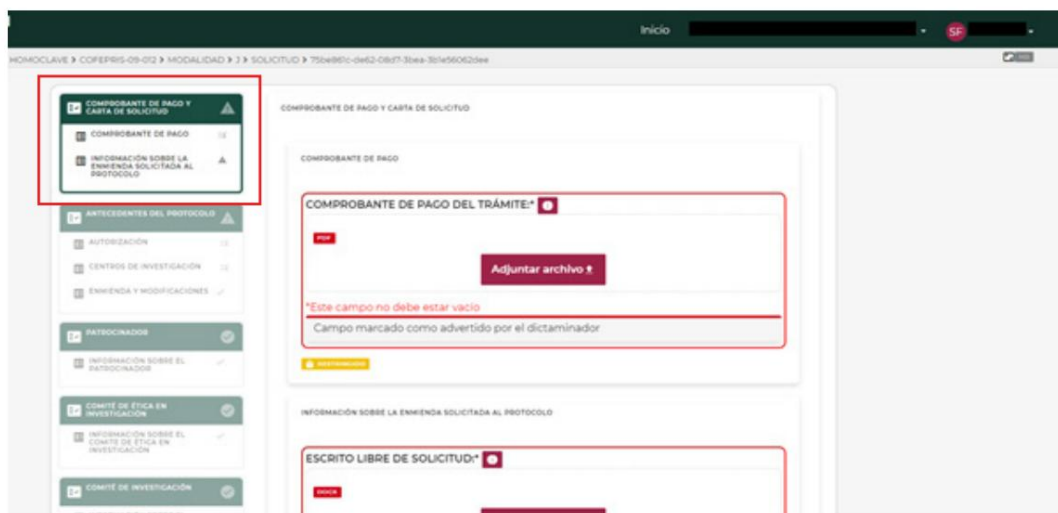
- Sections that make up an Application

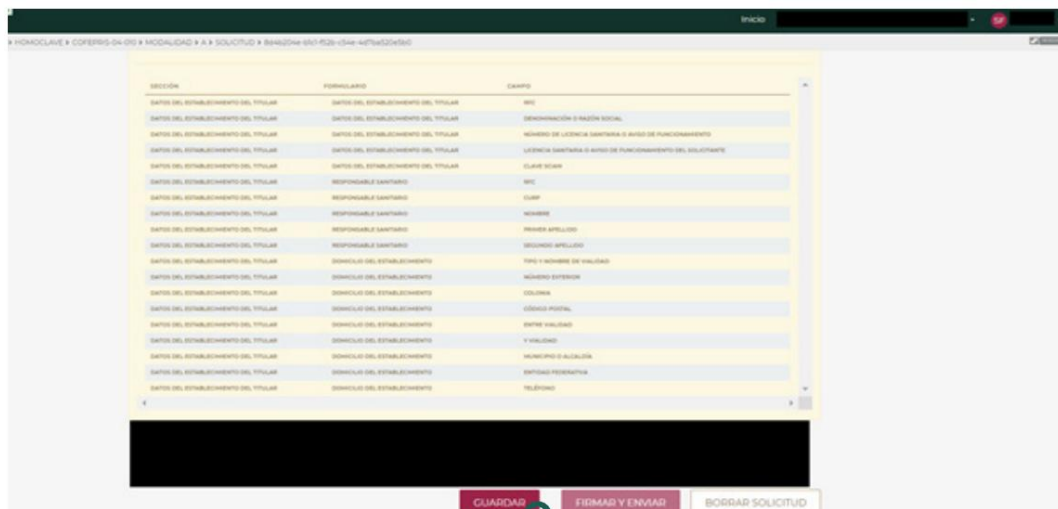- Capture information in a Request

- Upload files in a Request

DIGIPRIS

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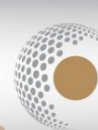**Request** within this manual.

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.

8. During the signing process, a pop-up window will be displayed. Please wait.

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.
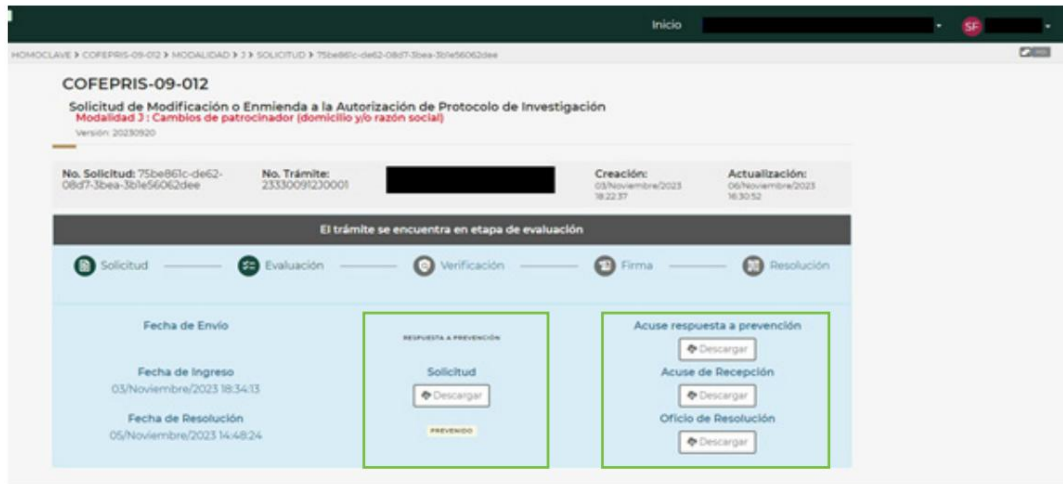
40

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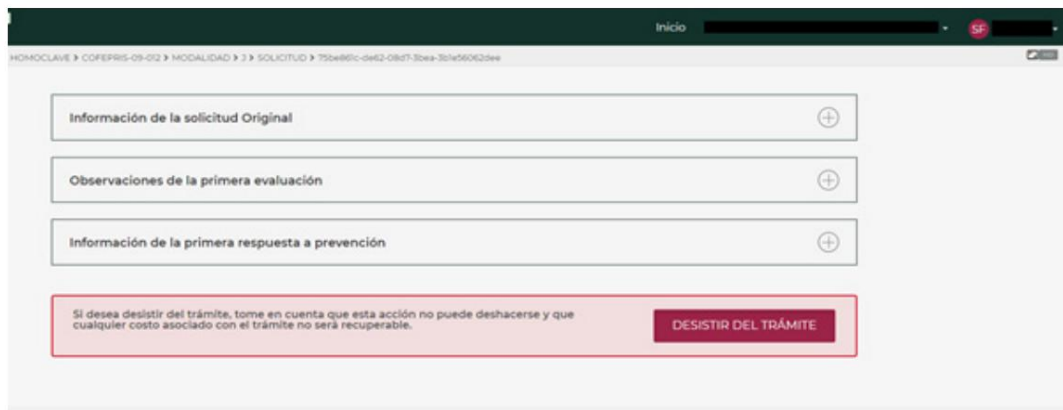
To continue with your procedures, click the **"Start" button.**
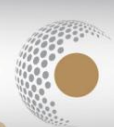
Abbreviations

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