DIGIPRIS

Online Regulation: Clinical Trials

QUESTIONS FREQUENT DIGIPRIS Platform: Online Regulation, Clinical Trials

Salud
Secretaría de Salud

COFEPRIS
COMISIÓN FEDERAL PARA LA PROTECCIÓN CONTRA RIESGOS SANITARIOS

Date: May 15, 2025

Regarding the entry of information in the application for an Essay procedure Clinicians through DIGIPRiS: Online Regulation

1. Should I fill in the sections marked as “Natural Person” if I am a legal entity?

No. If the user is a legal entity, they should not complete the sections labeled exclusively as “Natural Person.” However, it is important to note that there are sections identified as “Natural Person or Legal Entity,” in which the corresponding information must be entered, in accordance with the provisions of Article 15 of the LFPA, Article 153 of the RIS, section 6.1 of NOM-012, and the Procedures Agreement.

2. If I don't need to enter information in a text field of the application, can I leave it blank?

No. Leaving fields blank on the platform negatively impacts the proper functioning of the DIGIPRiS: Online Regulation platform's operational workflows. Therefore, if no information is required in a text field of the application, "N/A" should be entered. Fields for uploading files or entering dates can be left blank, as shown in the example:

3. Is it necessary to upload the CURP document of the legal representatives and authorized persons in the section "Data of the owner's establishment"?

No. Entering the CURP (Unique Population Registry Code) in the "Legal Representative" and "Authorized Person" sections of the DIGIPRiS: Online Regulation platform is optional. Furthermore, this information is validated using the provided Operating Notice, so it is not necessary to attach the CURP document of the legal representatives or authorized persons.

4. How should I enter the information in the fields of the sections corresponding to the "Home"?

The information in the address sections (such as: Tax address of the owner, Address of the owner's establishment, Address of the research center, Address of the importer, Address of the evaluation committees, etc.) must be referenced exactly as it appears in the supporting documents (Licenses, Notices of Operation, Committee Registrations, etc.), according to the following instructions:

or Roads:

In the roadway fields, you must first indicate the corresponding classification (for example: Avenue, Boulevard, Highway, Road, Private Road, Unpaved Road, among others), followed by the full name of the roadway. However, if the classification is "Street," only the name of the roadway needs to be entered, as this is automatically added to the DIGIPRiS: Online Regulation platform.

✘
TIPO Y NOMBRE DE VIALIDAD:*
Calle Oklahoma

✓
TIPO Y NOMBRE DE VIALIDAD:*
Oklahoma

TIPO Y NOMBRE DE VIALIDAD:*
Avenida Oklahoma

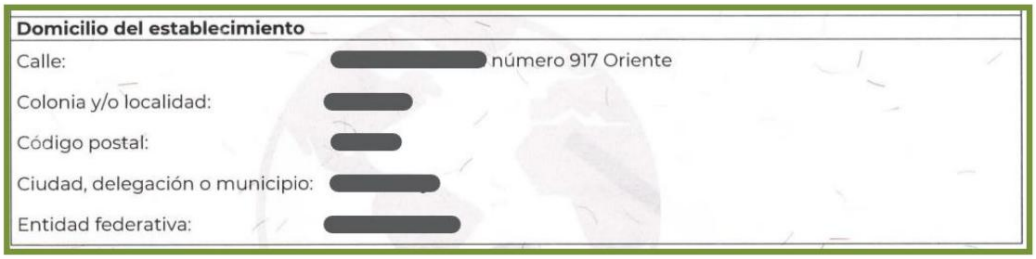
TIPO Y NOMBRE DE VIALIDAD:*
Boulevard Oklahoma

TIPO Y NOMBRE DE VIALIDAD:*
Privada Oklahoma

or "Outer number" and "Inner number" fields:

The information in these fields must be consistent with the supporting documents (Licenses, Operating Notices, Committee Registrations, etc.). If the establishment does not have an "Interior Number", enter "S/N", meaning No Number; as shown in the example:

NÚMERO EXTERIOR:*	NÚMERO INTERIOR:
917 Oriente	S/N

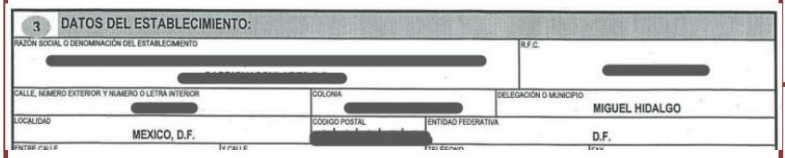


or Fields “Municipality or mayoralty” and “Federal Entity”:

The information in these fields must be entered exactly as it appears in the supporting document. For example, if the document refers to the state as “Veracruz,” it must be entered as such in the DIGIPRiS Online Regulation Platform. Similarly, if it is indicated as “Veracruz Ignacio de la Llave,” that is the correct way to register it.

However, in cases where the document uses the names “Federal District” or “State of Mexico”, “Mexico City” and “Mexico” should be entered, respectively.

Example:



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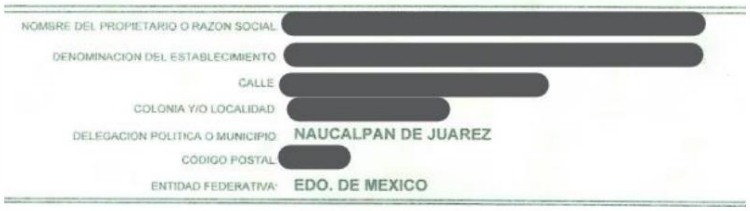

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Localidad: [redacted] Municipio o alcaldía: PACHUCA DE SOTO Entidad Federativa: HIDALGO Entre vialidad (tipo y nombre): [redacted] Y vialidad (tipo y nombre): [redacted] Vialidad posterior (tipo y nombre): [redacted] Lada: [redacted] Teléfono: [redacted] Extensión: [redacted]	MUNICIPIO O ALCALDÍA:* Pachuca de Soto PÚBLICO ENTIDAD FEDERATIVA:* Hidalgo	ÿ
	MUNICIPIO O ALCALDÍA:* Pachuca PÚBLICO ENTIDAD FEDERATIVA:* Hidalgo	ÿ
Municipio o alcaldía: Veracruz Entidad Federativa: Veracruz de Ignacio de la Llave Entre vialidad: [redacted] Y vialidad: [redacted] Vialidad posterior: [redacted] Teléfono: [redacted] Extensión:	MUNICIPIO O ALCALDÍA:* Veracruz PÚBLICO ENTIDAD FEDERATIVA:* Veracruz de Ignacio de la Llave	ÿ
	MUNICIPIO O ALCALDÍA:* Veracruz PÚBLICO ENTIDAD FEDERATIVA:* Veracruz	ÿ
NOMBRE DEL PROPIETARIO : [redacted] DENOMINACION DEL ESTABLECIMIENTO [redacted] DOMICILIO: [redacted] COLONIA: [redacted] LOCALIDAD: VERACRUZ MUNICIPIO: VERACRUZ	MUNICIPIO O ALCALDÍA:* Veracruz PÚBLICO ENTIDAD FEDERATIVA:* Veracruz	ÿ
	MUNICIPIO O ALCALDÍA:* Veracruz PÚBLICO ENTIDAD FEDERATIVA:* Veracruz de Ignacio de la Llave	ÿ

or Telephone:

In this field you must enter the 10 digits of the corresponding national telephone number.

5. When the applicant is a Contract Research Organization (CRO), what document should be entered in the field "Applicant's health license or notice of operation"?

In the "Owner's Establishment Data" section, you must attach sufficient and necessary information to validate the owner's establishment data; that is, since it is a Contract Research Organization (CRO), in the "Sanitary License or Notice of Operation of the Applicant" requirement, you must attach, in addition to the "FORM for establishments that do not require submitting a Notice of Operation or License Application", a simple copy of the notarized power of attorney or articles of incorporation of the Contract Research Organization (CRO), the above in order to accredit the legal personality of the applicant based on article 15 of the Federal Law of Administrative Procedure.

6. What documents should I attach in the field "Copy of the study driving authorization"?

In the field "Copy of the authorization to conduct the study" you must enter the Official letter of authorization to conduct the study (Homoclave COFEPRIS-04-010 of modality A, B, C or D), including the Official letters of modification and/or internal correction to the authorization to conduct the study that have been authorized.

7. What documents should I attach in the field "Copy of the inclusion letters from all centers"? of the study"?

In the field "Copy of the inclusion letters for all study centers," you must enter all the Center Inclusion Authorization Letters (COFEPRIS Code 09-012) corresponding to the protocol, as well as any modification and/or internal correction letters that have been authorized for the aforementioned center inclusions. For research centers authorized in the initial study authorization letter, these must be attached in the field "Copy of the study authorization."

8. If I request authorization for more than one Informed Consent Form, what information should I enter in the fields "Date of Informed Consent Version" and "Informed Consent Version"?

If you are requesting authorization for more than one informed consent form, in the fields
"Date of the informed consent version" and "Informed consent version" should refer to the information corresponding to the main Informed Consent Form, as shown in the example:

9. If I have more than one approval opinion issued by the evaluation committees, what information should I enter in the "Date of favorable opinion" fields?

In cases where more than one favorable opinion is presented, the user must place (in the requirement "DATE OF FAVORABLE OPINION") the date of the document that contains the approval of the most recent versions of the documents in this priority (Protocol ÿ Manual ÿ Informed Consent Form/Informed Assent Form).

10. For the COFEPRIS-09-012 Homoclave procedures, in the "Research Centers" subsection of the "Protocol Background" section, should I enter the information and documents of all research centers authorized to conduct the study? Or can I only include the ones listed?

The authorization letter from the research center where the amendment process is being carried out?

In the "Research Centers" subsection of the "Protocol Background" section, you must enter the information and documentation for all research centers authorized to conduct the research protocol. This is because this information is transferred to the official resolution and is necessary to maintain traceability in the research study.

11. Can the fields corresponding to the "Letters of Non-Vote" of the Evaluation Committees

Will this requirement leave you without information?

No. In the event that the members of the evaluation committees are not part of the team of

For investigations, a letter must be submitted stating this, in order to provide traceability of the information and clarify the reason for omitting the aforementioned letters.

In compliance with the provisions of numerals 9.2.3, 12.1, 12.2 and 12.3 of the Official Mexican Standard NOM-012.

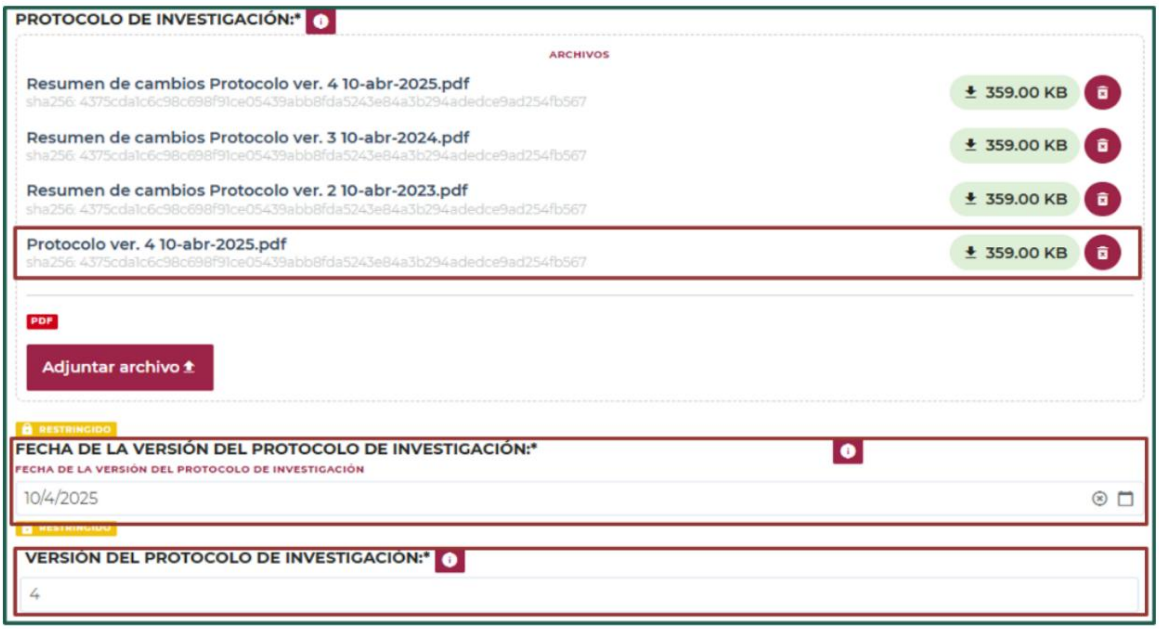
12. What is the procedure for requesting authorization for multiple consecutive versions of a study base document?

Due to the operation of the "DIGIPRiS: Online Regulation" Platform, it has been established that in a The application may include up to three consecutive versions with respect to the last authorized version. of the study documents (Manual, Protocol or Consent Form).

In addition to the above, in order for the resolution document to be issued correctly, the information and documents must be entered according to the following instructions:

a) All documents must include the approval opinions issued by the corresponding Evaluation Committees; these opinions must be entered in the corresponding fields ("Favorable opinion of the Research Ethics Committee", "Favorable opinion of the Research Committee" and/or "Favorable opinion of the Committee of
Biosafety").

b) Latest version of the document:
The latest version of the document and the summary of changes must be entered in the corresponding section ("Research Protocol", "Investigator's Manual or equivalent document" or "Informed Consent"), likewise, in the "Date" and "Version" fields
You will need to enter the information from this latest updated version.



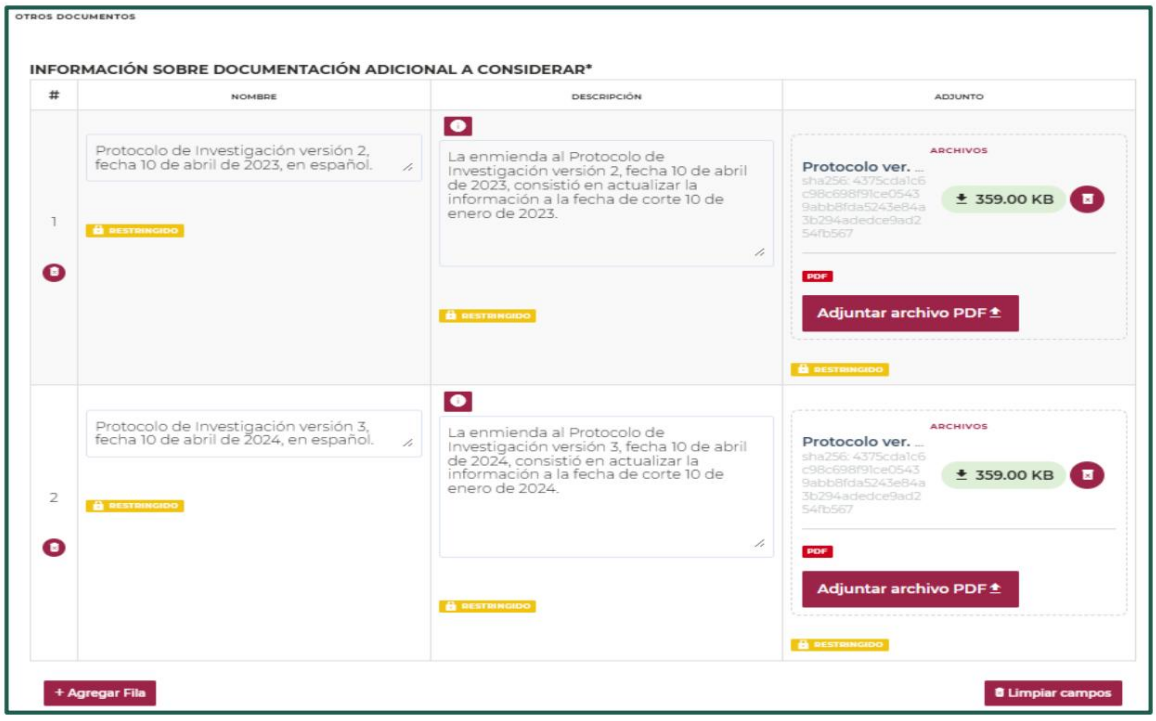
c) Previous versions of the document:
Previous versions of documents (in their final version, without change control) must be entered in the table "Information on additional documentation to consider", in the "Other documents" section, according to the following instructions:

In the “Name” field, the title of the document must be entered, as referred to in the approval opinion of the Research Ethics Committee.

In the "Description" field, you should provide a brief summary that allows the reader to understand the content of the document.

In the "Document" field, you must enter the Manual, Protocol or Consent Form in its final version, without control and/or summary of changes.

or Abstracts and/or change controls should be entered in the fields “Research protocol” or “Investigator's manual or equivalent document”, as appropriate.



13. If authorization has been requested to conduct a protocol or to include more than one research center, is it possible to subsequently withdraw any of the centers initially included in the application?

No. Due to the characteristics of the “DIGIPRiS: Online Regulation” platform, it is not possible to remove any of the research centers included in the initial application. Therefore, it is recommended to ensure that the centers included in the application comply with the requirements established in current health research legislation.

14. Although the amendment procedures (Homoclave COFEPRIS-09-012) have been classified by Regarding the different types of amendments available on the “DIGIPRiS: Online Regulation” platform, can I submit a request for more than one type of amendment in a single procedure on the “DIGIPRiS: Online Regulation” platform

No. Due to the design of the “DIGIPRiS: Online Regulation” Platform, each amendment request must be submitted according to the available methods for the Homoclave.

COFEPRIS-09-012, which are listed below:

Modalities for the COFEPRIS-09-012 Homoclave Request for Modification or Amendment to the Research Protocol Authorization.	
Modality	**Description**
A	Basic Documents.
B	Center inclusion (subsequent protocol).
C	Changes to the Research Center (change of address and/or name).
D	Change of Principal Investigator.
AND	Change or integration into the Research Team.
F	Changes to the Emergency Center (address and/or name).
G	Changes to the Evaluation Committees.
H	Security Amendment.
I	Changes to the owner (change of address and/or name).
J	Changes of sponsor (address and/or company name).
K	Change or addition of importer.
L	Other modifications.

15. If a protocol has been digitized and its information is available in RNEC 2.0, should I
Update the information on the previous RNEC platform?

Yes. Because the protocol was registered on the previous National Clinical Trials Registry platform, you must update the information on this platform until the study is completed.

16. What is the process for submitting an internal correction request to an Authorization Letter?
digital?

To make an internal correction request for the Authorization Letters issued through the “DIGIPRiS: Online Regulation” Platform, you must submit a COFEPRIS-CI14 homoclave request for internal correction through the window of the Comprehensive Services Center (CIS).

The request must include a written statement indicating the identification details of the research protocol and the digital authorization document for which internal correction is being requested (such as: protocol number, application number, and authorization number). All supporting documentation for the correction request must also be attached. This written request will be answered with a blank letter informing the applicant whether the internal correction request is approved or denied.

If the internal correction request is deemed "Approved," the corrected document will be available on the "DIGIPRiS: Online Regulation" platform. In addition to the internal correction document issued through the platform, a blank response document will also be generated for the submitted COFEPRIS-CI14 free-form document.

Additionally, regarding the internal correction request, it is important to remember that:

The submission of the internal correction request must be entered within the period of ten business days, counted from the next business day in which the notification of the corresponding authorization letter takes effect. It is important to remember that the aforementioned period is non-extendable, with the WARNING that in case of not entering the request in time and form in terms of articles 28, 32 and 59 of the Federal Law of Administrative Procedure, its processing will be inadmissible.

The "Internal Correction" request is not applicable to correcting information fields that have been completed by the user on the "DIGIPRiS: Online Regulation" platform and have therefore been migrated to the Authorization Letter. This is in accordance with the General Terms and Conditions of Use of the DIGIPRiS: Online Regulation Service, available on the platform.

in the page start of the https://digiprisregulacionenlinea.cofepris.gob.mx/sitio/home

The internal correction request for procedures submitted through the “DIGIPRiS: Online Regulation” Platform is only applicable to Authorization Letters, not to Prevention Letters, Disposal Letters or Free Writings.

17. What is the procedure for correcting information in the Authorization Letter that has been entered by the user?

If you identify that an Authorization Letter contains incorrect information derived from data entered by the user, you must submit a request for amendment/modification to the Authorization Letter through the corresponding modality on the DIGIPRiS platform: Online Regulation.
This application must comply with the requirements established in the applicable modality and must be accompanied by the documentation that supports the requested correction, after payment of the corresponding fees.

18. What should I do if the e.firma certificate of the legal entity under which the procedures are entered on the platform has been updated due to an update of the company information?

• For applications for authorization of a new clinical trial (entered under the code COFEPRIS-04-010, in the corresponding modality), this Authority must be notified of the update of the e.firma certificate of the legal entity through the consultation email (sigc@salud.gob.mx) referred to in the PLATFORM'S TERMS OF USE, prior to the submission of the new Application for Authorization of Research Protocol in Human Beings, so that this Commission can manage the relevant changes for the update of the certificate in the system.

• Similarly, for requests for authorization of procedures submitted under the homoclave COFEPRIS-09-012 that have a digital record on the DIGIPRiS platform: Regulation in

Line generated through the authorization of a procedure through said tool (regardless of whether the initial protocol was authorized physically or digitally through the initial management document), this Authority must be notified of the update of the e.firma certificate of the legal entity through the consultation email (sigc@salud.gob.mx) referred to in the PLATFORM'S TERMS OF USE, prior to the submission of new Applications
Authorization for amendment, modification and inclusion of the center, so that this Commission can manage the relevant changes for the update of the certificate in the system.

It should be noted that if the update of the e.firma certificate involves updating the RFC, address and/or business name of the holder, the applicant must request the corresponding amendment for the authorization of the changes to the holder through the homoclave COFEPRIS-09-012, modality I; once the e.firma certificate has been updated in the system.

19. In an Amendment request (Homoclave COFEPRIS-09-012) of modality "A: Basic Documents" of multicenter type, is it necessary to enter information in the field "Name of the research center"?

Yes. In a multicenter application of modality "A: Basic Documents", in the field "Name of the research center" you must enter the information corresponding to the research center from which you present the favorable opinions of the evaluation committees.

Please remember that leaving fields blank on the platform is of great importance because it negatively impacts the proper functioning of the operational flows of the DIGIPRiS platform: Online Regulation.

20. What should I do if I receive a prevention notice but I do not have any field enabled on the platform to respond to said notice?

Technical, usage and operational queries arising from the DIGIPRIS application, as well as inconsistencies, failures or anomalies related to the operation and use of the platform, should be reported through the query email (sigc@salud.gob.mx) referred to in the PLATFORM'S TERMS OF USE, for your due attention. Therefore, please do not submit Free Writings (ES45, ES45-A) related to the operation and use of the platform.

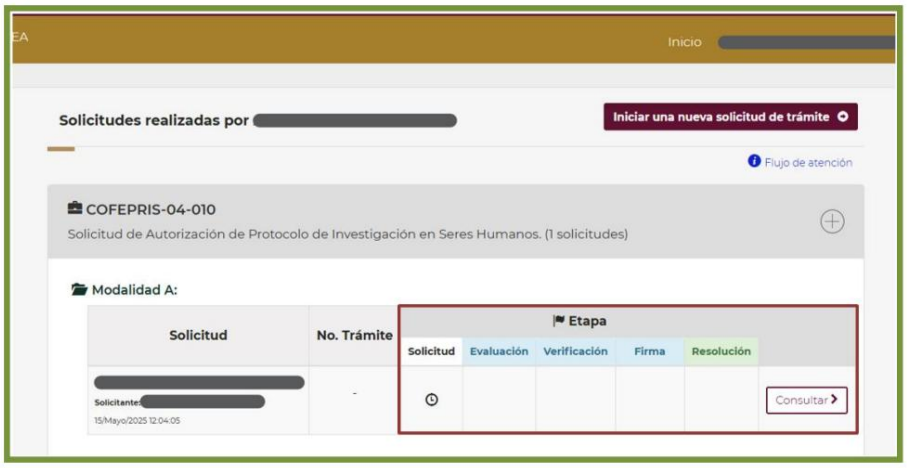
21. Is there a problem if I wait until the last day of my deadline to submit the response to prevention?

It is suggested not to wait until the last day for the response to the prevention letter, since the platform has pre-established operational flows and it is not possible to enable the fields or modify the deadlines for entering said response to prevention.

22. Where can I check the status of my application?

The status of a procedure submitted through the DIGIPRiS Platform: Online Regulation can be checked on the "Home" page of your account, in the "Requests Made" section, where it will be displayed
a list of the procedures you have submitted and the stage they are in (Application, Evaluation,

Verification, Signature or Resolution), as shown in the image:



In addition, the status of a procedure can also be checked by entering the application; the "Procedure Status Panel" is displayed at the top of the screen, as shown below:

Glossary:

- LFPA: Federal Law of Administrative Procedure. •
NOM-012: Official Mexican Standard, which establishes the criteria for the execution of projects of research for health in human beings (NOM-012-SSA3-2012).
- RIS: Health Supplies Regulation.