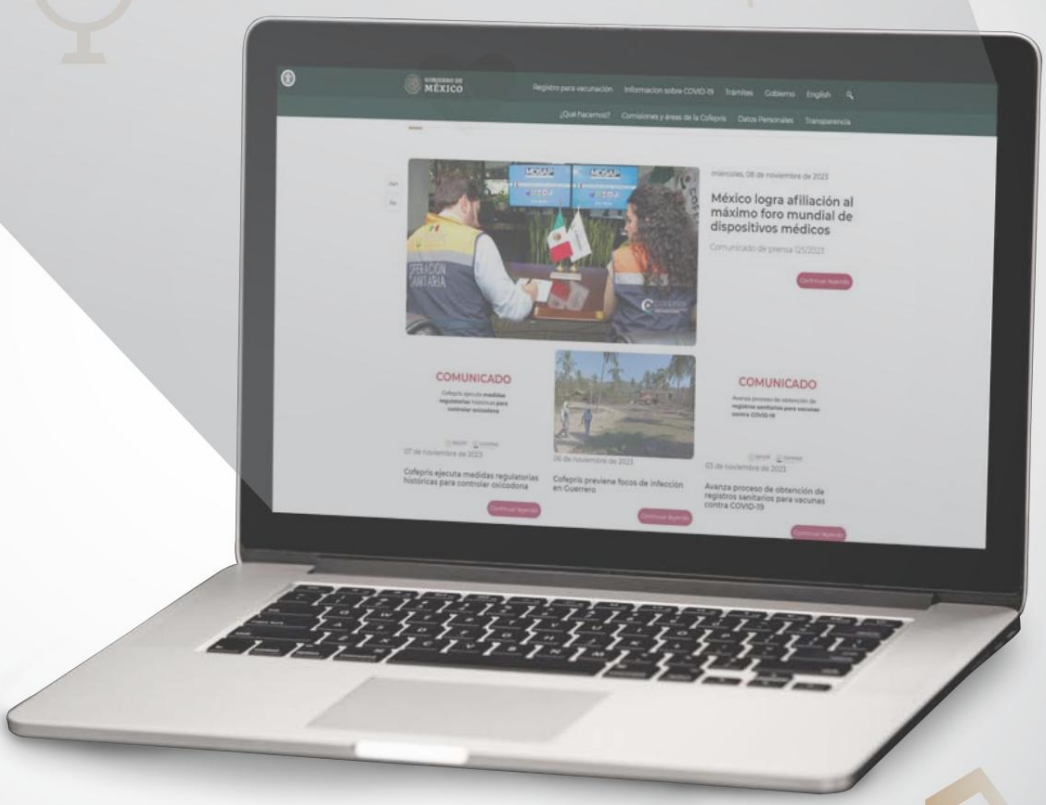
DIGIPRiS:

Research and Clinical Trials



GUIDE FOR REQUESTING PROTOCOLS RESEARCH IN HUMAN BEINGS

(HOMOKEY COFEPRIS 04-010)

GUIDE FOR REQUESTING RESEARCH PROTOCOLS IN HUMAN BEINGS (HOMOKEY COFEPRIS 04-010) IN THE *"DIGIPRiS: Research and Clinical Trials"* PLATFORM

INTRODUCTION:

On the "DIGIPRiS: Research and Clinical Trials" platform you can submit procedures for "Request for Authorization of Research Protocols in Human Beings" (homoclave COFEPRIS-04-010), review the applications and procedures that your organization has entered; consult and download the documents of the procedures in process and resolved; as well as visualize the flow and status of the entire procedure process (application, evaluation, verification, signature and resolution).

Remember that you can have several requests and procedures in all stages simultaneously. You will be able to enter as many times as necessary, so your data, procedures and requests will be protected.

This guide will detail the requirements and documents for the entry of procedures with homoclave COFEPRIS-04-010 in all its modalities. For more details about access to the platform, roles and permissions, generating a request, data capture, uploading information, signing procedures, among others, we suggest you consult the user manuals available on the COFEPRIS website. .

II. OBJECTIVE: To guide users on the correct way in which the information and documentation required for the entry of a "Request for Authorization of Research Protocol on Human Beings" should be presented.
(COFEPRIS-04-010, modalities A, B, C or D), through the "DIGIPRiS: Research and Clinical Trials" platform.

III. SCOPE: Of public interest; for any natural or legal person who wishes to submit a "Request for Authorization of Research Protocol on Animals".
Humans" (COFEPRIS-04-010, modalities A, B, C or D).

IV. FIELD OF APPLICATION: This guide is aimed at all health professionals involved in the development of clinical research protocols (owners, sponsors, contract research organizations; principal investigators and research team; research centers; health institutions; research ethics committees; research committees; biosafety committees, among others). others).

V. MODALITIES FOR APPLICATIONS FOR THE AUTHORIZATION OF RESEARCH PROTOCOLS

Request for Authorization of Research Protocols on Human Beings	
COFEPRIS-04-010-A	Modality A.- Medications, Biological and Biotechnological.
COFEPRIS-04-010-B	Modality B.- Medications: Bioequivalence Studies.
COFEPRIS-04-010-C	Modality C.- New Resources (study of materials, grafts, transplants, prostheses, physical, chemical and surgical procedures) and other methods of prevention, diagnosis, treatment and rehabilitation carried out on human beings or their biological products, except pharmacological ones. .
COFEPRIS-04-010-D	Modality D.- Risk-Free Research: observational studies (studies that use documentary research techniques and methods, in which no intentional intervention or modification is made in the physiological, psychological and social variables of the research subjects).

SAW. SYMBOLOGY

In the sections of the "DIGIPRiS: Research and Clinical Trials" platform you can find the following symbols:

Example	Meaning
	**MANDATORY REQUIREMENT:** Fields that appear with an asterisk **(*)** at the end of their name, a **red** box and a warning triangle to the right, correspond to mandatory requirements.
	NON-MANDATORY REQUIREMENT: The fields that appear under this format are not mandatory. If the requirement does not apply to your request or the information is not available, the field must be requested with **N/A.** Some non-mandatory fields are marked in **red,** because they must have a specific format, however, this does not mean that they are mandatory.
	**TOOLTIP:** At the end of some requirements you will find this icon; clicking on it will display a description referring to the most relevant information of the requested requirement.
	**DATE REQUIREMENT:** When the requirement is a date, it must be selected from the calendar that will be displayed when clicking on the requirement field. This date cannot be later than the date on which the information is being entered.
	**"MORE" ICON:** You will find this symbol located in the sections where it is allowed to add more fields within the same form to enter more information. Example: an additional NAICS key.
	**BUTTON: "CLEAR FIELDS"** This element will allow you to delete required and previously captured information in the form fields.

VII. ABBREVIATIONS

- **Art.:** Article.
- **GCP:** Good Clinical Practices.
- **COFEPRIS:** Federal Commission for the Protection against Health Risks.
- **CRO:** Contract Research Organization (CRO).
  English).
- **CURP:** Unique Population Registry Code.
- **FL:** Legal basis.
- **ICH E6 (R2):** ICH Guide to Good Clinical Practice E6 (Revision 2)
  International Council for Harmonization (ICH). • **PI:** Principal Investigator. • **LFD:**
Federal Law of Rights.

- **LFPA:** Federal Law of Administrative Procedure.
- **LGS:** General Health Law.
- **NOM-012:** Official Mexican Standard, Which establishes the criteria for the execution of research projects for health in human beings (NOM-012-SSA3-2012).

- **NOM-059:** Official Mexican Standard, Good manufacturing practices for medicines (NOM-059-SSA1-2015).
- **NOM-073:** Official Mexican Standard, Stability of drugs and medications, as well as herbal remedies (NOM-073-SSA1-2015).
- **NOM-164:** Mexican Official Standard, Good drug manufacturing practices (NOM-164-SSA1-2015).
- **RFC:** Federal Taxpayer Registry.
- **RIS:** Regulation of Health Supplies.
- **RLGSMIS:** Regulations of the General Health Law on Health Research for Health.
- **RNEC:** National Registry of Clinical Trials.
- **NAICS:** North American Industrial Classification System. • **SHCP:** Ministry of Finance and Public Credit.
- **TRDS:** Trial Registration Data Set, the requirements identified with this label are requested in accordance with the guidelines established by the World Health Organization (WHO).

VIII. INFORMATION CLASSIFICATION LABELS

These labels will help you know the use, treatment and controls that the information will have within the COFEPRIS "DIGIPRiS: Research and Clinical Trials" platform.

Label	Description
PÚBLICO	The information identified with this label will be in the public domain, without any particular treatment. It corresponds to the information that will be publicly disclosed in RNEC once the research protocol has been authorized.
INTERNO	The information identified with this label will be for consultation, review and validation purposes by the personnel of the different areas of COFEPRIS. -
RESTRINGIDO	The Information identified with this label will only be used by authorized Clinical Trials personnel for the evaluation of the procedure.

IX. GENERAL CONSIDERATIONS FOR CAPTURING INFORMATION AND UPLOADING DOCUMENTATION

Before capturing the information, we suggest you take into account the following considerations:

- **Although the procedures for legal entities are requested and signed by natural persons, in all cases the application process must be carried out with the role of "editor" or "authorizer" as appropriate.**

- **Due to the above, procedures signed by a natural person (as a physical applicant, instead of "authorizer") in which the documentation reflects a legal entity as the owner, will not be able to continue the evaluation process and will be prevented.**

- If any requirement does not apply to your request, the corresponding text field must be entered with "N/A" (not applicable).
  If the data is captured incorrectly, it will be marked as prevention because it affects the authorization document; Therefore, they must be eliminated to comply with the authorization format.

  - Example: in the case of protocols that do not involve evaluation by the biosafety committee, all the fields in which reference is made to this must be completed with "N/A", in addition to leaving the calendar fields blank where it is indicated. asks to select a date.

- **Likewise, avoid uploading other types of documents other than those requested in the form fields, otherwise, the item will be marked as a prevention point.**

- All documents must be uploaded in ".pdf" format (unrestricted text file), unless another format is specified.

- In the case of "Research Documents", the information requested in the fields must coincide with what was approved by the corresponding evaluation committees. **Examples:**

  - Protocolo_versionX_fecha_dd-mm-yy
  - Manual_researcher_versionX_date_dd-mm-yy (if you have more than one manual you must add the name of the corresponding molecule)

  - Main_consent_format_versionX_date_dd-mm-yy

- You can upload more than one document (file) in the same field, if so it requires

- Example: you have a main informed consent, two optional sample consents and an informed assent; On the platform, they all correspond to the field called “Informed consent”, so you must upload all the documents in this area.

- If a document covers one or more requirements, you must upload the same document in both items to avoid leaving empty elements.
  - Example: you have a letter from the investigation committee stating the non-vote of the committee members and the declaration of no conflict of interest, however, the platform requests these requirements in separate fields: “Non-vote letter from the Committee investigation” and “Non-conflict letter from the Investigation Committee.” In this case, the same document must be uploaded in both fields.

- All file names must match what is stated in the text field and the content of the attached files. It is important to mention that names with codes, abbreviations or references other than what is declared in the content of the corresponding file will not be accepted. **Examples:**

  - **Correct file name:**

    Protocolo_versionX_fecha_dd-mm-yy.

  - **Incorrect file name:**

    05. MoH Authorization_vX_23XXRTZXXXX_VV-TMF-XAEOND

- **Once the procedure is authorized, some data will be automatically migrated from the information captured by the applicant to the resolution letter and to the RNEC, so it will not be possible to make corrections once the application is signed. It is suggested to check that the information is expressed in accordance with the supporting documentation.**
  - To more easily identify the fields that will be migrated directly to the resolution documents, throughout this Guide you will find them in **bold, green and underlined.**
  - To identify the fields that will be migrated directly to the RNEC once their procedure is authorized, throughout this Guide you will find the **RNEC** legend under the name of the corresponding field.

X. SECTIONS THAT MAKE UP A "REQUEST FOR RESEARCH PROTOCOLS IN HUMAN BEINGS"

Each of the requests for the COFEPRIS-04-010 homoclave is made up of the following sections (with the corresponding adjustments according to the modality): **• Owner information • Information about the owner establishment •**

Proof of payment and request letter • Sponsor • Research documents •

Research product • Research center • Emergency care center • Principal

investigator • Research team • Research ethics committee • Research committee •

Biosafety committee • Importer •

Supplementary information

XI. GENERAL REQUIREMENTS, APPLICABLE TO ALL SECTIONS AND MODALITIES

Contact and identification data	
FL: LFPA Art. 15, RIS Art. 153, NOM-012 section 6.1 and Procedures Agreement.	
REQUIREMENT	**TYPE, CLASSIFICATION AND DESCRIPTION**
RFC	TYPE: **MANDATORY** Classification: **RICTED** Alphanumeric code of the Federal Taxpayer Registry (RFC) in accordance with the information registered with the SHCP. All fields must be required without abbreviations, spaces or special characters.
curp	TYPE: **MANDATORY** Classification: **RICTED** The Unique Population Registration Code must be provided with the 18 elements of an alphanumeric code. All fields must be required without abbreviations, spaces or special characters.
Telephone	TYPE: **OPTIONAL** Classification: **TRICTED** or **PUBLIC** (as applicable) Enter the 10-digit telephone number, including the password. **Example:** 5557314952
Mail Electronic	TYPE: **MANDATORY** Classification: **RESTRICTED** or **PUBLIC** (as applicable) Write the email address in lowercase letters and without spaces. **Example:** *example@domain.com* All fields must be required without abbreviations, spaces or special characters.

XII. GENERALITIES ABOUT ADDRESS APPLICABLE TO ALL SECTIONS AND MODALITIES.

The addresses requested throughout the sections of the platform are made up of the following fields:

Addresses	
REQUIREMENT	**TYPE, CLASSIFICATION AND DESCRIPTION**
Type and name of road	TYPE: MANDATORY Classification: Refer to the classification (Avenue, Boulevard, Street, Highway, Road, Private, Terrace, etc.) and the full name of the road where the address is located. **Example:** "Avenida Periférico", "Cerrada de San Ignacio", "Carretera Picacho Ajusco".
Outdoor Number	TYPE: MANDATORY Classification: Indicate the outside number where the vehicle is geographically located. establishment.
Interior number	TYPE: **OPTIONAL** Classification: Indicate the number or interior letter where the address is located that identifies the road where the geographic address is established. **Example:** "Level 1 and 2", "D", "Interior 3"
Between roads and roads	TYPE: **OPTIONAL** Classification: Write the type and name of the streets between which the establishment is geographically located. **Example:** *"Avenida del Rincón", "Alley Jesús María".*
Cologne	TYPE: MANDATORY Classification: Write the full name without abbreviations of the human settlement, where the address is located (condominium, neighborhood, hacienda, ranch, subdivision, section, sector, among others). **Examples:** *"Nápoles", "Del Carmen", "Colonia Centro", "Rancho las Américas"*
Code Postal	TYPE: MANDATORY Classification: Write the number consisting of five digits (coinciding with the official information of Correos de México), which allows the geographical identification of the place. **Example:** *02267*
Municipality or Alcaldía	TYPE: **OPTIONAL** Classification: TRICTED or PUBLIC appropriate) Write the full name of the territorial delegation or municipality where the address is geographically located.
Entity Federative	TYPE: **OPTIONAL** Classification: TRICTED or PUBLI as appropriate) Write the full name of the State of the Mexican Republic where the address is geographically located. **For example:** *"Mexico City", "Baja California", "State of Mexico"*

Remember that the address data must match the document that supports them (operating notice, health license or Committee registration granted by COFEPRIS or CONBIOÉTICA, as the case may be).

XIII. SPECIFIC SECTIONS OF THE PROCEDURE ON THE PLATFORM

I. Owner Information (FF-01)

Physical or moral person

FL: LFPA Art. 15, RIS Art. 153, NOM-012 section 6.1, and Procedures Agreement.

This information will be part of the Authorizations, Certificates and Visits Form that will be generated when you sign the procedure.

REQUIREMENT	TYPE, CLASSIFICATION AND DESCRIPTION	MODALITIES A	B	C	D		
Name or reason social	TYPE: MANDATORY Classification: Write the "Name" of the natural person or the "Company Name" of the legal entity (as applicable). It must correspond to what is registered with the SHCP.	ÿ	ÿ	ÿ	ÿ		
Surname	TYPE: MANDATORY (natural person) Classification: RESTRICTED If you establish the figure of a natural person in the previous field, complete the requirement in accordance with what is registered with the SHCP.	ÿ	ÿ	ÿ	ÿ		
Second Surname TYPE:	(natural person) Classification: RESTRICTED If you establish the figure of a natural person in the name or company name, complete the requirement in accordance with what is registered with the SHCP.	ÿ	ÿ	ÿ	ÿ		
Telephone, extension and email	TYPE: MANDATORY Classification: ESTRICTED Review the general requirements (section XI).	ÿ	ÿ	ÿ	ÿ		

Legal representative

FL: LFPA Art. 15, RIS Art. 153, NOM-012 section 6.1, and Procedures Agreement.

This information will be part of the Authorizations, Certificates and Visits Form that will be generated when you sign the procedure.

REQUIREMENT	TYPE, CLASSIFICATION AND DESCRIPTION	MODALITIES A	B	C	D		
First name(s), first last name and second last name	TYPE: MANDATORY Classification: Write the name(s), first and second last name of the legal representative who requests and signs the procedure.	ÿ	ÿ	ÿ	ÿ		
Telephone, extension and email	TYPE: MANDATORY Classification: Review the general requirements (section XI).	ÿ	ÿ	ÿ	ÿ		

Tax Address of the Owner

REQUIREMENT	TYPE, CLASSIFICATION AND DESCRIPTION	MODALITIES A	B	C	D		
Tax address of the owner.	TYPE: MANDATORY Classification: Review the generalities of the addresses (section XII).	ÿ	ÿ	ÿ	ÿ		

II. Owner Establishment Data (FF-01)

Owner Establishment Data

FL: LFPA Art. 15, RIS Art. 153, NOM-012 section 6.1, and Procedures Agreement.

This information will be part of the Authorizations, Certificates and Visits Form that will be generated when you sign the procedure.

REQUIREMENT	TYPE, CLASSIFICATION AND DESCRIPTION	MODALITIES A B C D		
RFC **RNEC**	TYPE: MANDATORY Classification: Review the general requirements (section XI).	ÿ ÿ ÿ ÿ		
Denomination o Company name of the establishment RNEC	TYPE: MANDATORY Classification: Write the full name of the owner establishment, which must match the document that supports it (operating notice, health license or registration of the Committee granted by COFEPRIS or CONBIOÉTICA, as the case may be) **Examples:** *"Farmacia Lupita", "Laboratorios Terra, SA de CV"*	ÿ ÿ ÿ ÿ		
License number Health or operating notice	TYPE: MANDATORY Classification: ERNAL Refer the complete number of the Health License authorization *(for example: 09 002 008 10017)* or **"N/A",** if it corresponds to an operating notice.	ÿ N/A ÿ ÿ		
Health License Notice of functioning	TYPE: **OPTIONAL** Classification: ESTRICTED Attach the corresponding document, in accordance with what was reported in the previous requirement.	ÿ N/A ÿ ÿ		
Clave SCIAN	TYPE: **OPTIONAL** Classification: ESTRICTED Write the complete number of the North American Industrial Classification System (NAICS) that allows you to identify the activities carried out by the establishment. You can add up to 4 keys.	ÿ ÿ ÿ ÿ		
Description SCIAN TYPE: **OPTIONAL** Classification :	Describe the nature of the activity(s) carried out by the establishment.	ÿ ÿ ÿ ÿ		

Health Manager

FL: LFPA Art. 15, RIS Art. 153, NOM-012 section 6.1, and Procedures Agreement.

This information will be part of the Authorizations, Certificates and Visits Form that will be generated when you sign the procedure.

REQUIREMENT	TYPE, CLASSIFICATION AND DESCRIPTION	MODALITIES A B C D		
RFC and CURP	TYPE: **OPTIONAL** Classification: ESTRICTED Review the general requirements (section XI).	ÿ ÿ ÿ ÿ		
First name(s), first last name and second last name	TYPE: **OPTIONAL** Classification: ESTRICTED Write the name(s), first last name and second last name of the health person responsible.	ÿ ÿ ÿ ÿ		

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Address of the titular Establishment

REQUIREMENT	TYPE, CLASSIFICATION AND DESCRIPTION	MODALITIES				
		A	B	C	D	
Establishment address RNEC	TYPE: MANDATORY Classification: STRICTED Review the generalities of the addresses (section	ÿ	ÿ	ÿ	ÿ	
Legal representatives)						
FL: LFPA Art. 15, RIS Art. 153, NOM-012 section 6.1, and Procedures Agreement. *This information will be part of the Authorizations, Certificates and Visits Form that will be generated when you sign the procedure.*						
REQUIREMENT	**TYPE, CLASSIFICATION AND DESCRIPTION**	**MODALITIES**				
		A	**B**	**C**	**D**	
curp	TYPE: **OPTIONAL** Classification: ESTRICTED Review the general requirements (section XI).	ÿ	ÿ	ÿ	ÿ	
First name, first last name and second last name	TYPE: MANDATORY Classification: STRICTED Write the name(s), first surname and second surname of the legal representative who requests and signs the procedure.	ÿ	ÿ	ÿ	ÿ	
Telephone, extension and email	TYPE: MANDATORY Classification: STRICTED Review the general requirements (section XI).	ÿ	ÿ	ÿ	ÿ	
Authorized persons)						
REQUIREMENT	**TYPE, CLASSIFICATION AND DESCRIPTION**	**MODALITIES**				
		A	**B**	**C**	**D**	
curp	TYPE: MANDATORY Classification: STRICTED Review the general requirements (section XI).	ÿ	ÿ	ÿ	ÿ	
First name, first last name and second last name	TYPE: MANDATORY Classification: STRICTED Write the name(s), first last name and second last name of the Authorized Person.	ÿ	ÿ	ÿ	ÿ	
Telephone, extension and email	TYPE: MANDATORY Classification: STRICTED Review the general requirements (section XI).	ÿ	ÿ	ÿ	ÿ	

III. Proof of payment and request letter

Proof of payment

FL: LFD Art. 195-I Fracc. VI, Procedures agreement and the others indicated by the applicable legal provisions.

REQUIREMENT	TYPE, CLASSIFICATION AND DESCRIPTION	MODALITIES A	B	C	D		
Proof of payment of the Procedure	TYPE: MANDATORY Classification: Proof in which the current amount for the application is covered, issued by a banking institution in terms of the Federal Law of Rights. **The information on the receipt must match the item on the payment key, otherwise the payment will be invalidated and the request inadmissible.**	ÿ	ÿ	ÿ	ÿ		
payment key	TYPE: MANDATORY Classification: Refer the 10 alphanumeric characters associated with the duty payment receipt attached in the previous field. **The payment key is unique for each payment.**	ÿ	ÿ	ÿ	ÿ		

Information about the Protocol

FL: LFPA Art. 15, LGS Art. 102 Fracc. I, NOM-012 Sections 6.3, 6.3.1, 6.3.2.

REQUIREMENT	TYPE, CLASSIFICATION AND DESCRIPTION	MODALITIES A	B	C	D		
Free writing request	TYPE: MANDATORY Classification: Attach the document that describes the request, in editable format (.docx). Must include: • Identification data of the study (title, name of the researcher, etc.). • Description of the risk level of the study. • Duration of the study: estimated start and end dates (DD/MM/YYYY). **In the case of response to prevention, you may make all the clarifications you consider pertinent through this document.**	ÿ N/A		ÿ	ÿ		

IV. Sponsor					
Sponsor Information					
REQUIREMENT	**TYPE, CLASSIFICATION AND DESCRIPTION** *LEGAL BASIS (FL)*	**MODALITIES**			
		A	**B**	**C**	**D**
Sponsor **RNEC**	TYPE: MANDATORY Classification: Refer to the full name **without abbreviations** of the natural person or legal entity responsible for initiating, managing and financing the research protocol. ***FL: NOM-012 Numeral 4.18***	ÿ	ÿ	ÿ	ÿ
Letter of acceptance and delegation of responsibilities from the research sponsor	TYPE: MANDATORY Classification: It must include the delegation of activities (of the sponsor) to other institutions and/or companies duly empowered to accept the obligations, responsibilities and rights imposed by the development and conduct of the study. In the case of legal entities, the position must be accepted by the authorized person or legal representative in accordance with the organizational chart or constituent regime. The letter must contain at least the following: • Company name and address of the sponsor; • Detailed description of the obligations and rights regarding the protocol; • Signature of the legal representative of the sponsor or authorized person; • Sponsor's contact telephone number and/or email; • Protocol number. When applicable, you must include the certified copy of the apostilled, notarized and translated power of attorney. ***FL: RLGSMIS Art. 58 Fracc. III and Art. 120, NOM-012 numerals 6.3.2.4, 6.3.2.7, 7.2 and 11.1***	ÿ	ÿ	ÿ	ÿ
Letter of no conflict of interest from the sponsor	TYPE: MANDATORY Classification: Document signed by the sponsor, where guarantee that it will not generate conflicts of interest that could cause the interruption of treatment for the research subject. ***FL: RLGSMIS Art. 63 y 120, NOM-012 Numeral 7.4.5***	ÿ	ÿ	ÿ	ÿ
Letter describing the human and material resources that will be allocated for the research	TYPE: MANDATORY Classification: Document issued by the sponsor or CRO in the which specifies the human and material resources that will be allocated for research and the way in which they will be distributed to the research centers. ***FL: RLGSMIS Art.14 Fracc. VI, NOM-012 Section 6.3.2.4 and 7.4.5***	ÿ	N/A	ÿ	ÿ

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Follow-up letter from the sponsor of the conduct of the research	TYPE: MANDATORY Classification: Document referring to the follow-up plan (scientific, technical and ethical), monitoring and audits, which will be carried out by the sponsor during the investigation. It must contain the following information: • Type of plan: Audit/Monitoring. • Objective and scope. • Frequency of application. • Responsible for monitoring (if applicable, mention the third party who will carry out the activity). • Profile of the monitor or auditor. • Evaluation tools and methodology implemented. • Classification of findings and decision-making decisions (severity classification). • Communication and notification strategies between the researcher, sponsor, Evaluation Committees and the Regulatory Authority. • Design of the Action Plan: Corrective, Improvement and Preventive. • Format of the Annual Report of progress and results through the Partial Technical Report. *FL: NOM-012 Numeral 7.2*	ÿ ÿ ÿ ÿ		
Current document that expresses the financial fund or study insurance	TYPE: MANDATORY Classification: Simple copy of the financial fund or current Insurance Policy, through which the continuity of the medical treatment and the compensation to which the subject will be legally entitled are guaranteed in the event of suffering damages directly related to the development of the research. *FL: NOM-012 Sections 5.14 and 7.2.*	ÿ ÿ ÿ ÿ		

V. Investigation Documents

Research protocol

REQUIREMENT	TYPE, CLASSIFICATION AND DESCRIPTION *LEGAL BASIS (FL)*	MODALITIES A B C D			
Scientific title of the protocol **RNEC**	TYPE: MANDATORY Classification: Indicate the scientific title of the study, as it appears on the cover of the research protocol. It must coincide with what was approved in the opinions of the Evaluation Committees. ***FL: NOM-012 Numerals 6.1 and 6.2.1, ICH E6 (R2)***	ÿ ÿ ÿ ÿ			
Public title of the protocol **RNEC**	TYPE: MANDATORY Classification: Write the short title in easy-to-understand language, intended for non-specialized audiences. ***FL: NOM-012 Numerals 6.1 and 6.2.1, ICH E6 (R2)***	ÿ ÿ ÿ ÿ			
Protocol number **RNEC**	TYPE: MANDATORY Classification: Indicate the alphanumeric name or number of the protocol identification. ***FL: ICH E6 (R2)***	ÿ ÿ ÿ ÿ			
Acronym **RNEC**	TYPE: **OPTIONAL** Classification: Enter the acronym or short term that allows you to designate another name to identify the study. ***FL: ICH E6 (R2)***	ÿ ÿ ÿ ÿ			
Research protocol	TYPE: MANDATORY Classification: Attach the study protocol document in PDF format (in text and without restriction). It must present the analysis of the risks inherent in the development of the research (diagnostic methods, established treatment procedures); expectation of the subject's living conditions with and without the proposed procedure/treatment; description of the elements and conditions that allow evaluating compliance with Good Clinical Practices and guaranteeing the safety of research subjects. It must be presented in Spanish, indicate the version and date of the document, and must contain As minimum: • Protocol title • Theoretical framework • Definition of the problem • Background and justification • Hypothesis • Objective and purpose of the protocol • Protocol design, including analysis and the statistical justification • Inclusion, exclusion and elimination criteria of the subjects • Treatment(s) and/or procedure(s) • Assessment Criteria	ÿ ÿ ÿ ÿ			

	• Direct access to data/documents fountain • Quality control and assurance • Ethical Considerations • Bibliographic references • Other documents related to the research project or protocol ***FL: LGS Art. 100 Fracc. I, II and III, 102 Fracc. II, III and IV; RLGSMIS Art. 14 Fracc. I, II, III and IV, 15, 17, 62 Fracc. I and IX, 65, 66, 69, 70, 72, 73, 74 and 116 Fracc. YO; NOM-012 Numerals 5.2, 5.3, 5.5, 5.6, 5.8, 5.9, 5.10, 5.12, 6, 6.2, 6.2.1, 6.2.2, 6.2.3, 6.2.4, 6.2.5, 6.2.6, 6.2. 7, 6.2.8, 6.2.9, 6.2.10, 6.2.11, 6.2.12, 6.3, 6.3.2, 6.3.2.1, 6.3.2.2, 6.3.2.3 and 10.2; and Procedures agreement.***				
Research protocol version date	TYPE: **MANDATORY** Classification: **STRICTED** Select the date of the version of the document that was attached in the previous field; It must coincide with what is recorded as approved in the opinions of the Evaluation Committees. ***FL: ICH E6 (R2)***	ÿ ÿ ÿ ÿ			
Research protocol version	TYPE: **MANDATORY** Classification: **STRICTED** Indicate the version of the current protocol; It must coincide with what is stated in the attached document and with what is recorded as approved by the Evaluation Committees. ***FL: ICH E6 (R2)***	ÿ ÿ ÿ ÿ			
Schedule of the study	TYPE: **OPTIONAL** Classification: **ESTRICTED** The Calendar that establishes the activities and the expected duration for the development of the research. **If the requirement is presented as an annex within the Research Protocol, it will not be necessary to request this field.** ***FL: NOM-012 Sections 5.8, 5.9 and 6.3.2.2, Procedures agreement; and ICH E6 (R2)***	ÿ ÿ ÿ ÿ			
Informed consent					
REQUIREMENT	**TYPE, CLASSIFICATION AND DESCRIPTION** *LEGAL BASIS (FL)*	**MODALITIES** **A B C D**			
Consent informed and/or informed consent of the research subject	TYPE: **MANDATORY** Classification: **STRICTED** Attach in PDF format (in text and without restriction) the Consent and/or Informed Assent Forms (as the case may be), through which the research subject agrees to participate (and have the experimental maneuver applied) voluntarily, once has received sufficient, timely, clear and truthful information about the expected risks and benefits. You can attach more than one. ***LGS Art. 100 Fracc. IV and 103; RLGSMIS Art. 14 Fracc. V, 20, 21, 22 and 36; NOM-012, Sections 4.3, 5.7, 6.3, 6.3.2.10, 8.5, 10.6, 10.7, 11.2 and 11.3; and Procedures agreement.***	ÿ ÿ ÿ ÿ			

Version date of informed consent	TYPE: MANDATORY Classification: Select the date of the version of the Consent/Informed Assent (main). It must coincide with what is stated in the attached document and with what is recorded as approved in the opinions of the Evaluation Committees. ***FL: ICH E6 (R2)***	ÿ ÿ ÿ ÿ		
Version of the informed consent	TYPE: MANDATORY Classification: Indicate the version of the current Informed Consent/Assent (main). It must coincide with what is stated in the attached document and with what is recorded as approved in the opinions of the Evaluation Committees. ***FL: ICH E6 (R2)***	ÿ ÿ ÿ ÿ		
Investigator's Manual				
REQUIREMENT	**TYPE, CLASSIFICATION AND DESCRIPTION** *LEGAL BASIS (FL)*	**MODALITIES** **A B C D**		
Manual of the investigator the equivalent document	TYPE: MANDATORY Classification: Attach in PDF format (in text and without restriction) the document that contains the non-clinical and clinical information previously obtained, which justifies the use and management of the investigational product. It must contain at least the following: • Index. • Summary. • Introduction. • Properties (physical, chemical and pharmaceutical) and Formulation (including information on manufacturing, labeling, storage, packaging and stability, when applicable). • Preclinical information: o Non-Clinical Pharmacology. o Pharmacokinetics and Metabolism in animals. or Toxicology. • Clinical information: o Pharmacokinetics and Metabolism in humans. o Experience during marketing. o Data Summary and Guide for the Investigator. ***FL: LGS Art. 100 Fracc. I, II, III, 102 Fracc. II and III; RLGSMIS Art. 14 Fracc. II, III, 62 Fracc. VIII, 66, 67, 68, 69, 70 Fracc. I, 73; NOM-012 Numerals 4.7 and 5.10; Procedural Agreement and ICH E6 (R2)***	ÿ ÿ ÿ N/A		

Continued on next page

Manual version date Investigator	TYPE: MANDATORY Classification: Select the date of the version of the document that was attached in the previous field; It must coincide with what is recorded as approved in the opinions of the Evaluation Committees. ***FL: ICH E6 (R2)***	ÿ ÿ ÿ N/A			
Investigator's Manual Version	TYPE: MANDATORY Classification: Indicate the version of the current Researcher's Manual; It must coincide with what is stated in the attached document and with what is recorded as approved in the opinions of the Evaluation Committees. ***FL: ICH E6 (R2)***	ÿ ÿ ÿ N/A			
Investigator's Manual					
REQUIREMENT	**TYPE, CLASSIFICATION AND DESCRIPTION** *LEGAL BASIS (FL)*	**MODALITIES** **A B C D**			
Study phase **RNEC**	TYPE: MANDATORY Classification: Note the stage of the clinical trial for which you are requesting approval (as applicable). Examples: Phase I, Phase II, Phase III, Phase IV, etc. ***FL: RLGSMIS Articles 66 and 69; ICH E6 (R2)***	ÿ N/A ÿ N/A			
Study Design TYPE:	Classification: RESTRICTE Describe the general procedures, techniques and methods applicable to the research, citing the type of research, blinding, allocation method (randomized/ non-randomized), allocation (single arm, parallel, crossover or factorial), among others. ***FL: RLGSMIS Articles 15; NOM-012 Number 6.2.9; ICH E6 (R2)***	ÿ ÿ ÿ ÿ			
Primary objective **RNEC**	TYPE: MANDATORY Classification: Write clearly and precisely the result you want to obtain from the intervention(s) of the study. investigation. ***FL: ICH E6 (R2)***	ÿ ÿ ÿ ÿ			
Key inclusion criteria **RNEC**	TYPE: MANDATORY Classification: List all conditions and/or eligibility characteristics that candidate subjects must meet to participate in the research and that will help the researchers during the selection process. ***FL: ICH E6 (R2)***	ÿ ÿ ÿ ÿ			
Key criteria of exclusion **RNEC**	TYPE: MANDATORY Classification: List all conditions and/or eligibility characteristics that prevent the participation of candidate subjects in clinical research, and that will help researchers during the selection process to identify subjects who **are not eligible** to participate in the study, with the aim in order to ensure patient safety. ***FL: ICH E6 (R2)***	ÿ ÿ ÿ ÿ			

Primary endpoints **RNEC**	TYPE: MANDATORY Classification: List the main variables to be evaluated as established in the protocol. ***FL: ICH E6 (R2)***	ÿ ÿ ÿ ÿ		
Criteria valuation secondary **RNEC**	TYPE: MANDATORY Classification: List the evaluations that support the primary objectives. ***FL: ICH E6 (R2)***	ÿ ÿ ÿ ÿ		
Investigator's Manual				
REQUIREMENT	**TYPE, CLASSIFICATION AND DESCRIPTION** *LEGAL BASIS (FL)*	**MODALITIES** **A B C D**		
Sample size of research at a global level **RNEC**	TYPE: **OPTIONAL** Classification: Write the total number of participants the trial plans to enroll globally. In the case of national studies, the field must be required with **"N/A"** in a standardized manner. ***FL: ICH E6 (R2)***	ÿ N/A ÿ ÿ		
Type of research population at a global level **RNEC**	TYPE: **OPTIONAL** Classification: Describe the set of elements (clinical and demographic characteristics, age, sex, etc.) that define the group of participants that you wish to enroll in clinical research. In the case of national studies, the field must be required with "N/A" in a standardized manner. ***FL: ICH E6 (R2)***	ÿ N/A ÿ ÿ		
Sample size in Mexico **RNEC**	TYPE: MANDATORY Classification: Write the total number of participants the trial plans to enroll in Mexico. ***FL: ICH E6 (R2)***	ÿ ÿ ÿ ÿ		
Type of research population in Mexico	TYPE: MANDATORY Classification: Describe the set of elements (clinical and demographic characteristics, age, sex, etc.) that define the group of participants that you wish to enroll in clinical research carried out in Mexico. ***FL: ICH E6 (R2)***	ÿ ÿ ÿ ÿ		
Study interventions **RNEC**	TYPE: MANDATORY Classification: Table that presents the information on the arms of the study and/or the interventions that will be carried out during the development of the research. It must be in editable format (.docx) and contain the treatment group, the assigned intervention, and the duration of treatment. ***FL: ICH E6 (R2)***	ÿ ÿ ÿ N/A		

SAW. Research product

Research Product Information

REQUIREMENT	TYPE, CLASSIFICATION AND DESCRIPTION *LEGAL BASIS (FL)*	MODALITIES A B C D			
Product name in Investigation RNEC	TYPE: MANDATORY Classification: Indicate the name(s) of the investigational product that identifies the drug(s) or biopharmaceutical(s) that will be investigated in the clinical trial. It generally corresponds to the international nonproprietary name (INN) recommended by the WHO. ***FL: RLGSMIS Article 65, NOM-012 Numerals 4.16, International Nonproprietary Names (INN), WHO***	ÿ ÿ ÿ ÿ			
Route of administration RNEC	TYPE: MANDATORY Classification: Establish the route(s) that will be used to administer the investigational product to the participating subjects. **Examples:** Oral, Intravenous, Otic, Nasal, Cutaneous, Intramuscular, Ocular, etc. ***FL: RLGSMIS Article 67; WHO.***	ÿ ÿ N/A/A			
Letter of import inputs used in the research study	TYPE: MANDATORY Classification: STRICTED Document that clearly establishes the quantity and description of supplies that will be imported during each stage of the study, detailing the following: investigational product or placebo (when applicable), pharmaceutical form, presentation, concentration and number of subjects to enroll in Mexico. Consider only a 20% surplus. **IMPORTANT:** The input information provided in this item is only considered informative, not authorization, and will not be cited in the authorization letter. ***FL: NOM-012 Section 6.4; Procedures agreement.***	ÿ ÿ ÿ ÿ			
Compliance information Good Practices Manufacturing	TYPE: MANDATORY Classification: STRICTED Attach sufficient documentation to support that the investigational product and the placebo have and maintain the characteristics of identity, purity, safety, potency and quality required for their use, thus ensuring the state of compliance with Good Manufacturing Practices in accordance with the applicable legal provisions. ***FL: NOM-059 Numerals 10.9, 10.9.1.2, 10.9.1.3, 10.9.2.1, 10.9.2.2, 10.9.2.2.1, 10.9.2.2.2, 10.9.2.2.3, 10.9.5.1, 10.9.5.2 and 10.9.6.1; NOM-164 Numerals 16.4.1, 16.4.2, 16.5.1, 16.5.2, 16.5.4, 16.5.5 and 16.10.1.***	ÿ ÿ ÿ N/A			

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Investigational Product Stability Information	TYPE: MANDATORY Classification: STRICTED Attach the results of the stability studies that support that the investigational product and the placebo comply with the physical, chemical and biological parameters that the investigational product must comply with throughout its useful life, to maintain over time. storage and use, the established quality specifications that prove the conservation of its properties. ***FL: NOM-059 Numeral 10.9.7.1; NOM-073 Numerals 7.1, 7.2, 10.6 and 10.27.***	ÿ ÿ ÿ	N/A		

VII. Research Center

Information about the Research Center

REQUIREMENT	TYPE, CLASSIFICATION AND DESCRIPTION *LEGAL BASIS (FL)*	MODALITIES A B C D		
Denomination of the Center Investigation **RNEC**	TYPE: MANDATORY Classification: Write the full name of the Research Center where the study will be carried out. The information must match the Company Name of the Establishment declared in the Notice of Operation or Health License presented, as applicable. **Example:** Joaquín Negrete Hospital, Clínica SA de CV ***FL: LGS Art. 45, 47, 198 Fracc. IV and V, 200 Bis, 315, 368, 369, 373; RLGSMIS Art. 31 and 98; NOM-012 Numeral 4.11; Procedures agreement.***	ÿ ÿ ÿ ÿ		
Resource description letter humans and materials that will be allocated for Research	TYPE: MANDATORY Classification: Document that details the description of the available resources of the Institution or establishment where the research will be carried out, including areas, equipment, auxiliary laboratory services and cabinets; number and type of human resources. ***FL: LGS Art. 100 Fracc. V and VIII; RLGSMIS Art. 14 Fracc. VI and VIII, 62 Fracc. IV and IX; NOM-012 Numerals 6.3.2.4 and 7.4.5; Procedures agreement.***	ÿ ÿ ÿ ÿ		
Authorization letter from Owner of the center where the out the Investigation	TYPE: MANDATORY Classification: Attach in PDF format the authorization letter signed by the head of the institution or establishment, authorizing the research to be carried out. It must include at least the following: • Title and number of the protocol. • Name of the main researcher. • Name, signature and position of the Head of the Institution or Establishment. • Name and address of the center investigation. ***FL: LGS Art. 102 Fracc. V; RLGSMIS Art. 14 Fracc. VI, VIII, 62 Fracc. II and IX; NOM-012 Section 6.3.2.6, 7.2, 8.2 and 8.4; Procedures agreement.***	ÿ ÿ ÿ ÿ		
Health License or Notice of Functioning	TYPE: MANDATORY Classification: Attach in PDF format, the document issued by the corresponding Authority, which allows a public or private person to carry out an activity related to the establishment in an establishment. human health (as applicable). ***FL: LGS Art. 45, 47, 198 Fracc. IV and V, 200 Bis, 315, 368, 369, 373; RLGSMIS Art. 31 and 98; NOM-012 Numeral 4.11; Procedures agreement.***	ÿ N/A ÿ ÿ		

Number of the Sanitary license	TYPE: **OPTIONAL** Classification: **TERNAL** Refer the complete number of the Health License authorization *(for example: 09 002 008 10017)* or "N/A", in case of an operating notice. ***FL: LGS Art. 45, 47, 198 Fracc. IV and V, 200 Bis, 315, 368, 369, 373; RLGSMIS Art. 31 and 98; NOM-012 Section 4.11; and Procedures agreement.***	ÿ N/A ÿ ÿ			
Address of the research center					
REQUIREMENT	**TYPE, CLASSIFICATION AND DESCRIPTION** *LEGAL BASIS (FL)*	**MODALITIES** **A B C D**			
Domicile of Research Center **RNEC**	TYPE: **MANDATORY** Classification: **RESTRICTED** and **PUBLIC** Review the general requirements (section XI). All data is restricted except for the **municipality or mayor's office and the federal entity,** which will be public knowledge.	ÿ ÿ ÿ ÿ			

VIII. Emergency care center

Emergency Care Center Information

REQUIREMENT	TYPE, CLASSIFICATION AND DESCRIPTION *LEGAL BASIS (FL)*	MODALITIES A B C D			
Denomination of the Emergency care center **RNEC**	TYPE: MANDATORY Classification: Write the full name of the unit or institution that will provide care for medical emergencies arising from the Investigation, it must match the Name of the Establishment indicated in the Health License presented. **Example:** *"Hospital Joaquín Negrete, Clínica SA de CV"* ***FL: RLGSMIS Art. 14 Fracc. X, 62 Fracc. IV,V and NOM-012 numerals 6.3.2.9, 8.6***	ÿ ÿ ÿ N/A			
Description of available resources of the Unit or Institution where will attend to the Medical emergency	TYPE: MANDATORY Classification: Document that details the description of the available resources of the institution in charge of providing Medical Emergency Care derived from the Research, including: areas, equipment, auxiliary laboratory and cabinet services, number of personnel and other resources designated specifically and solely for the development of the study. The letter must include at least: • Title and protocol number. • Name of the Principal Investigator. • Human resources (Number of people). • Areas, Equipment, Auxiliary Laboratory and Cabinet Services. ***FL: LGS Art. 100 Fracc. VII; RLGSMIS Art. 14 Fracc. X, 62 Fracc. V; NOM-012 Sections 6.3.2.4, 6.3.2.9, 8.6 and Procedures Agreement.***	ÿ ÿ ÿ N/A			
Letter of Authorization of Holder of the Establishment where Emergencies will be attended Doctors	TYPE: MANDATORY Classification: Letter of authorization signed by the head of the Institution in charge of providing care for Medical Emergencies derived from the Research, in which he authorizes the medical emergencies derived from the study to be attended to. It must include at least: • Title and protocol number • Name of the Principal Investigator • Name, signature and position of the Owner of the Institution or Establishment responsible for the care of medical emergencies. • Name and address of the research center. ***FL: LGS Art. 100 Fracc. VII; RLGSMIS Art. 14 Fracc. X, 62 Fracc. V; NOM-012 Numerals 6.3.2.4, 6.3.2.9, 8.6; and Procedures agreement.***	ÿ ÿ ÿ N/A			

Health License of the Establishment	TYPE: MANDATORY Classification: Legible Health License of the Institution in charge of providing care for Medical Emergencies derived from the Research, issued by the corresponding Authority. *FL: LGS Art. 45, 198 Fracc. V, 368, 369, 373; NOM-012 Section 8.6*	ÿ ÿ ÿ N/A			
Number of the Sanitary license	TYPE: MANDATORY Classification: Refer the complete number of the Health License authorization of the Institution in charge of providing Medical Emergency care. It must match the document referred to in the previously required field. ***Example:*** *11 AM 20 007 000.* *FL: LGS Art. 45, 198 Fracc. V, 368, 369, 373; NOM-012 Section 8.6*	ÿ ÿ ÿ N/A			
Agreement for the Attention of Medical emergency	TYPE: MANDATORY Classification: For Research Centers that enter into agreements for the care of Medical Emergencies with other Institutions, a simple, legible copy of the current Agreement must be included. It must include at least: • Title and protocol number • Name of the Principal Investigator • Scope, Clauses and Validity • Signature of the owners or Legal Representatives of both Institutions • Establish medical emergency care *RLGSMIS Art. 14 Fracc. X, 62 Fracc. IV,V; NOM-012 numerals 6.3.2.9, 8.6*	ÿ ÿ ÿ N/A			
Address of the emergency center					
REQUIREMENT	**TYPE, CLASSIFICATION AND DESCRIPTION** *LEGAL BASIS (FL)*	**MODALITIES** **A B C D**			
Domicile of urgent care center **RNEC**	TYPE: MANDATORY Classification: TRICTED and PUBL Review the general requirements (section XI). Most of the data in this area is confidential and restricted, with the exception of the **municipality or mayor's office and the federal entity,** which will be public knowledge. -	ÿ ÿ ÿ N/A			

IX. Principal Investigator

Principal Investigator Information

REQUIREMENT	TYPE, CLASSIFICATION AND DESCRIPTION *LEGAL BASIS (FL)*	MODALITIES A B C D			
Name of Investigator Principal RNEC	TYPE: MANDATORY Classification: Write the full name of the health professional who has the appropriate academic training, specialty and experience to conduct the study, whom the Ministry of Health will authorize as responsible for conducting, coordinating and monitoring the development of the research, in accordance with the objective and scope. ***FL: LGS Art 100, Fracc. V and VI, 102 Fracc V; RLGSMIS Art 14 Fracc. VI, IX, 64 Fracc. I, III, 113, 119, 120; NOM-012 Numerals 8.9, 10.2, 10.9, 12.1, 12.3***	ÿ ÿ ÿ ÿ			
Position of Investigator Principal RNEC	TYPE: MANDATORY Classification: Provide the position held by the IP within the Institution or Establishment where it will be carried out. the investigation. ***FL: ICH E6 (R2)***	ÿ ÿ ÿ ÿ			
Affiliation of the Investigator Principal RNEC	TYPE: **OPTIONAL** Classification: Provide the name of the Institution or Establishment to which the Principal Investigator belongs and in which he carries out his duties. ***FL: ICH E6 (R2)***	ÿ ÿ ÿ ÿ			
Principal Investigator Email RNEC	TYPE: MANDATORY Classification: Review the general requirements (section XI).	ÿ ÿ ÿ ÿ			
Investigator Acceptance of Responsibility Letter Main, No Interest conflict, Event Report Adverse and Confidentiality	TYPE: MANDATORY Classification: Document in which the main researcher accepts: • The responsibility of conducting the research study in accordance with GCP and other applicable National and International Guidelines. • The commitment to carry out the study with strict confidentiality of the information generated from the research. • Not have any conflict of Interest that could affect the objectivity or performance of their duties. • The commitment to report to the corresponding Authorities all **Suspected Adverse Reactions and Events** that may occur during the conduct of the study. ***FL: LGS Art 100 Fracc. V, VI, 102 Fracc. V; RLGSMIS Art. 14 Fracc. VI, IX, 64 Fracc. I, III, 113, 119, 120; NOM-012 Numerals 8.9, 10.2, 10.9, 12.1, 12.3.***	ÿ ÿ ÿ ÿ			

Researcher's Professional History Principal	TYPE: MANDATORY Classification: Professional history of the principal investigator that includes his academic preparation, representative scientific production and clinical practice related to the conduct and development of clinical studies. You must attach the updated CV, dated and signed by IP; as well as a simple copy of the documentation legally issued and registered by the competent educational authorities in Mexico (e.g. professional ID), which accredits the academic preparation described above. ***FL: LGS Art. 100 Fracc. V; RLGSMIS Art. 14 Fracc. VI, 62 Fracc. VI, 113, 114; NOM-012 Sections 10.1, 10.4.1 and Procedures Agreement.***	ÿ ÿ ÿ ÿ			

X. Research Team

Information about the Research Team

REQUIREMENT	TYPE, CLASSIFICATION AND DESCRIPTION *LEGAL BASIS (FL)*	MODALITIES A B C D		
Preparation Academic and Experience of medical staff, Paramedic and others Experts	TYPE: MANDATORY Classification: CTED Summary of the academic preparation and professional experience of the medical staff and other experts who will participate in the Research activities. The updated CV, dated and signed, of each of the members must be attached; and include a simple copy of the documentation legally issued and registered by the competent educational authorities in Mexico, which accredits the academic preparation described above. NOTE: The experience and profile of the members must be congruent with the delegated activity(s). You must generate a file for each member of the research team. ***FL: LGS Art. 100 Fracc. V, RLGSMIS Art. 14 Fracc. VI, 62 1 VII, IX, 114, 116 Fracc. V, 117, 118; NOM-012 Section 10.1, 10.4, 10.4.1 and Procedures Agreement.***	ÿ ÿ ÿ ÿ		
Descriptive Letter of the Delegation of Responsibility of the Researcher at Team of Investigation	TYPE: MANDATORY Classification: CTED Document through which the Principal Investigator delegates functions and activities to each of the team members. The letter must contain at least: • Title and protocol number. • Detailed description of the activities to be delegated to the research team. • Name and signature of the Principal Investigator. • Signature of each team member. ***FL: LGS Art. 100 Fracc. V; RLGSMIS Art. 14 Fracc. VI, 62 Fracc. VII, IX, 114, 117, 118; NOM-012 Section 10.1, 10.4, 10.4.1 and Procedures Agreement.***	ÿ ÿ ÿ ÿ		
License of Store	TYPE: **OPTIONAL** Classification: TRICTED Document issued by the corresponding Authority, which endorses the authorization for the operation of a deposit and distribution warehouse **for biological products for human use, narcotics or psychotropics.** ***FL: LGS Art. 45, 198 Fracc. I, 200, 257; RIS Art. 102 Fracc. II, 113 and NOM-012 section 8.1.***	ÿ ÿ N/A/A		

XI. Research Ethics Committee

Information about the Research Ethics Committee

REQUIREMENT	TYPE, CLASSIFICATION AND DESCRIPTION *LEGAL BASIS (FL)*	MODALITIES A B C D		
Denomination of the Establishment of the Research Ethics Committee **RNEC**	TYPE: MANDATORY Classification: Write the full name of the Establishment Name of the Research Ethics Committee, in accordance with what was declared in the current Registry of said Committee. **Examples:** *"Hospital Joaquín Negrete", "Clínica SA de CV", etc.* ***FL: LGS 41 bis Fracc. II, 98 Fracc. II; RLGSMIS Art. 99 Fracc. I, 101, 104, 107, 108, 109 and 112; NOM-012 Section 6.3.2.5, 9, 9.1, 9.1.1, 9.2 and 9.2.1; NOM-177 Numerals 10.2.1, 10.2.1.1, 10.2.2 and 10.2.2.1; Procedures agreement.***	ÿ ÿ ÿ ÿ		
Name of President of Ethics Committee in Investigation **RNEC**	TYPE: MANDATORY Classification: Write the full name of the President of the Research Ethics Committee registered with the National Bioethics Commission (CONBIOÉTICA); in accordance with the current Registry provided. ***FL: ICH E6 (R2); NOM-012 Numeral 9.2.4***	ÿ ÿ ÿ ÿ		
Name of Secretary of the Ethics Committee in Investigation **RNEC**	TYPE: MANDATORY Classification: Write the full name of the Secretary (member) of the Research Ethics Committee registered with the National Bioethics Commission (CONBIOÉTICA); in accordance with the current Registry provided. ***FL: ICH E6 (R2), NOM-012 Numeral 9.2.4***	ÿ ÿ ÿ ÿ		
Research Ethics Committee Registration Number	TYPE: MANDATORY Classification: Refer the complete number of the current registration (for example: *CONBIOÉTICA-11-CEI-003-20160708)* of the Research Ethics Committee, issued by the National Bioethics Commission (CONBIOÉTICA). ***FL: LGS 41 bis Fracc. II and 98 Fracc. II; RLGSMIS Art. 99 Fracc. I, 101, 104, 107, 108, 109 and 112, NOM-012 Numerals 6.3.2.5, 9, 9.1, 9.1.1, 9.2 and 9.2.1; NOM-177 Section 10.2.1, 10.2.1.1, 10.2.2 and 10.2.2.1; Procedures agreement.***	ÿ ÿ ÿ ÿ		
Registration of the Ethics Committee in Investigation	TYPE: MANDATORY Classification: Attach in PDF format the document that recognizes the Research Ethics Committee as an Institutional, interdisciplinary, plural and consultative body, created to evaluate and rule on Research Protocols on Human Beings. **NOTE:** The Registry must be legible, without deletions or amendments, it must include the complete list of the name and position of the Committee Members, opinions from Committees that do not have a current registry will NOT be accepted. ***FL: LGS 41 bis Fracc. II and 98 Fracc. II; RLGSMIS Art. 99 Fracc. I, 101, 104, 107, 108, 109 and 112; NOM-012***	ÿ ÿ ÿ ÿ		

	Section 6.3.2.5, 9, 9.1, 9.1.1, 9.2 and 9.2.1; NOM-177 Section 10.2.1, 10.2.1.1, 10.2.2 and 10.2.2.1; Procedures agreement.				
Favorable Opinion of the Research Ethics Committee	TYPE: **MANDATORY** Classification: Attach in PDF format (in text and without restriction), the favorable opinion by which the Committee of Research Ethics **approves** the study documents that will be used in the corresponding Research Center. Must include: • Full name of the IP corresponding to the Research Center • Company name and address of the Research Center • Full title and research protocol number. • Detailed description of the documents evaluated and **approved** in Spanish, citing version and date. • Validity of the approving opinion (no more than 1 year). • Name, position and signature of the person responsible who endorses the opinion. • Confirmation of the evaluation of ethical aspects, the risk/benefit of the protocol as well as the guarantee and well-being of the subjects. • It must be issued on letterhead, specifying the company name and address of the Committee (consistent with its current registration) • Date of issuance of the opinion (day, month not anymore) **NOTE:** Only Opinions will be accepted with the signature of the President (or, if applicable, the Vocal Secretary), attaching the “NO VOTE” letter or justification for the absence of the president. ***FL: LGS Art. 41 Bis Fracc. II, 98 Fracc. II, 100 Fracc. I, II, III, IV, V and VIII; RLGSMIS Art. 14 Fracc. VII, 22 Fracc. II, 62 Fracc. III, 102 and 109; NOM-012 Numerals 6.3.2.8, 9.2, 9.2.3, 9.2.7, 9.2.8, 9.2.9, 9.2.10 and 9.2.12; NOM-177 Numerals 8.6.1, 8.7.4, 10.2.1, 10.2.1.1, 10.2.1.2, 10.2.2, 10.2.2.1, 10.2.2.2 and 10.2.2.3; Procedures agreement.***	ÿ ÿ ÿ ÿ			

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No Vote Letter from Ethics Committee in Investigation	TYPE: **OPTIONAL** Classification: ESTRICTED Attach the document in PDF format, through which the members of the Research Ethics Committee refrain from participating in the evaluation and issuance of opinions of the research in which they are participating as members of the research team. *FL: RLGSMIS Art. 108 Fracc. VIII; NOM-012 Section 9.2.3.*	ÿ ÿ ÿ ÿ			
Letter of No Conflict of the Ethics Committee in Investigation	TYPE: MANDATORY Classification: D Attach the document in PDF format, through which the members of the Committee declare that there is and will not be a conflict of interest that could affect the objectivity or performance of their functions, in addition to guaranteeing the confidentiality of the information in the Research Protocol. *FL: RLGSMIS Art. 108 and 112; NOM-012 Numerals 9.2.3, 12.1, 12.2 and 12.3.*	ÿ ÿ ÿ ÿ			
Letter of Follow-up Continue to Study by the Ethics Committee in Investigation	TYPE: MANDATORY Classification: D Attach the document in PDF format, containing the description of the monitoring process that the Committee will carry out during the progress of the study. *FL: RLGSMIS Art. 109; NOM-012 Numerals 7, 7.2 and 9.2.3.*	ÿ ÿ ÿ ÿ			
Contact of the Ethics Committee in Investigation RNEC	TYPE: MANDATORY Classification: Telephone and email of the Research Ethics Committee. *FL: Review general requirements (section VII).*	ÿ ÿ ÿ ÿ			
Opinion Date Favorable of Ethics Committee in Investigation RNEC	TYPE: MANDATORY Classification: Select the date of approval of the approved documents by the Committee. It must coincide with the information presented in the attached document of the Opinion of the Evaluation Committee. *FL: ICH E6 (R2)*	ÿ ÿ ÿ ÿ			
Address of the Research Ethics Committee					
REQUIREMENT	**TYPE, CLASSIFICATION AND DESCRIPTION** *LEGAL BASIS (FL)*	**MODALITIES** **A B C D**			
Domicile of Ethics Committee in Investigation RNEC	TYPE: MANDATORY Classification: RESTRICTED and PUBLIC Review the general requirements (section XI). All data is restricted except for the **municipality or mayor's office and the federal entity,** which will be public.	ÿ ÿ ÿ ÿ			

XII. Investigation Committee

Information about the Investigation Committee

REQUIREMENT	TYPE, CLASSIFICATION AND DESCRIPTION *LEGAL BASIS*	MODALITIES A B C D			
Denomination of the Establishment of the Committee Investigation **RNEC**	TYPE: MANDATORY Classification: Write the full name of the Establishment Name of the Investigation Committee, it must match what was declared in the current Registry correspondent. Examples: “Hospital Joaquín Negrete”, “Clínica SA de CV” ***FL: LGS Art. 98, Fracc. YO; RLGSMIS Art. 99 Fracc. III, 102, 103, 106, 107, 108, 111 and 112; NOM-012 Numerals 6.3.2.5, 9, 9.1, 9.1.1, 9.1.2, 9.2 and 9.2.1; Procedures agreement.***	ÿ ÿ ÿ ÿ			
Name of President of Committee of Investigation	TYPE: MANDATORY Classification: Write the full name of the President of the Investigation Committee registered with the Federal Commission for the Protection against Sanitary Risks (COFEPRIS); in accordance with the current Registry provided. ***FL: ICH E6 (R2); NOM-012 Numeral 9.2.4***	ÿ ÿ ÿ ÿ			
Name of Secretary of the Committee of Investigation	TYPE: MANDATORY Classification: Write the full name of the Secretary of the Investigation Committee registered with the Federal Commission for the Protection against Sanitary Risks (COFEPRIS); in accordance with the current Registry provided. ***FL: ICH E6 (R2); NOM-012 Numeral 9.2.5***	ÿ ÿ ÿ ÿ			
Committee Registration Number Investigation	TYPE: MANDATORY Classification: Refer to the current Registration number of the Investigation Committee, issued by the Federal Commission for the Protection against Sanitary Risks (COFEPRIS). ***FL: LGS Art. 98 Fracc. YO; RLGSMIS Art. 99 Fracc. III, 102, 103, 106, 107, 108, 111 and 112; NOM-012 Numerals 6.3.2.5, 9, 9.1, 9.1.1, 9.2 and 9.2.1; Procedures agreement.***	ÿ ÿ ÿ ÿ			
Record of the Investigation Committee	TYPE: MANDATORY Classification: Attach in PDF format, the complete document that recognizes the Research Committee to evaluate and rule on Research protocols in human beings. **NOTE:** The record must be legible, without erasures or amendments, it must include the complete list with the name and position of the Committee members, opinions from Committees that do not have a current record will NOT be accepted. ***FL: LGS Art. 98 Fracc. YO; RLGSMIS Art. 99 Fracc. III, 102, 103, 106, 107, 108, 111 and 112; NOM-012 Numerals 6.3.2.5, 9, 9.1, 9.1.1, 9.1.2, 9.2 and 9.2.1; Procedures agreement.***	ÿ ÿ ÿ ÿ			

Favorable Opinion of the Committee Investigation	TYPE: MANDATORY Classification: Attach in PDF format (in text and without restriction), the favorable opinion by which the Research Committee **approves** the study documents that will be used in the corresponding research center. Must include: • Full name of the IP corresponding to the Research Center • Company name and address of the Research Center • Full title and research protocol number. • Detailed description of the documents evaluated and **approved** in Spanish, citing version and date. • Validity of the approval opinion (no more than 1 year) • Name, position and signature of the person responsible endorses the opinion. • Confirmation of the evaluation of scientific aspects, the risk/benefit of the protocol as well as the guarantee and well-being of the subjects. • It must be issued on letterhead, specifying the company name and address of the Committee (consistent with its current registration) • Date of issuance of the opinion (day, month not anymore) **NOTE:** Only opinions will be accepted with the signature of the president (or, if applicable, the vocal secretary), attaching the "NO VOTE" letter or justification for the absence of the president. ***FL: LGS Art. 98 Fracc. I, 100 Fracc. I, II, III, IV, V and VIII; RLGSMIS Art. 14 Fracc. VII, 62 Fracc. III, 102, 103, 106, 111 and 112; NOM-012 Numerals 6.3.2.8, 9.2, 9.2.3, 9.2.7 and 9.2.12; Processing agreement.***	ÿ ÿ ÿ ÿ			
Non-voting letter from Committee of Investigation	TYPE: **OPTIONAL** Classification: ED Attach the document in PDF format, through which the members of the Investigation Committee refrain from participating in the evaluation or issuance of opinions of the investigations in which they are participating as members of the investigation team. ***FL: RLGSMIS Art. 108 Fracc. VIII; NOM-012 Section 9.2.3.***	ÿ ÿ ÿ ÿ			

Letter of No Investigative Committee Conflict	TYPE: MANDATORY Classification: Attach the document in PDF format, through which the members of the Committee declare that there is and will not be a conflict of interest that could affect the objectivity or performance of their functions, in addition to guaranteeing the confidentiality of the information in the research protocol. *FL: RLGSMIS Art. 108 and 112; NOM-012 Numerals 9.2.3, 12.1, 12.2 and 12.3.*	ÿ ÿ ÿ ÿ			
Letter of Continuous monitoring by the Committee Investigation	TYPE: MANDATORY Classification: Attach the document in PDF format, containing the description of the monitoring process that the Committee will carry out during the progress of the study. *FL: RLGSMIS Art. 109; NOM-012 Numerals 7, 7.2 and 9.2.3.*	ÿ ÿ ÿ ÿ			
Date of Favorable opinion of the Committee Investigation	TYPE: MANDATORY Classification: Select the date of approval of the documents evaluated by the Committee. It must coincide with the information presented in the attached document of the Opinion of the Evaluation Committee. *FL: ICH E6 (R2).*	ÿ ÿ ÿ ÿ			
Address of the Investigation Committee					
REQUIREMENT	**TYPE, CLASSIFICATION AND DESCRIPTION** *LEGAL BASIS*	**MODALITIES** **A B C D**			
Domicile of Committee of Investigation **RNEC**	TYPE: MANDATORY Classification: RESTRICTED and PUBLIC Review the general requirements (section XI). All data is restricted except for the **municipality or mayor's office and the federal entity,** which will be public.	ÿ ÿ ÿ ÿ			

XIII. Biosafety Committee

Information about the Biosafety Committee

REQUIREMENT	TYPE, CLASSIFICATION AND DESCRIPTION *LEGAL BASIS (FL)*	MODALITIES A B C D			
Denomination of the Establishment of the Committee Biosecurity **RNEC**	TYPE: **OPTIONAL** Classification: Write the full name of the Establishment Name of the Biosafety Committee, which must coincide with what is declared in the current registry of said Committee. **Examples:** *"Hospital Joaquín Negrete", "Clínica SA de CV", etc.* ***FL: LGS Art. 98 Fracc. III; RLGSMIS Art. 99 Fracc. II, 102, 103, 105, 106, 107, 108, 110 and 112; NOM-012 Numerals 6.3.2.5, 9, 9.1, 9.1.1, 9.1.2, 9.2 and 9.2.1; Procedures agreement.***	ÿ ÿ ÿ ÿ			
Name of President of Committee of Biosecurity	TYPE: **OPTIONAL** Classification: ESTRICTED Write the full name of the President of the Biosafety Committee registered with the Federal Commission for the Protection against Sanitary Risks (COFEPRIS); in accordance with the current registration provided. ***FL: ICH E6 (R2); NOM-012 Numeral 9.2.4.***	ÿ ÿ ÿ ÿ			
Name of Secretary of the Committee of Biosecurity	TYPE: **OPTIONAL** Classification: ESTRICTED Write the full name of the Secretary of the Biosafety Committee registered with the Federal Commission for the Protection against Sanitary Risks (COFEPRIS); in accordance with the current registration provided. ***FL: ICH E6 (R2); NOM-012 Numeral 9.2.5.***	ÿ ÿ ÿ ÿ			
Committee Registration Number Biosecurity	TYPE: **OPTIONAL** Classification: TERNAL Refer to the current registration number of the Biosafety Committee, issued by the Federal Commission for the Protection against Sanitary Risks (COFEPRIS). ***FL: LGS Art. 98 Fracc. III; RLGSMIS Art. 99 Fracc. II, 102, 103, 105, 106, 107, 108, 110 and 112; NOM-012 Numerals 6.3.2.5, 9, 9.1, 9.1.1, 9.1.2, 9.2 and 9.2.1; Procedures agreement.***	ÿ ÿ ÿ ÿ			
Biosafety Committee Registry	TYPE: **OPTIONAL** Classification: ESTRICTED Attach in PDF format, the complete document that recognizes the Biosafety Committee to evaluate and rule on Research protocols in Human Beings. **NOTE:** The record must be legible, without deletions or amendments, it must include the complete list of the name and position of the members of the Committee. Opinions from Committees that do not have a current record will NOT be accepted. ***FL: LGS Art. 98 Fracc. III; RLGSMIS Art. 99 Fracc. II, 102, 103, 105, 106, 107, 108, 110 and 112; NOM-012 Numerals 6.3.2.5, 9, 9.1, 9.1.1, 9.1.2, 9.2 and 9.2.1; Procedures agreement.***	ÿ ÿ ÿ ÿ			

Favorable Opinion of the Committee Biosecurity	TYPE: **OPTIONAL** Classification: ED Attach in PDF format (in text and without restriction), the favorable opinion by which the Biosafety Committee **approves** the study documents that will be used in the corresponding Research Center. Must include: • Full name of the IP corresponding to the Research Center • Company name and address of the Research Center • Full title and research protocol number. • Detailed description of the documents evaluated and **approved** in Spanish, citing version and date. • Validity of the approval opinion (no more than 1 year) • Name, position and signature of the person responsible endorses the opinion. • It must be issued on letterhead, specifying the company name and address of the Committee (consistent with its current registration) • Date of issuance of the opinion (day, month not anymore) **NOTE:** Only opinions will be accepted with the signature of the president (or, if applicable, the vocal secretary), attaching the "NO VOTE" letter or justification for the absence of the president. ***FL: LGS Art. 98 Fracc. I, 100 Fracc. I, II, III, IV, V and VIII; RLGSMIS Art. 14 Fracc. VII, 62 Fracc. III, 102, 103, 105, 110; NOM-012 Numerals 6.3.2.8, 9.2, 9.2.1, 9.2.3, 9.2.7, 9.2.11 and 9.2.12; Agreement of procedures.***	ÿ ÿ ÿ ÿ		
No Vote Letter from Committee of Biosecurity	TYPE: **OPTIONAL** Classification: ED Attach the document in PDF format, through which the members of the Biosafety Committee refrain from participating in the evaluation or issuance of opinions of the research in which they are participating as members of the research team. ***FL: RLGSMIS Art. 108 Fracc. VIII; NOM-012 Section 9.2.3.***	ÿ ÿ ÿ ÿ		
Letter of No Continuous conflict by the Biosafety Committee	TYPE: **OPTIONAL** Classification: ED Attach the document in PDF format, through which the members of the Committee declare that there is and will not be a conflict of interest that could affect the objectivity or performance of their functions, in addition to guaranteeing the confidentiality of the information in the Research Protocol. ***FL: RLGSMIS Art. 108, 112; NOM-012 Numerals 9.2.3, 12.1, 12.2 and 12.3.***	ÿ ÿ ÿ ÿ		

Letter of Continuous monitoring by the Committee Biosecurity	TYPE: **OPTIONAL** Classification: ESTRICTED Attach the document in PDF format, containing the description of the monitoring process that the committee will carry out during the progress of the study. ***FL: RLGSMIS Art. 109; NOM-012 Numerals 7, 7.2 and 9.2.3.***	ÿ ÿ ÿ ÿ			
Date of Opinion Favorable of Committee of Biosecurity	TYPE: **OPTIONAL** Classification: ESTRICTED Select the date of approval of the documents evaluated by the Committee. It must coincide with the information presented in the attached document of the Opinion of the Evaluation Committee. ***FL: ICH E6 (R2).***	ÿ ÿ ÿ ÿ			
Address of the Biosafety Committee					
REQUIREMENT	**TYPE, CLASSIFICATION AND DESCRIPTION** *LEGAL BASIS (FL)*	**MODALITIES** **A B C D**			
Domicile of Committee of Biosecurity RNEC	TYPE: MANDATORY Classification: RESTRICTED and PUBLIC Review the general requirements (section XI). All data is restricted except for **the municipality or mayor's office and the federal entity,** which will be public.	ÿ ÿ ÿ ÿ			

XIV. importer					
Information about the Biosafety Committee					
REQUIREMENT	**TYPE, CLASSIFICATION AND DESCRIPTION** *LEGAL BASIS (FL)*	**MODALITIES**			
		A	**B**	**C**	**D**
Importer name	TYPE: **MANDATORY** Classification: **ERNAL** Write the full name of the Importer of the Investigational Product and/or the inputs required for the study; must match the Name of the Establishment declared in the Notice of Operation or Health License (as applicable), presented for the establishment. ***FL: LGS Art. 194, 295 and 375 Fracc. VIII; RIS Art. 132 Fracc. III, 196 Fracc. I and 200 Fracc. IV; NOM-012 Numeral 6.4 and 7.2 incised c; Agreement of procedures.***	ÿ	ÿ	ÿ	ÿ
Health license or Notice of Operation of the Importer	TYPE: **MANDATORY** Classification: **ERNAL** Attach the document in PDF format, which supports the establishment's business as a warehouse and/or Distributor in the National Territory of inputs intended for Scientific Research. ***FL: LGS Art. 194, 295 and 375 Fracc. VIII; RIS Art. 132 Fracc. III, 196 Fracc. I and 200 Fracc. IV; NOM-012 Numeral 6.4 and 7.2 incised c; Agreement of procedures.***	ÿ	ÿ	ÿ	ÿ
License number importer's health	TYPE: **MANDATORY** Classification: **ERNAL** Refer the complete number of the Health License authorization *(for example: 09 002 008 10017)* or "N/A", in case of notice of operation from the importer. ***FL: LGS Art. 194, 295 and 375 Fracc. VIII; RIS Art. 132 Fracc. III, 196 Fracc. I and 200 Fracc. IV; NOM-012 Numeral 6.4 and 7.2 incised c; Agreement of procedures.***	ÿ	ÿ	ÿ	ÿ
Letter of Delegation of Responsibility to the Importer	TYPE: **MANDATORY** Classification: **STRICTED** Attach the document in PDF format, where the **delegation** of responsibilities to the importer is indicated ; The letter must be issued and signed by the study sponsor. ***FL: LGS Art. 194, 295 and 375 Fracc. VIII; RIS Art. 132 Fracc. III, 196 Fracc. I and 200 Fracc. IV; NOM-012 Numeral 6.4 and 7.2 incised c; Agreement of procedures.***	ÿ	ÿ	ÿ	ÿ
Letter of Acceptance of Responsibility from the Importer	TYPE: **MANDATORY** Classification: **STRICTED** Attach the document in PDF format, indicating the **express acceptance** of the responsibilities by the Importer. The letter must be signed by the Legal Representative of the Importer. ***FL: LGS Art. 194, 295 and 375 Fracc. VIII; RIS Art. 132 Fracc. III, 196 Fracc. I and 200 Fracc. IV; NOM-012 Numeral 6.4 and 7.2 incised c; Agreement of procedures.***	ÿ	ÿ	ÿ	ÿ

Importer's Address					
REQUIREMENT	TYPE, CLASSIFICATION AND DESCRIPTION *LEGAL BASIS (FL)*	MODALITIES			
		A	B C D		
Domicile of Importer	TYPE: MANDATORY Classification: ESTRICTED Review the general requirements (section XI). All data is restricted except for the municipality or mayor's office and the federal entity, which will be public.	ÿ	ÿ ÿ ÿ		

XV. Complementary Information

Supplementary information about the study

REQUIREMENT	TYPE, CLASSIFICATION AND DESCRIPTION *LEGAL BASIS (FL)*	MODALITIES A B C D			
Countries where will carry out the Investigation **RNEC**	TYPE: **MANDATOR** Classification: **PUBLIC** Indicate the Countries in which the Investigation. ***In accordance with the guidelines of the World Health Organization.***	ÿ N/A ÿ ÿ			
Conditions of Health or Problems Studied **RNEC**	TYPE: **MANDATOR** Classification: **PUBLIC** Indicate the Condition(s) or health problems studied in the Research. **Examples:** *Breast Cancer, Lung Cancer, Systemic Lupus Erythematosus, Multiple Sclerosis, etc.* ***FL: RLGSMIS Articles 3 Fracc. III and 14 Fracc. I, and in accordance with the guidelines of the World Health Organization.***	ÿ ÿ ÿ ÿ			

Public consultation contact information

REQUIREMENT	TYPE, CLASSIFICATION AND DESCRIPTION ***In accordance with the guidelines of the World Health Organization.***	MODALITIES A B C D			
Name of Contact **RNEC**	TYPE: **MANDATOR** Classification: **PUBLIC** Write the name of the contact who will respond to Public Queries.	ÿ ÿ ÿ ÿ			
Affiliation of the Contact **RNEC**	TYPE: **MANDATOR** Classification: **PUBLIC** Write the name of the Institution or Establishment to which the Public Consultation Contact belongs, and in which he or she performs his or her duties.	ÿ ÿ ÿ ÿ			
Contact details and ID **RNEC**	TYPE: **MANDATORY** Classification: Review the general requirements (section XI). All data is restricted except for the municipality or mayor's office and the federal entity, which will be public	ÿ ÿ ÿ ÿ			

Contact information for scientific inquiries

REQUIREMENT	TYPE, CLASSIFICATION AND DESCRIPTION ***In accordance with the guidelines of the World Health Organization.***	MODALITIES A B C D			
Name of Contact **RNEC**	TYPE: **MANDATORY** Classification: Write the name of the person responsible for scientific leadership (study doctor) and for answering Scientific Queries related to the Study.	ÿ ÿ ÿ ÿ			
Affiliation of the Contact **RNEC**	TYPE: **MANDATORY** Classification: Write the name of the Institution or Establishment to which the Contact for attention to Scientific Consultations belongs, and in which they carry out their functions.	ÿ ÿ ÿ ÿ			
Telephone and email **RNEC**	TYPE: **MANDATORY** Classification: Review the general requirements (section XI).	ÿ ÿ ÿ ÿ			

XVI. Other documents						
Information on Additional Documentation to Consider						
REQUIREMENT	**TYPE, CLASSIFICATION AND DESCRIPTION** ***FL: NOM-012 Numeral 6, 6.2.12*** **The documents listed in this section will be included in the authorization letter under the heading "Acknowledgment of receipt of other documents" and must coincide with what was approved by the evaluation committees.**	**MODALITIES**				
		A	**B**	**C**	**D**	
Name of Document	TYPE: **OPTIONAL** Classification: **ESTRICTED** Refer the identification names of the files that are attached in the following fields as Additional Information. **For example:** *triptico_participant_Version1_aaaa_mm_dd*	ÿ	ÿ	ÿ	ÿ	
Description of Document	TYPE: **OPTIONAL** Classification: **ESTRICTED** Briefly describe the content of the additional documents. **For example:** *The participant's diary is attached to monitor Adverse Reactions during the follow-up period.*	ÿ	ÿ	ÿ	ÿ	
Document / Adjunct	TYPE: **OPTIONAL** Classification: **ESTRICTED** Attach the document(s) in PDF format, which contain additional information, and which serves as support for the request.	ÿ	ÿ	ÿ	ÿ	

XIV. OTHER SPECIFIC REQUIREMENTS BY MODALITY

MODALITY B: DATA OF THE OWNER'S ESTABLISHMENT	
REQUIREMENT	**TYPE, CLASSIFICATION AND DESCRIPTION** ***LEGAL BASIS***
Number of Authorization of Authorized Third Party as a Clinical Unit	TYPE: Classification: **MANDATORY** Refer the complete authorization number of the Authorized Third Party as a Clinical Unit. ***FL: LGS Articles 17 Bis Fracc. IV, 102 Bis, 368, 371, 372 and 391 Bis; RIS Articles 210, 211 and 213; NOM-0177 Numerals 4.97, 4.100, 8.11.6, 8.11.7, 8.11.8, 8.11.9, 10.1.1 and 10.5.2.***
Authorization of Authorized Third Party as Clinical Unit	TYPE: Classification: **MANDATORY** Attach the document in PDF format, issued by the corresponding Authority, for the Authorization of the Clinical Unit. ***FL: LGS Articles 17 Bis Fracc. IV, 102 Bis, 368, 371, 372 and 391 Bis, RIS Articles 210, 211 and 213; NOM-0177 Numerals 4.97, 4.100, 8.11.6, 8.11.7, 8.11.8, 8.11.9, 10.1.1 and 10.5.2.***
Number of Authorization of Authorized Third Party as a Unit Analytics	TYPE: Classification: **MANDATORY** Refer the complete authorization number of the Authorized Third Party as an Analytical Unit. ***FL: LGS Articles 17 Bis Fracc. IV, 102 Bis, 368, 371, 372 and 391 Bis; RIS Articles 210, 211 and 213; NOM-0177 Numerals 4.97, 4.100, 8.11.6, 8.11.7, 8.11.8, 8.11.9, 10.1.1 and 10.5.2; Agreement of procedures.***
Authorization of Authorized Third Party as a Unit Analytics	TYPE: Classification: **MANDATORY** Attach the document in PDF format, issued by the corresponding Authority, for the Authorization of the analytical unit. ***FL: LGS Articles 17 Bis Fracc. IV, 102 Bis, 368, 371, 372 and 391 Bis; RIS Articles 210, 211 and 213; NOM-0177 Numerals 4.97, 4.100, 8.11.6, 8.11.7, 8.11.8, 8.11.9, 10.1.1 and 10.5.2.***
Address of the Third Party Authorized as Clinical Unit **RNEC**	TYPE: Classification: **MANDATORY** or **PUBLIC** Review the general requirements (section XII). All data is restricted except for the **municipality or mayor's office and the federal entity,** which will be public.

MODALITY D: DATA OF THE OWNER'S ESTABLISHMENT	
Study information	
REQUIREMENT	**TYPE, CLASSIFICATION AND DESCRIPTION** ***LEGAL BASIS***
Study design **RNEC**	TYPE: **OPTIONAL** Classification: ED Describe the general procedures applicable to the investigation, citing the type of investigation. ***FL: ICH E6 (R2; RLGSMIS Artículo 17; NOM-012 Numeral 6.2.9***
Procedures	
REQUIREMENT	**TYPE, CLASSIFICATION AND DESCRIPTION** ***LEGAL BASIS***
Description of procedures **RNEC**	TYPE: **OPTIONAL** Classification: Concisely describe the procedures that will be implemented during the development of the study. ***FL: ICH E6 (R2).***
Study procedures **RNEC**	TYPE: **OPTIONAL** Classification: Attach in editable format (.xls or .doc format), the descriptive table of the procedures to be performed and the duration of the study. ***FL: ICH E6 (R2).***