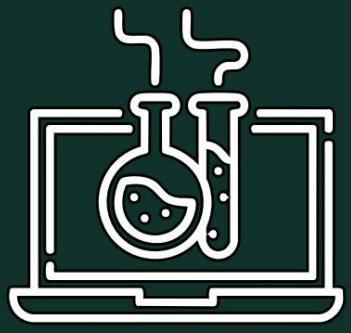
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Salud
Secretaría de Salud

COFEPRIS
COMISIÓN FEDERAL PARA LA PROTECCIÓN CONTRA RIESGOS SANITARIOS



GUIDE FOR THE APPLICATION OF RESEARCH PROTOCOLS IN HUMAN BEINGS (HOMOCLAVE COFEPRIS 04-010) ON THE PLATFORM “DIGIPRiS: Online Regulation”

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I. INTRODUCTION

Through the “DIGIPRiS: Online Regulation” platform you can submit the “Application for Authorization of Research Protocols in Human Beings” (COFEPRIS code COFEPRIS-04-010). Likewise, the platform allows for the submission of multiple applications and procedures in a simultaneous.

This guide describes the requirements and documentation necessary for submitting procedures with the COFEPRIS-04-010 code in its different modalities A, B or C.

Previously, in accordance **with the AGREEMENT establishing the criteria for the authorization of research protocols in human beings that have prior authorization from a foreign regulatory authority** (DOF. 03/24/2025), the **Agreement establishing simplification actions for procedures carried out before the Federal Commission for Protection against Sanitary Risks (DOF. 04/28/2025), and the Agreement updating the means of presentation of the procedures cofepris-04-010 “Application for Authorization of Research Protocol in Human Beings” and cofepris-09-012 “Application for Modification or Amendment to the Authorization of Research Protocol”,** (DOF. 05/04/2026).

II. AIM

To guide users on the correct way to present the information and documentation required for the “Application for Authorization of Research Protocol in Human Beings” (COFEPRIS-04-010, modalities A, B or C), through the platform “DIGIPRiS: Regulation in Line".

III. REACH

This guide is of public interest and is addressed to all individuals or legal entities (organizations) government entities, research centers, the pharmaceutical industry, health institutions, or Authorized Third Parties) that wish to submit a “Request for Authorization of Research Protocol in Human Beings” (COFEPRIS-04-010, modalities A, B, or C).

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IV. SCOPE

This guide is intended for any legal or natural person involved in the development of essays. clinical trials in humans for the purpose of health registration, including owners, sponsors, Contract research organizations; principal investigators and research teams; research centers; ethics and research committees, among others, responsible for filling out the “DIGIPRiS: Online Regulation” platform.

V. APPLICATION METHODS FOR THE AUTHORIZATION OF RESEARCH PROTOCOLS

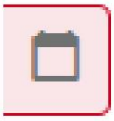
Application for Authorization of Research Protocols in Human Beings

COFEPRIS- 04-010-A Modality A.- Medicines, Biologicals and Biotechnologicals.	
COFEPRIS- 04-010-B Modality B.- Medicines: 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 that are carried out in human beings or in their biological products, except pharmacological ones.

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VI. SYMBOLOGY

In the sections of the “DIGIPRiS: Online Regulation” platform you will find the following symbols:

Example	Meaning
	**TOOLTIP:** At the end of some requirements you will find this icon; clicking on it will display a description regarding the most relevant information of the requested requirement.
	**DATE REQUIREMENT:** When the requirement is a date, it must be selected from the calendar that appears when you click 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 sections where you can add more
	fields within the same form to enter more information. Example: an additional SCIAN code.
	**BUTTON: “CLEAR FIELDS”** This element will allow you to delete required and previously captured information in the form fields.

VII. ABBREVIATIONS

- **Art.:** Article.
- **BPC:** Good Clinical Practices.
- **COFEPRIS:** Federal Commission for Protection against Sanitary Risks. • **CONBIOÉTICA:** National Bioethics Commission.
- **CRO:** Contract Research Organization (CRO).
- **CURP:** Unique Population Registry Code.

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- **FL:** Legal basis.
- **ICH E6 (R3):** ICH Guidelines for Good Clinical Practice E6 (Revision 3) Council International Harmonisation (ICH).
- **IP:** 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 health research projects 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 medicines, as well as of herbal remedies (NOM-073-SSA1-2015).
- **NOM-164:** Official Mexican Standard, Good manufacturing practices for drugs (NOM-164-SSA1-2015).
- **RFC:** Federal Taxpayer Registry.
- **RIS:** Health Supplies Regulation.
- **RLGSMIS:** Regulations of the General Health Law on Research for the Health.
- **RNEC:** National Registry of Clinical Trials.
- **NAICS:** North American Industry 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).

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GENERAL CONSIDERATIONS FOR CAPTURE
VIII. ON INFORMATION AND DOCUMENTATION UPLOAD

- Although the procedures corresponding to legal entities are requested and signed by natural persons, in all cases the application must be prepared with the role of "editor" or of "authorizer", as appropriate.

- Therefore, when the procedures are signed by a natural person as the applicant physical, but the documentation presented identifies a legal entity as the owner As the holder, they will not be able to continue the evaluation process and will be warned.

- Pay special attention to the fields indicated for uploading documents, in accordance with the specifications described in the column **"SPECIFICATIONS BY FIELD"**

- Similarly, avoid uploading any documents other than those requested in the form fields.

- When (not and requirement no sea applicable, "N/A" apply) in the field of text corresponding capture.

  For example: for protocols that do not involve evaluation by the biosafety committee, the fields that refer to this should be completed with "N/A", and
  Leave blank the calendar fields where you are asked to select a date.

- 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 match what was approved by the corresponding evaluation committees.
  Examples:

  Protocol_versionX_closes_dd-mm-yy

  or Prescribing Information (if there is more than one manual [or document] [equivalent] must add the name of the corresponding molecule).

- When necessary, you can upload more than one document (file) in the same field.

- The file names must correspond to the requested requirement and with the Content of attached files. Names with codes or abbreviations will not be accepted. or references other than what is stated in the content of the corresponding file.

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Examples:

or Correct file name: Protocol_versionX_date_dd-mm-yy.

or Incorrect file name: 05. MoH Authorization_vX_23XXRTZXXXX_VV-TMF

IX. SECTIONS THAT MAKE UP AN "APPLICATION" OF RESEARCH PROTOCOLS IN BEINGS HUMANS

Each application corresponding to the COFEPRIS-04-010 code is made up of the following sections (with the corresponding adjustments according to the modality and requirements established in the Simplification Agreements):

- Owner details
- Details of the establishment owner
- Proof of payment and letter of request
- Sponsor
- Research documents • Research product • Research center • Emergency care center • Principal investigator • Research team • Research ethics committee • Research committee • Biosafety committee • Importer • Additional information

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X. GENERAL REQUIREMENTS, APPLICABLE TO ALL SECTIONS AND MODALITIES

Contact and identification details

FL: LFPA Art. 15, RIS Art. 153, NOM-012 numeral 6.1.

REQUIREMENT	TYPE, CLASSIFICATION AND DESCRIPTION
RFC	Alphanumeric key of the Federal Taxpayer Registry (RFC) in accordance with the information registered with the SHCP. All fields must be completed without abbreviations, spaces, or special characters.
CURP	The Unique Population Registry Code must be provided with the 18 elements of an alphanumeric code. All fields must be completed without abbreviations, spaces, or special characters.
Telephone	Provide the 10-digit phone number, including the area code. Example: 5557314952
Email	Write the email address in lowercase letters and without spaces. Example: example@domain.com

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Homes

FIELD IN PLATFORM	TYPE, CLASSIFICATION AND DESCRIPTION
Type and name of road	Refer to the classification (Avenue, Boulevard, Street, Highway, Road, Private) and the full name of the road where the address is located. Example: “Periférico Avenue”, “San Ignacio Closed Road”, “Picacho Ajusco Highway”.
Exterior number	Please indicate the exterior number where the establishment is geographically located.
Interior number	Indicate the interior number or letter where the address is located, which identifies the road where the geographic address is established. Example: “Level 1 and 2”, “D”, “Interior 3”
Between roads and road infrastructure	Write the type and name of the streets between which the establishment is geographically located. with Example: “Avenida del Rincón”, “Callejón Jesús María”.
Cologne	Write the full name without abbreviations, where the address is located (condominium, neighborhood, hacienda, ranch, subdivision, section, sector, among others). Examples: “Naples”, “Del Carmen”, “Colonia Centro”, “Rancho las Américas”
Postal Code	Write the five-digit number (matching the official postal code from Correos de México) that allows for the geographic identification of the location. Example: 02267
Municipality or Mayor's Office	Write the full name of the territorial delegation or municipality where the address is geographically located.
Federal Entity	Write the full name of the Mexican state where the address is geographically located. For example: “Mexico City”, “Baja California”, “Mexico” (for the State of Mexico).

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

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XI. SPECIFIC SECTIONS OF THE PROCEDURE IN THE PLATFORM

I. Owner's Details

Physical or Moral Person

FL: LFPA Art. 15, NOM-012 numeral 6.1, AGREEMENT establishing simplification actions for procedures carried out before the Federal Commission for Protection against Sanitary Risks, which are indicated therein (28/04/2025) and AGREEMENT by which the means of presentation of the procedures COFEPRIS-04-010 “Application for authorization of research protocol in human beings” are updated and COFEPRIS-09-012 “Request for modification or amendment to the authorization of research protocol (04/05/2026).
This information will form part of the Authorizations, Certificates and Visits Form that will be generated when you sign the procedure.

FIELD IN PLATFORM	TYPE, CLASSIFICATION AND DESCRIPTION	MODALITIES A	MODALITIES B	MODALITIES C	SPECS BY FIELD
Requirements: Complete the online form.					
Name or company name	Natural person	✓	✓	✓	Only complete if the applicant is a natural person (according to information presented to prove legal representation).
First Surname	Natural person	✓	✓	✓	
Second Surname	✓	✓	✓	✓	
Telephone, extension, and email address	✓	✓	✓	✓	Otherwise you must place “N/A” in each of the fields.

Legal Representative

FL: LFPA Art. 15, NOM-012 numeral 6.1.
This information will form part of the Authorizations, Certificates and Visits Form that will be generated when you sign the procedure.

FIELD IN PLATFORM	TYPE, CLASSIFICATION AND DESCRIPTION	MODALITIES A	MODALITIES B	MODALITIES C	SPECS BY FIELD
Name(s), first surname and second surname	Natural person	✓	✓	✓	Fill in fields according to the information presented.
Telephone, extension, and email address	Review the general requirements (section XI).	✓	✓	✓	

Owner's Tax Address

FIELD IN PLATFORM	TYPE, CLASSIFICATION AND DESCRIPTION	MODALITIES A	MODALITIES B	MODALITIES C	SPECIFICATIONS BY FIELD
Tax domicile of owner.	Review the general information about addresses (section XII).				Fill in fields according to the information presented

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II. Details of the Holder's Establishment

FL: LFPA Art. 15, RIS Art. 153, NOM-012 numeral 6.1., AGREEMENT establishing simplification actions for procedures carried out before the Federal Commission for the
Protection against Health Risks, which are indicated therein (28/04/2025) and AGREEMENT by which the means of presentation of the procedures COFEPRIS-04-010 “Application for authorization of research protocol in human beings” and COFEPRIS-09-012 “Application of modification or amendment to the research protocol authorization (04/05/2026).
This information will form part of the Authorizations, Certificates and Visits Form that will be generated when you sign the procedure.

FIELD IN PLATFORM	TYPE, CLASSIFICATION AND DESCRIPTION	MODALITIES			SPECS BY FIELD
		A	B	C	
RFC	Review the general requirements (see contact and identification details section).	✓	✓	✓	
Denominación o Company Name of the establishment	Write the full name of the establishment of the holder, which must match with the document that supports it (Example: notice of operation, health license, etc.) Examples: “Lupita Pharmacy”, “Terra Laboratories, SA de CV”	✓	✓	✓	Request complete and accurate information.
License number Health permit or operating notice	Please provide the full number of the Health License authorization or operating notice. For the COFEPRIS-04-010-B procedures, it is You must cite the Authorization No. as a Clinical Unit to perform Bioavailability and/or Bioequivalence tests to demonstrate Interchangeability in Medicines. **Requirement:** **Natural person: A simple power of attorney from the attorney or a document proving legal representation must be presented.** **Legal entity: It must submit a public instrument that proves legal representation.**	✓	N/A	✓	In this field you should Enter the document that proves legal representation.
Health License or Operating Notice	N/A	N/A	N/A	N/A	Document not required (do not enter information)
Clave SCIAN	Write the complete North American Industry Classification System number (SCIAN) that allows the identification of activities carried out by the establishment. You can add up to 4 keys.	✓	✓	✓	Request complete and accurate information.
SCIAN Description	Describe the nature of the activity(ies) carried out by the establishment.	✓	✓	✓	

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Health Officer

FL: LFPA Art. 15, NOM-012 numeral 6.1. This information will form part of the Authorizations, Certificates and Visits Format that will be generated when you complete the signing process.

FIELD IN PLATFORM	TYPE, CLASSIFICATION AND DESCRIPTION	MODALITIES A	MODALITIES B	MODALITIES C	SPECS BY FIELD
RFC and CURP	Review the general requirements (see contact and identification details section).	✓	✓	✓	Request complete and accurate information. Not applicable for CRO: Enter N/A
Name(s), first surname and second surname	Write the name(s), first surname and second surname of the health officer.	✓	✓	✓	

Address of the Establishment Owner

FIELD IN PLATFORM	TYPE, CLASSIFICATION AND DESCRIPTION	MODALITIES A	MODALITIES B	MODALITIES C	SPECIFICATIONS BY FIELD
Address of the establishment	Review the general information about addresses (section XII).	✓	✓	✓	Request complete and accurate information.

Legal Representative(s)

FL: LFPA Art. 15, NOM-012 numeral 6.1.
This information will form part of the Authorizations, Certificates and Visits Form that will be generated when you sign the procedure.

FIELD IN PLATFORM	TYPE, CLASSIFICATION AND DESCRIPTION	MODALITIES A	MODALITIES B	MODALITIES C	SPECS BY FIELD
CURP	Review the general requirements (section XI).	✓	✓	✓	Request complete and accurate information.
Name(s), first surname and second surname	Write the name(s), first surname and second surname of the legal representative who requests and signs the procedure.	✓	✓	✓	
Telephone, extension, and email address	Review the general requirements (section XI).	✓	✓	✓	

Authorized Person(s)

FIELD IN PLATFORM	TYPE, CLASSIFICATION AND DESCRIPTION	MODALITIES A	MODALITIES B	MODALITIES C	SPECS BY FIELD
CURP	Review the general requirements (section XI).	✓	✓	✓	Request complete and accurate information.
Name(s), first surname and second surname	Write the name(s), first surname and second surname of the Authorized Person.	✓	✓	✓	
Telephone, extension, and email address	Review the general requirements (section XI).	✓	✓	✓	

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III. Proof of payment and letter of request

Proof of Payment

FL: Article 1, 2, last paragraph; 3, first, second and third paragraphs; 195-I, section VI; and 195-L, sections I and II, of the Federal Law of Rights (LFD, last Reform DOF 07-11-2025); Agreement establishing simplification actions for procedures carried out before the Federal Commission for Protection against Sanitary Risks, which in the same indicates, Agreement by which the means of presentation of the procedures COFEPRIS-04-010 "Application for Authorization of Research Protocol in Human Beings" and cofepris-09-012 are updated "Application for Modification or Amendment to the Research Protocol Authorization", Agreement updating the means of presentation of the procedures cofepris-04-010 "Application for Authorization of Research Protocol in Human Beings" and cofepris-09-012 "Application of Modification or Amendment to the Research Protocol Authorization" and others that are indicated by the applicable legal provisions.

FIELD IN PLATFORM	TYPE, CLASSIFICATION AND DESCRIPTION	MODALITIES			SPECS BY FIELD
		A	B	C	
Proof of payment for the procedure	**Requirement:** **- Corresponding proof of payment.** In which the current amount for the application is covered according to the applicable Fee Catalog (available at https://www.gob.mx/cofepris/acciones-y-programas/pago-de-dere-chos-productos-y-aprovechamientos), and issued by a banking institution in accordance with the Federal Law of Rights.	✓	✓	✓	Attach proof of payment
Payment key	Refer to the 10 alphanumeric characters associated with the attached receipt of payment of rights in the previous field. ~~**The payment key is unique for each payment.**~~	✓	✓	✓	Request information, which must match the payment receipt information. The payment must be valid for the requested procedure

Information about the Protocol

FIELD IN PLATFORM	TYPE, CLASSIFICATION AND DESCRIPTION	MODALITIES			SPECIFICATIONS BY FIELD
		A	B	C	
Free-form written request	**N/A**	N/A	N/A	N/A	This document is no longer required, do not enter information.

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IV. Sponsor

Information about the Sponsor

FIELD IN PLATFORM	TYPE, CLASSIFICATION AND DESCRIPTION *LEGAL BASIS (FL)*	MODALITIES A	 B	 C	SPECS BY FIELD
Sponsor	Provide the full name, without abbreviations, of the individual or legal entity responsible for initiating, managing, and financing the protocol. research. FL: NOM-012 Numeral 4.18	✓	✓	✓	Attach proof of payment
Letter of acceptance and delegation of sponsor responsibilities.	**Requirement: Unique sponsor format, duly requested.** *FL: Agreement establishing simplification measures for procedures before the Federal Commission for Protection against Sanitary Risks, as specified therein. Agreement updating the means of submission for procedures cofepris-04-010 "Application for Authorization of Research Protocol in Human Beings" and cofepris-09-012 "Application for Modification or Amendment to the Authorization of Research Protocol".*	✓	✓	✓	You must enter the Single Format from the sponsor, duly requested
Letter of no conflict of interest to the sponsor	**N/A**	N/A	N/A	N/A	These documents are no longer required, do not enter information.
Letter describing the human and material resources that will be allocated for research	**N/A**	N/A	N/A	N/A	
Follow-up letter from the sponsor of the investigation	**N/A**	N/A	N/A	N/A	
Current document that expresses the financial fund or studio insurance	A simple copy of the financial fund or policy of Valid insurance policy, which guarantees the continuity of medical treatment and the compensation to which the patient is legally entitled. subject in case of suffering damages directly related to the development of the investigation. *FL: NOM-012 Section 5.14, Agreement establishing simplification actions for procedures carried out before the Federal Commission for Protection against Sanitary Risks, as indicated therein. Agreement updating the means of presentation of the procedures cofepris-04-010 "Application for Authorization of Research Protocol in Human Beings" and cofepris-09-012 "Application for Modification or Amendment to the Authorization of Research Protocol".*	*	*	*	You must submit this document: 1. In the initial submission of the procedure*, the 2. Once the research protocol has been authorized, within a period of no more than 15 business days, in this in case keep the field NO DATA.

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V. Research Documents

Research protocol

FIELD IN PLATFORM	TYPE, CLASSIFICATION AND DESCRIPTION *LEGAL BASIS (FL)*	MODALITIES A	B	C	SPECS BY FIELD
Scientific title of the protocol	State the scientific title of the study, such as It appears on the cover of the research protocol. It must match what was approved in the reports by the Evaluation Committees. *FL: NOM-012 Sections 6.1 and 6.2.1, ICH E6 (R3)*	☐	☐	☐	Request complete and accurate information
Public title of the protocol	Provide a short title in easy-to-understand language, intended for a non-specialized audience. *FL: NOM-012 Sections 6.1 and 6.2.1, ICH E6 (R3)*	☐	☐	☐	
Protocol number	Indicate the alphanumeric designation or number of the protocol identification. *FL: ICH E6 (R3)*	☐	☐	☐	
Acronym	Enter the term that allows for another name to be used to identify the study (and apply).	☐	☐	☐	
Date of the research protocol version	Select the date of the document version that was attached in the previous field; it must match what was approved in the opinions of The Evaluation Committees. *FL: ICH E6 (R3)*	☐	☐	☐	
Version of the research protocol	Indicate the current version of the protocol; it must match what is stated in the attached document and what was approved by the Committees. Evaluators. *FL: ICH E6 (R3)*	☐	☐	☐	
Protocol of investigation	Requirement: Research Protocol Please attach the study protocol document in PDF format (plain text only, no restrictions). If the document is in Spanish, please indicate the version and date. *FL: LGS Art. 41 Days Fracc. II and III (final DOF reform 15-01-2026); LGS Art. 100 Sections I, II and III, 102 Sections II, III and IV; RLGSMIS Art. 14 Sections I, II, III and IV, 15, 17, 62 Section. I and IX, 65, 66, 69, 70, 72, 73, 74 and 116 Section I; 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. FL: Agreement establishing simplification measures for procedures before the Federal Commission for Protection against Sanitary Risks, as specified therein. Agreement updating the means of submitting procedures cofepris-04-010 "Application for Authorization of Research Protocol in Human Beings" and cofepris-09-012 "Application for Modification or Amendment to the Authorization of Research Protocol".*	☐	☐	☐	Attach Research Protocol

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V. Research Documents

Study timeline	N/A	✓	✓	✓	These documents are no longer required, do not enter information.

Informed Consent

FIELD IN PLATFORM	TYPE, CLASSIFICATION AND DESCRIPTION *LEGAL BASIS (FL)*	MODALITIES A	B	C	SPECS BY FIELD
Informed consent and/or informed assent of the research subject	**Do not request information**	*	*	*	You will need to submit this document: 1. In the initial submission of the procedure*,
Date of the informed consent version	**Do not request information**	N/A	N/A	N/A	the 2. Once authorized research protocol, within a period of no more than 15 business days.
Informed consent form	**Do not request information** *FL: LGS Art. 41 Bis Sections II and III (last amended DOF 15-01-2026); Agreement establishing simplification measures for procedures before the Federal Commission for Protection against Sanitary Risks, as indicated therein. Agreement updating the means of submitting procedures cofepris-04-010 "Application for Authorization of Research Protocol in Human Beings" and cofepris-09-012 "Application for Modification or Amendment to the Authorization of Research Protocol".*	N/A	N/A	N/A	*In this case, you must enter the documents of "Informed Consent and/or assent, previously approved by the Ethics and Research Committee", in the field: "Informed Consent and/or informed assent of the research subject."

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Researcher's Manual

FIELD IN PLATFORM	TYPE, CLASSIFICATION AND DESCRIPTION *LEGAL BASIS (FL)*	MODALITIES A	 B	 C	SPECS BY FIELD
Researcher's manual or equivalent document	**Requirement:** **Researcher's Manual or equivalent document.** *FL: LGS Art. 41 Bis Section II and III (last amendment DOF 15-01-2026); LGS Art. 100 Section I, II, III, 102 Section II and III; RLGSMIS Art. 14 Section II, III, 62 Section VIII, 66, 67, 68, 69, 70 Section I, 73; NOM-012 Numbers 4.7 and 5.10; Agreement establishing simplification actions for procedures carried out before the Federal Commission for Protection against Sanitary Risks, which are indicated therein. Agreement updating the means of presentation of the procedures cofepris-04-010 "Application for Authorization of Research Protocol in Human Beings" and cofepris-09-012 "Application for Modification or Amendment to the Authorization of Research Protocol".*	✓	✓	✓	Enter Manual of Investigator the equivalent document
Date of the Manual version Researcher	Select the date of the document version that was attached in the previous field; it must match what is recorded as approved in the Committees' opinions. Evaluators. *FL: ICH E6 (R3)*	✓	✓	✓	Request complete and accurate information
Investigator's Manual Version	*Indicate the current version of the Researcher's Manual; it must match what is stated in the attached document and what is recorded as approved in the opinions of the Evaluation Committees.* *FL: ICH E6 (R3)*	✓	✓	✓	

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DIGIPRIS PLATFORM FIELDS "STUDY INFORMATION"

FIELD IN PLATFORM	TYPE, CLASSIFICATION AND DESCRIPTION *LEGAL BASIS (FL)*	MODALITIES A	 B	 C	SPECS BY FIELD
Study phase	Indicate the stage of the clinical trial for which approval is being requested (as applicable). Examples: Phase I, Phase II, Phase III, or Bioequivalence. *FL: RLGSMIS Articles 66 and 69; ICH E6 (R3)*	✓	N/A	✓	Request complete and accurate information.
Studio design	Describe the general procedures, techniques, and methods applicable to the research, citing the type of research, blinding, allocation method (randomized/non-randomized), the allocation (single arm, parallel, crossover, or factorial), among others. *FL: RLGSMIS Articles 15; NOM-012 Number 6.2.9; ICH E6 (R3)*	✓	✓	✓	
Primary objective	Write clearly and precisely, in accordance with the Research Protocol. *FL: ICH E6 (R3)*	✓	✓	✓	Request complete and accurate information.
Key inclusion criteria	Write clearly and precisely, in accordance with the Research Protocol. *FL: ICH E6 (R3)*	✓	✓	✓	Request complete and accurate information.
Key exclusion criteria	Write clearly and precisely, in accordance with the Research Protocol. *FL: ICH E6 (R3)*	✓	✓	✓	
Primary assessment criteria	Write clearly and precisely, in accordance with the Research Protocol. *FL: ICH E6 (R3)*	✓	✓	✓	
Secondary assessment criteria	Write clearly and precisely, in accordance with the Research Protocol. *FL: ICH E6 (R3)*	✓	✓	✓	

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DIGIPRIS platform fields
"Study Interventions"

FIELD IN PLATFORM	TYPE, CLASSIFICATION AND DESCRIPTION *LEGAL BASIS (FL)*	MODALITIES A	 B	 C	SPECS BY FIELD
Global research sample size	Write the total number of participants to enroll globally. *FL: ICH E6 (R3)*	✓	N/A	✓	Request complete and accurate information. Note: For studies that will be carried out only in In Mexico, the following will need to be completed: sample size fields and "global" population type with the same information established in the sample size and population type fields in Mexico.
Type of population of the Research at a global level	Describe the set of elements (clinical and demographic characteristics, age, sex, etc.) that define the group of participants that you wish to enroll in the clinical research. *FL: ICH E6 (R3)*	✓	N/A	✓	
Sample size in Mexico	Write the total number of participants that the trial plans to enroll in Mexico. *FL: ICH E6 (R3)*	✓	✓	✓	
Type of research population in Mexico	Describe the set of elements (clinical and demographic characteristics, age, sex, etc.) that define the group of participants that we wish to enroll in the clinical research developed in Mexico. *FL: ICH E6 (R3)*	✓	✓	✓	
Study interventions	**N/A**	N/A	N/A	N/A	This document is no longer required, do not enter information.

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VI. Research Product

Research product information

FIELD IN PLATFORM	TYPE, CLASSIFICATION AND DESCRIPTION *LEGAL BASIS (FL)*	MODALITIES A	B	C	SPECS BY FIELD
Product name in Investigation	Indicate the name(s) of the product under investigation that identifies the drug(s) or biopharmaceutical(s) to be investigated in the trial clinical. It generally corresponds to the international nonproprietary name (INN) recommended by the WHO. *FL: RLGSMIS Article 65, NOM-012 Numerales 4.16, International Nonproprietary Names (INN), WHO*	✓	✓	✓	Request complete and accurate information.
Route of administration	Establish the route(s) that will be used to Administer the investigational product to participating subjects. Examples: Oral, Intravenous, Otic, Nasal, Cutaneous, Intramuscular Ocular, etc. *FL: RLGSMIS Article 67; WHO*	✓	✓	N/A	
List of imported supplies used in the research study	**N/A**	N/A	N/A	N/A	This document is no longer required, do not enter information.
Information on compliance with Good Practices of Manufacturing	**Requirement:** **Certificate of compliance with Good Manufacturing Practices for research products or equivalent document.** *FL: Agreement establishing simplification measures for procedures before the Federal Commission for Protection against Sanitary Risks, as specified therein. Agreement updating the means of submitting procedures cofepris-04-010 "Application for Authorization of Research Protocol in Human Beings" and cofepris-09-012 "Application for Modification or Amendment to the Authorization of Research Protocol".*	✓	✗	✓	Enter GMP certificate or equivalent
Information on the stability of the research product	**Requirement:** **Report and Results of Stability of the Investigational Product and placebo.** *FL: Agreement establishing simplification measures for procedures before the Federal Commission for Protection against Sanitary Risks, as specified therein. Agreement updating the means of submitting procedures cofepris-04-010 "Application for Authorization of Research Protocol in Human Beings" and cofepris-09-012 "Application for Modification or Amendment to the Authorization of Research Protocol".*	✓	✓	✓	Enter stability report and results

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VII. Information about the Research Center

Information about the Research Center

FIELD IN PLATFORM	TYPE, CLASSIFICATION AND DESCRIPTION *LEGAL BASIS (FL)*	MODALITIES A B C	SPECS BY FIELD
Name of the Center Investigation	Full name of the Research Center where the study will be conducted. The information must match the "Establishment Name" or "Company Name or Designation" declared in the Notice of Operation or Sanitary License submitted, 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.*	✓ ✓ ✓	Request complete and accurate information.
Letter describing the human and material resources that will be allocated for Research	**Requirement:** **Unique form of the head of the institution or establishment where the research will be carried out, duly completed.** *FL: Agreement establishing simplification measures for procedures before the Federal Commission for Protection against Sanitary Risks, as specified therein. Agreement updating the means of submitting procedures cofepris-04-010 "Application for Authorization of Research Protocol in Human Beings" and cofepris-09-012 "Application for Modification or Amendment to the Authorization of Research Protocol".*	✓ ✓ ✓	In this field you should Enter the unique form of the head of the institution or establishment where the investigation will be carried out.
Letter of authorization from Owner of the center where the Investigation	**N/A**	N/A N/A N/A	This document is no longer required, do not enter information.
Health License or Operating Notice	**N/A**	N/A N/A N/A	Request complete and accurate information.
Number of the Health License	Provide the complete number of the Sanitary License or Notice of Operation authorization. For COFEPRIS-04-010-B procedures, You must cite the Authorization No. as a Clinical Unit to perform Bioavailability and/or Bioequivalence tests to demonstrate the Interchangeability in Medicines. *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.*	✓ ✓ ✓	Request complete and accurate information.

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Address of the research center

FIELD IN PLATFORM	TYPE, CLASSIFICATION AND DESCRIPTION *LEGAL BASIS (FL)*	MODALITIES A	 B	 C	SPECS BY FIELD
Address of the research center	(see section XI)	✓	✓	✓	Request Information

VIII. Emergency Care Center

Information from the Emergency Care Center

FIELD IN PLATFORM	TYPE, CLASSIFICATION AND DESCRIPTION *LEGAL BASIS (FL)*	MODALITIES A	 B	 C	SPECS BY FIELD
Name of the Emergency Care Center	***Do not request information under any circumstances; enter N/ A or leave "NO DATA" as appropriate.***	N/A	N/A	N/A	You will need to submit this document: 1.During the initial submission of the procedure*, the 2. Once the research protocol has been authorized, within a period of no more than 15 business days. *In this case, you must Simply enter the "Single Medical Emergency Form" and the "Agreement or contract for medical emergency care" in the field: "Description of available resources of the Unit or Institution where the emergencies will be attended to" doctors", **without requiring the platform fields.**
Description of available resources of the Unit or Institution where the following will be attended to Medical Emergencies*		*	*	*	
Letter from Authorization of the Holder of Establishment where services will be provided the Emergency Room Doctors		N/A	N/A	N/A	
Establishment Health License		N/A	N/A	N/A	
Health License Number		N/A	N/A	N/A	
Agreement for the Emergency Medical Care		N/A	N/A	N/A	

Address of the emergency center

FIELD IN PLATFORM	TYPE, CLASSIFICATION AND DESCRIPTION *LEGAL BASIS (FL)*	MODALITIES A	 B	 C	SPECS BY FIELD
Address of the Emergency Care Center	**N/A**	N/A	N/A	N/A	Request Information

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IX. Principal Investigator

Information from the Principal Investigator

FIELD IN PLATFORM	TYPE, CLASSIFICATION AND DESCRIPTION *LEGAL BASIS (FL)*	MODALITIES A	B	C	SPECS BY FIELD
Name of the Researcher Principal	Full name of the health professional with the appropriate academic training, specialty, and experience to conduct the study, whom the Ministry of Health will authorize as responsible for To conduct, coordinate and monitor the development of the research, in accordance with the objective and field of application. *FL: LGS Art 100, Sections V and VI, 102 Section V; RLGSMIS Art 14 Sections VI, IX, 64 Sections I, III, 113, 119, 120; NOM-012 Numbers 8.9, 10.2, 10.9, 12.1, 12.3*	✓	✓	✓	Request complete and accurate information.
Position of Researcher Principal	Provide the position held by the PI within the Institution or Establishment where the investigation will be carried out. *FL: RLGSMIS Article 14 Section VI; ICH E6 (R3)*	✓	✓	✓	
Membership of Researcher Principal	*Provide the name of the Institution or Establishment to which the Principal Investigator belongs and in which he/she performs his/her duties. FL: RLGSMIS Article 14 Section VI; ICH E6 (R3)*	✓	✓	✓	
Principal investigator's email address	Review the general requirements.	✓	✓	✓	
Investigator's Letter of Acceptance of Responsibility Main, No Conflict of Interest, Report of Adverse Events and Confidentiality	**Requirement: Single form of the Principal Investigator and the Research Team, duly completed as well as the certificates of studies that accredit the technical competence, in good clinical practices and specialized experience of the principal investigator and the Research Team.** *FL: Agreement establishing simplification measures for procedures before the Federal Commission for Protection against Sanitary Risks, as specified therein. Agreement updating the means of submitting procedures cofepris-04-010 "Application for Authorization of Research Protocol in Human Beings" and cofepris-09-012 "Application for Modification or Amendment to the Authorization of Research Protocol".*	✓	✓	✓	In this field you should enter Single Format of Principal Investigator and of Research Team

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IX. Principal Investigator

Information from the Principal Investigator

FIELD IN PLATFORM	TYPE, CLASSIFICATION AND DESCRIPTION *LEGAL BASIS (FL)*	MODALITIES A	 B	 C	SPECS BY FIELD
	Requirement: **Single form of the Principal Investigator and the Research Team, duly completed as well as the certificates of studies that accredit the technical competence, in good clinical practices and specialized experience of the principal investigator and the Research Team.**				
Researcher's Professional History Principal	*FL: Agreement establishing simplification measures for procedures before the Federal Commission for Protection against Sanitary Risks, as specified therein. Agreement updating the means of submitting procedures cofepris-04-010 "Application for Authorization of Research Protocol in Human Beings" and cofepris-09-012 "Application for Modification or Amendment to the Authorization of Protocol of Investigation".*	✓	✓	✓	In this field you should Enter the Single Format of the Principal Investigator and the Research Team.

X. Research Team

Information about the Research Team

FIELD IN PLATFORM	TYPE, CLASSIFICATION AND DESCRIPTION *LEGAL BASIS (FL)*	MODALITIES A	 B	 C	SPECS BY FIELD
	Requirement: **Proof of studies that accredit the technical competence, in good clinical practices and specialized experience of the Research Team.**				
Preparation Academic and Experience of Medical Staff, Paramedic and others Experts	*FL: LGS Art. 100 Fracc. V, RLGSMIS Art. 14 Fracc. VI, 62 1 VII, IX, 114, 116 Section V, 117, 118; NOM-012 Numeral 10.1, 10.4, 10.4.1 and Agreement establishing simplification actions for procedures carried out before the Federal Commission for Protection against Sanitary Risks, which are indicated therein. Agreement updating the means of presentation of the procedures cofepris-04-010 "Application for Authorization of Research Protocol in Human Beings" and cofepris-09-012 "Application for Modification or Amendment to the Authorization of Research Protocol".*	✓	✓	✓	Submit proof of studies that demonstrate technical competence, good clinical practices, and experience specialized member **of the Research Team.**

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X. Research Team

Information about the Research Team

FIELD IN PLATFORM	TYPE, CLASSIFICATION AND DESCRIPTION *LEGAL BASIS (FL)*	MODALITIES A B C	SPECS BY FIELD
Descriptive Letter of the Delegation of Responsibility from the Investigator to the Team Investigation	**N/A**	N/A N/A N/A	This document is no longer required, do not enter information.
Warehouse License	**N/A**	N/A N/A N/A	

XI. Research Ethics Committee

Information about the Research Ethics Committee

FIELD IN PLATFORM	TYPE, CLASSIFICATION AND DESCRIPTION *LEGAL BASIS (FL)*	MODALITIES A B C	SPECS BY FIELD
Name of the Establishment of the Ethics Committee in Investigation	Write the full name of the Establishment Denomination of the Committee Research Ethics, in accordance with what is stated in the current Registry/Accreditation of said Committee. Examples: “Joaquín Negrete Hospital”, “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 Numeral 6.3.2.5, 9, 9.1, 9.1.1, 9.2 and 9.2.1; NOM-177 Numerales 10.2.1, 10.2.1.1, 10.2.2 and 10.2.2.1.*	✓ ✓ ✓	Request complete and accurate information.
Name of the President of the Ethics Committee in Investigation	Write the full name of the Chair of the Research Ethics Committee registered with the National Bioethics Commission (CONBIOÉTICA); in accordance with the current Registration/Accreditation provided. *FL: NOM-012 Numeral 9.2.4*	✓ ✓ ✓	
Name of the Secretary of Ethics Committee in Investigation	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 registration/accreditation provided. *FL: NOM-012 Numeral 9.2.4*	✓ ✓ ✓	
Research Ethics Committee Registration Number	Please provide the full registration number of the current Research Ethics Committee, issued by the National Bioethics Commission (CONBIOÉTICA). *FL: LGS Art. 41 Bis Fracc. II and III (last amendment DOF 15-01-2026); RLGSMIS Art. 99 Fracc. I, 101, 104, 107, 108, 109 and 112, NOM-012 Numerales 6.3.2.5, 9, 9.1, 9.1.1, 9.2 and 9.2.1; NOM-177 Numeral 10.2.1, 10.2.1.1, 10.2.2 and 10.2.2.1.*	✓ ✓ ✓	

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XI. Research Ethics Committee

Information about the Research Ethics Committee

FIELD IN PLATFORM	TYPE, CLASSIFICATION AND DESCRIPTION *LEGAL BASIS (FL)*	MODALITIES A	B	C	SPECS BY FIELD
Registration of Ethics Committee in Investigation	**Requirement: Registration/Accreditation of the Ethics and Research Committee.** *FL: LGS Art. 41 Bis Sections II and III (last amended DOF 15-01-2026); Agreement establishing simplification measures for procedures before the Federal Commission for Protection against Sanitary Risks, as indicated therein. Agreement updating the means of submission for procedures cofepris-04-010 "Application for Authorization of Research Protocol in Human Beings" and cofepris-09-012 "Application for Modification or Amendment to the Authorization of Protocol of Investigation".*	✓	✓	✓	Enter Registration/Accreditation of the Ethics and Research Committee. * It will be possible to enter the "Research Ethics Committee Registry" while following up on the statement of the, Practical Guide: Implementation of the reform to the General Health Law on Ethics and Research Committees (CEI) issued by CONBIOETICA on June 15 of 2026.
Favorable Opinion of the Research Ethics Committee	**Requirement: Approval from the Ethics and Research Committee.** *FL: LGS Art. 41 Bis Sections II and III (last amended DOF 15-01-2026); Agreement establishing simplification measures for procedures before the Federal Commission for Protection against Sanitary Risks, as indicated therein. Agreement updating the means of submission for procedures cofepris-04-010 "Application for Authorization of Research Protocol in Human Beings" and cofepris-09-012 "Application for Modification or Amendment to the Authorization of Protocol of Investigation".*	✓	✓	✓	In this field you should enter the Unified Format for the opinion of the CEI, in accordance with what is established on the CONBIOETICA website
Letter of Non-Vote from Ethics Committee in Investigation	**N/A**	N/A	N/A	N/A	This document is no longer required, do not enter information.
Letter of No Conflict of Ethics Committee in Investigation		N/A	N/A	N/A	
Letter from Follow-up I continue the study by the Ethics Committee in Investigation		N/A	N/A	N/A	

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XI. Research Ethics Committee

Information about the Research Ethics Committee

FIELD IN PLATFORM	TYPE, CLASSIFICATION AND DESCRIPTION *LEGAL BASIS (FL)*	MODALITIES A	 B	 C	SPECS BY FIELD
Contact of Ethics Committee in Investigation	Telephone and email address of the Research Ethics Committee. ***FL: Review the general requirements (section XI. Research Ethics Committee).***	✓	✓	✓	Request complete and accurate information.
Date of Opinion Favorable from Ethics Committee in Investigation	Select the approval date of the documents approved by the Committee. It must match the information presented in the Single Committee Format.	✓	✓	✓	
Address of the Ethics Committee in Investigation	Review the general requirements (section XI). Research Ethics Committee). All data are restricted except for the municipality or borough and the federal entity, which will be public.	✓	✓	✓	

XII. Research Committee

Information about the Investigation Committee

FIELD IN PLATFORM	TYPE, CLASSIFICATION AND DESCRIPTION *LEGAL BASIS (FL)*	MODALITIES A	 B	 C	SPECS BY FIELD
Name of the Establishment of the Committee Investigation	The full name of the Establishment Designation of the Investigation Committee must match what was declared in the current Registry. Examples: “Joaquín Negrete Hospital”, “Clínica SA de CV” *FL: LGS Art. 98, Section I; LGS Art. 41 Bis Section II and III (last amendment DOF 15-01-2026); RLGS-MIS Art. 99 Section III, 102, 103, 106, 107, 108, 111 and 112; NOM-012 Numbers 6.3.2.5, 9, 9.1, 9.1.1, 9.1.2, 9.2 and 9.2.1.*	✓	✓	✓	If you have: -An Ethics and Research Committee should be placed N/A in all categories. -If you have a The Research Ethics Committee must complete the required sections. with complete and correct information
Name of the Chairman of the Committee Investigation	Write the full name of the President of the Research Committee in accordance with the current Registration issued by COFEPRIS. *FL: LGS Art. 41 Bis Fracc. II and III (last amendment DOF 15-01-2026); NOM-012 Numeral 9.2.4*	✓	✓	✓	
Name of the Secretary of Committee of Investigation	Write the full name of the President of the Research Committee in accordance with the current Registration issued by COFEPRIS. *FL: LGS Art. 41 Bis Fracc. II and III (last amendment DOF 15-01-2026); NOM-012 Numeral 9.2.5*	✓	✓	✓	

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XII. Research Committee

Information about the Investigation Committee

FIELD IN PLATFORM	TYPE, CLASSIFICATION AND DESCRIPTION *LEGAL BASIS (FL)*	MODALITIES A	 B	 C	SPECS BY FIELD
Committee Registration Number Investigation	Refer to the current Registration number of the Research Committee, issued by the Federal Commission for Protection against Sanitary Risks (COFEPRIS). *FL: LGS Art. 98 Section I; LGS Art. 41 Bis Section II and III (last amendment DOF 15-01-2026); RLGSMIS Art. 99 Section III, 102, 103, 106, 107, 108, 111 and 112; NOM-012 Numbers 6.3.2.5, 9, 9.1, 9.1.1, 9.2 and 9.2.1.*	✓	✓	✓	
Record of the Investigation Committee	**NO DATA**	N/A	N/A	N/A	This document is no longer required, do not enter information.
Favorable Opinion of the Committee Investigation	*FL: LGS Art. 41 Bis Sections II and III (last amendment DOF 15-01-2026); Agreement establishing simplification actions for procedures carried out before the Federal Commission for Protection against Sanitary Risks, as indicated therein. Agreement updating the means of presentation of the procedures cofepris-04-010 "Application for Authorization of Research Protocol in Human Beings" and cofepris-09-012 "Application for Modification or Amendment to the Authorization of Research Protocol".*	✓	✓	✓	If you have: An Ethics Committee and Research, maintain "WITHOUT" GIVEN" -If you have a The Research Ethics Committee must submit the opinion. CI approval.
Non-voting letter from the Committee Investigation		N/A	N/A	N/A	
Letter of No Committee Conflict research	**NO DATA**	N/A	N/A	N/A	This document is no longer required, do not enter information.
Letter from Continuous monitoring by the Committee Investigation		N/A	N/A	N/A	
Date of the favorable opinion of the Investigation Committee	Select the approval date of the documents evaluated by the Committee. It must match the information presented in the Committee's Single Format.	✓	✓	✓	Request complete and correct information (if applicable).
Address of the Investigation Committee	Review the general requirements (section XII). Research Committee). All data is restricted except for the municipality or borough and the federal entity, which will be public.	✓	✓	✓	

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XIII. Biosafety Committee

Information about the Biosafety Committee

FIELD IN PLATFORM	TYPE, CLASSIFICATION AND DESCRIPTION *LEGAL BASIS (FL)*	MODALITIES A	B	C	SPECS BY FIELD
Name of the Establishment of the Committee Biosecurity	Full name of the Establishment Name of the Biosafety Committee, in accordance with the provisions of the current registry. Examples: “Joaquín Negrete Hospital”, “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 Numbers 6.3.2.5, 9, 9.1, 9.1.1, 9.1.2, 9.2 and 9.2.1.*	✓	✓	✓	If applicable, please provide complete information and correct.
Name of the Chairman of the Committee Biosecurity	Full name of the President of the Biosafety Committee registered with COFEPRIS; in in accordance with the current registry. *FL: NOM-012 Numeral 9.2.4.*	✓	✓	✓	
Name of the Secretary of Committee of Biosecurity	Full name of the President of the Biosafety Committee registered with COFEPRIS; in in accordance with the current registry. *FL: NOM-012 Numeral 9.2.5.*	✓	✓	✓	
Committee Registration Number Biosecurity	Refer to the current registration number of the Biosafety Committee, issued by the Federal Commission for 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 Numbers 6.3.2.5, 9, 9.1, 9.1.1, 9.1.2, 9.2 and 9.2.1.*	✓	✓	✓	
Biosafety Committee Record	**NO DATA**	N/A	N/A	N/A	This document is no longer required, do not enter information.
Favorable Opinion of the Committee Biosecurity	**Requirement: Approval opinion of the CommitteeFL: LGS** *Article 41 Bis Section II and III (last amendment DOF) 15-01-2026); LGS Art. 98 Section I, 100 Sections I, II, III, IV, V and VIII; RLGSMIS Art. 14 Section VII, 62 Section. III, 102, 103, 105, 110 and 112; NOM-012 Sections 6.3.2.8, 9.2, 9.2.1, 9.2.3, 9.2.7, 9.2.11 and 9.2.12; Agreement establishing simplification actions for procedures carried out before the Federal Commission for Protection against Sanitary Risks, as indicated therein. Agreement updating the means of presentation of the procedures cofepris-04-010 “Application for Authorization of Research Protocol in Human Beings” and cofepris-09-012 “Application for Modification or Amendment to the Authorization of Research Protocol”.*	✓	✓	✓	In this field you should Enter the Committee's approval opinion (when applicable).

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XIII. Biosafety Committee

Information about the Biosafety Committee

FIELD IN PLATFORM	TYPE, CLASSIFICATION AND DESCRIPTION *LEGAL BASIS (FL)*	MODALITIES A	B	C	SPECS BY FIELD
Letter of Non-Vote from the Committee Biosecurity	**NO DATA**	N/A	N/A	N/A	This document is no longer required, do not enter information.
Letter of No Ongoing conflict by the Biosafety Committee	**NO DATA**	N/A	N/A	N/A	
Letter from Continuous monitoring by the Committee Biosecurity	**NO DATA**	N/A	N/A	N/A	
Date of the Opinion Favorable from Committee of Biosecurity	Select the approval date of the documents evaluated by the Committee. It must match the information presented in the Single Committee Format.	✓	✓	✓	If applicable, please provide complete and accurate information.
Address of the Biosafety Committee	Review the general requirements (section XIII). All data is restricted except for the municipality or mayor's office and the federal entity, which will be public.	✓	✓	✓	

XIV. Importer

FIELD IN PLATFORM	TYPE, CLASSIFICATION AND DESCRIPTION *LEGAL BASIS (FL)*	MODALITIES A	B	C	SPECS BY FIELD
Importer's name	Write the full name of the Importer of the Product under Investigation and/or the inputs required for the study. *FL: LGS Art. 194, 295 and 375 Fracc. VIII; RIS Art. 132 Section III, 196 Section I and 200 Section IV; NOM-012 Number 6.4 and 7.2 subsection c.*	✓	✓	✓	Request complete and accurate information.
Health license or Notice of How it works Importer	**NO DATA**	✓	✓	✓	Document not required, keep “NO DATA”
Importer's health license number	**NO DATA**	✓	✓	✓	
Address of the Importer	Review the general requirements.	✓	✓	✓	Request complete and accurate information

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XV. Additional Information

Additional information from the study

FIELD IN PLATFORM	TYPE, CLASSIFICATION AND DESCRIPTION *LEGAL BASIS (FL)*	MODALITIES A	 B	 C	SPECS BY FIELD
Countries where the Investigation	Indicate the countries in which it will be developed The Investigation. *In accordance with the guidelines of the World Health Organization.*	✓	N/A	✓	Request complete and accurate information.
Conditions of Health or Problems Studied	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 Section III and 14 Section I, and in accordance with the guidelines of the World Health Organization.*	✓	✓	✓	

Information on contacting public consultations

FIELD IN PLATFORM	TYPE, CLASSIFICATION AND DESCRIPTION *In accordance with the guidelines of the World Health Organization.*	MODALITIES A	 B	 C	SPECS BY FIELD
Name of the Contact	Write the contact name that will respond to Public Inquiries.	✓	✓	✓	Request complete and accurate information.
Membership of Contact	Write the name of the Institution or Establishment to which the Public Consultation Contact belongs.	✓	✓	✓	
Contact and identification details	Review the general requirements.	✓	✓	✓	

Information on contacting scientific inquiries

FIELD IN PLATFORM	TYPE, CLASSIFICATION AND DESCRIPTION *In accordance with the guidelines of the World Health Organization.*	MODALITIES A	 B	 C	SPECS BY FIELD
Name of the Contact	Write the name of the person responsible for scientific leadership (study physician) and of to address related Scientific Inquiries with the Study.	✓	✓	✓	Request complete and accurate information.
Membership of Contact	Write the name of the Institution or Establishment to which the Scientific Consultation Contact belongs.	✓	✓	✓	
Telephone and email	Review the general requirements.	✓	✓	✓	

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XVI. Other Documents

Information on Additional Documentation to Consider

FIELD IN PLATFORM	TYPE, CLASSIFICATION AND DESCRIPTION *In accordance with the Organization's guidelines World Health*	MODALITIES A	B	C	SPECS BY FIELD
Name of the Document	**NO DATA**	N/A	N/A	N/A	Document not required, keep "NO DATA"
Description of Document	**NO DATA**	N/A	N/A	N/A	
Document / Assistant	**NO DATA**	N/A	N/A	N/A	

XIII. OTHER SPECIFIC REQUIREMENTS BY MODALITY

OPTION B: ESTABLISHMENT DETAILS OF THE OWNER

FIELD ON PLATFORM	TYPE, CLASSIFICATION AND DESCRIPTION *LEGAL BASIS*	SPECIFICATIONS BY FIELD
Third Party Authorization Number Authorized as a Clinical Unit	Please cite the Authorization No. as a Clinical Unit to perform Bioavailability and/or Bioequivalence tests to demonstrate Interchangeability in Medicines. *FL: LGS Articles 17 Bis Section IV, 102 Bis, 368, 371, 372 and 391 Bis; RIS Articles 210, 211 and 213; NOM-0177 Numbers 4.97, 4.100, 8.11.6, 8.11.7, 8.11.8, 8.11.9, 10.1.1 and 10.5.2.*	Request complete and accurate information.
Authorization of the Third Party Authorized as a Clinical Unit	**N/A**	Document not required (do not enter information)
Third Party Authorization Number Authorized as an Analytical Unit	Refer to the full authorization number of the Authorized Third Party as the Analytical Unit. *FL: LGS Articles 17 Bis Section IV, 102 Bis, 368, 371, 372 and 391 Bis; RIS Articles 210, 211 and 213; NOM-0177 Numbers 4.97, 4.100, 8.11.6, 8.11.7, 8.11.8, 8.11.9, 10.1.1 and 10.5.2.*	Request complete information and correct.
Authorization of Third Party as an Analytical Unit	**N/A**	Document not required (do not enter information)
Address of the Third Party Authorized as Clinical Unit	Review the general requirements.	Request complete and accurate information.

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COMISIÓN FEDERAL PARA LA PROTECCIÓN CONTRA RIESGOS SANITARIOS