Evaluation form

Application
Protocol Authorization
Research on Human Beings

Homoclave 04-010
Modalities:

A, C and D

Research and Clinical Trials

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Evaluation document for the request for authorization of research protocols in human beings (homoclave 04-010, modalities A, C and D)

The requirements and requirements of this document are named in an illustrative but not limiting manner, in such a way that the applicant for research protocols in human beings must adhere to the mandatory provisions established by the Mexican legal-health framework, as well as adapt to the scientific and ethical principles that justify the research it proposes, in universally accepted international regulatory instruments depending on the type of study, the phase, the type of product under investigation and other characteristics of the research.

This card is applicable for the evaluation of procedures of the following modalities:

Modality A: study, protocol or clinical trial in humans, to test pharma-chemical, biological or biotechnological medicines. This includes:

- **Phase I clinical trials:** the first time administration of a drug research to healthy human beings, without diagnostic or therapeutic benefit, in single or multiple, in small hospitalized groups, to establish pharmacological parameters initials
- **Phase II clinical trials:** the administration of an investigational drug when human, in single or multiple doses, in small groups to determine its initial efficacy and other pharmacological parameters in the body
- **Phase III clinical trials:** the administration of an investigational drug to groups large number of patients, to define its therapeutic usefulness and identify adverse reactions, interactions and external factors that may alter the pharmacological effect
- **Biocomparability protocols:** studies that aim to demonstrate quality, safety and/or efficacy of biocomparable biotechnological medicines
- **Extension studies.**

Modality C: study, protocol or clinical trial in human beings, to test new resources and other methods of prevention, diagnosis, treatment and rehabilitation carried out in human beings or their biological products, except pharmacological ones, for example:

- Grafts
- Prosthetics
- Transplants
- Surgical or rehabilitation procedures
- Medical devices (non-releasing medicines)

Mode D: risk-free research, which involves the collection and analysis of information or data from the subjects in which no intervention or intentional modification is made to their physiological, psychological and social variables; and in which documentary research techniques or methods can be used. This includes:

- **Phase IV clinical trials:** studies that are carried out after the drug is approved registration and authorization for its sale, and aims to generate new information on the safety of the drug during widespread and prolonged use

This certificate does not include Modality COFEPRIS-04-010-B (Bioequivalence), because the objective in these studies is to demonstrate similar bioavailability (rate and absorbed amount of the drug) in generic medications, and they have specific requirements, so They are evaluated with the requirements of the modality.

The specific card will be published later.

General requirements

1. Authorizations, Certificates and Visits Format (FF-COFEPRIS-01)	
ÿ Current format ÿ Signed by the accredited legal representative ÿ Required with sections: 1, 2, 3 and 7: o Section 1: homoclave (04-010) and corresponding modality o Section 2: owner data according to tax data o Section 3: data of the owner establishment in accordance with the health license, operating notice or format of "Information on Establishments that Do Not Required to Submit Notice of Operation or License Application" for contract research organizations o Section 7: Complete information and in accordance with what is indicated in the written notice application.	**Compliant:** ÿ Yes ÿ No
Basis:	
Federal Law of Administrative Procedure, Article: 15 Mexican Official STANDARD NOM-012-SSA3-2012, Which establishes the criteria for the execution of research projects for health in human beings, Section 6.1 AGREEMENT by which the various procedures and services are made known, as well as the formats applied by the Ministry of Health, through the Federal Commission for the Protection against Sanitary Risks, registered in the Federal Registry of Procedures and Services of the Federal Commission for Regulatory Improvement, published on January 28, 2011.	

2. Proof of payment of rights	
ÿ Carried out by the establishment that owns the research ÿ Addressed to the "Federal Commission for the Protection against Health Risks" agency; ÿ Amount paid for the corresponding application in accordance with the applicable rate published in the Official Gazette of the Federation ÿ Voucher payment key ÿ Date of payment (must be made prior to submitting the procedure) ÿ Approval from the banking institution (digital seal or electronic signature)	**Compliant:** ÿ Yes ÿ No
Basis:	
Federal Law of Administrative Procedure, Article: 15 Mexican Official STANDARD NOM-012-SSA3-2012, Which establishes the criteria for the execution of research projects for health in human beings, Section 6.1 AGREEMENT by which the various procedures and services are made known, as well as the formats applied by the Ministry of Health, through the Federal Commission for the Protection against Sanitary Risks, registered in the Federal Registry of Procedures and Services of the Federal Commission for Regulatory Improvement, published on January 28, 2011.	

3. Document to prove the address of the owner's establishment	
ÿ Current and updated health license, without suspension in accordance with the License Database available https://www.gob.mx/cofepris/documentos/bases-de-datos-de-licencias-sanitarias-de- insumos-para-la-salud), **either** in _____ ÿ Operation notice (with current and updated entry number, signed by the accredited legal representative), **or** ÿ Format of "Information on Establishments that Do not Require to Present Notice of Operation or License Application", in the case of contract research organizations (CRO)	**Compliant:** ÿ Yes ÿ No
Basis:	
Article 15 of the Federal Law of Administrative Procedure	

4. Application letter	
ÿ Written in free text in which the requested request is briefly and clearly stated. ÿ Includes study identification data, risk level and duration (estimated start and end date of the research) ÿ Signed by the accredited legal representative or authorized person ÿ The information contained in the headers and footers must be consistent with the company name and address of the applicant	**Compliant:** ÿ Yes ÿ No

Basis:

General Health Law, Article: 102, Section: I
Federal Law of Administrative Procedure, Article: 15
Agreement that modifies the various procedures and services, as well as the formats that apply to the Ministry of Health, through the Federal Commission for the Protection against Health Risks, registered in the Federal Registry. of Procedures and Services of the Federal Commission for Regulatory Improvement, Third Section, Request for Authorization of Research Protocol on Human Beings, Homoclave COFEPRIS-04-010-A Regulations of the General Health Law on Health Research, Article : 62, Fraction: V

Mexican Official Standard NOM-012-SSA3-2012, Which establishes the criteria for the execution of research projects for health in human beings, Number: 6.3, 6.3.1, 6.3.2, 6.3.2.4, 6.3.2.9, 8.6

Research documents

1. Research protocol	
ÿ Title of the research protocol (corresponds to the opinions of the committees evaluators) ÿ Version of the document and date of the version (corresponds to the opinions of the evaluation committees) ÿ Theoretical framework ÿ Problem definition ÿ Background ÿ Justification ÿ Research hypotheses (includes statistical hypotheses) ÿ General objective (specific, primary, secondary or exploratory objectives) ÿ Material and methods ÿ Study design ÿ Phase and type of study ÿ Sample size (global and local, as appropriate) ÿ Countries where the research will be carried out ÿ Health conditions or problems studied ÿ Inclusion, exclusion and elimination criteria ÿ Capture, processing, analysis and interpretation of the information obtained ÿ Route of administration, dose, dosing regimen and treatment period(s) ÿ Ethical considerations ÿ Study schedule (document detailing the activities to be carried out during the investigation) ÿ Bibliographic references	**Compliant:** ÿ Yes ÿ No

Basis:

Regulations of the General Health Law on Health Research; Article: 14; Fraction: I, II, III, IV; Article: 15, 17; Article: 62, Fraction: I; Article: 65, 66, 69, 70, 72, 73, 74; Item: 116, Fraction: I
Official Mexican Standard NOM-012-SSA3-2012, Which establishes the criteria for the execution of research projects for health in human beings
Number: 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, 10.2
General Health Law, Article: 100, Section: I, II, III; Article: 102, Fraction: II, III, IV
Agreement that modifies the various procedures and services, as well as the formats that apply to the Ministry of Health, through the Federal Commission for the Protection against Health Risks, registered in the Federal Registry. of Procedures and Services of the Federal Commission for Regulatory Improvement; Third Section, Request for Authorization of Research Protocol in Human Beings, Homoclave COFEPRIS-04-010-A

2. Investigator's manual	
ÿ Study identification data (title, protocol number, sponsor) ÿ Identification data of the investigational product (common name international, commercial name, if applicable) ÿ Version of the document and date of the version (coinciding with the approving opinions of the evaluation committees) ÿ Previously obtained clinical and non-clinical information that justifies the use and clinical management of the investigational product ÿ Physicochemical and pharmaceutical properties of the product under investigation ÿ Formulation	**Compliant:** ÿ Yes ÿ No

Note. The information in this document must be presented in a concise, simple, objective and balanced manner that allows the doctor or principal investigator, as well as others involved in the trial, the suitability of the proposed trial, emphasizing the relevant and updated scientific information of the product in question. research such as doses and interval, method of administration and procedures to monitor the safety of the participant.

Basis:

Regulations of the General Health Law on Health Research; Article: 14, Fraction: II, III; Article: 62, Section: VIII; Item: 66, 67, 68, 69, 70, Item: 73
General Health Law, Article: 100, Section: I, II, III; Article: 102, Fraction: II, III
Agreement that modifies the various procedures and services, as well as the formats that apply to the Ministry of Health, through the Federal Commission for the Protection against Health Risks, registered in the Federal Registry. of Procedures and Services of the Federal Commission for Regulatory Improvement. Third Section, Request for Authorization of Research Protocol in Human Beings, Homoclave COFEPRIS-04-010-A Mexican Official Standard NOM-012-SSA3-2012, Which establishes the criteria for the execution of research projects
for health in human beings , Number: 5.10

3. Informed consent

ÿ Written document, through which the research subject agrees to voluntarily participate in research and have an experimental maneuver applied to them, once they have received sufficient, timely, clear and truthful information about the expected risks and benefits.

ÿ Identification data: Title and protocol number, version, version date, data from the Research Center, name of the principal investigator, data from the medical emergency unit and data from the Research Ethics Committee

ÿ Version of the document and date of the version (coinciding with the opinions of the evaluation committees)

ÿ Information about:

- o Justification and objectives of the research
- o Explains the blinding of the study (if applicable) and what it consists of
- o Allocation method
- o Procedures to be carried out, purpose and justification, making mention of those that correspond to experimental procedures
- o Discomfort and/or expected risks
- o Possible benefits to the participant (physical examination, laboratory tests and cabinet are not benefits)
- o Alternative procedures that could be advantageous to the subject

ÿ Guaranteeing that the research subject:

- o You will receive a response for any clarification, concern and/or question about the treatment, procedures, risks, benefits and other matters related to the research.
- o You may withdraw consent at any time to stop participating in the study without generating prejudice in order to continue with the medical treatment treatment.
- o Confidentiality of the information (includes personal data and those derived of the study)
- o The availability of medical treatment and corresponding compensation

ÿ Specific who to contact, as well as the communication channels and data to request clarification of doubts, or report possible adverse events;

ÿ Signature format included in the document of the voluntary declaration of informed consent of the participant or his legal representative (acceptance by signature), as well as the declaration of compliance with what is described by the main researcher (acceptance by signature).

- o It must include the section for the signature of two witnesses of the participant (full name, address, link and signature).

Note. The information must be presented in a clear, concise, simple and understandable language for the participant, which must allow them to understand the risk-benefit of the research in which they are invited to participate.

Compliant:
ÿ Yes
ÿ No

Basis:

General law of health; Article: 100, Fraction: IV; Item: 103
Regulations of the General Health Law on Health Research; Article: 14, Fraction: V; Item: 20, 21, 22, 36
Agreement that modifies the various procedures and services, as well as the formats that apply to the Ministry of Health, through the Federal Commission for the Protection against Health Risks, registered in the Federal Registry. of Procedures and Services of the Federal Commission for Regulatory Improvement. Third Section, Section Request for Authorization of Research Protocol on Human Beings, Homoclave COFEPRIS-04-010-A Mexican Official Standard NOM-012-SSA3-2012, Which establishes the criteria for the
execution of research projects for health in beings humans, Number: 4.3, 5.7, 6.3, 6.3.2.10, 8.5, 10.6, 10.7, 11.2,
11.3

Sponsor Documents

1. Letter of express acceptance of obligations and rights of the position of research sponsor	
ÿ Indicates the obligations and rights that the research project or protocol imposes to the sponsor ÿ The obligations and rights are accepted by the sponsor	**Compliant:** ÿ Yes ÿ No
Basis:	
Regulations of the General Health Law on Health Research; Article: 58, Section: III; Item: 120 Mexican Official Standard NOM-012-SSA3-2012, Which establishes the criteria for the execution of research projects for health in human beings, Number: 6.3.2.7, 7.2, 11.1	

2. Letter of follow-up on the conduct of the investigation	
ÿ Monitoring and audit plan with the frequency of application ÿ Person(s) responsible for monitoring ÿ Objective and scope ÿ Evaluation tool ÿ Methodology to carry out scientific, technical and ethical monitoring ÿ Classification of findings ÿ Notification mechanisms to the principal investigator, the committees and the authority ÿ Design of the corrective, improvement or preventive action plan, mitigation plan risks, etc.	**Compliant:** ÿ Yes ÿ No
Basis:	
Mexican Official Standard NOM-012-SSA3-2012, Which establishes the criteria for the execution of research projects for health in human beings; Number: 7.2	

3. Insurance policy or current document from the financial fund that covers all study participants at the local level	
ÿ Document that guarantees coverage to the subject in case of injury or damage related to research	**Compliant:** ÿ Yes ÿ No
Basis:	
Mexican Official Standard NOM-012-SSA3-2012, Which establishes the criteria for the execution of research projects for health in human beings; Number: 5.14, 7.2	

4. Delegation of responsibilities/granting of functions document	
ÿ Sponsor document for the importer, warehouse, study owner (in case this figure is different from the study sponsor)	**Compliant:** ÿ Yes ÿ No
Basis:	
General Health Law, Articles 194, 295 and 375 Section VIII Mexican Official STANDARD NOM-012-SSA3-2012, Which establishes the criteria for the execution of research projects for health in human beings; Sections 6.4 and 7.2 section C AGREEMENT by which the various procedures and services are made known, as well as the formats applied by the Ministry of Health, through the Federal Commission for the Protection against Sanitary Risks, registered in the Federal Registry of Procedures and Services of the Federal Commission for Regulatory Improvement, published on January 28, 2011.	

5. Letter of No conflict of interest, which guarantees that it will not lead to the interruption of the treatment of the research participants	
ÿ It must be guaranteed that the sponsor will not generate conflicts of interest that could cause the interruption of treatment for the research subject.	**Compliant:** ÿ Yes ÿ No
Basis:	
Regulations of the General Health Law on Health Research, Article: 63, 120 Mexican Official Standard NOM-012-SSA3-2012, Which establishes the criteria for the execution of research projects for health in human beings, Number: 7.4.5	

6. Letter describing the available human and material resources	
ÿ It must be issued by the sponsor/CRO specifying the human and material resources that will be allocated for the research and the way in which they will be provided and distributed to the research site. ÿ Describes areas, equipment and auxiliary services of laboratories and cabinets	**Compliant:** ÿ Yes ÿ No

Basis:

Regulations of the General Health Law on Health Research, Article: 14, Section: VI
Mexican Official Standard NOM-012-SSA3-2012, Which establishes the criteria for the execution of research projects for health in human beings, Number: 6.3.2.4, 7.4.5

7. Letter describing import inputs that expresses the approximate quantity of the product under investigation	
ÿ The information is consistent with the proposed study design ÿ Document in which the quantity and description of imported inputs are established that will be used during the investigation	**Compliant:** ÿ Yes ÿ No

Basis:

Agreement that modifies the various procedures and services, as well as the formats that apply to the Ministry of Health, through the Federal Commission for the Protection against Health Risks, registered in the Federal Registry. of Procedures and Services of the Federal Commission for Regulatory Improvement. Third Section
General Foreign Trade Rules for 2020, Number: 3.1.4
Official Mexican Standard NOM-012-SSA3-2012, Which establishes the criteria for the execution of research projects for health in human beings, Number: 6.4

From the importer and the warehouse for the research product

1. Letter of acceptance of responsibility from the importer	
ÿ Express acceptance of responsibilities by the importer ÿ Signed by the Legal Representative of the importing establishment ÿ Does not apply if the owner is the importer	**Compliant:** ÿ Yes ÿ No

Basis:

General Health Law, Articles 194, 295 and 375 Section VIII
Mexican Official STANDARD NOM-012-SSA3-2012, Which establishes the criteria for the execution of research projects for health in human beings, Section 6.4 and 7.2

2. Sanitary license of the storage and distribution warehouse for the research product (only controlled and biological)	
ÿ Does not apply to other products that are not controlled or biological. ÿ Distributor license in the National Territory of controlled medications or products biological for human use	**Compliant:** ÿ Yes ÿ No

Basis:

General Health Law, Articles 45, 102, 198, 200 and 257
Mexican Official STANDARD NOM-012-SSA3-2012, Which establishes the criteria for the execution of research projects for health in human beings, Section 8.1

From the research center

1. Health license or operating notice of the establishment where the research will be carried out	
ÿ The operating warning is acceptable if the risk level of the company's interventions research is low	**Compliant:** ÿ Yes ÿ No

Basis:

General law of health; Article: 45, 47; Article: 198, Fraction: IV, V
Mexican Official Standard NOM-012-SSA3-2012, Which establishes the criteria for the execution of research projects for health in human beings, Number: 4.11
General law of health; Article: 200 Bis, 315, 368, 369, 373
Regulations of the General Health Law on Health Research; Item: 31, 98

2. Letter of acceptance/authorization from the head of the institution where the research will be carried out for the development of the research protocol	
ÿ The head of the institution or establishment grants authorization for it to be carried out. the research protocol	**Compliant:** ÿ Yes ÿ No

Basis:

General law of health; Article: 102, Fraction: V
Agreement that modifies the various procedures and services, as well as the formats that apply to the Ministry of Health, through the Federal Commission for the Protection against Health Risks, registered in the Federal Registry. of Procedures and Services of the Federal Commission for Regulatory Improvement, Third Section
Mexican Official Standard NOM-012-SSA3-2012, Which establishes the criteria for the execution of research projects for health in human beings, Number: 6.3.2.6, 7.2, 8.2, 8.4
Regulations of the General Health Law on Health Research, Article: 14, Section: VI, VIII; Article: 62, Fraction: II, IX

3. Letter describing the available resources of the establishment where the research will be carried out	
ÿ Describes the available resources of the institution or establishment ÿ Must include areas, equipment, auxiliary laboratory services, cabinets, number and type of available human resources, etc.	**Compliant:** ÿ Yes ÿ No

Basis:

Mexican Official Standard NOM-012-SSA3-2012, Which establishes the criteria for the execution of research projects for health in human beings; Number: 6.3.2.4, 7.4.5
Regulations of the General Health Law on Health Research; Article: 14, Fraction: VI, VIII; Article: 62, Fraction: IV, IX
General Health Law, Article: 100, Section: V, VIII
Agreement that modifies the various procedures and services, as well as the formats that apply to the Ministry of Health, through the Federal Commission for the Protection against Health Risks, registered in the Federal Registry. of Procedures and Services of the Federal Commission for Regulatory Improvement. Third Section

From the emergency center

1. Health license of the establishment to carry out medical emergency care	
ÿ Health License for Health Care Establishments where Acts are performed Surgical or Obstetric ÿ Does not apply to the protocols of the COFEPRIS-04-010-D modality	**Compliant:** ÿ Yes ÿ No

Basis:

General law of health; Article: 45, 198, 368, 369, 373
Name: Official Mexican Standard NOM-012-SSA3-2012, Which establishes the criteria for the execution of research projects for health in human beings, Number: 8.6

2. Agreement or contract of the establishment for the care of medical emergencies of the research	
ÿ Agreement or contract that the institution or establishment has to be able to provide care of medical emergencies derived from research	**Compliant:** ÿ Yes ÿ No

Basis:

Official Mexican Standard NOM-012-SSA3-2012, Which establishes the criteria for the execution of research projects for health in human beings, Number: 6.3.2.9, 8.6
Regulations of the General Health Law on Health Research, Article: 14, Section: X; Article: 62, Fraction: IV, V

3. Letter of authorization from the owner of the establishment where medical emergencies will be treated	
ÿ Contains the acceptance and description of the available resources of the institution or establishment in which medical emergencies arising from the research will be treated.	**Compliant:** ÿ Yes ÿ No

Basis:

Regulations of the General Health Law on Health Research, Article: 14, Section:
General Health Law, Article: 100, Section: VII

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From the principal investigator and the research team

1. Letter of acceptance of responsibility from the principal investigator, of no conflict of interest, of the reporting of adverse events and of confidentiality	
ÿ Establishes the acceptance of the principal investigator for the conduct of the clinical protocol, as well as the commitment regarding the reporting of adverse events and the confidentiality of the subjects and the information generated during the research.	**Compliant:** ÿ Yes ÿ No
Basis:	
General Health Law, Article: 100, Section: V Regulations of the General Health Law on Health Research; Article: 14, Fraction: VI; Article 62, Section: VII; Article: 116, Fraction: V; Article: 117, 118 Mexican Official Standard NOM-012-SSA3-2012, Which establishes the criteria for the execution of research projects for health in human beings; Number: 10.1, 10.4, 10.4.1	

2. Professional history of the principal investigator	
ÿ Updated Curriculum Vitae: describes the academic training and experience according to the research to be carried out, includes academic preparation, representative scientific production and clinical practice ÿ Professional title or equivalent document ÿ Professional license ÿ Certificate of good clinical practices	**Compliant:** ÿ Yes ÿ No
Basis:	
General Health Law, Article: 100 Mexican Official Standard NOM-012-SSA3-2012, Which establishes the criteria for the execution of research projects for health in human beings; Number: 10.1, 10.4.1 Regulations of the General Health Law on Health Research; Article: 14; Fraction: VI Agreement that modifies the various procedures and services, as well as the formats that apply to the Ministry of Health, through the Federal Commission for the Protection against Health Risks, registered in the Federal Registry. of Procedures and Services of the Federal Commission for Regulatory Improvement. Third Section Regulations of the General Health Law on Health Research; Article: 62, Fraction: VI; Item: 1113, 114	

3. Academic preparation and experience of medical, paramedical personnel and other participants	
ÿ Updated Curriculum Vitae: describes academic training and experience, includes academic preparation, representative scientific production and clinical practice (if applicable) ÿ Professional title or equivalent document ÿ Professional license (if applicable) ÿ Certificate of good clinical practices (if applicable) ÿ Consistent with the activities to be carried out as part of the research team	**Compliant:** ÿ Yes ÿ No
Basis:	
Regulations of the General Health Law on Health Research; Article: 14, Fraction: VI; Article: 62, Fraction: VII, Article: 114, 116, Fraction: V; Article 117, 118 Mexican Official Standard NOM-012-SSA3-2012, Which establishes the criteria for the execution of research projects for health in human beings, Number: 10.1, 10.4, 10.4.1 Name: Agreement that modifies the various procedures and services, as well as the formats that apply to the Ministry of Health, through the Federal Commission for the Protection against Health Risks, registered in the Federal Registry of Procedures and Services of the Federal Commission for Regulatory Improvement. Third Section Other: Section Request for Authorization of Research Protocol on Human Beings, Homoclave COFEPRIS-04-010-A General Health Law; Item: 100, Fraction: V	

4. Descriptive letter of the delegation of responsibility from the researcher to the research team	
ÿ Describes the delegation of the activities and responsibilities of each member who participate in research	**Compliant:** ÿ Yes ÿ No
Basis:	
General Health Law, Article: 100, Section: V Regulations of the General Health Law on Health Research; Article: 14, Fraction: VI; Article: 62, Section: VII; Article: 116; Fraction: V; Article: 117, 118 Mexican Official Standard NOM-012-SSA3-2012, Which establishes the criteria for the execution of research projects for health in human beings; Number: 10.1, 10.4, 10.4.1	

5. Express letter of no conflict of interest to conduct the research, signed by the principal investigator and his work team	
ÿ Expresses the commitment that conflicts of interest will not be generated that could produce interruption in the treatment of the research subject ÿ (It can be a letter signed by everyone or individual documents)	**Compliant:** ÿ Yes ÿ No
Basis:	
Mexican Official Standard NOM-012-SSA3-2012, Which establishes the criteria for the execution of research projects for health in human beings, Number: 7.4.5 Regulations of the General Health Law on Health Research, Article: 63	

From the evaluation committees

1. Records of the Evaluation Committees	
ÿ Research Ethics Committee (CEI) ÿ Investigation Committee (IC) ÿ Biosafety Committee (CB), if applicable	**Compliant:** ÿ Yes ÿ No

Basis:

General Health Law, Article: 41 bis
Official Mexican Standard NOM-012-SSA3-2012, Which establishes the criteria for the execution of research projects for health in human beings, Number: 6.3.2.5, 9, 9.1, 9.1.1, 9.1.2, 9.1.3 , 9.1.4
General Health Law, Article: 98
Regulations of the General Health Law on Health Research, Article: 99, 101, 103, 104, 105, 106, 107, 108

2. Favorable opinion of each evaluation committee	
ÿ Favorable resolution based on the ethical aspects, the risk/benefit of the protocol, the guarantee and well-being of the subjects, the technical quality and scientific merit of the research proposed through the approval of the study documents: o Citation of the protocol with version and date o Cite the researcher's manual with version and date o Cite the informed consent form(s) with version and date o If it is a translation into Spanish, cite it ÿ On letterhead paper ÿ Indicates the address of the committee ÿ Specifies the date of issuance of the opinion ÿ Specifies name of the main researcher ÿ Indicates the company name and address of the research center ÿ Indicates the title of the study and protocol number ÿ Specifies the status of the documents (must be approved or favorable) ÿ Specify the name and position of the signatory who endorses the opinion (it must be the President or Secretary Member) ÿ The opinion is signed	**Compliant:** ÿ Yes ÿ No

Basis:

General Health Law, Article: 41 bis; Article: 98; Item: 100, Fraction: I, II, III, IV, V
Regulations of the General Health Law on Health Research, Article: 14, Section: VII, Article: 22; Article: 62, Section: III; Article: 102, 109, 110, 111
Agreement that modifies the various procedures and services, as well as the formats that apply to the Ministry of Health, through the Federal Commission for the Protection against Health Risks, registered in the Federal Registry. of Procedures and Services of the Federal Commission for Regulatory Improvement, Third Section
Official Mexican Standard NOM-012-SSA3-2012, Which establishes the criteria for the execution of research projects for health in human beings, Number: 6.3.2.8, 9.2, 9.2.3, 9.2.7, 9.2.8, 9.2 .9, 9.2.11, 9.2.12

3. Non-voting letter from committee members who are members of the research team	
ÿ Committee members must excuse themselves from participating in the evaluation or issuance of opinions on investigations in which they are participating. ÿ Only applies if the committee members are participating in the investigation	**Compliant:** ÿ Yes ÿ No

Basis:

Regulations of the General Health Law on Health Research, Article: 108, Section: VII
Mexican Official Standard NOM-012-SSA3-2012, Which establishes the criteria for the execution of research projects for health in human beings, Number: 9.2.3

4. Letter of no conflict of interest, and confidentiality of protocol information	
ÿ The members of the committees must guarantee that no conflict of interest exists or will be generated, as well as guarantee the confidentiality of the information in the research protocol. ÿ Applies to all members who participated in the opinion	**Compliant:** ÿ Yes ÿ No

Basis:

Mexican Official Standard NOM-012-SSA3-2012, Which establishes the criteria for the execution of research projects for health in human beings, Number: 9.2.3, 12.1, 12.2, 12.3
Regulations of the General Health Law on Health Research, Article: 108, 112

5. Letter of continuous monitoring of the study (includes a description of the monitoring process)	
ÿ Contains the description of the study follow-up process, which may or may not include the committee's standard operating procedure	**Compliant:** ÿ Yes ÿ No
Basis:	
Regulations of the General Health Law on Health Research, Article: 109 Mexican Official Standard NOM-012-SSA3-2012, Which establishes the criteria for the execution of research projects for health in human beings, Number: 7, 7.2, 9.2.3	

From the research product

1. Information on compliance with Good Manufacturing Practices	
ÿ Letter of commitment that the investigational and placebo products are manufactured under quality standards, intended to ensure that the investigational product has and maintains the identity, purity, safety, efficacy and quality characteristics required for its use, **or** ÿ Certificate of good practices for the research product, **or** ÿ Pharmaceutical product certificate	**Compliant:** ÿ Yes ÿ No
Basis:	
Official Mexican Standard NOM-164-SSA1-2015, Good drug manufacturing practices, Number: 16.4.1, 16.4.2, 16.5.1, 16.5.2, 16.5.4, 16.5.5, 16.10.1 Name: Official Mexican Standard NOM-059-SSA1-2015, Good drug manufacturing practices, Number: 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, 10.9.6.1	

1. Investigational Product Stability	
ÿ Commitment letter guaranteeing the useful life of the investigational drug from the date of manufacture to the date of the last administration in the investigational protocol, **or** ÿ Information related to the tests carried out on the product under investigation for a certain time under the influence of temperature, humidity or light in the container that contains it, to protect its useful life from the date of manufacture to the date of the last administration. , **either** ÿ Certificates of analysis expressing the stability of the research product from the date of manufacture to the date of the last administration in the research protocol	**Compliant:** ÿ Yes ÿ No
Basis:	
Mexican Official Standard NOM-073-SSA1-2015, Stability of drugs and medications, as well as herbal remedies, Number: 7.1, 7.2, 10.6, 10.27 Mexican Official Standard NOM-059-SSA1-2015, Good drug manufacturing practices, Number: 10.9.7.1	