# GUIDE FOR THE SUBMISSION FOR RESEARCH PROTOCOL IN HUMAN BEINGS

**HOMOKEY COFEPRIS 04-010 A**

**Version Date: SEPTEMBER 2016**

**Version No. 2.3**

ÿ **OBJECTIVE:** To describe the requirements for the "Application for Authorization of Research Protocol on Human Beings" in order to standardize the submissions.

ÿ **SCOPE:** Any natural or legal person who intends to submit a "Request for Authorization of Research Protocol on Human Beings" modality A before COFEPRIS.

ÿ **RESPONSIBILITIES:** Sponsors; Contract Research Organizations; Principal Investigator and work team; Research Centers; Health Institutions; Research Ethics Committee; Research Committee; Biosafety Committee.

ÿ **DESCRIPTION OF ACTIVITIES.**

**PRE SUBMISSION TO COFEPRIS**

**ÿIDENTIFICATION OF THE TYPE OF RESEARCH**

The promoter must identify the modality of the procedure that corresponds to him, according to the origin of the product or procedure object of the investigation:
This guide can be a reference for all the modalities currently published in the Procedures Agreement for homoclave 04-010; however, it must be taken into account that it has requirements that do not apply to modality B (bioequivalence studies) and D (Research without risk) that will be the subject of an independent guide.

a. The **COFEPRIS 04-010 Modality A homoclave** may include but is not limited to:
Protocols, during their assessment through phases I to IV that involve: - Medications of
Pharmacochemical Origin; -Biotechnological;

-Vaccines;
-Biological products;
-Hemoderivatives;
-Products that are herbal remedies and intend to study some therapeutic property to be marketed as medicines; -Products that are food supplements and intend to study some therapeutic property to be marketed as medicines; -Protocols that involve taking biological samples;

- Pharmacogenetic and/or pharmacogenomic studies;
-Others;

**ÿPRE REPORT BY UHAP** - The
applicant may request a pre-report evaluation with the Qualified Pre-Report Support Units (see list of enabled UHAPs in the investigation protocols section of the COFEPRIS website);

- The promoter will contact the UHAPs to request the evaluation of their information, through the website or means of contact established by each UHAP.
- The information to be presented to the UHAP must include the folio, subject to the UHAP establishing another mechanism.
- The evaluation by UHAP is a "voluntary" option for the applicant, considering that it includes a cost.
- The presentation of a pre-assessment by UHAP has the benefit that once the request is submitted to COFEPRIS, the response will be issued within a maximum of 30 business days (provided that the promoter notifies the Clinical Trials area that its procedure was submitted with a pre-assessment). ).

**ÿAPPOINTMENT REQUEST FOR SUBMISSION TO COFEPRIS THROUGH THE INTEGRAL SERVICES CENTER (CIS):**

To request an appointment online:

-Enter the COFEPRIS portal, to the "Appointment for the Entry of Procedures" page: http://www.cofepris.gob.mx/TyS/Paginas/Solicitud-de-Cita-para-el-Ingreso-de- Tr%C3%A1mites.aspx (Access only after 8:30 AM)
-Enter data and select time (Appointments are scheduled only for the next day, so you have to request an appointment the day before admission)

To request an appointment by phone:

-Dial the CIS Comprehensive Services Center at the following
number: For the Federal District and the interior of the Republic:
01-800 033-50-50 Select option 3: Appointment request for the entry of procedures to the CIS (Office hours: Monday to Friday from 8:30 a.m. to 6:00 p.m.)

**ÿ SUBMISSION TO COFEPRIS**

-For procedures with **pre opinion:**

• Send an email to **uhap@cofepris.gob.mx** indicating the entry number before the CIS with a preliminary ruling for identification and follow-up. • In the presentation of the information, a cover must be included indicating that it is a “PROCESSING WITH PRE-DICTION BY UHAP”. • All documents must be numbered and with original UHAP stamps (Procedures with a copy of the file evaluated by UHAP or, where appropriate, order of information other than that established by UHAP are not accepted). • The order of documents reviewed by UHAP should not be changed.

For protocols involving **Biotechnological** products (biosimilars, recombinant vaccines) and also orphan drugs

• The evaluation process of the Subcommittee for the Evaluation of Biotechnological Products (SEPB) is optional and voluntary for the promoter. • The benefit of requesting the meeting with the SEPB is to validate the design of the protocol, or the information available on the product, to facilitate the sanitary registration of the product, making the process more effective and efficient.

• In the event of deciding to request a meeting with the SEPB, this can be carried out in parallel to the review process by the Research Ethics Committee and the Research or Biosafety Committee, or even from the selection process of centers or before;

• The SEPB's response must be included as part of the submission of the "Request for Authorization of a Research Protocol on Human Beings" and the identifier EL48 or EL49 must be requested in the CIS.

• Refer PROCESSING WITH SEPB EVALUATION.

## MODULE I: PRESENTATION OF INFORMATION

i. The information that integrates the procedure must be presented in the strict order established in this guide.
All the information must be presented printed with a legible folio on each page with text on the upper right side, starting on the last page with folio 001 and ending on the first page with the last corresponding folio, except for the proof of payment, the which will not be foliated

ii. Each section should be separated only by colored sheet

iii. The information must be presented with a lateral clasp (left side), without binding or folders.

IV. Submit all the documentation in electronic format on USB or CD, ADDITIONAL TO THE PHYSICAL PRESENTATION.

v. All documentation must be submitted only in Spanish. (Agreement of procedures, RIS Art. 153)

saw. All simple copies must be legible and complete. (LEFEPA)

| documentary requirements | Requirement Description | legal basis | compliant | Folio |
|---|---|---|---|---|
| 1. "Request" format. | Duly required and in force | LEFEPA Art. 15.<br>RIS Article 153.<br>NOM-012 Numeral 6.1 .<br>Procedures agreement. | | NA |

| **MODULE II: PAYMENT OF RIGHTS** | | | | |
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| documentary requirement | Requirement Description | legal basis | Does it comply? | Folio |
| 2. Original and two copies of proof of payment of rights. | | Procedures agreement.<br>Federal Law of Rights. | | NA |

| **MODULE III: INFORMATION OF THE PROMOTER** | | | | |
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| documentary requirement | Requirement Description | legal basis | Does it comply? | Folio |
| 3. Letter of express acceptance of the position of the sponsor of the research in which each and every one of the institutions and/or companies to which the sponsor has assigned some activity in conducting the research is described. When there is sponsorship or other forms of remuneration, the necessary measures must also be described to prevent these from giving rise to conflicts of interest for the main researcher regarding the protection of the rights of the research subjects, for the preservation of the veracity of the results and in the allocation of resources. | In which the obligations and rights that the research project or protocol imposes on the sponsor are indicated and accepted.<br>In the case of legal entities, the position must be accepted by the person empowered to do so or by their legal representative, in accordance with their organic structure or constitutive regime. | | | |

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| 4. Letter describing the human and material resources that will be used for research at the research sites. | The letter 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 sites, referring to the public and/or private institutions that would provide resources when applicable. | NOM-012 Numeral 6.3.2.4 y 7.4.5.<br>RLGSMIS Art.14 Section VI, 11. | | |
| 5. Follow-up letter from the sponsor of the conduct of the investigation. | Description of the monitoring plan and audits that will be carried out on the investigation, including at least the following information:<br>-Type of plan: Audit or Monitoring;<br>-Frequency of application;<br>-Responsible for monitoring, where appropriate, summon the third party to carry out the activity;<br>-Objective and scope of monitoring;<br>-Evaluation tool;<br>-Methodology to carry out scientific, technical and ethical monitoring;<br>-Communication strategies between the researcher, sponsor and Committees;<br>-Profile of the monitor or auditor.<br>-Classification of findings;<br>-Decision making derived from the findings according to their seriousness;<br>-Notification mechanism to the principal investigator, the Committees and the Authority;<br>-Design of the Corrective, Improvement or Preventive Action Plan.<br>-Results reporting format through the Annual Partial Technical Report. | NOM-012 Numeral 7.2. | | |

## MODULE IV. PROTOCOL INFORMATION

| documentary requirement | Requirement Description | legal basis | Does it comply? | Folio |
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| 6. Research protocol | It must contain an objective and complete analysis of the risks involved compared to the risks of the established diagnostic and treatment methods and the life expectancy of the subject with and without the proposed procedure or treatment, in Spanish and indicating the version and date. of the document. It must describe compliance with Good Clinical Practices and must contain at least the following elements: i. Title of the project or research protocol; ii.<br><br>Theoretical framework; iii. Definition of the problem; iv.Background; v.Justification; It must include: sufficient information and technical elements to assume that the knowledge to be acquired cannot be obtained by any other means. 4.6 Assumptions (if any); saw. General objective (if applicable, specific objectives); vii.<br>Material and methods; viii. Design: inclusion and exclusion criteria, capture, processing, analysis and interpretation of information; ix.<br>Bibliographic references; Other documents related to the research project or protocol. | RLGSMIS Art. 62-I<br>NOM-012 Numeral 5.2, 5.6, 5.10, 6.2, 6.2.1 to 6.2.12. | | |

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| 7. Sample Letter of Informed Consent in writing that will be provided to the research subject or, where appropriate, to their legal representative, in Spanish, and indicating the version and date of the document | It must contain at least: i. The justification and objectives of the research ii. Procedures to be used and their purpose, including identification of procedures that are experimental; iii. The expected inconveniences or risks; IV. The benefits that can be observed; v. Alternative procedures that might be advantageous to the subject; saw. The guarantee of receiving an answer to any question and clarification to any doubt about the procedures, risks, benefits and the investigation and treatment of 58 and 71. subject; vii. The freedom to withdraw your consent in any time and stop participating in the study, without therefore being create bias to continue your care and treatment; viii. The assurance that the subject will not be identified and that information related to their privacy will be kept confidential; ix. The commitment to provide updated information obtained during the study, even though this could affect the subject's willingness to continue participating; x. The availability of medical treatment and the compensation to which he would legally be entitled, by the health care institution, in the case of damages that merit it, directly caused by the investigation, and xi. That if there are additional expenses, these will be absorbed by the research budget. | LGS Art. 100 Fraction IV and VIII; Title Five Bis RLGSMIS Art. 14, 20, 21, 22, 26, 29, 36, 43 49, 51, 57, other matters related to RIS Art. 153. Agreement of procedures. NOM-012, Numeral 4.3, 5.7, 5.14, 6.3.1, 6.3.2.10, 7.2, 10.6, 11.1, 11.2 y 11.3. National guide for the integration and operation of Research Ethics Committees - CONBIOETICA, Section: Requirements for the evaluation of protocols. | | |

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| 8. Informed Assent Document. | It must be presented when it applies to a population over 7 years of age and under 18 years of age in Spanish and indicating LGS Art. version and date, it must also be customized for RLGSMIS Art. 36 each Research Center, indicating at least the reason National the center consistent with the authorization of the Research Ethics Committees - of operation of each center, as well as the for the and direction of the Committees involved. protocol evaluation.<br><br>The assent must be closely related to age and/or emotional and intellectual maturity considering, at all times, the seriousness of the decision. | 100.<br>and 37.<br>Guide for the integration and social functioning and direction of company name CONBIOETICA, Section: Requirements | | |
| 9. Study schedule. | In case the Schedule is already referred to in NOM-012 Section 6.3.2.2 the protocol will not need to be included as a Paperwork Agreement document. besides. It is suggested to clarify in the free writing. | | | |
| 10. Description letter of the approximate total quantity of supplies that require importation at each stage of the study. | The input information provided is considered for informational purposes only and will not be cited in the authorization letter. | NOM-012 numeral 6.4<br>Procedures agreement. | | |
| 11. Simple copy of the current document in which the financial fund or insurance of the study is expressed | Simple copy of the certificate of the current Global Insurance Policy. | NOM-012 Numeral 5.14, 7.2. | | |

## MODULE V. COMMITTEE INFORMATION

| documentary requirement | Requirement Description | legal basis | Does it comply? | Folio |
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| 12. Simple copy of the current Registry of the Research Ethics Committee (CEI) issued by the competent authority (COFEPRIS or CONBIOETICA) | The information (business name and address) must be consistent with that contained in the informed consent letter and attached documents.<br>The record must be legible, without erasures, amendments, and must present the legible seal of the issuing institution; Reports from Committees that do not have the registry will NOT be accepted. | LGS Art. 41 Bis, 98 and 316.<br>RLGSMIS Art. 101 and 109<br>NOM-012 Numeral 6.3.2.5 and 9.1.4.<br>Procedures agreement.<br>National guide for the integration and operation of Research Ethics Committees - CONBIOETICA, Section: Requirements for the evaluation of protocols<br><br>AGREEMENT that amends and adds the various ones that issue the General Provisions for the Integration and Functioning of Research Ethics Committees and establish the hospital units that must have them, in accordance with the criteria established by the National Bioethics Commission, published on October 31, 2012. | | |
| 13. Simple copy of the Registry of the Investigation Committee issued by COFEPRIS, or, if applicable, a copy of the modification | The information (business name and address) must be consistent with that contained in the informed consent letter and attached documents.<br>The record must be legible, without erasures, amendments, and must present the legible seal of the issuing institution; Reports from Committees that do not have the registry will NOT be accepted. | LGS Art. 41 bis y 316.<br>RLGSMIS Art. 101 and 111.<br>NOM-012 Numeral 6.2.3.5 y 9.1.4. | | |

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| 14. Simple copy of the Biosafety Registry issued by COFEPRIS, when applicable. | The information (business name and address) must be consistent with that contained in the informed consent letter and attached documents.<br>The record must be legible, without erasures, amendments, and must present the legible seal of the issuing institution; Reports from Committees that do not have the registry will NOT be accepted. | LGS Art. 41 bis y 316.<br>RLGSMIS Art. 101 and 111.<br>NOM-012 Numeral 6.2.3.5 y 9.1.4. | | |
| opinion issued by the National Guide Committee for the integration and operation of Research Ethics (CEI) | i. Detailed description of the documents evaluated and 15. Favorable approved in Spanish, citing version and date. of the Research greater than 1 year; CONBIOETICS.<br>iii. Be issued on letterhead; NOM-012 Numeral 6.2.3.5<br>iv.Specify the corporate name and address of the Committee consistent with its registration; v.Date of issuance of the opinion (day, month and year) vi.Full name of the researcher consistent with his professional license; vii. Company name and address of the center consistent with its operating authorization; LGS Art. 98 Section I and 100. | LGS Art. 41 Bis Section II, 98, 100.<br>RLGSMIS Art. 14 Section VII, 22 Section II 62 Section III, 71, 99, 101, 109 and 112. NOM-012 Numeral 4.6, 6.3.2.8, 9.2.9 and 10.3<br>Ethics Committees - ii. The approval opinion date may not be | | |
| 16. Favorable opinion of the Committee of Research (IC). | viii. Full title and protocol number consistent with RLGSMIS Art 14 Section Section III, 100 and 111.<br>ix.Specify the opinion (approved); Validity of the opinion;<br>xi. Name, position and signature of the person endorsing the opinion according to the Committee's registry.<br>xii.Only opinions signed by the president or, where appropriate, by the secretary will be accepted, attaching a “NO VOTE” letter when applicable.<br><br>NOTE: In the event that the favorable Opinion is issued by a CU... it must adhere to the provisions of the Collaboration Bases for the formation of Single Committees, issued by CCINSHAE. | VII, 62 section III, 71 protocol document; Section I, 99<br><br>NOM-012 Numeral 4.6, 6.3.2.8, 7.2, 8.8, 9, 9.1, 9.1.4 and x. 9.2. | | |

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| 17. Favorable opinion issued by the Collaboration Committee for the formation of Single Committees, issued applicable committee by CCINSHAE. | operating authorization; viii. Full title and protocol number consistent with the protocol document; ix.Specify the opinion (approved); x. Validity of the opinion; xi. Name, position and signature of the person endorsing the to the Committee record. xii.Only opinions signed by the president or, where appropriate, by the secretary will be accepted, attaching a “NO VOTE” letter when applicable. NOTE: In the event that the favorable Opinion is issued by a CU... it must adhere to the provisions of the Bases of LGS Art. 98 Section III and 100. | RLGSMIS Art 14 biosafety in accordance with the Regulation of 84), II (Art. 85 to 88) and III (Art. 89 to 97) of the Research Title and its modification) according to Section II of the RLGSMIS | Section VII, 62 Section III, 99 Biosafety (CB) (if Section II, 105, 108, 110, 111, Chapter I (Art. 75 to Art 99 Room of the Biosafety of the Facilities. | | |
| 18. List of members of the Research Ethics Committee. | The function of each member of the Committee must be described, only the member authorized to do so may sign the opinion. | | RLGSMIS Art. 108. National guide for the integration and operation of Research Ethics Committees - CONBIOETICA. | | |
| 19. Non-voting letter for each member who is part of the research team. | When applicable, the members of the Committees must excuse themselves from participating in the evaluation or issuance of reports on investigations in which they have participated. | | RLGSMIS Art. 108 NOM-012 Numeral 9.2.3. | | |
| 20. Letter from the Committee for Continuous Monitoring of the study by the Committee. | It must contain a description of the study follow-up process, which may or may not include the Committee's standard operating procedure. | | RLGSMIS Art. 84. NOM-012 Numeral 7.2 section a) and 9.28 National guide for the integration and operation of Research Ethics Committees - CONBIOETICA. | | |
| 21. Express letter of No Conflict of Interest and confidentiality, signed by each and every one of the external members of the Evaluation Committee, assistants in the review and approval of the protocol. | | | National guide for the integration and operation of Research Ethics Committees - CONBIOETICA. | | |

**MODULE VI. INFORMATION ON THE INSTITUTION OR ESTABLISHMENT WHERE HEALTH RESEARCH IS CARRIED OUT**

| documentary requirement | Requirement Description | Legal basis LGS Art. | Does it comply? | Folio |
|---|---|---|---|---|
| 22. Simple copy of the operating authorization (Health license or operating notice as the case may be) | Sanitary license or notice of operation depending on the case | 45, 47, 198, 200, 200 Bis, 315, 318, 368, 369, 370, 371 and 375.<br>RLGSMIS Art. 10 Section I and 62 Section II.<br>NOM-012 Numeral 8.1.<br>Procedures agreement. | | |
| 23. Authorization letter to carry out the research, signed by the head of the unit or institution where the research will be carried out. | It must include at least:<br>-Name and protocol number;<br>-Name of the principal investigator<br>-Name, signature and position of the Head of the Unit. | LGS Art. 102 Section V.<br>RLGSMIS, Art. 14 Section I to X, 62 Section II and 98.<br>NOM-012 Numeral 6.3.2.6<br>Procedures agreement. | | |
| 24. The document where the description of the available resources of the unit or institution where the investigation will take place is expressed.<br>research, including areas, equipment, auxiliary laboratory services and cabinets, number of personnel, all of the above solely and specifically for the development of the study. | The letter must include at least:<br>-Protocol name and number<br>-Name of Principal Investigator<br>-Human resources (Number of people)<br>- Areas<br>-Teams<br>-Auxiliary laboratory and cabinet services.<br>-Red car, if applicable | LGS Art. 100<br>RLGSMIS Art. 14, 62 Section IV to V and 98.<br>NOM-012 Numeral 6.3.2.9<br>paperwork agreement | | |
| 25. In the case of research centers that enter into agreements for medical emergency care with other institutions, a simple copy of the current agreement must be included. | The agreement must include at least:<br>-Agreements are accepted by Institution, by molecule and/or by protocol.<br>- Reach<br>-Clauses (if applicable)<br>-Validity<br>-Signature of the owners or legal representatives of both institutions | LGS Art. 100<br>RLGSMIS Art. 14, 62 Section IV to V and 98.<br>NOM-012 Numeral 6.3.2.9 y 8.6<br>Procedures agreement. | | |

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| 26. Simple Copy of the Institution's Operating Authorization for emergency care. | Sanitary license | LGS Art. 45, 47, 198, 200, 315, 368 y 375. | | |
| 27. Letter describing the resources available for emergency management | | LGS Art. 100<br>RLGSMIS Art. 14, 62 Section IV to V and 98.<br>NOM-012 Numeral 6.3.2.9<br>paperwork agreement | | |

**MODULE VII. INFORMATION ON THE PRINCIPAL INVESTIGATOR AND WORK TEAM**

| documentary requirement | | legal basis | Does it comply? | Folio |
|---|---|---|---|---|
| 28. Letter of acceptance, confidentiality and commitment to report suspected reactions and adverse events, dated and signed by the principal investigator. | The letter must include at least:<br>-Protocol name and number<br>-Name of Principal Investigator<br>-Acceptance of the Principal Investigator to conduct the Research Protocol.<br>-Commitment of the Principal Investigator to maintain the confidentiality of the protocol information<br>-Monitoring of the protocol according to Good Clinical Practices.<br>-Commitment to report suspected reactions and adverse events | LGS Art. 100 Section V.<br>RLGSMIS Art. 14 Section IX, 64 Section I, 113, 116, 119.<br>NOM-012 Numeral 10.9 y 12.1.<br>NOM-220 Numeral 7.1, 7.2, 7.2.2, 7.2.3, 7.3 y 7.4. | | |

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| 29. Summary of the professional history of the principal investigator. | He must be a health professional and have the appropriate academic training and experience to direct the study to be conducted, including academic preparation, representative scientific production and clinical practice focused on the study to be conducted. History updated, signed and dated. The summary of the professional history of the main investigator should not exceed 10 pages and the main investigator's experience and specialty should be consistent with the condition to be studied in the Protocol. | RLGSMIS Art. 14 Fraction VI, 62 VI, 113 and 114. NOM-012 Numeral 10.4.1. Procedures agreement. | | |
| 30. Simple copy of the documentation legally issued and registered by the competent educational authorities. | If applicable, refer to the ID number or numbers professional. | | | |
| 31. Summary of the academic preparation and experience of the medical and paramedical staff and other experts who will participate in the research activities. | The summary of the professional history of the personnel who will participate in the investigation should not exceed 10 pages. The experience and profile of the work team must be consistent with the delegated activity. | RLGSMIS Art. 14 Section VI, 18 Section VI, 62 Section VII, 113, 114 NOM-012 Numeral 10.4 y 10.4.1. Procedures agreement. | | |
| 32. Descriptive letter of the delegation of responsibility of the research team. | Letter describing the delegation of the activities of each member of the investigation team, signed by Principal Investigator Paperwork Agreement. | RLGSMISArt. 116 Number V, 117 and 118 NOM-012 Numeral 10.4 and 10.4.1. | | |

**MODULE VIII. INVESTIGATION PRODUCT INFORMATION**

| documentary requirement | | legal basis | Does it comply? | Folio |
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| 33. Investigator's manual or equivalent document. | Summary of the preclinical and clinical information previously obtained, justifying the use of the product, the dose, pharmaceutical form, route of administration, rate of administration, study population, etc. The abstract must contain the following minimum information for each cited reference:-Characteristics of the product (pharmaceutical form, physicochemical characteristics, formula, route and interval of administration, etc.); -Information regarding manufacturing, labeling, storage, packaging, stability, if applicable; -Preclinical and clinical information available regarding: a) Absorption, distribution, metabolism and elimination; b) Toxicology, genotoxicity, carcinogenicity, teratogenicity, etc. -Clinical information available regarding: Safety, reaction data and adverse events; Efficacy, drug interactions, food interactions, dose determination, summary of previous clinical studies, etc. | LGS Art. 102 Section II and III<br>RLGSMIS Art. 14 Section II, 66, 67, 68, 69, 70 and 73.<br>Procedures agreement. | | |
| 34. Simple copy of the document in which the necessary information is expressed to ensure that the drugs used in clinical research comply with Good Manufacturing Practices (GMP) and have the expected quality characteristics (cGMPs) only for the product under investigation, or letter under oath to tell the truth that GMP is met. | | NOM-059 Numeral 10.7.1.2. | | |

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| 35. Status of the stability studies, or letter under protest to tell the truth that the stability studies of the product in accordance with the applicable regulations. | | NOM-059 Numeral 10.7.2.2.3. | | |
| 36. The others indicated by the current Sanitary Regulation in the Matter of Research for the Health of Human Beings | | LGS Art. 100 Section VIII, Chapters I and III of the Eighteenth Title.<br>RLGSMIS Art. 127. | | |

**INTERNAL EVALUATION OF YOUR APPLICATION**

Once the application has been submitted, the CIS will assign them an "entry number" with their respective printed ballot that they must keep for any follow-up and to collect their response.

The technical area that evaluates your request is called Clinical Trials, for its acronym EC and belongs to the Sanitary Authorization Commission. For any follow-up, you should check the status of your request through the COFEPRIS website, in the Available Resolutions link http://189.254.115.245/EstadoTramite/Default.aspx; If your procedure is still “In Evaluation” and the stipulated response time has been exceeded, immediately contact the technical area at 5080-5200 ext. 1072 or 4373 or via email **rlegaspi@cofepris.gob.mx**

If for any reason you have submitted a "withdrawal of your application" through Escrito Libre (EL), you must give notice to the email **rlegaspi@cofepris.gob.mx** indicating the withdrawal entry number for your attention.

**Issuance of the resolution by COFEPRIS:**

The Clinical Trials Area may issue a resolution letter such as **"authorization" or "prevention"** at your request based on the evaluation of the information submitted and compliance with the requirements regarding health research.

**Reception of the resolution by the petitioner:**

-Only the following figures may collect the respective resolution at the CIS window: **Health Responsible, Legal Representative and/or Authorized Persons.**

-If you have received an **"authorization letter"** you will receive a confidential envelope with the access code to the National Registry of Clinical Trials (RNEC) and you have 5 business days to update the information in said system.

o Remember that to submit amendments or inclusion of a new center, later related to the previously authorized protocol, you must have updated information in RNEC, otherwise your request will not proceed.

o Note: RNEC applies only to new protocol authorization requests, entered from 2013 to date.

o For any information related to the **RNEC, you** can consult the section at: **http://**
**www.cofepris.gob.mx/AS/Paginas/Ensayos%20Clínicos/Registro%20Nacional%20de%20Ensayos%20Clínicos%20(RNEC)/Registro- National-of-Clinical-Trials-(RNEC).aspx**

-If you have received a prevention letter, you must respond to what is mentioned in said letter, within a period not exceeding 30 calendar days from the receipt of your letter.

o If you exceed the time established in the resolution document, you will not be able to enter subsequent information and your process will be considered completed.

o Also, if you do not present what was requested in the resolution official letter, the process will be considered concluded and discarded.

-If you have received an **"authorization" or "disposal"** letter (after submitting the response to prevention "CT"), and detected any erroneous information in the letter issued by COFEPRIS, you must submit the request for internal correction within **a period not greater than 30 calendar days** from the receipt of your letter.

-You may submit procedures related to the initial application such as amendment or inclusion of a center, even if you do not physically have the authorization document, as long as you refer to the entry number or present a simple copy of the initial application in all subsequent procedures. .

The only cases in which "amendment or modification authorization request" applies through HOMOKEY 09-012, are the ones mentioned below:

ÿRequest for Modification or Amendment to the Research Protocol Authorization.

Modality.- **Inclusion of a new center**

ÿRequest for Modification or Amendment to the Research Protocol Authorization.

Modality- **Protocol Amendment**

ÿRequest for Modification or Amendment to the Research Protocol Authorization.

Modality.- **Security amendment**

Only for patient safety and it is of immediate application, late application implies a critical finding that can invalidate the study data.

ÿRequest for Modification or Amendment to the Research Protocol Authorization.

Modality.- **Modification of official authorization due to change of company name or address of the initial applicant**

-Only in this modality is the official letter presented in original with the autograph signature of the one that requires modification

-Changes due to ownership of the promoter (Assignment, sale or equivalent to another company) only apply for studies with recruitment and/or active treatment, and where appropriate inclusion of centers and must present the respective initial authorization letter in original with autograph signature.

ÿRequest for Modification or Amendment to the Research Protocol Authorization.

Modality.- **Amendment to previous clinical and/or preclinical information (investigator's manual).**

ÿRequest for Modification or Amendment to the Research Protocol Authorization.

Modality.- **Changes associated with the committee(s) (Change of Committee; Change of company name and/or address; Change of members, etc.).**

ÿRequest for Modification or Amendment to the Research Protocol Authorization.

Modality.- **Amendment to consent form and/or informed assent.**

ÿRequest for Modification or Amendment to the Research Protocol Authorization.

Modality.- **Change of principal investigator.**

ÿRequest for Modification or Amendment to the Research Protocol Authorization.

Modality.- **Changes associated with the Institution or establishment where the research is carried out (Change of health license and/or notice of operation)**

Any other document that was not referred to above, such as information collection tools (surveys, measurement scales, etc.) and information material for the research subject (brochures, manuals, etc.) must be submitted through the **Report Partial Technical** Report (which is presented once a year) and/or **Final Technical Report.**