



## TUTORIAL: REGISTRATION REQUEST RESEARCH ETHICS COMMITTEE (CEI)

### I. GENERAL CHARACTERISTICS OF THE APPLICATIONS

- In accordance with article 41 Bis of the General Health Law, those public, social or private **health care establishments that carry out research activities on human beings** and that carry out research activities in human beings may request registration from the Research Ethics Committee (CEI). , **according to their degree of complexity and level of resolution** (correspond to the establishments referred to in article 70 of the Regulation of the General Health Law on the Provision of Medical Care Services), are able to install and guarantee the operation of said committee.
- Applications for registration of the Research Ethics Committee will be subject to the provisions of article 41 Bis and 98 of the General Health Law, the current General Provisions issued by CONBIOÉTICA for the Integration and Functioning of the CEI. (To consult them, use the following links: issuance of the Provisions in 2012: <https://sidof.segob.gob.mx/notas/5276107>, first modification <https://sidof.segob.gob.mx/notas/5422410> 2020: <https://sidof.segob.gob.mx/notas/5607368>) and the National Guide for the Integration and Functioning of the CEI, 6th edition 2018 (and its modification available at: [https://www.gob.mx/cms/uploads/attachment/file/460756/7\\_Guia\\_CEI\\_2018\\_6a.pdf](https://www.gob.mx/cms/uploads/attachment/file/460756/7_Guia_CEI_2018_6a.pdf)).
- You can request advice and support from the State Bioethics Commission (CEB) of your entity for the presentation of your procedures. For further reference you can locate your CEB at: <https://www.gob.mx/salud/conbioetica/articulos/perfiles-de-las-misiones-estatales-de-bioetica?state=published>
- **The application for CEI registration must be presented in the current official format, signed by the director, the director or the person who acts as owner of the establishment, and presented to the National Bioethics Commission, on business days and hours, in format physical. Directed to:**

*Recipient:* Dr. Patricio Javier Santillán Doherty, National Bioethics Commissioner.

At'n to the M. en C. Areli Cerón Sánchez, Director of Bioethics Committees.

*Address:* Calzada Arenal number 134, **floor 3**, Colonia

Arenal - Tepepan, Alcaldía Tlalpan, Mexico City,  
CP 14610.

*Telephone:* 5554872760 ext. 59471



## TUTORIAL: REGISTRATION REQUEST RESEARCH ETHICS COMMITTEE (CEI)

### Application submission options:

1. Sending documents by certified mail or parcel, with postage paid by the establishment.
2. In person, it will only be received if you have an appointment, so you must request it at 5554872760 ext. 59471 or [cei.conbioetica@salud.gob.mx](mailto:cei.conbioetica@salud.gob.mx)

ÿ **Submit the documentation in letter size, in the strict order established in this tutorial, it must be legible and without erasures or amendments, without crimping, stapling, without folders or dividers.** No additional documentation not requested for the respective procedure will be received.

ÿ It is important to let you know that the different **examples of formats** presented in this tutorial are intended to guide users, they can be adapted according to the needs of each establishment, including the minimum elements established in the National Guide for Integration and CEI Operation, 6th edition 2018 (GNIF-CEI). **The current application format is not an example, so it should not be modified. You can access them at the following link:**

<https://www.gob.mx/salud/conbioetica/articulos/tramite-de-registro-de-comites-de-etica-en-investigacion-cei>


ÿ It is the responsibility of the applicant CEI to ensure that the contact information (telephone numbers and emails) entered in the registration application are correct. If they are subsequently modified, they must notify in a timely manner through the email [cei.conbioetica@salud.gob.mx](mailto:cei.conbioetica@salud.gob.mx) to the National Bioethics Commission.

ÿ To prepare the documentation, it is necessary to consult the **National Guide for the integration and operation of Research Ethics Committees**, 6th edition 2018 (GNIF-CEI), which is available for download at:

[https://www.gob.mx/cms/uploads/attachment/file/460756/7\\_Guia\\_CEI\\_2018\\_6a.pdf](https://www.gob.mx/cms/uploads/attachment/file/460756/7_Guia_CEI_2018_6a.pdf)

## TUTORIAL: REGISTRATION REQUEST RESEARCH ETHICS COMMITTEE (CEI)

### II. REQUIREMENTS TO CARRY OUT PROCEDURE 1

	REQUIREMENT	CONSIDERATIONS TO FACILITATE COMPLIANCE		
1.	Original <b>application for first-time registration</b> , duly requested and with the handwritten signature of the director or the person who acts as owner of the establishment.	<p>ÿ <b>Download the current application at:</b>  <a href="https://www.gob.mx/cms/uploads/attachment/file/825494/Solicitud_registroCEI_V2023.pdf">https://www.gob.mx/cms/uploads/attachment/file/825494/Solicitud_registroCEI_V2023.pdf</a></p> <p>ÿ Starting in 2021, <b>it is mandatory for the CEI to have their own email</b>, which must be for exclusive use with the purpose of being used as the first means of contact between the CEI and CONBIOÉTICA. Which must be registered in field (16) of the request:</p> <div style="text-align: center;">  <table border="1" data-bbox="1018 592 1705 673"> <tr> <td style="padding: 5px;">(16) Correo electrónico del CEI y/o del contacto <small>(puede añadir al personal de apoyo administrativo que no forme parte del CEI)</small></td> <td style="width: 150px; height: 20px;"></td> </tr> </table> </div> <p>ÿ <b>If the CEI is made up of more than 6 people</b>, reproduce section 4.  Integration of the Application <i>Committee</i> , on an additional sheet and write down the rest of the members, the director, the director or the person who acts as the owner of the establishment must sign the additional sheet.  Use the <b>example format</b> for more than 6 members in:  <a href="https://www.gob.mx/cms/uploads/attachment/file/825493/Anexo_4_Integracion_of_Committee_docx">https://www.gob.mx/cms/uploads/attachment/file/825493/Anexo_4_Integracion_of_Committee_docx</a></p>	(16) Correo electrónico del CEI y/o del contacto <small>(puede añadir al personal de apoyo administrativo que no forme parte del CEI)</small>	
(16) Correo electrónico del CEI y/o del contacto <small>(puede añadir al personal de apoyo administrativo que no forme parte del CEI)</small>				
2.	Simple copy of the document that certifies the <b>legal representation of the Establishment.</b>	<p><b>For public institutions:</b> ÿ  Appointment of the director, the director or the person who serves as the head of the establishment.</p> <p>ÿ If another person (other than the director, the director or the person who serves as the owner of the establishment) serves as legal representative, they must present: Creation decree or internal regulation indicating the position/position held by the legal representation and appointment of the occupant of said position.</p> <p><b>For private or social institutions and some public ones:</b>  ÿ Article of incorporation or power of attorney indicating the name of the person holding legal representation and the type of powers or attributions conferred.</p>		

\* In accordance with the Agreement that modifies the various provisions by which the General Provisions for the Integration and Functioning of the Research Ethics Committees are issued and the hospital units that must have them are established, in accordance with the established criteria by the National Bioethics Commission, published on October 31, 2012 (DOF 12/10/2020).



## TUTORIAL: REGISTRATION REQUEST RESEARCH ETHICS COMMITTEE (CEI)

REQUIREMENT	CONSIDERATIONS TO FACILITATE COMPLIANCE
<p>3. Simple copy of the <b>health license of the medical care establishment</b>.</p> <p>If you do not have this, you must present:</p> <ul style="list-style-type: none"> <li>ÿ Simple copy of an operating notice that accredits it as a medical care establishment.</li> <li>ÿ For <b>third parties authorized as clinical units to perform interchangeability and tests</b>, present a simple copy of the current authorization issued by COFEPRIS. In these cases, the CEI registration will be valid as long as the authorization issued by COFEPRIS remains in force.</li> <li>ÿ For <b>higher education institutions, the health license requirement does not apply</b>; They may request CEI registration if they have programs academics in the health area, and in these research activities for health in human beings are carried out. This requirement will be evaluated in the manifest submitted for requirement number 4 described in this tutorial and, in the case of private institutions, the corresponding RVOE.</li> </ul>	<p>The medical care establishments, provided for in the regulations that can carry out research, according to their degree of complexity and resolution power, correspond to: General Hospital, Specialty Hospital or Institute.</p> <p>Additionally, include a description of the characteristics of the establishment and the research protocols it carries out:</p> <ul style="list-style-type: none"> <li>ÿ For <b>establishments that carry out research on human beings that require authorization from the Secretary</b> (as provided in article 14, section VIII, of the RLGSMIS), present a simple copy of the last 3 authorizations issued by the Federal Commission for the Protection against Sanitary Risks (COFEPRIS) where the establishment is designated as a Research Center for a specific protocol.</li> </ul> <p><b>Unforeseen cases</b> will be reviewed individually, and documentation must be presented that proves their research activities in human beings and, where appropriate, with the respective authorization from the competent authority.</p>
<p>4. Original of the <b>writing in which it is stated under oath to tell the truth that the</b></p>	<p>ÿ Submit in free writing format, on letterhead, dated, addressed to Dr. Patricio Javier Santillán Doherty, National Commissioner of Bioethics, and with</p>



## TUTORIAL: REGISTRATION REQUEST RESEARCH ETHICS COMMITTEE (CEI)

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<p><b>establishment</b> is located, in the cases provided for in articles 41 BIS and 98 of the General Health Law and has the infrastructure that guarantees the technical, material, human and financial capacity, as well as the facilities, equipment and technology to carry out carry out the tests, studies, trials, verifications and other activities necessary to carry out research activities on human beings, in accordance with the criteria established in current regulations, where [describe the type and level of risk of the research carried out carry out the establishment as referred to in article 17 of the Regulations of the General Health Law on Health Research].</p>	<p>handwritten signature of the director, the director or the person who acts as the owner of the establishment.</p> <p>For a better reference, use the <b>example format of the Manifesto of assumptions art 41 and 98 LGS</b>, available at:  <a href="https://www.gob.mx/cms/uploads/attachment/file/825492/Ejemplo_Manifiesto_Arts_41_98.docx">https://www.gob.mx/cms/uploads/attachment/file/825492/Ejemplo_Manifiesto_Arts_41_98.docx</a></p> <p>ÿ To specify the type and level of risk of the research carried out by the establishment where the CEI will be installed, consider the types of projects carried out by the establishment and the text of article 17 of the Regulations of the General Health Law. in Current Health Research, which can be completed <a href="https://www.diputados.gob.mx/LeyesBiblio/regley/Reg_LGS_MIS.pdf">https://www.diputados.gob.mx/LeyesBiblio/regley/Reg_LGS_MIS.pdf</a>  Consult _____ in:</p>
<p>5. <b>Simple copy of the Installation Record of the the</b></p>	<p>ÿ It must <b>contain the elements indicated in section 5.3 Installation (page 24) of the GNIF-IEC</b></p> <p>to. Name or company name and address of the institution or establishment where the CEI is installed.</p> <p>b. Name, profession and position held by each person who makes up the CEI.</p> <p>c. Legal basis that contains the powers of the director, the director or the person who acts as the owner of the establishment to install the CEI.</p> <p>d. Statement of the director, the director or the person who acts as holder of the establishment stating that the CEI is established under its responsibility.</p> <p>and. Handwritten signature of the director, the director or the person who acts as the owner of the establishment.</p> <p>F. Place, date and time of installation of the Committee.</p> <p>ÿ Consult the <b>example installation certificate</b> format at:  <a href="https://www.gob.mx/cms/uploads/attachment/file/821842/Ejemplo_Acta_de_instalacion_CEI.docx">https://www.gob.mx/cms/uploads/attachment/file/821842/Ejemplo_Acta_de_instalacion_CEI.docx</a></p>



## TUTORIAL: REGISTRATION REQUEST RESEARCH ETHICS COMMITTEE (CEI)

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<p>6. <b>Simple copy of the approved Procedures Manual of the Research Ethics Committee.</b></p>	<p>ÿ The procedures manual approved by the Research Ethics Committee must include the essential internal operating procedures, the internal operating mechanisms in the sessions, the requirements of the sessions and reviews, the criteria for the evaluation of research, the taking decision making, documentation management and archiving. For more details, review pages 12 to 31 of the GNIF-CEI.</p> <p>Based on the above, the essential elements that the Manual must incorporate are the following:</p> <p>to. Indicate the criteria for the selection, functions and obligations of the people who make up the committee and occupy the following positions: the presidency, the members, including the secretary, the representatives of the affected nucleus (RNA) or the users of the health services (RPUSS), including the commitment to 80% in-person attendance.</p> <p>b. Incorporate policies, guidelines or guides in accordance with good clinical practices of the establishment.</p> <p>c. Indicate the obligations of the establishment where the CEI is installed, as well as those of the director, the director or the person who acts as the owner of the establishment.</p> <p>d. Describe the resources and source of financing for the operation of the CEI.</p> <p>and. Define the policies for the renewal, replacement or resignation of members.</p> <p>F. Point out the mechanisms to prevent and manage conflicts of interest.</p> <p>g. Outline the requirements of IEC sessions, including legal quorum and registration of the same.</p> <p>h. Indicate the decision-making mechanism of the CEI, which must be by consensus, including the methodology to be used and the way in which the decision will be documented, prioritizing transparency and accountability.</p> <p>Yo. Select and incorporate an instrument (check list, questionnaire, etc.), through which the minimum ethical requirements will be evaluated in accordance with the GNIF-CEI and current regulations. It can be based on the pilot instrument for the evaluation of ethical aspects in research protocols for health in human beings, CONBIOÉTICA. elaborated Available <a href="https://www.gob.mx/cms/uploads/attachment/file/691505/Instrumento_Aspectos_e">https://www.gob.mx/cms/uploads/attachment/file/691505/Instrumento_Aspectos_e</a> by _____ the _____ in: <a href="#">ticos.pdf</a></p> <p>j. Determine the control and monitoring activities of the protocols in advance approved.</p> <ul style="list-style-type: none"> <li>• In the event that the CEI reviews external protocols, it must indicate the transfer and reception mechanisms, as well as establish the mechanisms to carry out monitoring visits and the elements that it will evaluate. Use the guidelines in this regard, issued by CONBIOÉTICA,</li> </ul>



## TUTORIAL: REGISTRATION REQUEST RESEARCH ETHICS COMMITTEE (CEI)

	REQUIREMENT	CONSIDERATIONS TO FACILITATE COMPLIANCE
		<p>available in:  <a href="https://www.gob.mx/cms/uploads/attachment/file/691504/Criterios_Protocolo_the externals.pdf">https://www.gob.mx/cms/uploads/attachment/file/691504/Criterios_Protocolo_the externals.pdf</a></p> <p>k. Point out the mechanisms for training and continuous dissemination in bioethics, research ethics and good clinical practices for the members of the CEI, the establishment's staff and researchers, and potential research subjects.</p> <p>l. If it is decided to use information and communication technologies, describe the incorporation of the computer system in the tasks of the CEI, guaranteeing compliance with all the obligations of the members of the CEI.</p> <p>m. Indicate the mechanisms for the protection and control of the CEI archive, which must be physically and within the facilities of the establishment.</p>
7.	<p>Simple copy of the <b>appointment certificates</b> of each of the committee members.</p>	<p>• The selection of the members must consider everything provided in section 5. <i>Members and installation of the Research Ethics Committee</i> (pages 19 to 24), especially what is stated in section 5.2 <i>Designation of members</i> of the GNIF-CEI.</p> <p>In accordance with current regulations, the people proposed as members of the CEI must meet the following requirements:</p> <p>• <b>Requirements for chairperson (e), vocal secretary (or) and vocals</b></p> <p>to. Have a degree and professional license in: medicine, psychology, nursing, social work, sociology, anthropology, philosophy, law or those professions related to the therapeutic or knowledge areas on which the establishment researches, for example: pharmaceutical chemistry biological, industrial pharmaceutical chemical or nutrition.</p> <p>b. Training and experience in research related to the therapeutic or knowledge areas that the CEI will review. c. Training in research ethics, bioethics or good clinical practices.</p> <p>d. <b>They must not belong to the governing body of the institution, nor to positions that may limit the autonomy of the CEI.</b></p> <p>and. Preferably work in the institution.</p> <p>F. Have availability to comply with 80% in-person attendance to the total sessions carried out by the CEI during the school year.</p> <p>g. Accept the position honorably (without payment).</p>



## TUTORIAL: REGISTRATION REQUEST RESEARCH ETHICS COMMITTEE (CEI)

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	<p>ÿ See the <b>example</b> format of proof of appointment for <b>President (e)</b> in:  <a href="https://www.gob.mx/cms/uploads/attachment/file/821843/Ejemplo_Constancia_de_designacion.Presidente.docx">https://www.gob.mx/cms/uploads/attachment/file/821843/Ejemplo_Constancia_de_designacion.Presidente.docx</a></p> <p>ÿ <b>Requirements for the representatives of the affected nucleus (RNA) or the people users of health services (RPUSS).</b></p> <p style="margin-left: 40px;">to. It does not require professional training or prior training in bioethics, it is strongly suggests <b>not having scientific training.</b></p> <p style="margin-left: 40px;">b. They must not belong to the governing body of the institution, nor to positions that may limit the autonomy of the CEI.</p> <p style="margin-left: 40px;">c. Have availability to comply with 80% in-person attendance to the total sessions carried out by the CEI during the school year.</p> <p style="margin-left: 40px;">d. Accept the position honorably (without payment).</p> <p>ÿ Consult the <b>example</b> format of proof of designation for <b>other members</b> at:  <a href="https://www.gob.mx/cms/uploads/attachment/file/821841/Ejemplo_Constancia_de_designacion.Otros_integrantes.docx">https://www.gob.mx/cms/uploads/attachment/file/821841/Ejemplo_Constancia_de_designacion.Otros_integrantes.docx</a></p>
<p>8. Simple copy of the <b>professional license</b> of each member and postgraduate degree, if applicable.</p> <p><b>Except</b> for the representative of the affected group or the users of health services.</p>	<p>ÿ All proposed people (even if they are foreigners) must have a professional license issued by the SEP, to be part of the CEI.</p> <p>ÿ The professions provided for in current regulations for CEI members are: medicine, psychology, nursing, social work, sociology, anthropology, philosophy and law.</p> <p>ÿ Professionals from other professions may be accepted as long as they are related to the therapeutic or knowledge areas on which the applicant establishment researches, for example: biological pharmaceutical chemistry, industrial pharmaceutical chemical, nutrition, etc.</p> <p>ÿ If the members have specialty or postgraduate certificates, they must attach them, but they <b>DO NOT</b> replace the bachelor's degree certificates.</p>
<p>9. Original of the <b>curriculum vitae</b> of each member (including the representatives of the affected nucleus or of the users of the health services</p>	<p>Maximum length of 5 pages, without supporting documents. Consult the <b>sample</b> resume format at:  <a href="https://www.gob.mx/cms/uploads/attachment/file/821844/Ejemplo_CV_para_integrantes_del_CEI.docx">https://www.gob.mx/cms/uploads/attachment/file/821844/Ejemplo_CV_para_integrantes_del_CEI.docx</a></p>





## TUTORIAL: REGISTRATION REQUEST RESEARCH ETHICS COMMITTEE (CEI)

	health	CONSIDERATIONS TO FACILITATE COMPLIANCE
	with your signature on each page and signature on the last one.	<p><b>For the representatives of the affected nucleus or of the users of health services, the following must be indicated:</b></p> <ul style="list-style-type: none"> <li>ÿ Academic preparation (should not have scientific training).</li> <li>ÿ Previous and current work experience (position, position held, period and institution).</li> <li>ÿ If applicable, previous experience in areas of citizen participation, Research Ethics Committees or related activities.</li> </ul> <p><b>For president (e), secretary member (o) and members, you must indicate:</b></p> <ul style="list-style-type: none"> <li>ÿ Academic preparation.</li> <li>ÿ Previous and current work experience (position, position held, period and institution), in this section include experience in clinical practice and research.</li> <li>ÿ Previous experience in Ethics Committees in Research or activities related.</li> <li>ÿ Representative scientific production related to their functions in the committee, no more than 10 publications.</li> </ul>
10.	<p>Simple copy of the <b>training certificates in research ethics, bioethics or good clinical practices</b> of each member, obtained during the last 5 years.</p> <p><b>Except</b> for the representative of the affected group or the users of health services.</p>	<ul style="list-style-type: none"> <li>ÿ <b>Only records directly related to the the 3 themes indicated.</b></li> <li>ÿ Submit a maximum of 5 certificates per member (select the most recent and related to research ethics or CEI). In case of choosing bioethics, the issue of consistency must be directly linked to the actions of the committee.</li> <li>ÿ Training certificates should preferably be <b>issued by the National Bioethics Commission, the State Bioethics Commission (CEB) of the entity to which they belong or academic institutions external to the establishment.</b></li> </ul>

### III. IMPORTANT INFORMATION REGARDING YOUR APPLICATION

ÿ In accordance with current regulations, only the **legal representative and/or authorized person(s) indicated in fields (4) and (5) of the registration application form will be provided with information regarding** the status of the request and **will be authorized to collect the respective resolution** at the facilities of the National Bioethics Commission.

**If you had advice and/or support from the State Bioethics Commission (CEB) of your entity, you can add the contact information of the CEB as people authorized to receive notifications in field (5) of the registration application form.**



## TUTORIAL: REGISTRATION REQUEST RESEARCH ETHICS COMMITTEE (CEI)

Therefore, make sure to register them correctly in the section:



(4) Nombre del representante legal	
(5) Nombre de la persona autorizada para oír y recibir notificaciones	

• When CONBIOÉTICA concludes the evaluation of the registration application, you will be informed of the availability of the resolution letter corresponding to the email addresses registered in said application, to coordinate sending it to the establishment.

• In order to guarantee the safety of the subjects participating in the research and the scientific integrity thereof, the National Bioethics Commission will reserve the right to request additional documentation or information in accordance with the current CEI General Provisions, for further reference. See the link: <https://sidof.segob.gob.mx/notas/5607368>

• The current CEI records are published at: <https://www.gob.mx/salud/conbioetica/articulos/comites-de-etica-en-investigacion-140023>

• If you have received a resolution, and detected any erroneous information in the issued letter, you must request the **correction within a period of no longer than 10 calendar days** from receipt of the letter.

• Consult the comprehensive and simplified privacy notices regarding the procedures associated with CEI at: [https://www.conbioetica-mexico.salud.gob.mx/Transparencia/gobmx/Proteccion\\_de\\_datos\\_personales.html](https://www.conbioetica-mexico.salud.gob.mx/Transparencia/gobmx/Proteccion_de_datos_personales.html)

#### IV. CONTACT INFORMATION

 [cei.conbioetica@salud.gob.mx](mailto:cei.conbioetica@salud.gob.mx)

 01 (55) 5487 2760 ext. 59471

 <https://www.gob.mx/salud/conbioetica>