

**PROCEDURE**  
**REGISTER OF RESEARCH ETHICS COMMITTEES**  
**(CEI) FOR HEALTH RESEARCH WITH BEINGS**  
**HUMANS**

**PRT-OGITT-OEI-001**

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## 1. OBJECTIVE

Standardize the stages of the registration of Research Ethics Committees (CEI), within the framework of the provisions of the Technical Document: Ethical considerations for health research with human beings, approved by Ministerial Resolution No. 233-2020-ONCE.

## 2. SCOPE OF APPLICATION

This document is mandatory for the servers of the General Office of Research and Technology Transfer (OGITT) of the INS, responsible for carrying out the CEI Registration process.

## 3. BASE LEGAL

- 3.1. Legislative Decree No. 1504, which strengthens the National Institute of Health for prevention and control of diseases.
- 3.2. Supreme Decree No. 001-2003-SA, which approves the Regulations of Organization and Functions of the National Institute of Health.
- 3.3. Ministerial Resolution No. 233-2020/MINSA, which approves the Technical Document "Ethical Considerations for Health Research with Human Beings".
- 3.4. Headquarters Resolution No. 175-2013-J-OPE/INS, which approves Directive No. 001-INS/OGAT-V.04 "Directive for the planning, preparation, review, approval, dissemination and updating of the documents of the Management System of the National Institute of Health."

## 4. GENERAL ASPECTS

### 4.1 Operational Definitions:

- 4.1.1 **Accreditation of a CEI:** Procedure that, in addition to complying with the requirements by Ministerial Resolution No. 233-2020-MINSA must comply with the requirements of Art. 63 of Supreme Decree No. 021-2017-SA.
- 4.1.2 **Registration Request File:** Group of documents requested in the first stage of the procedure, through which the OGITT of the INS receives a registration request, which are subjected to evaluation.
- 4.1.3 **Registration application evaluator:** INS OGITT personnel assigned to comply with the second stage of the procedure, which consists of evaluating compliance with the proper completion of the registration application form, Annexes 1 and 2, and the information and attached documentation required on them.
- 4.1.4 **National Registry of Research Ethics Committees:** INS public database where all CEIs that met the immediate requirements required in the registration procedure are registered.
- 4.1.5 **Proof of registration:** Document granted by the OGITT to the entity or institution that met the immediate requirements required in the registration procedure of its CEI.
- 4.1.6 **Suspension of registration:** Measure that the OGITT of the INS takes with the CEI when, having elapsed the two-year period for the implementation of the progressive requirements required for registration, these were not met.

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## 4.2 IEC Registration

4.2.1 The registration of a CEI is the procedure by which entities or institutions comply with a set of requirements framed in the international standards of research ethics established with RM N° 233-2020-MINSA.

4.2.2 The CEI Registry is in charge of the Executive Office of Research (OEI) of the OGITT.

4.2.3 The requirements for the Registry are mandatory for the CEIs to comply with. For CEI registration, compliance with the following requirements must be verified grouped according to the following criteria:

- to. Regulatory framework of the entity or institution
- b. Constitution of the CIS
- c. Composition of the CEI
- d. CEI operation
- and. Transparency and accountability of the CEI

4.2.4 Depending on its implementation period, the registry can be:

- to. **Immediate:** Your implementation must be ready at the time of the request record.
- b. **Progressive:** Its implementation is carried out during a maximum period of two years after the initial registration of the CEI.

During the period for the implementation of the progressive requirements, the OGITT can provide advice and guidance to the CEI that requests it.

### 4.2.5 Stages of CEI Registration

The CEI Registration procedure has three stages:

- to. Reception of registration request;
- b. Registration application evaluation; and
- c. Response to the request.

4.2.6 CEI registration is not equivalent to its Accreditation.

## 5. DEVELOPMENT OF THE PROCEDURE

### 5.1 Reception of registration request

5.1.1. This stage consists of receiving the complete registration application file from the CEI and culminates with the transfer of the file to the registration application evaluator.

5.1.2. The OEI-OGITT receives the Registration Request File, sent by the entity or institution that has established the CEI through the email: [mesadepartesogitt@ins.gob.pe](mailto:mesadepartesogitt@ins.gob.pe); in PDF format convertible to Word.

5.1.3. The aforementioned file is considered complete if it contains:

- a) CEI registration request letter (according to annex 01 model).
- b) CEI registration application format (annex 02).
- c) Updated descriptive list of CEI members (annex 03).

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d) Copy of the CEI constitution document.

e) Copy of the CEI Regulations.

f) Copy of the CEI Procedures Manual

In addition to having the integrity of these documents, they must be duly completed (without omitting data or information), without deletions or amendments, and with the corresponding signatures.

5.1.4. The complete file continues with the next stage: evaluation of the registration application, or failing that, it is returned to the requesting entity or institution in order to complete the missing requirements.

## **5.2. Registration application evaluation**

5.2.1. The evaluation of the registration application consists of verifying whether the file minimally complies with all of the immediate requirements. This stage does not exceed 30 business days.

5.2.2. During the evaluation stage, the OEI-OGITT may request additional documentation in order to clarify or specify any relevant information.

5.2.3. The evaluator contrasts the information contained in annexes 02 and 03 with the provisions of the CEI Regulations and Procedures Manual that requests its registration.

5.2.4. Next, the evaluator verifies compliance with immediate and progressive requirements, based on the information contained in the application file. The immediate requirements are identified with an asterisk (\*) within annex 02.

5.2.5. Regardless of the degree of compliance with the requirements in the file, it always continues with the third stage: response to the registration request.

## **5.3. Response to registration request**

5.3.1. WHEN THE REGISTRATION FILE MEETS THE REQUIREMENTS:

- a) The evaluator prepares a favorable response report and project of proof of registration, addressed to the Executive Directorate of the OEI-OGITT, when the immediate requirements are met and the information contained in the annexes coincides with the Regulations and Manual of Procedures of the CEI that requests its registration.
- b) Once the favorable response report has been received, the Executive Directorate of the OEI-OGITT evaluates and endorses it, sending the aforementioned report and draft registration certificate to the General Directorate of the OGITT.
- c) The General Directorate of the OGITT issues the certificate of registration of the CEI and incorporates it into the "National Registry of Research Ethics Committees" database.

5.3.2. WHEN THE REGISTRATION FILE DOES NOT MEET THE REQUIREMENTS:

- a) When the immediate requirements are not met and/or the information contained in the annexes does not coincide with the regulations and Procedures Manual of the CEI that requests its registration, the evaluator prepares a response report and

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ex officio draft with observations, addressed to the Executive Directorate of OEI-OGITT.

- b) The Executive Directorate sends the report and project to the OEI-OGITT ex officio with observations to the General Directorate of the OGITT.
- c) The General Directorate of the OGITT will send the letter with observations to the requesting entity or institution, giving it a period of ten (10) business days for its preparation:

5.3.3. When the entity or institution responds within the assigned period and manages to raise the observations satisfactorily, the favorable response activities to the registration request (a, b and c of section 5.3.1) are carried out.

5.3.4. When the entity or institution does not respond within the deadline and/or fails to raise the observations in a satisfactory manner, the evaluator prepares a response report and the draft document denying registration. The Executive Directorate of the OEI-OGITT sends both documents to the General Directorate, which sends the denial letter and a copy of the report to the requesting entity or institution.

5.3.5. The provisions of section 5.3.4 are associated with a stage of *ex novo* evaluation, whose duration does not exceed 30 business days, according to the section 5.2 of this Technical Procedure.

#### **5.4. Regarding non-compliance with progressive implementation requirements**

5.4.1. Entities or institutions that, having obtained the registration of their CEI, do not comply with the implementation of progressive requirements during the aforementioned period of 02 years, **automatically lose their registration**, a situation that is communicated through an official letter from the General Directorate of OGITT.

### **6. RESPONSIBILITIES**

6.1 The OEI-OGITT is responsible for the implementation of what is established in this Procedure.

6.2 The General Directorate of the OGITT is responsible for supervising compliance with what is established in this Procedure.

### **7. FORMS**

There are no application forms for this procedure.

### **8. ATTACHMENTS**

ANNEX 1: Model request letter for CEI Registration.

ANNEX 2: CEI registration application format.

ANNEX 3: Updated descriptive list of CEI members.

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**ANNEX 1**

**MODEL REQUEST LETTER FOR REGISTRATION OF THE ETHICS COMMITTEE IN  
INVESTIGATION (CEI)**

(Place and date)

General Directorate

General Office of Research and Technology Transfer

National Institute of Health

Dear Doctor:

Please send this letter to greet you and request the registration of the Research Ethics Committee "*(name)*" of *(name of the entity or institution)*, within the framework of the Technical Document: Ethical considerations for health research with human beings , approved by Ministerial Resolution No. 233-2020-MINSA.

The following documents are attached to this request letter:

- CEI registration application form (Annex 2).
- Updated descriptive list of CEI members (annex 3).
- Copy of the CEI constitution document.
- Copy of the CEI Regulations.
- Copy of the CEI Procedures Manual.

Without further ado, I bid you farewell.

Carefully,

\_\_\_\_\_  
Signature of the highest authority of the entity or institution

Names and surnames: .....

Cargo: .....

DAYS N° .....

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## ANNEX 2

### CEI REGISTRATION APPLICATION FORM

I. GENERAL INFORMATION OF THE RESEARCH ETHICS COMMITTEE	
<b>Name of the entity or institution that constitutes the CEI:</b>	
<b>Sector to which the entity or institution that constitutes the CEI belongs:</b>	Public <input type="checkbox"/> Private <input type="checkbox"/>  Specify type ( <i>IPRESS, MINSA Organs, Universities, Non-profit Legal Entities, others</i> ):
<b>Maximum Authority of the entity or institution (accredited in the corresponding legal document):</b>	
<b>Name of the CEI</b>	
<b>CEI email:</b>	
<b>CEI address:</b>	
<b>CEI Telephone:</b>	
<b>It has accreditation record before the INS:</b>	<input type="checkbox"/> No
	<input type="checkbox"/> Yes, detail N°:
<b>Has registration with another national or international entity or institution:</b>	<input type="checkbox"/> No
	<input type="checkbox"/> Yes, detail:
<b>Designation of the CEI by another entity or institution:</b>	If the CEI has been designated by another entity or institution as a committee, please complete the following information. <i>If there is more than one designation agreement, please respond to this information by agreement.</i>  a) There is a written agreement between the CEI entity or institution and another entity or institution establishing the designation of the CEI and the responsibilities of the parties: <input type="checkbox"/> Yes <input type="checkbox"/> No  b) No. and date of the appointment agreement:  c) Name of the entity or institution that designates the external CEI:  d) Sector to which the entity or institution that designates the external CEI belongs: Public <input type="checkbox"/> Private <input type="checkbox"/>

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	Specify type ( <i>IPRESS, MINSA Organs, Universities, Non-profit Legal Entities, others</i> ):
<b>II. GENERAL INFORMATION FROM THE PRESIDENT OF THE CEI</b>	
<b>Names and surnames:</b>	
<b>Profession or occupation:</b>	
<b>Email:</b>	
<b>III. CRITERIA FOR THE REGISTRATION OF THE RESEARCH ETHICS COMMITTEE</b>	
<b>Regulatory framework of the entity or institution</b>	<b>Answer</b>
1. The entity or institution to which the CEI belongs requires that every health research project with human beings that involves it be reviewed, before its start, by the CEI. (*)	ÿ Yes ÿ No  <i>Indicate name and date of the document, policy, standard or other:</i>
2. The entity or institution to which the CEI belongs has policies and standards on scientific integrity.	ÿ Yes ÿ No  <i>Indicate name and date of the document, policy, standard or other:</i>
3. The entity or institution to which the CEI belongs has policies or regulations that ensure that institutional publications comply with international standards of research ethics.	ÿ Yes ÿ No  <i>Indicate name and date of the document, policy, standard or other:</i>
<b>Constitution of the CEI</b>	<b>Answer</b>
1. The CEI has been established by means of a document (statute, resolution or other type of document) issued by the entity or institution to which it belongs. (*)	ÿ Yes ÿ No  <i>(Indicate number and date)</i>
2. The document by which the CEI was established indicates its mission as a committee. (*)	ÿ Yes ÿ No
3. The document by which the CEI was established establishes its members (names and surnames). (*)	ÿ Yes ÿ No
4. The document by which the CEI was established specifies the positions (minimum: presidency and technical secretary) of its members in the CEI. (*)	ÿ Yes ÿ No

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5. The document by which the CEI was established indicates the affiliation of the members to the entity or institution to which the CEI belongs (internal or external members). (*)	ÿ Yes ÿ No
6. The CEI is non-profit. (*)	ÿ Yes ÿ No
<b>Composition of the CEI</b>	<b>Answer</b>
1. The CEI has a minimum of five members. (*)	<p style="text-align: center;">ÿ Yes ÿ No</p> <p>Total # of members: _____</p> <p># of regular members: _____</p> <p># of alternate/alternate members: _____</p> <p><i>Indicate article number/provision Regulations and/or Manual of Procedures:</i></p>
2. The CEI has members from different professions, occupations, practices and areas of knowledge. (*)	<p style="text-align: center;">ÿ Yes ÿ No</p> <p>ÿ It has members with scientific knowledge (formal, empirical, health sciences, social sciences, behavioral sciences and others).</p> <p>ÿ It has members with knowledge in legal matters.</p> <p>ÿ Has knowledgeable members in Ethics and Bioethics.</p> <p>ÿ It has members who represent the community.</p> <p>ÿ It has members external to the entity or institution to which the CEI belongs.</p> <p><i>Indicate article number/provision Regulations and/or Manual of Procedures:</i></p>

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3. The CEI ensures that its members have the appropriate experience and knowledge for the ethical review of health research involving human beings. (*)	<input type="checkbox"/> Yes <input type="checkbox"/> No <i>Indicate article number/provision Regulations and/or Manual of Procedures:</i>
4. The CEI has members of both sexes. (*)	<input type="checkbox"/> Yes <input type="checkbox"/> No <i>Indicate article number/provision Regulations and/or Manual of Procedures:</i>  % women: % men:
5. All members of the CEI have received training in research ethics with human beings and have certificates that accredit it. (*)	<input type="checkbox"/> Yes <input type="checkbox"/> No <i>Indicate article number/provision Regulations and/or Manual of Procedures:</i>
6. The CEI does not have among its members authorities, directors or the main managers of the entity or institution to which it belongs. (*)	<input type="checkbox"/> Yes <input type="checkbox"/> No <i>Indicate article number/provision Regulations and/or Manual of Procedures:</i>
<b>CEI operation</b>	<b>Answer</b>
1. The CEI has the necessary and sufficient resources to fulfill its activities, functions and objective; the same ones that are provided by the entity or institution to which it belongs. (*)	The Regulations and/or Manual of Procedures contain provisions referring to CEI resources:  <input type="checkbox"/> Yes <input type="checkbox"/> No <i>Indicate article(s)/provision(s) of the Regulations and/or Manual of Procedures:</i>  <i>Check the types of resources and describe each one:</i>  <input type="checkbox"/> Budget:  <input type="checkbox"/> Infrastructure (office, meeting room, files, etc.):

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	<p>ÿ Human Resources (<i>support staff, administrative staff, etc.</i>):</p> <p>ÿ Work materials (<i>computer, printer, internet access, stationery, etc.</i>):</p> <p>ÿ Training for members:</p> <p>ÿ Compensation to members:</p> <p>ÿ Others:</p>
2. The CEI has regulations approved by the entity or institution that established it. (*)	<p>ÿ Yes ÿ No</p> <p>(Indicate document number and date)</p>
3. The CEI has a procedures manual approved by the entity or institution that established it. (*)	<p>ÿ Yes ÿ No</p> <p>(Indicate document number and date)</p>
4. The procedures relating to its composition are contemplated in the regulations or manual of procedures of the CEI. (*)	<p>ÿ Yes ÿ No</p>
<p>4.1. If the previous answer is yes, please complete the following information:</p> <p>a) The structure on which the CEI is governed is established (<i>president, vice president, technical secretary, etc.</i>): ÿ Yes ÿ No</p> <p><i>Indicate article(s)/provision(s) of the Regulation and/or Manual of Procedures:</i></p> <p>a) The criteria and conditions for the designation and selection of members of the CEI are established: ÿ Yes ÿ No</p> <p><i>Indicate article(s)/provision(s) of the Regulation and/or Manual of Procedures:</i></p>	

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<p>b) The responsibilities of each of the members within the CEI are established:  <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><i>Indicate article(s)/ provision(s) of the Regulation and/or Manual of Procedures:</i></p>	
<p>c) Other procedures related to the composition of the CEI are established, detail: <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><i>Indicate article(s)/ provision(s) of the Regulation and/or Manual of Procedures:</i></p>	
<p>5. The procedures related to its ethical reviews are contemplated in the CEI regulations or procedures manual. (*)</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>5.1. If the previous answer is yes, please complete the following information:</p> <p>a) The procedures for review, approval, monitoring and surveillance of the investigations throughout the investigation process: <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><i>Indicate article(s)/ provision(s) of the Regulation and/or Manual of Procedures:</i></p>	
<p>b) The types of review (complete review, expedited review and exempt review) and the rules for submitting research projects to each of these reviews are established:  <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><i>Indicate article(s)/ provision(s) of the Regulation and/or Manual of Procedures:</i></p>	
<p>c) The classification of the decisions adopted by the CEI is established: <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><i>Indicate article(s)/ provision(s) of the Regulation and/or Manual of Procedures:</i></p>	
<p>d) The reconsideration/appeal processes for CEI decisions are established:  <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><i>Indicate article(s)/ provision(s) of the Regulation and/or Manual of Procedures:</i></p>	
<p>e) The procedures for presenting amendments, deviations, events are established. adverse and others: <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><i>Indicate article(s)/ provision(s) of the Regulation and/or Manual of Procedures:</i></p>	
<p>f) The communication channels used by the CEI to communicate with the investigators or other agents involved in the investigation: <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><i>Indicate article(s)/ provision(s) of the Regulation and/or Manual of Procedures:</i></p>	

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<p>g) Other matters of internal regulation that govern the operation and activities are contemplated. of the CEI, detail: <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><i>Indicate article(s)/provision(s) of the Regulation and/or Manual of Procedures:</i></p>	
<p>6. The REC's decisions on the ethical acceptability of research projects are based on a process of debate and deliberation. (*)</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>
<p>7. The CEI's decisions on the ethical acceptability of research projects are based on internationally recognized ethical criteria. (*)</p>	<p style="text-align: center;"><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><i>Indicate which ones:</i></p> <p><input type="checkbox"/> Scientific validity and social value of research.</p> <p><input type="checkbox"/> Balance benefits/risks relationship, favorable.</p> <p><input type="checkbox"/> Equitable selection of research subjects.</p> <p><input type="checkbox"/> Adequate informed consent process.</p> <p><input type="checkbox"/> Respect for people.</p> <p><input type="checkbox"/> Community participation and commitment</p> <p><input type="checkbox"/> Others:</p>
<p>8. The decisions made by the CEI are supported by normative research ethics documents. (*)</p>	<p style="text-align: center;"><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><i>Indicate which ones:</i></p> <p><input type="checkbox"/> <i>International ethical guidelines for health-related research involving human beings</i> from the Council for International Organizations of Medical Sciences.</p> <p><input type="checkbox"/> Declaration of Helsinki.</p> <p><input type="checkbox"/> Nuremberg Code.</p> <p><input type="checkbox"/> Belmont Report</p> <p><input type="checkbox"/> Universal Declaration of Bioethics and Human Rights (UNESCO).</p>

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	<p>ÿ Others:</p>
<p>9. The decisions made by the CEI on the ethical acceptability of research projects are adopted by consensus or, in the second instance, by vote. (*)</p>	<p style="text-align: center;">ÿ Yes ÿ No</p> <p>Whose:</p> <p>Describe decision making:</p> <p><i>Indicate article(s)/provision(s) of the Regulations and/or Manual of Procedures:</i></p>
<p>10. Members of the community and external members always participate in the decision-making processes of the RECs on the ethical acceptability of research projects. (*)</p>	<p style="text-align: center;">ÿ Yes ÿ No</p> <p><i>Indicate article(s)/provision(s) of the Regulations and/or Manual of Procedures:</i></p>
<p>11. The CEI has a mechanism to request external consultants to address or resolve doubts about research projects in complex situations or situations that require specialized knowledge. (*)</p>	<p style="text-align: center;">ÿ Yes ÿ No</p> <p><i>Indicate article(s)/provision(s) of the Regulations and/or Manual of Procedures:</i></p>
<p>12. The deliberation process, decision-making and justification of these are recorded in minutes. (*)</p>	<p style="text-align: center;">ÿ Yes ÿ No</p>
<p>13. The REC asks its members to declare their conflicts of interest and takes appropriate measures to mitigate them. (*)</p>	<p style="text-align: center;">ÿ Yes ÿ No</p> <p><i>Indicate article(s)/provision(s) of the Regulations and/or Manual of Procedures:</i></p>
<p>14. The CEI has planned the procedure it will follow if one of its members is related to a research project that requires review.</p>	<p style="text-align: center;">ÿ Yes ÿ No</p> <p>Describe:</p> <p><i>Indicate article(s)/provision(s) of the Regulations and/or Manual of Procedures:</i></p>
<p>15. The CEI has mechanisms that protect the privacy of people who participate in research projects, as well as the confidentiality of data related to participants and the research. (*)</p>	<p style="text-align: center;">ÿ Yes ÿ No</p> <p>Describe:</p> <p><i>Indicate article(s)/provision(s) of the Regulations and/or Manual of Procedures:</i></p>

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16. The CEI has mechanisms to manage researchers' conflicts of interest and safeguard their duty of confidentiality.	<input type="checkbox"/> Yes <input type="checkbox"/> No Describe:  <i>Indicate article(s)/provision(s) of the Regulations and/or Manual of Procedures:</i>
17. The CEI ensures the suitability of the researcher and corroborates among others, their knowledge in the ethics of health research with human beings.	<input type="checkbox"/> Yes <input type="checkbox"/> No Describe:  <i>Indicate article(s)/provision(s) of the Regulations and/or Manual of Procedures:</i>
18. The CEI has procedures for monitoring and monitoring the progress of the investigations they have approved, until they are completed or terminated. (*)	<input type="checkbox"/> Yes <input type="checkbox"/> No Describe:  <i>Indicate article(s)/provision(s) of the Regulations and/or Manual of Procedures:</i>
19. The CEI has ethical review procedures and mechanisms that guarantee their speed and rigor in the event of emergencies or disease outbreaks. (*)	<input type="checkbox"/> Yes <input type="checkbox"/> No <i>Indicate article(s)/provision(s) of the Regulations and/or Manual of Procedures:</i>
20. The CEI has virtual systems that facilitate the presentation and review processes of research projects.	<input type="checkbox"/> Yes <input type="checkbox"/> No System name:
21. The CEI implements and guarantees compliance with its internal regulations.	<input type="checkbox"/> Yes <input type="checkbox"/> No
<b>Transparency and accountability of the CEI</b>	<b>Answer</b>
1. The CEI has transparency mechanisms for its activities, actions and results, excluding confidential information. (*)	<input type="checkbox"/> Yes <input type="checkbox"/> No
1.1. If the previous answer is affirmative, please complete the following information:  a) The CEI has a link on the website of its entity or institution where relevant information about its activities and operation is published, including its internal regulatory documents and the management it carries out annually: <input type="checkbox"/> Yes <input type="checkbox"/> No  <i>Indicate link:</i>	

	<b>PROCEDURE</b>	<b>PRT-OGITT-OEI-001</b>
	<b>REGISTER OF RESEARCH ETHICS COMMITTEES (CEI) FOR HEALTH RESEARCH WITH BEINGS HUMANS</b>	<b>Edition No. 01</b>

b) The CEI has a publicly accessible record of its reviews and decisions adopted:  Yes  No

*Indicate link:*

c) The CEI presents annual reports on its work to the entity or institution to which it belongs:  Yes  No

*Indicate article(s)/ provision(s) of the Regulation and/or Manual of Procedures:*

d) The CEI promotes collaboration with other CEIs and actors involved in research in health with human beings:  Yes  No

*Indicate article(s) / provision(s) of the Regulation and/or Manual of Procedures:*

**IV. SIGNATURES OF THE PRESIDENT OF THE ETHICS COMMITTEE IN INVESTIGATION AND THE HIGHEST AUTHORITY OF THE ENTITY OR INSTITUTION TO THE ONE THAT BELONGS**

All information included in this form is correct and truthful, as declared by those who sign it. As a sign of agreement we sign this document.

Place and date:

Names and surnames:

DAYS/CE:

\_\_\_\_\_

Business

Place and date:

Names and surnames:

DAYS/CE:

\_\_\_\_\_

Business

**ANNEX 3: UPDATED DESCRIPTIVE LIST OF CEI MEMBERS**

Name and surname of member	Sex (F/M)	Profession or occupation	charge that occupies the CEI	Regular, alternate or substitute member	Information on the latest training(s) received on research ethics  (max. 3) *	Member affiliated with the institution (But)	Position held in the institution or outside the institution
1.							
2.							
3.							
4.							
5.							
6.							
7.							
8.							

\* Indicate i) title of the diploma, training, degree, workshop or other, ii) modality: virtual, in-person, iii) institution that provided the training and iv) year in which the training was carried out.