

	FORM	FOR-OGITT-027
	VERIFIER OF COMPLIANCE WITH THE STANDARDS OF ACCREDITATION OF THE INSTITUTIONAL ETHICS COMMITTEE IN RESEARCH - CIEI	Edition No. 01

I. GENERAL INFORMATION FROM THE INSTITUTIONAL RESEARCH ETHICS COMMITTEE

Research Institution:	
Name of the CIEI:	
Has prior registration with the INS:	☐ No
	☐ Yes, detail N°: _____

II. COMPLIANCE WITH ACCREDITATION STANDARDS

N°	Accreditation Standard	Checker	FULFILLS		Observations
			Yeah	No	
1	Governance				
1.1	The CIEI has a document from the highest authority of the research institution that establishes its constitution and authorizes its operation.	Original or copy of the Minutes, Letter, Resolution or other institutional document.			
1.2	The CIEI constitution document defines the main mission of the CIEI, which consists of the responsibility to protect the rights, safety and well-being of research subjects.	Original or copy of the Minutes, Letter, Resolution or other institutional document.			
1.3	to. The CIEI's founding document establishes an independent operating policy for the institution, with functional autonomy.	Original or copy of the Minutes, Letter, Resolution or other institutional document.			
	b. Through the founding document of the CIEI, the Research Institution guarantees all the necessary resources such as human, infrastructure, logistical and financial resources for the CIEI to fulfill its mandate.	Original or copy of the Minutes, Letter, Resolution or other institutional document.			
1.4	The Research Institution approves Original or copy of the internal regulatory documents of the Minutes, Charter, CIEI, such as Regulations, Resolution Manual or other procedures or others.	institutional document.			
1.5	The CIEI, based on its powers to evaluate, approve, monitor and supervise research protocols, establishes a policy of responsibilities for researchers.	Regulations and/or Manual of Procedures			

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2	Composition, Organization and CIEI structure	Checker	Yeah	No	Observations
2.1	The CIEI has defined the number of members:				
	a) The number of regular and alternate members that ensures the quorum necessary for the operation of the CIEI is described in the Regulations.	Regulations and/or Manual of Procedures			
	b) It is made up of a minimum of 5 regular members.				
2.2	The CIEI is made up of professionals from various disciplines and members of the community:				
	a) At least one member has scientific expertise in the field of health (including research methodology).	Regulations, Curriculum Vitae, certificate and/or documents that support the experience, studies and/or training.			
	b) At least one member with expertise in behavioral or social sciences.				
	c) At least one member has expertise in ethical matters.				
	d) At least one member with expertise in legal matters.				
	e) At least one representative member of the community who is not a health professional and who does not belong to the institution.				
	f) At least one member has training in Good Clinical Practices.				
	g) At least one member has training in bioethics (at least postgraduate studies in bioethics awarded by a university).				
	h) The participation of members of both sexes.				
i) All members have at least a basic training certificate in research ethics.					
2.3	The CIEI establishes the criteria and Regulations and/or procedures for the election of the Manual of full and alternate members.	Procedures			
2.4	a) The structure of the CIEI includes at least a president and a technical secretary.	Regulations and/or Manual b)			
	The CIEI defines, in its internal regulations, Procedures the roles and responsibilities of				

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	president, the technical secretary and all its members.				
2.5	The CIEI defines, in its internal regulations, the criteria and procedures for selecting the president.	Regulations and/or Manual of Procedures			
2.6	The CIEI establishes the procedure for calling external consultants.	Regulations and/or Manual of Procedures			
2.7	The CIEI has an internal evaluation procedure (self-evaluation)	Regulations and/or Manual of Procedures			
3	CIEI Resources	Checker	But		Observations
3.1	The Institution has the following resources for the operation of the CIEI				
	a) Basic office supplies for the development of your sessions.	Field verification visit (ballots, memos, freckles, etc.)			
	b) Space and secure shelving for storage of files and records that guarantee their confidentiality.				
	c) Meeting room that guarantees the privacy and confidentiality of the matters discussed.				
	d) Administrative support staff.				
	e) Access to telephone, computer with internet, printer and multimedia equipment.				
	f) A virtual space hosted on the research institution's website and/or online systems.	Website and (or online systems for reviewing protocols (e.g. ProEthos)			
3.2	The CIEI has the facilities for the exercise of its functions and training: a) There is a formal document of the				
	institution that defines the time of dedication of its professionals and administrative staff to the functions of the CIEI.	Regulations and/or Resolution of the constitution of the CIEI			
	b) The Research Institution provides financial resources to guarantee the proper functioning of the CIEI, in accordance with the provisions of the Clinical Trials Regulations.	Plan, Trades, freckles, sales receipts, invoices. Execution of the intangible fund for research and operation purposes of the CIEI			

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	c) The institution regularly evaluates the needs for CIEI actions.	CIEI work plans, evaluation reports of said plans, etc.			
4	Conflicts of Interest, Confidentiality and Independence of CIEI Members a) The CIEI has a policy and procedures	Checker	But		Observations
4.1	to manage possible conflicts of interest of its members.	Regulation, Manual of Procedure, Minutes and/or Curriculum vitae			
	b) The authorities or directors of the research institution that constitutes the CIEI are not members.				
	c) Before reviewing the research protocols, the members of the CIEI declare conflicts of interest, and if applicable, they refrain from participating during the decision-making process (deliberation and final decision).				
	d) In decision-making, the CIEI quorum has one member not affiliated with the institution the committee represents.				
	e) The CIEI guarantees that researchers and entities that sponsor or manage research do not participate in decision-making (deliberation and final decision).				
4.2	The research institution ensures the independence of the committee members or staff, guaranteeing that they are not unduly influenced by third parties to obtain particular results.	Original or copy of the Minutes, Letter, Resolution or other institutional document.			
4.3	a) The CIEI has policies and procedures to guarantee confidentiality (which include access to confidential documentation and its destruction, meetings in private environments, etc.)	Regulation and/or Manual of Procedures			
	b) There are written commitments from the committee members to actively participate, guarantee the confidentiality of the matters discussed and declare conflicts of interest.				
5	Training of CIEI Members	Checker	But		Observations
5.1.	The CIEI presents a training plan annual approved by the Institution.	Approved plan by the Institution			
5.2	CIEI members participate in training or continuing education initiatives in the last year (which includes training in research ethics), promoted by the Institution.	Diplomas, certificates or certificates from the last year			

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6	Transparency , Accountability and Quality of the CIEI	Checker	But		Observations
6.1	The CIEI, through its Procedures Manual, establishes communication procedures during the evaluation and decision-making process with:	Regulations and MAPRO			
	a) The principal investigator, OIC or Sponsor.				
	b) The highest authority of the institution or whoever represents him.				
	c) The National Institute of Health or other health authority.				
	d) Other CIEI				
	and. Research Institutions				
6.2	The institution and the CIEI guarantee the dissemination of the regulations, Manual of procedures and making other knowledge and public availability for researchers and the community.	Through the website, printed materials or other institutional mechanisms.			
6.3	To maintain transparency, the CIEI has an updated and published record of the research projects evaluated and the decisions adopted.	Through the website, printed materials or other institutional mechanisms.			
6.4.	The CIEI presents procedures to address complaints or questions from research subjects participating in clinical trials.	Regulations and/or Manual of Procedures, website, emails, letters, etc.			
6.5	The CIEI publishes the annual report or report of the activities carried out, which includes at least:				
	a) Name and position of the members of the CIEI, as well as the start and end date of your designation.	Annual memory.			
	b) Calendar of scheduled and held meetings.				
	c) Member attendance report at meetings (in percentage).				
	d) List of projects: presented, approved, disapproved or other considered.				
	e) List of changes to the Regulations, Procedures Manual or other internal documents, if applicable.				
	f) Summary of the training of CIEI members per year.				
	g) List of complaints received, the actions taken to resolve them and a comment on the result.				
7	Ethical Bases of the CIEI Decision	Checker	But		Observations

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7.1	The CIEI in its Regulations and Procedures Manual incorporate ethical guidelines in accordance with the provisions of:				
	• General Health Law, Art 28 of the Law No. 260842, •	Archive of standards on research ethics, Regulations and/or Manual of Procedures			
	Regulation of clinical trials, DS No. 021- 2017-SA.				
	• Declaration of Helsinki				
	• International Ethical Guidelines for Health-Related Research with Human Subjects (CIOMS).				
	• Other applicable international ethical national and regulations.				
7.2	The CIEI uses the following ethical acceptability criteria for the review and decision on research protocols: a) Scientific validity and social value of the Regulation and/or research.				
	risk-benefit balance and Minutes, risk minimization.	Procedures Manual, b) Favorable c) Equitable d) Adequate by reviewers of e)			
	selection of research evaluation subjects.				
	research informed consent process.				
	Respect for people: protection of CIEI vulnerable groups, protection of privacy and confidentiality of data of research participants, protection from harm, among others. f) Participation and commitment of communities				
8	CIEI Review and Decision Making	Checker	But		Observations
8.1	The CIEI establishes requirements for the presentation of research protocols:				
	a) The CIEI publishes guidelines for requesting review of research protocols.	Regulations and/or Manual of Procedures, website, etc.			
	b) The CIEI establishes deadlines for the review and approval procedures of research protocols, and for other related procedures.	Regulations and/or Manual of Procedures			
	c) The CIEI has guidelines to guide researchers in writing their informed consent forms.	Regulations and/or Manual of Procedures			
8.2	The following items (at a minimum) are requested from Principal Investigators when they present their research protocol to the CIEI:				
	a) Review request				

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	b) Complete protocol. c)	Regulations and/or Manual of Procedures			
	Informed Consent and Assent Form (if applicable)				
	d) Qualifications of the principal investigator (e.g. CV).				
	e) Declaration of conflict of interest of the researchers f)				
	Recruitment material (for (e.g., advertisements, banners, posters, etc.), if applicable.				
	g) Questionnaires/surveys to be used in the research, if applicable.				
	h) Investigator's Manual or Technical Data Sheet of the product under investigation				
	i) Insurance policy				
8.3	The CIEI has defined the types of review and the procedures that correspond to them for the approval of the study.	Regulations and/or Manual of Procedures			
8.4	The CIEI has defined procedures for the submission and approval of amendments or other procedures after study approval.	Regulations and/or Manual of Procedures			
8.5	The CIEI has established that it can request the assistance of expert consultants on different topics when required for the review of a particular protocol.	Regulations and/or Manual of Procedures			
8.6	The CIEI meets with a minimum of 5 members who meet the skills of standard 2.2. The specific quorum requirements must include the minimum number of members required, which must not have exclusive participation of members of the same profession or same sex and must include at least one member of the community, who does not belong to the health field. nor to the research institution.	Regulations and/or Manual of procedures, Minutes			
8.7	All CIEI decisions are made by consensus or majority.	Regulations and/or Manual of procedures, Minutes			
8.8	There are procedures for the preparation of minutes, which achieve at least: management of conflict of interest, attendees, quorum, deliberation and justification of their decisions, date, time and signatures.	Regulations and/or Manual of procedures, Minutes			

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8.9	The CIEI has the approval certificate model contemplated in the Manual of Clinical Trial Procedures.	Regulations and/or Manual of Procedures			
8.10	The CIEI has appeal mechanisms for its decisions.	Regulations and/or Manual of Procedures			
8.11	The CIEI has procedures for monitoring and supervising approved research protocols.	Regulations and/or Manual of Procedures			

III. VERIFICATION VISIT DATA			
DATE:			
START TIME:			
END TIME:			
OGITT REPRESENTATIVES			
Names and surnames	Cargo	Email	Business
	Personal OEI Technician OGITT		
	Personal OEI Technician OGITT		
CIEI REPRESENTATIVES			
Names and surnames	Cargo	Email	Business