	FORM	FOR-OGIT-026
	AFFIDAVIT OF COMPLIANCE WITH THE STANDARDS OF ACCREDITATION OF THE INSTITUTIONAL RESEARCH ETHICS COMMITTEE - CIEI	Edition No. 02

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**	**FULFILLS**	
1	**Governance**	**But**	
1.1	The CIEI has a document from the highest authority of the research institution that establishes its constitution and authorizes its operation.		
1.2	The founding document of the CIEI defines the main mission of the CIEI, which consists of the responsibility to protect the rights, safety and well-being of research subjects.		
1.3	to. The CIEI's founding document establishes an independent operating policy for the institution, with functional autonomy.		
	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.		
1.4	The Research Institution approves the internal regulatory documents of the CIEI, such as Regulations, Procedures Manual or others.		
1.5	The CIEI, based on its powers to evaluate, approve, monitor and supervise research protocols, establishes a policy of responsibilities for researchers.		
2	**Composition, Organization and Structure of the CIEI**	**But**	
The CIEI establishes in its regulatory documents:			
2.1	The CIEI has defined the number of members:		
	to. The number of regular and alternate members that ensures is described in the Regulations. the quorum necessary for the operation of the CIEI.		
	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:		
	to. It has at least one member with scientific expertise in the field of health (including research methodology).		
	b. It has at least one member with expertise in behavioral or social sciences.		
	c. It has at least one member with expertise in ethical matters.		
	d. It has at least one member with expertise in legal matters.		

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	and. At least one representative member of the community who is not a health professional and that does not belong to the institution.		
	F. At least one member with 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.		
	Yo. All members have at least a basic ethics training certificate in research		
2.3	The CIEI establishes the criteria and procedures for the election of regular and alternate members.		
2.4	to. The structure of the CIEI includes at least a president and a technical secretary.		
	b. The CIEI defines, in its internal regulations, the functions and responsibilities of the president, of the technical secretary and all its members.		
2.5	The CIEI defines, in its internal regulations, the criteria and procedures for selecting the president.		
2.6	The CIEI establishes the procedure for calling external consultants.		
2.7	The CIEI has an internal evaluation procedure (self-evaluation).		
3	**CIEI Resources**	**But**	
3.1	The Institution has the following resources for the operation of the CIEI:		
	to. Basic office supplies for the development of your sessions.		
	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 matters treated.		
	d. Administrative support staff.		
	and. 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.		
3.2	The CIEI has the facilities to carry out its functions and training:		
	to. 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.		
	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.		

	c. The institution regularly evaluates the needs for CIEI actions (For example: budget, supervision of clinical trials, need to adapt material resources, adaptation of regulations and procedures, and documentation of the training requirements of CIEI members).		
4	**Conflict of Interest, Confidentiality and Independence of CIEI Members**	**But**	
4.1	to. The CIEI has a policy and procedures to manage possible conflicts of interest of members.		
	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 that constitutes the committee.		
	and. 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.		
4.3	to. The CIEI has policies and procedures to guarantee confidentiality (including access to confidential documentation and its destruction, meetings in private environments, etc.)		
	b. There are written commitments from committee members to actively participate, guarantee the confidentiality of the matters discussed and declare conflicts of interest.		
5	**Training of CIEI Members**	**But**	
5.1.	The CIEI presents an annual training plan approved 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.		
6	**Transparency, Accountability and Quality of the CIEI**	**But**	
6.1	The CIEI, through its Procedures Manual, establishes communication procedures during the evaluation and decision-making process with:		

	to. The principal investigator, OIC or Sponsor.		
	b. The highest authority of the institution or whoever represents it.		
	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, Procedures Manual and other documents, making them known and publicly available to researchers and the community.		
6.3	To maintain transparency, the CIEI has an updated and published record of the research projects evaluated and the decisions adopted.		
6.4.	The CIEI presents procedures to address complaints or questions from research subjects participating in clinical trials.		
6.5	The CIEI publishes the annual report or report of the activities carried out, which includes at least:		
	to. Name and position of the members of the CIEI, as well as the start and end date of their designation.		
	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.		
	and. List of changes to the Regulations, Procedures Manual or other internal documents, if applicable.		
	F. Summary of the training of CIEI members by year.		
	g. List of complaints received, actions taken to resolve them, and a comment on the outcome.		
7	**Ethical Bases of the CIEI Decision**	**But**	
7.1	The CIEI in its Regulations and Procedures Manual incorporate ethical guidelines in accordance with the provisions of: i. General		
	Health Law, Law No. 260842.		
	ii. Regulation of clinical trials, DS N° 021-2017-SA.		
	iii. Declaration of Helsinki.		
	iv. International Ethical Guidelines for Health-Related Research with Human Beings humans (CIOMS).		
	in. Other applicable national and international ethical 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 research.		
	b. Favorable risk-benefit balance and risk minimization.		

	c. Equitable selection of research subjects.		
	d. Appropriate informed consent process.		
	and. Respect for people: protection of vulnerable groups, protection of privacy and confidentiality of data of research participants, protection from harm, among others.		
	F. Community participation and commitment		
8	**CIEI Review and Decision Making**	**But**	
8.1	The CIEI establishes requirements for the presentation of research protocols:		
	to. The CIEI publishes guidelines for requesting review of the protocols of investigation.		
	b. The CIEI establishes deadlines for protocol review and approval procedures investigation, and for other related procedures.		
	c. The CIEI has guidelines to guide researchers in writing their forms of informed consent.		
8.2	The following items (at a minimum) are requested from Principal Investigators when they present their research protocol to the CIEI:		
	to. Review request		
	B. Complete protocol.		
	c. Informed Consent and Assent Form (if applicable)		
	d. Qualifications of the principal investigator (e.g. CV).		
	and. Declaration of conflict of interest of researchers f. Recruitment materials		
	(e.g., advertisements, banners, posters, etc.), if corresponds.		
	g. Questionnaires/surveys to be used in the research, if applicable.		
	h. Investigator's manual or Technical Data Sheet of the product under investigation		
	Yo. 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.		
8.4	The CIEI has defined procedures for the submission and approval of amendments or other procedures after study approval.		
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.		
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.		
8.7	All CIEI decisions are adopted by consensus or majority.		

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

III. CONTENT OF THE DECLARATION

they, _____, identified with DNI / CE No. _____,

highest authority of the Research Institution, **I declare** that the Institutional Ethics Committee, as the Investigation _____:

Yo. Complies with the eight (08) CIEI accreditation standards *described in section II of this document and which are established* in the Manual of Clinical Trial Procedures. Therefore, assume the responsibilities and obligations provided for in the Clinical Trials Regulations approved by Supreme Decree N° 021-2017-SA.

ii. It has the human, infrastructure, logistical and financial resources to fulfill its objectives. functions in accordance with articles 59 and 60 of the Clinical Trial Regulations approved by the Supreme Decree No. 021-2017-SA.

I make this sworn statement stating that the information provided is true and I authorize the verification of what was declared in accordance with the "Principle of Presumption of Truth" of article IV, numeral 1.7 of the TUO of Law No. 27444, Law of General Administrative Procedure, approved with Supreme Decree 004-2019-JUS.

IV. SIGNATURE OF THE HIGHEST AUTHORITY OF THE RESEARCH INSTITUTION

As a sign of agreement, I sign this document.

City,…….of……..of 20…

_____

Name and signature
DAYS/CE