| | FORM | FOR-DIIS-026 |
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| | AFFIDAVIT OF COMPLIANCE WITH THE STANDARDS OF ACCREDITATION OF THE INSTITUTIONAL ETHICS COMMITTEE IN RESEARCH - CIEI | Edition No. 01 |

| I. GENERAL INFORMATION OF THE INSTITUTIONAL RESEARCH ETHICS COMMITTEE | |
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| Research Institution: | |
| Name of the CIEI: | |
| Account with Registration | ☐ No |
| | ☐ Yes, detail No.:_____ |

| II. | COMPLIANCE WITH ACCREDITATION STANDARDS | | |
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| N° | Accreditation Standard | BIRTHDAY | |
| 1 | Governance | But | |
| 1.1 | The CIEI has a document from the highest authority of the research institution that certifies its constitution and authorizes its operation. | | |
| 1.2 | The CIEI's founding document defines the CIEI's primary mission, which is the responsibility to protect the rights, safety, and well-being of research subjects. | | |
| 1.3 | a. The CIEI's founding document establishes a policy for the institution's independent operation, with functional autonomy. b. Through the CIEI's founding | | |
| | document, the Research Institution guarantees all necessary resources, such as human resources, infrastructure, logistics, and finances, for the CIEI to fulfill its mandate. | | |
| 1.4 | The Research Institution approves the internal regulatory documents of the CIEI, such as the Regulations, Procedures Manual, and others. | | |
| 1.5 | The CIEI, based on its powers to evaluate, approve, monitor, and supervise research protocols, establishes a policy on the responsibilities of 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: a. The number | | |
| | of regular and alternate members that it ensures is described in the Regulations. the quorum necessary for the CIEI to operate. b. It is | | |
| | composed 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. It has at least one member with scientific expertise in the health field (including research methodology). | | |
| | b. It has at least one member with expertise in behavioral or social sciences. | | |
| | c. Has at least one member with expertise in ethics matters. d. Has at | | |
| | least one member with expertise in legal matters. | | |

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| | e. At least one representative member of the community who is not a health professional and 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. Participation of members of both sexes. | | |
| | i. All members have at least a basic ethics training certificate under investigation | | |
| 2.3 | The CIEI establishes the criteria and procedures for the election of regular and alternate members. | | |
| 2.4 | a. 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: | | |
| | a. Basic office supplies for the development of your sessions. | | |
| | b. Secure storage space and shelving for files and records that guarantee their confidentiality. | | |
| | c. Meeting room that guarantees the privacy and confidentiality of matters treaties. | | |
| | 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. | | |
| 3.2 | The CIEI has the following facilities for the exercise of its functions and training: | | |
| | a. There is a formal document from the institution that defines the time commitment of its professionals and administrative staff to the CIEI functions. | | |
| | b. The Research Institution provides financial resources to ensure the proper functioning of the CIEI, in accordance with the provisions of the Clinical Trials Regulations. | | |

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| | c. The institution regularly assesses the needs for CIEI activities (for example: budget, clinical trial oversight, need for adequate material resources, adaptation of regulations and procedures, and documentation of training requirements for CIEI members). | | |
| 4 | Conflict of Interest, Confidentiality and Independence of CIEI Members | But | |
| 4.1 | a. The CIEI has a policy and procedures to handle 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 research protocols, CIEI members declare any conflicts of interest and, if applicable, abstain from participating in the decision-making process (deliberation and final decision). | | |
| | d. In decision-making, the quorum of the CIEI includes a member not affiliated with the institution that constitutes the committee. | | |
| | e. The CIEI ensures that researchers and entities sponsoring or managing research do not participate in decision-making (deliberation and final decision). | | |
| 4.2 | The research institution ensures the independence of committee members or staff, ensuring that they are not unduly influenced by third parties to obtain particular results. | | |
| 4.3 | a. The CIEI has policies and procedures to ensure confidentiality (including access to and destruction of confidential documentation, meetings in private settings, etc.) | | |
| | b. Committee members have written commitments to actively participate, ensure 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 have participated in training or continuing education initiatives (including research ethics training) promoted by the institution over the past year. | | |
| 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: | | |

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| | 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. | | |
| | e. Research Institutions | | |
| 6.2 | The institution and the CIEI ensure the dissemination of the regulations, Manual of Procedures, and other documents, making them known and publicly available to researchers and the community. | | |
| 6.3 | To maintain transparency, the CIEI maintains an updated and published record of the research projects evaluated and the decisions made. | | |
| 6.4. | The CIEI has procedures for addressing complaints or questions from research subjects participating in clinical trials. | | |
| 6.5 | The CIEI publishes the annual report on 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 their designation. | | |
| | b. Calendar of scheduled and held meetings. | | |
| | c. Report of attendance of members at meetings (in percentage). | | |
| | d. List of projects: submitted, approved, disapproved or other considered. | | |
| | e. List of changes to the Regulations, Procedures Manual or other internal documents, if applicable. | | |
| | f. Summary of CIEI member training sessions by year. g. List of complaints received, | | |
| | actions taken to resolve them, and a commentary on the outcome. | | |
| 7 | **Ethical Basis of the CIEI Decision** | **But** | |
| 7.1 | The CIEI, in its Regulations and Procedures Manual, incorporates ethical guidelines in accordance with the provisions of: i. General Health | | |
| | Law, Law No. 260842. ii. Clinical Trials Regulations, DS | | |
| | No. 021-2017-SA. iii. iv. International Ethical Guidelines for Health-related | | |
| | Declaration of Helsinki. | | |
| | 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 reviewing and deciding on research protocols: a. Scientific validity and social value | | |
| | of the research. b. Favorable risk-benefit balance and risk | | |
| | minimization. | | |

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| | c. Fair selection of research subjects. d. Adequate informed consent process. e. Respect for persons: protection of vulnerable groups, protection of the privacy and confidentiality of research participants' data, protection from harm, among others. f. Community participation and engagement | | |
| 8 | CIEI Review and Decision-Making | But | |
| 8.1 | The CIEI establishes requirements for the submission of research protocols: | | |
| | a. The CIEI publishes guidelines for requesting review of protocols investigation. | | |
| | b. The CIEI establishes deadlines for protocol review and approval procedures research, and for other related procedures. | | |
| | c. The CIEI has guidelines to guide researchers in writing their forms informed consent. | | |
| 8.2 | The following items (as a minimum) are requested from Principal Investigators when submitting their research protocol to the CIEI: | | |
| | a. Request for review | | |
| | b. Completed protocol. c. Informed Consent and Assent Form (if applicable) d. Qualifications of the principal investigator (e.g., CV). e. Declaration of conflict of interest of the investigators f. Recruitment materials (e.g., advertisements, posters, etc.), if applicable corresponds. | | |
| | g. Questionnaires/surveys to be used in the research, if applicable. | | |
| | h. Researcher's Manual or Technical Sheet of the investigational product | | |
| | 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. | | |
| 8.4 | The CIEI has defined procedures for the submission and approval of amendments or other procedures following study approval. | | |
| 8.5 | The CIEI has established that it may request the assistance of expert consultants in various topics when required for the review of a particular protocol. | | |
| 8.6 | The CIEI meets with a minimum of five members who meet the expertise of Standard 2.2. Specific quorum requirements must include the minimum number of members required, which must not be exclusively comprised of members of the same profession or same sex and must include at least one member from the community, not from the health field or the research institution. | | |
| 8.7 | All decisions of the CIEI are taken by consensus or majority. | | |

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| 8.8 | There are procedures for preparing minutes that address at least: conflict of interest management, attendance, quorum, deliberation and justification of decisions, date, time, and signatures. | | |
| 8.9 | The CIEI has the approval certificate model contemplated in the Clinical Trials Procedures Manual. | | |
| 8.10 | The CIEI has mechanisms for appealing 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 Number _____,

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

i. Complies with the eight (08) CIEI accreditation standards described in numeral II of this document and established in the Clinical Trials Procedures Manual. Therefore, it assumes the responsibilities and obligations provided for in the Regulations for Clinical Trials approved by Supreme Decree No. 021-2017-SA.

ii. It has the human, infrastructure, logistical and financial resources to fulfill its functions in accordance with articles 59 and 60 of the Clinical Trials 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 the statements in accordance with the "Principle of Presumption of Truth" of article IV, section 1.7 of the TUO of Law No. 27444, General Administrative Procedure Law, approved by Supreme Decree 004-2019-JUS.

## IV. SIGNATURE OF THE HIGHEST AUTHORITY OF THE RESEARCH INSTITUTION

In token of conformity, I sign this document.

City,…….of…….of 20…

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Name and signature DNI / CE