	FORM	FOR-DIIS-023
	AFFIDAVIT OF COMPLIANCE WITH THE MINIMUM CI REQUIREMENTS	Edition No. 01

I. GENERAL INFORMATION ABOUT THE RESEARCH CENTER	
Research Institution:	
Name of the Research Center:	
It has an ID record	☐ No
	☐ Yes, detail number:_____

II. Minimum requirements for a research center 2.1. Research	Complies	
Center Documents. a. Copy of the current document	And	No
by which DISA/DIRESA/GERESA grants the Health Establishment Category to the research institution.		
b. Approval document for the operation of the Research Center signed by the legal representative of the research institution.		
c. List of personnel assigned to the Research Center, indicating membership number, specialty and qualifications (as applicable), duties and positions.		
d. Copy of the current Clinical Trials Regulations in Peru.		
and. Copy of the current contract with the company responsible for the collection, transportation, and final disposal of solid waste, if it is done through a third party contract.		
f. Copy of contract/agreement with Health Establishments for care in medical emergency situations (for institutions without hospitalization)		
g. Copy of contract/agreement for the transfer of patients in a situation of emergencies. (for non-residential institutions)		
2.2 Procedure Manuals a. Sampling	And	No
Procedure.		
b. Procedure for the Processing, Conservation and Storage of Biological Samples.		
c. Procedure for the Management, Treatment and Disposal of Waste Solids.		
d. Procedure for the Packaging and Transportation of Biological Samples.		
e. Procedure for the Entry and Management of Clinical Trial Data.		
f. Procedure to maintain data confidentiality (including infrastructure and computer systems)		
g. Procedure for filing documentation related to trials Clinical.		

h. Procedure to prevent the destruction of documentation, related to EC in case of disasters.		
i. Procedure for the Conservation and Storage of Products in Investigation.		
j. Procedure for the dispensing of investigational products.		
Biosecurity Standards and Procedures.		
kl Contingency plan or response in case of power outage.		
m. Scheduled training program for health personnel (professional, technician and assistant) assigned to the research center, related to clinical trials and, according to the assigned functions and activities.		
n. Preventive Maintenance and Equipment Calibration Program medical, electro-medical, security and others, according to the nature of their activities (specifying their own from those provided by third parties), differentiating those for shared and exclusive use by the Research Center.		
o. Procedure for immediate response to serious adverse events, including those occurring during the administration of the investigational product and/or clinical trial procedures.		

2.3. CHARACTERISTICS OF THE RESEARCH CENTER

Conditioning	And	No
Hospitalization Area (for first-level establishments without hospitalization, Art. 57 of the REC must be taken into account)		
Consulting Room Area (consulting room area according to NTS-113, informed consent and medical evaluation area that guarantees the privacy and confidentiality of the research subject)		
Nursing Area (vital functions and triage area with adequate equipment)		
Waiting room		
Hygienic Services for research team		
Hygienic Services for Study Subjects		
Research Center Administration and Management Area (independent area from the consulting room area)		

Investigational product storage area (exclusive, controlled-access area that complies with good storage practices)		
Investigational product dispensing area (with appropriate personnel who follow good dispensing practices)		
Sampling area (area and personnel that comply with biosafety standards)		
Clinical laboratory area (current calibration certificates, verifiable on each piece of equipment)		
Sample processing and storage area (current calibration certificates, verifiable on each piece of equipment)		
Emergency and urgent care area (for first-level establishments without hospitalization, Article 57 of the REC must be taken into account)		
Access for medical emergencies and emergencies (with adequate infrastructure and equipment)		
Equipment	**And**	**No**
Calibrated equipment (calibration certificates)		
Medical emergency kit (have an emergency kit in the investigational product administration area)		
Computer equipment, for example: computer or laptop, printer, photocopier, scanner, internet access.		
Human resources	**And**	**No**
It has a researcher responsible for the research center		
It has a research studies coordinator.		

III. CONTENT OF THE DECLARATION

Affidavit of compliance with the minimum requirements of the Research Center (CI).

In my capacity as legal representative of the research institution, I declare under oath and in accordance with the principle of truthfulness provided for in the General Administrative Procedure Law, Law No. 27444 that: The Research Center: ……..

1. It meets the minimum requirements established in Annex 3 and detailed in section II of this document, which have been provided for in the Clinical Trials Regulations approved by Supreme Decree No. 021-2017-SA,

IV. SIGNATURE OF THE DECLARANTS

As proof of what is expressed in this document, I sign below:

Names: ……..

Last Names: ……..

DNI: ……Tel.:……., email: ……

Date: / /

Signature of the legal representative of the research institution: ……..

The information contained in this document is sworn. The Directorate of Health Research and Innovation (DIIS) will take the information contained therein into account, reserving the right to carry out the corresponding verifications and request accreditation. If it is found that false, omitted, or concealed information has been submitted, the appropriate administrative and criminal actions will be taken.