	FORM	FOR-OGITT-023
	AFFIDAVIT OF COMPLIANCE WITH THE MINIMUM IQ REQUIREMENTS	Edition No. 01

I. GENERAL INFORMATION ABOUT THE RESEARCH CENTER	
Research Institution:	
Name of the Research Center:	
Has IC Registration	☐ No
	☐ Yes, detail No.:_____

II. Minimum requirements of a research center 2.1.	**Compliant**	
Research Center Documents. to. Copy of the	**And**	**No**
current Document, through which the DISA/DIRESA/GERESA grants the Category of Health Establishment 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 tuition number, specialty and qualification (as applicable), functions and positions.		
d. Copy of the current Regulations for Clinical Trials in Peru.		
It is. Copy of the current contract with the company that is responsible for the collection, transportation and final disposal of solid waste, if it is done by contracting it to third parties.		
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-inpatient institutions)		
2.2 Procedure Manuals a. Procedure for	**And**	**No**
Taking Samples.		
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 Packaging and Transport of Biological Samples.		
and. 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 Tests Clinicians.		

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h. Procedure to prevent the destruction of documentation, related to EC in case of disasters.		
Yo. Procedure for the Conservation and Storage of Products in Investigation.		
j. Procedure for dispensing research products.		
k. Biosafety standards and procedures.		
l. Contingency or response plan 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.		
either. Procedure for immediate attention to serious adverse events, including those that occurred during the administration of the investigational product and/ or clinical trial procedures.		

23. 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)		
Office Area (office area according to NTS-113, informed consent and medical evaluation area that guarantees the privacy and confidentiality of the research subject)		
Nursing Area (area for taking vital functions and triage that has adequate equipment)		
Waiting room		
Hygienic services for research team		
Hygienic services for study subjects		
Administration and management area of research centers (area independent of the office area)		

Storage area for the investigational product (exclusive area, with controlled access, that complies with good storage practices)		
Dispensing area for the investigational product (with appropriate personnel who comply with good dispensing practices)		
Sample collection 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 emergency area (for first-level establishments without admission, Art 57 of the REC must be taken into account)		
Access for emergencies and medical emergencies (with adequate infrastructure and equipment)		
equipment	And	**No**
Calibrated equipment (calibration certificates)		
Medical emergency team (have an emergency briefcase 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 coordinator of research studies.		

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. Complies with 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 N°021-2017-SA,

IV. SIGNATURE OF THE DECLARANTS

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

Names: ……..

Surnames: ……

ID: ……Phone:……., email: ……..…….

Date: / /

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

The information contained in this document is in the nature of an Affidavit. The General Office of Research and Technology Transfer – OGITT, will take into account the information contained therein, reserving the right to carry out the corresponding verifications; as well as request its accreditation. If it is detected that false information has been omitted, hidden or recorded, the corresponding administrative and criminal actions would be taken.