PURPOSE: This Guide constitutes a Checklist to verify on-site the conditions of the Research Center, which allow authorization of registration for the conduct of Clinical Trials, with the objective of safeguarding respect for dignity, protection of rights, physical and mental integrity, as well as the protection of data of the research subjects.

RCI Application No.:

Verification Date: Day Month Year

REFERENCE	1. GENERAL DATA OF THE RESEARCH INSTITUTION (HEALTH ESTABLISHMENT)	
Art. 29° DS 013-2006	**1.1** Name of the Research Institution (Health Establishment), according to external signage that identifies the Health Establishment.	
	a) Address (Av., Jr., Street, No.)	
	(b) District,	
	c) Province, Department	
	d) Unique RENAES code number	
	e) Company Name (According to RUC)	
	f) RUC number	
Art. 4°, Art 54° DS 013-2006-SA	**1.2** Name of the Medical Director/Health Care Manager of the Research Institution **(Health Facility)** (The Medical Director of the General Care Hospital, Specialized Care Hospital and Health Institutes Specialized, they may not be simultaneously responsible for administrative management)	
	a) Professional Membership Number:	
	b) Specialty:	
	c) National Specialist Registry Number:	
Art. 54° DS 013-2006	**1.3** Name of the Legal Representative of the Research Institution **(Health Establishment)**	
	a) Profession:	
	b) Professional Membership Number:	
	c) Specialty	
	1.4 Belongs to the Sub-Sector:	Public ( ) Private ( )
Art. 3° DS 013-2006	**1.5** Institution to which it belongs: (Mark with an X, as appropriate)	MINSA ( ) EsSALUD ( ) Health EP ( ) Health FFAA ( ) PNP Health ( ) Naval Health ( ) Regional Government ( ) Provincial Government ( ) Local Government ( ) NGOs ( ) Other ( ) Specify:
Art. 18° DS 013-2006	**1.6** Type of Research Institution (REI) according to the type of service provided. (Mark with an X, as appropriate)	Without Internment ( ) With Internment ( )
Art. 44°, 45°, 51° y 52° DS 013-2006	**1.7** Classification of the Research Institution (Health Facility) (Check as appropriate) (Mark with an X, as appropriate)	**Without hospitalization:** Health post ( ) Health post ( ) Health center ( ) Medical Center ( ) Polyclinic ( ) Specialized Medical Center ( ) Medical Office ( ) **With Internment:** General care hospital ( ) General care clinic ( ) Specialized care hospital ( ) Specialized care clinic ( ) Health Center with hospital beds ( ) Geriatric care centers ( ) Specialized health institute ( )
	1.8 Scope or jurisdiction of the Health Administration to which the Research Institution **(EESS)** belongs (Mark with an X, as appropriate)	DISA ( ) DIRESA ( ) Health ( ) EsSalud ( ) Directorial Resolution No: **Institution and date RD:**
NT 021-MINSA/DGSP1	**1.9** Category of the Research Institution **(Health Establishment)** (According to Certificate of	**I – 1** ( ) **I – 2** ( ) **I – 3** ( ) **I – 4** ( )

[1] NT 021-MINSA/DGSP. Standard for Categories of Health Sector Establishments, approved by RM 769-2004/MINSA

Attached: Annex **"DOCUMENTATION",** which must be available at the Research Center.

	Categorization or Directorial Resolution, in force) (Mark with an X, as appropriate)	**II – 1** ( ) **II – 2** ( ) **III – 1** ( ) **III – 2** ( )			
NT 021-MINSA/DGSP1 Art. 16° DS 013-2006 Art. 7° no. 43 DS 006-2007	**1.10** Does the Research Institution (Health Establishment) have a Teaching and Research Unit, which manages the registration of Research Centers?	And ( ) No ( )			
		Specify:			
	a) Name of the person in charge of the Unit Teaching and Research				
	b) Professional Membership Number (as applicable):				
	c) Specialty:				
	d) RNE number (as applicable):				
	e) Telephone, fax, e-mail:				
Art. 51° and 54° DS 006-2007-SA	**2. RESEARCH CENTER: FUNCTIONAL UNIT OF THE RESEARCH INSTITUTION (HEALTH ESTABLISHMENT)**				
Art. 49° DS 017-2006	**2.1** Name of the Principal Investigator responsible for the Research Center (Designated by the Medical Director of the Health Establishment)				
	a) Professional Membership Number:				
	b) Specialty:				
	c) RNE number:				
	d) Telephone: Fax:				
	e) Cell phone:				
	f) Email:				
	g) **Name of the Research Center**				
Art. 49° inc. a) DS 017-2006-on	**2.2** Specify the **specialty in which the Clinical Trial will be conducted**				
Art. 58° DS 006-2007	**2.3** Specify the Institutional Research Ethics Committee (IREC) that will evaluate the Research Center's research protocols. (The IREC must be listed in the INS's Register of Ethics Committees.)				
Art. 5° y 29º DS 013-2006-SA	**2.4** Administrative **Area of the Research Center**	**YES**	**NO**		**OBSERVATIONS**
	a) Is all the updated and current documentation indicated in the **attached Annex** available at the Research Center ?				
	b) Do you have an area/environment dedicated to administrative activities (monitoring, auditing and inspection, etc.)?				
	c) Do you have an area/environment designated for data recording and processing?				
	d) Do you have computing resources to manage the information generated: printer and Internet access?				
	f) Do you have communication equipment: telephone, fax?				
	g) Do you have a photocopier or scanner?				
Chapter 2 in 2.10, 2.11 of BPC1	**2.5. On the Archives and the Conservation of Documents Related to Clinical Trials**	**BUT**			**OBSERVATIONS**
	a) Do you have an area/environment defined for archiving and conservation with restricted and controlled access? ensuring the confidentiality of records?				
Art. 38° DS 013-2006	b) Do you have designated staff to organize, maintain and manage the documentation file?				
	c) Do you have furniture (filing cabinets) for exclusive use for filing clinical trial documentation?				
	2.6. About the Clinical Area for Clinical Trials	**YES**	**NO**		**OBSERVATIONS**
	Waiting room				
	a) Do you have a waiting room?				

[1] GCP. Good Clinical Practice Standards approved by WHO 1995

Attached: Annex **"DOCUMENTATION",** which must be available at the Research Center.

	b) Is the waiting room adequate and comfortable for the research subjects?			
Art. 14° inc. d) BPA2	c) Are the sanitary services located outside the area designated for the conservation and storage of investigational products?			
	Environment for Informed Consent			
	a) Do you have an area/environment designated for interviewing the subject under investigation?			
	Triage Area			
Art, 12°, 32° inc. e) and Art. 37° DS 013-2006-SA	a) Is the equipment in the triage area calibrated (blood pressure monitor, scale)?			
Art. 32° DS 013-2006	b) Do the equipment and instruments have valid calibration certificates?			
	c) Does the equipment used in the triage area have a visible label indicating the date of the last calibration?			
	Medical Care Area for Research Subjects			
	a) Do you have an area designated for medical care and physical examination of the research subject?			
	b) Would the designated area protect the privacy and intimacy of the research subjects?			
	Emergency medical care			
	a) Do you have an emergency medical team for the timely care of subjects under investigation, in the event of any SAE or Unexpected Event?			
	b) If your Research Institution is a health facility WITHOUT hospitalization, in the event of an emergency, do you have an agreement or contract with a clinic or health center for such care?			
	2.7 Conservation of Research Products	**BUT**		**OBSERVATIONS**
Art. 14° BPA1	a) Do you have an area designated for the conservation and storage of research products?			
	b) Is the area for conservation and storage of these products restricted and with controlled access?			
Art. 37° inc. d) y Art. 38° DS 013-2006	c) Do you have designated personnel with technical and appropriate competence to ensure the correct conservation and storage of the research products?			
Art. 18°BPA2	d) Are the hygienic and sanitary conditions of the area designated for the conservation and storage of the products under investigation adequate?			
Art. 22° BPA2	e) Is the area for storing research products that require preservation at room temperature conditioned: does it have controlled temperature and humidity?			
	f) Do you have furniture (cabinets) designed for the proper and safe storage of research products at room temperature? Do each cabinet have a lock?			
Art. 16° BPA1	g) Do you have an exclusive refrigerator for the storage of research products that require special conditions for their storage?			
	h) Do you have a thermometer/thermo-hygrometer?			
Art. 14° DS 013-	i) Do you have devices that allow you to alert in the event of a power outage?			

[1] BPA: Good Practice Standards for the Storage of Pharmaceutical and Related Products approved with RM 585-99-SA/DM
[2] BPA: Good Practice Standards for the Storage of Pharmaceutical and Related Products approved with RM 589-99-SA/DM

Attached: Annex **"DOCUMENTATION",** which must be available at the Research Center.

2006	of electric fluid? Specify what type of device?			
	2.8 Dispensing Unit for Clinical Trials YES NO			**OBSERVATIONS**
Art. 90 DS 017-2006 SA	a) Do you have an area/environment for the dispensing of investigational products?			
Art. 37° inc. d) y Art. 38° DS 013-2006	b) Do you have designated personnel with technical and suitable competence to guarantee correct dispensing?			
	c) Do you have an area/environment to prepare and administer the investigational products for parenteral use?			
	3. ASPECTS RELATED TO THE LABORATORY YES NO			**OBSERVATIONS**
Art. 38° DS 013-2006	a) Do you have designated personnel to take samples from research subjects?			
	b) Do you have designated personnel for sample processing and storage?			
	c) Do you have a refrigerator assigned exclusively for the storage of biological samples?			
Art, 12°, 32° and 37° inc. e) DS 013-2006-SA	d) Are the laboratory equipment and instruments (Refrigerator, Centrifuge, thermometer) calibrated?			
Art. 32° DS 013-2006	e) Do the equipment and instruments (refrigerators, centrifuges, thermometers) have a visible label indicating the date of the last calibration?			
	f) Do the equipment and instruments have valid calibration certificates?			

RESPONSIBLE FOR THE RESEARCH CENTER	**DAYS**	**BUSINESS**
First and Last Names:		
REPRESENTATIVE OF THE RESEARCH INSTITUTION		
First and Last Names:		
EVALUATION TEAM		
First and Last Names:		
First and Last Names:		

Reference Regulations:

Law 26842, General Health Law (Article 37)

- Good Clinical Practice Standards approved by WHO
- Supreme Decree No. 017-2006-SA, Regulation of Clinical Trials in Peru.
- Supreme Decree No. 006-2007-SA, which modifies the Clinical Trials Regulations in Peru.
- Supreme Decree No. 013-2006-SA, Regulation of Health Establishments and Medical Support Services.
- RM No. 769 – 2004 - MINSA, Technical Standard 021-MINSA/DGSP/V.01 “Categories of Health Sector Establishments”.
- RM No. 585 – 99 - SA/DM, which approves the Manual of Good Practices for Storage of Pharmaceutical and Related Products.

ANNEX

Documentation that must be available at the Research Center

1. Copy of the current Document, by which the DISA/DIRESA/GERESA (as appropriate) grants the Category to the Health Establishment.
2. Copy of registration in RENAES (National Registry of Health Establishments).
3. Approval document from the Research Institution **(Health Establishment)** signed by the Medical Director/Health Care Manager[3] , for the operation of the Research Center[2] , 4. Payroll document of the health personnel (professional, technical and auxiliary) with the technical and suitable competence, assigned to the Research Center, indicating the registration number, specialty and its qualification (as appropriate), functions and positions, as appropriate. [4]
5. Copy of the Clinical Trials Regulations in Peru and its Amendments.
6. Copy of the current contract with the company in charge of the Collection, Transportation and Final Disposal of Solid Waste, if carried out by contracting to third parties. **5**
7. Copy of agreement with Health Establishments for care in medical emergency situations (for (non-residential institutions)

Standard Operating Procedures Manuals, Programs and Plans: 6

8. Procedure for Sampling.
9. Procedure for the Processing, Conservation and Storage of Biological Samples.
10. Procedure for the Management, Treatment and Disposal of Solid Waste.
11. Procedure for the Packaging and Transportation of Biological Samples.
12. Procedure for the Entry and Management of clinical trial data.
13. Procedure for Data Protection, Software. **7**
14. Procedure for Filing Documentation Related to Clinical Trials.
15. Procedure to Prevent the Destruction of Documentation, related to EC in case of disasters.
16. Procedure for the Conservation and Storage of Investigational Products.
17. Procedure for the Dispensing of Investigational Products.
18. Biosecurity Standards, Manual or Procedures.
19. Contingency or Response Plan in case of Power Outage.
20. Training Program for Health Personnel (professional, technical and auxiliary) assigned to the Center for Research, related to clinical trials, according to the assigned functions and activities. [8]
21. Preventive Maintenance and Calibration Program for Equipment (medical, electromedical, security and others according to the nature of its activities (specifying its own from those provided by third parties), differentiating those for shared and exclusive use by the Research Center[9] .

1 Article 54° DS No 017-2006-SA
2 Article 53° DS No 017-2006-SA
3Articles 4° and 5° DS No 013-2006-SA
4 Articles 3°, 4°, 5°, literal d) Art. 37° and Art. 38° DS No 013-2006-SA
[5] (Articles 11 and 34 of DS No. 013-2006-SA
Articles 3, 5 and 42 of DS No. 013-2006-SA
7Art. 5º DS-013-2006-SA, 5.9.4. y literal b) 8.10.2 BPC
Articles 3 and 41 of DS No. 013-2006-SA
[9] (Articles 12°, 32° and literal e) Art. 37° DS 013-2006-EN