	FORM	FOR-OGIT-028
	REQUEST FOR AUTHORIZATION OF THE CLINICAL TRIAL	Edition No. 03

Instructions: *Dear User, remember that the application must be filled out through the electronic form available in the Peruvian Registry of Clinical Trials – REPEC and in both languages Spanish and English, as requested. See http:// www.ensayosclinicos-repec.ins.gob.pe Information required on this form that does not apply or does not apply to your Institution or clinical trial must be completed with the acronym NA (Not applicable).*

RNE code:
(Automatically generated during electronic registration in the REPEC)

I. SPONSOR INFORMATION
(Fill in details as appropriate)

Foreign ☐ **National**

1. PERSONA NATURAL ☐
(Persona Individual)

Last name:		Mother's last name:	
Names:		DAYS/CE:	
Email:		Telephone and annex:	
Legal domicile: *(District, Province and Department)*			

2. LEGAL PERSON ☐
(Company, Corporation or Organization)

2.1 FOREIGN SPONSOR
(Previously registered in the REPEC of the INS)

Registered Name: *(Pursuant to the Certificate of Incorporation of the company, company or organization or the equivalent instrument in the country of origin).*		Tradenames Registered: *(From the company or Organization)*	
Commercial registration number:		Name and surname of legal representative: *(Duly empowered, to act as its representative and grant powers in your name)*	
Identity document number of the legal representative: *(The document equivalent to the country of origin)*		Position held in the organization:	
Email:		Telephone and annex:	
Legal domicile:		Postal Code:	

2.1.1 REPRESENTATIVE OF THE FOREIGN SPONSOR IN PERU
(Check one of the options)

FILIAL ☐ **BRANCH** ☐ **OIC** ☐ **OTHER:** ..... ☐

RUC:		Business name: *(Data of your legal representative add them in paragraph 2.3 and 2.4)*	
Tradename:		Telephone and annex:	

2.2 NATIONAL SPONSOR
(Previously registered in the REPEC of the INS)

RUC:		Business name: *(Data of your legal representative add them in paragraph 2.3 and 2.4)*	
Tradename:		Telephone and annex:	
Email:			

2.3 LEGAL REPRESENTATIVE (For a company, accredited in the validity of the power / for a public entity, accredited in the Resolution that designates it):
(If there is a person other than the legal representative as an attorney-in-fact, he must have the special power which must be expressly indicated by him. or the acts for which it was conferred)

Last name:		Mother's last name:	
Names:		DAYS/CE:	
Power registered in the Office Registry - SUNARP: *(Complete if you are from Lima or province)*		Cargo:	
Electronic item No.:		Seat No.:	
Resolution No. designating it: *(Complete this item only if it is an entity public and detail the full name of the resolution)*		Date: *(Day, month and year)*	
Email:		Telephone and annex:	

2.4 ADDRESS OF THE LEGAL REPRESENTATIVE

Address:		District:	
Province:		Department:	

2.5 OTHERS
If you consider any additional information important, add it.

II. GENERAL INFORMATION OF THE CLINICAL TRIAL

1. IDENTIFICATION OF THE CLINICAL TRIAL

Scientific Title (Spanish):	**Scientific Title (English):**
Title for the Public (Spanish):	**Title for the Public (English):**

Protocol Code:		**Secondary ID(s)**	
		WHO UTN:	
		Clinicaltrials.gov:	
		EUDRACT N°:	

Application Condition Authorization: (According to Article 68)	☐ It has authorization for research on human beings by Drug Regulatory Authorities of countries with high health surveillance. ☐ It is produced in our country, has pre-clinical research and adjusts to the policies and/or research priorities determined by the MINSA. ☐ Establishes therapeutic equivalence of pharmaceutical products or similarity of biological products. ☐ They are considered priorities for the country's public health or are within the policies and/or research priorities determined by the MINSA. ☐ At the request of the ANM, clinical trials are required to support its effectiveness and safety for health registration.

Total national budget of clinical trial (S/)		**Expiration Date Insurance policy**	
Clinical Phase from the study:	☐ I ☐ II ☐ III ☐ IV ☐ Does not apply	**Total duration of the trial Clinical:**	_____ months

Enrollment start date worldwide: (de/mm/asa):		**Estimated start date enrollment in Peru (of/mm/as) :**	
Recruitment status in Peru	☐ Without starting recruitment ☐ In recruitment ☐ Recruitment stopped ☐ Closed recruitment		
Other characteristics of the EC Superiority		☐ Yeah	☐ No
	Equivalence	☐ Yeah	☐ No
	Non-inferiority	☐ Yeah	☐ No
	Dose response **2.**	☐ Yeah	☐ No

OBJECTIVES AND DESIGN OF THE CLINICAL TRIAL

Allocation method	☐ Randomized ☐ Not randomized ☐ Does not apply	**Blinding type:**	☐ Double ☐ Triple ☐ Simple ☐ Open
Assignment	☐ single arm ☐ Parallel groups ☐ Crossed ☐ Factorial ☐ Other:_____(Spanish) _____(English)		

Detailed design description (Spanish):	**Detailed design description (English):**
Purpose/Primary Objective (Spanish):	**Purpose/Primary Objective(English):**

3. STUDY INTERVENTION

Product type in investigation	Indicate if the product is being developed as: ☐ pharmaceutical product ☐ medical device ☐ herbal product ☐ galenic product ☐ Complementary product ☐ Dietary product and sweetener ☐ Others: ……

Identification of the investigational product:

N°	Product name	Name of Product	kind of product	ATC
N°	**Comparator Name**	**Comparator**	**kind of product**	**ATC**

Description of the intervention(s): Point out:				**Description of Intervention(s):** *(English)* Point out:			
Name of Group	**Group Type**	**No. of subjects**	**Description of the intervention**	**Name of Group**	**Group Type**	**No. of subjects**	**Description of the intervention**
	☐ Experimental ☐ Control		*Name of the intervention, Form pharmaceutical, dosage and frequency, duration of treatment, route of administration.*		☐ Experiment ☐ Control		*Name of the intervention, Form pharmaceutical, dosage and frequency, duration of treatment, route of administration.*
	Experimental Control				☐ Experiment ☐ IControl		

Treatment time subjects		**Subject Follow-up Time:**	

4. STUDY POPULATION

Key Inclusion Criteria (Spanish): 1. 2. 3.	**Key Inclusion Criteria (English):**
	1.
	2.
	3.
Key Exclusion Criteria (Spanish): 1. 2.	**Key Exclusion Criteria (English):**
	1.
	2.
3.	3.

Disease or medical condition studied:			
Disease classification studied (ICD-10):		**Medical speciality:**	
Countries in which the recruitment:			
Number of subjects to include world level:		**Estimated number of subjects include in Peru:**	

Population to be included according to sex	☐ Women	☐ Men	☐ Both genders		
Indicate if the population of study includes:	healthy volunteers	☐ Yeah	☐ No		
	Subordinate groups	☐ Yeah	☐ No		
	Indigenous or native peoples	☐ Yeah	☐ No		
	Minors	☐ Yeah	☐ No		
	Subjects with disabilities to give consent	☐ Yeah	☐ No		
	Women of childbearing age	☐ Yeah	☐ No		
	Pregnant women	☐ Yeah	☐ No		
	Women during labor, postpartum or breastfeeding	☐ Yeah	☐ No		
	Fetuses	☐ Yeah	☐ No		
Age range of subjects include:	Adults (18-64 years)	☐ Yeah	☐ No		
	Older Adult (>= 65 years)	☐ Yeah	☐ No		
	Under 18 years old	☐ Yeah	☐ No		
	• In utero	☐ Yeah	☐ No		
	• Premature newborns (up to an age pregestational < 37 weeks)	☐ Yeah	☐ No		
	• Newborns (0-27 days)	☐ Yeah	☐ No		
	• Infants and preschoolers (28 days - 23 months)	☐ Yeah	☐ No		
	• Children (2 - 11 years)	☐ Yeah	☐ No		
	• Adolescents (12 - 17 years)	☐ Yeah	☐ No		

5. ASSESSMENT CRITERIA

Primary Assessment Criteria (Spanish)			Primary Assessment Criteria (English)		
Endpoint name	Measurement method used	time in which measurement assessment out	Name of the criterion of the	Measurement method used	Time in which the measurement will be carried out

Secondary Assessment Criteria (Spanish)			Secondary Assessment Criteria (English)		
Criterion name assessment will be carried out	Measurement method used the assessment	time in which used that will be me	Criterion name asured will be measured	Method of measurement	Time in the

6. DATA MONITORING

Is there an interim analysis planned?	☐ Yeah ☐ No	**Existence of a Data Monitoring Committee (CMD)**	☐ Yeah ☐ No

III. FINANCING SOURCE INFORMATION

1. INFORMATION ON THE SOURCE OF FINANCING

Sponsor name *(Responsible for financing a clinical trial)*	

2. SPONSOR RESPONSIBILITIES

(If transferring tasks and functions related to the EC, specify that its representative in the country must have the Delegation of Responsibilities. Likewise, clearly defined activities must be delegated one by one in order to prevent other unrelated activities from being carried out that are not known to the sponsor, who is the one who bears the responsibility for the initiation, maintenance, conclusion and financing of a project. clinical trial).

Name of the Institution	Responsibility	Observations
	Inform the OGITT of the INS when the first research subject is enrolled in Peru and the end date of enrollment in the country.	
	Present progress reports to the National Institute of Health during the execution of the Clinical Trial.	
	Present the final reports to the OGITT of the INS as well as the results, conclusions and publication of the clinical trial.	
	Notify the OGITT of the INS of adverse events and deviations as established by the Clinical Trials Regulations.	
	Inform and detail in writing the reasons for suspension and cancellation of the clinical trial.	
	Provide facilities for the inspection of the execution of the clinical trial by the staff of the General Office of Research and Technology Transfer (OGITT) of the National Institute of Health.	
	Detail one by one the activities to delegate:	
Document by which the sponsoring Legal *days, duly apostilled as established by the Hague* *(The document must be legible for the purpose of of the person from the foreign place of official document, the position held in the organization and the information of the person to whom the power is granted in Peru and the period of validity if applicable)*	**Document has delegated** *(Not older than 90 calendar Convention or Legalized by the Ministry of* **responsibilities for the EC.** *External relationships. If applicable, the simple translation must be attached with the indication and subscription of the duly identified translator, in order to display the name translations). who signs the*	**Date** dd/mm/aaaa

(Consign express powers for the withdrawal of the claim of the procedure of the EC authorization application and for the presentation of resources administrative if applicable).		

IV. RESEARCH CENTER, PRINCIPAL INVESTIGATOR and ETHICS COMMITTEE

1. RESEARCH CENTERS WHERE THE CLINICAL TRIAL WILL BE EXECUTED

Name of the Center Investigation	
RCI No.:	

2. PRINCIPAL INVESTIGATOR OF THE RESEARCH CENTER WHERE THE RESEARCH WILL BE EXECUTED CLINICAL TRIAL

Surnames and names:		Document No. Identity:	
Address:		District:	
Province:		Department:	
Telephone and annex:		Email:	

3. CO-INVESTIGATORS

Surnames and names:		Document No. Identity:	
Address:		District:	
Province:		Department:	
Telephone and annex:		Email:	

4. INSTITUTIONAL RESEARCH ETHICS COMMITTEE (CIEI) THAT APPROVED THE TEST FOR CENTER

Institution:			
Approval date V.		**Due date**	

CLINICAL TRIAL DOCUMENTS UNDER WHICH THE APPLICATION IS SUBMITTED

Protocol (Indicate version and date)	
Consent forms informed (Indicate version and date)	

SAW. SHARING OF CLINICAL TRIALS DATA (ANIMIZED INDIVIDUAL DATA)

Is there a plan for the data anonymized individuals of the research subjects, including data dictionaries, are available others researchers?	Choose one: ☐ Yeah ☐ No ☐ Not decided
	Description of the plan, in case of YES response
	Briefly describe which subject data sets will be shared, when will this data be available and how the data can be obtained.
Additional information that will be shared	Select all that apply ☐ Study protocol ☐ Statistical Analysis Plan ☐ Informed consent form ☐ Clinical Study Report ☐ Others: ……(Spanish), ... (English)

	Briefly describe when this information will be available and how it can be obtain.
URL	Website address where you can find additional information regarding the plans data sharing.
VII. EC Registration Date *(Automatically generated during electronic registration in REPEC)*	

VIII. INFORMATION OF CONTACT PERSONS OF THE CLINICAL TRIAL

1. INFORMATION OF THE CONTACT PERSON(S) FOR INQUIRIES ABOUT THE CLINICAL TRIAL

Names and surnames		**DAYS/CE**	
Email		**Telephone and attachment**	
Type of query to answer	☐ For general information: ☐ For administrative queries: ☐ For scientific inquiries:		

2. DATA OF THE PERSON WHO CARRIED OUT THE TRANSLATION OF THE DATA SHEET

Names and surnames		**DAYS/CE**	
Email		**Telephone and attachment**	

3. DATA OF THE PERSON RESPONSIBLE FOR THE INFORMATION REGISTRATION

Names and surnames		**DAYS/CE**	
Email		**Telephone and attachment**	

IX. REQUIREMENTS FOR REQUESTING CLINICAL TRIALS AUTHORIZATION

1. Request for authorization of the clinical trial, according to the registration form established in the Peruvian Registry of Clinical Trials (REPEC) that includes information from payment receipt No.…….. of closes ……./……./……. (FOR-OGITT-028)	
2. Copy of the approval document issued by the legal representative of the research institution(s) where the clinical trial will be carried out according to the model established in the Clinical Trial Procedures Manual.	
3. In the case of a foreign sponsor: Copy of the proof of the delegation of functions to the representative of the sponsor, duly apostilled, otherwise legalized by the Ministry of Foreign Affairs of Peru.	
4. Copy of current insurance policy (Insurance contract) acquired by the sponsor.	
5. Sworn declaration from the sponsor that it has a financial fund that immediately guarantees the free care and treatment of the research subject, in the event that they suffer any adverse event as a consequence of the clinical trial, as long as the activation of the research policy occurs. safe and according to the model established in the Clinical Trial Procedures Manual. (FOR-OGITT-029)	
6. Detailed total national budget for the clinical trial, according to the model established in the Manual of Clinical Trial Procedures. (FOR-OGITT-032)	
7. Affidavit according to the model established in the Clinical Trial Procedures Manual, signed by the sponsor and principal investigator, which establishes that there is no financial conflict of interest in the execution of the clinical trial. (FOR-OGITT-063)	
8. Affidavit signed by the sponsor and principal investigator on the conditioning of the research center where the clinical trial will be carried out, according to the model established in the Manual of Clinical Trials Procedures. (FOR-OGITT-064)	

9. Research protocol in Spanish version and in original language if it is different from Spanish, and Informed Consent Form(s), according to the respective Annex 1 and Annex 4, of the Clinical Trials Regulations, approved by the CIEI accredited by the INS, also attaching to each of them the copy of the approval document issued by the respective CIEI, according to the model established in the Manual of Clinical Trials Procedures. These documents are presented electronically (PDF format to copyable text).	
10. Updated Researcher's Manual, in Spanish version and original language if it is different from Spanish. This may be replaced according to the conditions indicated in Annex 2 of this Regulation. These documents are presented electronically (PDF format to copyable text).	
11. Information related to the quality of the product under investigation (electronic medium) according to Annex 5 of the this regulation.	
12. List of supplies necessary for the development of the test according to the format established in the Manual of Clinical Trial Procedures. (FOR-OGITT-033)	
13. Updated, undocumented curriculum vitae of the entire research team at each research center. research, according to the model established in the Manual of Clinical Trial Procedures, attaching a copy of the documents that accredit training in Good Clinical Practices and Ethics in Research in human beings of the entire research team, with a validity of no more than three (3) years of antiguaty. (FOR-OGITT-031)	

X. CONTENT OF THE DECLARATION

I declare that the information indicated below is an Affidavit, committing myself to the following:

- I will conduct this study in accordance with the guidelines of Good Clinical Practice and will assume the responsibilities provided for in Article 40 and 42 of the Clinical Trials Regulations.
- Likewise, I assume the responsibility of supervising that the Principal Investigator complies with the Good Practice guidelines. Clinical Practices, ethical standards and with the responsibilities provided for in Article 52 of the Trial Regulations Clinicians.

XI. SIGNATURE

I declare 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 numeral 1.7 of article IV of the Preliminary Title of the Single Ordered Text of Law No. 27444 - General Administrative Procedure Law, approved with Supreme Decree 004-2019-JUS.

As a sign of agreement, I sign this document.

City,……of .....of 20…

Name and signature
Legal Representative (section 2.3)

NOTE: *All documents must be paged, presented to the National Institute of Health in a folder or filing cabinet and arranged in order. according to what is established in the requirements, indicating the names of each of them using separators.*