	FORM	FOR-DIIS-036
	APPLICATION FOR EXPANSION OF THE NUMBER OF CENTERS INVESTIGATION	Edition No. 01

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

I. SPONSOR'S DATA		Foreign: ☐	National: ☐
1. NATURAL PERSON ☐			
Father's Surname:		Mother's Surname:	
Names:		DNI/ CE/ PAS:	
Email:		Telephone and extension:	
Legal Address: *(District, Province and Department)*			
2. LEGAL ENTITY ☐			
2.1. FOREIGN SPONSOR *(Previously registered in the INS REPEC)*			
Registered Name: *(According to the Certificate of Incorporation of the company, business or organization or instrument equivalent in the country of origin).*		Registered Trade Names: *(From the company or organization).*	
Commercial registration number:		Names and surnames of the legal representative: *(Duly empowered to act as representative of this 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 extension:	
Legal address:		Zip code:	
2.1.1. REPRESENTATIVE OF THE FOREIGN SPONSOR IN PERU *(Check one of the options)*			
☐ SUBSIDIARY:	☐ BRANCH:	☐ OIC:	☐ OTHER: _____
RUC:		Company Name: *(Data of your legal representative add them in numerals 2.3 and 2.4)*	
Trade Name:		Telephone and extension:	
2.2. NATIONAL SPONSOR: *(Previously registered in the INS REPEC)*			
RUC:		Company Name: *(Data of your legal representative added in numerals 2.3 and 2.4)*	
Trade Name:		Telephone and extension:	
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): *(If there is a person other than the legal representative as an attorney, he/she must have the special power which must expressly indicate the act(s) to be performed. which was conferred)*			
Father's Surname:		Mother's Surname:	
Names:		DNI/ CE/ PAS:	
Power of attorney registered at the Office Registry - SUNARP: *(Complete if you are from Lima or province)*		Post:	

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Electronic record No.:		Seat No.:	
Resolution number that designates him: *(Complete this item only if you are an entity public and detail the full name of the resolution)*		Date: *(Day, month and year)*	
Email:		Telephone and extension:	

2.4. ADDRESS OF THE LEGAL REPRESENTATIVE:
If you consider any additional information important, add it.

Address:		District:	
Province:		Department:	

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

TYPE OF INSTITUTION

II. GENERAL INFORMATION ABOUT THE CLINICAL TRIAL

Clinical Trial Title: *(Enter as shown in the REPEC)*			
EC INS No.:		Policy Expiration Date Insurance:	

III. INFORMATION REGARDING THE EXPANSION OF THE NUMBER OF RESEARCH CENTERS

3.1. Justification of the reasons for expanding the number of research centers
If you consider any additional information important, you can attach it as an annex.

Research Center 1 of 1

3.2. Data of the Research Center to be expanded

Research Institution:	
RCI No. and Name of the Center Investigation:	

3.3. Principal Investigator of the Research Center

First and Last Names:		Identity Document Number:	
Address:		District:	
Province:		Department:	
Telephone and extension:		Email:	

3.4. Co-researchers

Co-investigator 1 of 1

First and Last Names:		Identity Document Number:	
Address:		District:	
Province:		Department:	
Telephone and extension:		Email:	

3.5. Data from the Institutional Research Ethics Committee (CIEI)

Research Institution:			
RCIEI No. and name of the CIEI:			
Approval date:		Expiration date:	

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4. CLINICAL TRIAL DOCUMENTS UNDER WHICH THE APPLICATION IS SUBMITTED

4.1. PROTOCOL (version/date)

Note: The information you enter will be used verbatim to generate the resolution that resolves your request to expand the number of research centers.

4.2. Informed Consent Form(s) (version/date)

Initial Version of Consent Form

New Version of Consent Form

Note: The information you enter will be used verbatim to generate the resolution that resolves your request to expand the number of research centers.

IV. REQUIREMENTS FOR THE APPLICATION TO EXPAND THE NUMBER OF RESEARCH CENTERS

a Request for expansion of the number of research centers, justifying the reasons for the expansion, includes information on the Payment voucher No. ... dated ... (FOR-DIIS-036) ☐

b Copy of the approval document issued by the legal representative of the research institution(s) where the clinical trial will be conducted, according to the model established in the Clinical Trials Procedures Manual, for the additional research center ☐

c Copy of the research protocol approval document and the informed consent form(s) issued by the respective CIEI accredited by the INS, according to the model established in the Clinical Trials Procedures Manual, for the additional research center. ☐

d Informed consent form(s) according to Annex 4 of these regulations, approved by the CIEI. ☐

and 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-DIIS-063). ☐

f 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 Clinical Trials Procedures Manual (FOR-DIIS-064). ☐

g Updated undocumented curriculum vitae of the entire research team of each research center, according to the model established in the Clinical Trials Procedures Manual, attaching a copy of the documents that prove training in Good Clinical Practices of the entire research team, with a validity of no more than three (3) years old. (FOR DIIS-031) ☐

V. FIRMA

I declare that the information provided is true and I authorize the verification of the statements in accordance with the "Principle of Presumption of Truth" of section 1.7 of article IV of the Preliminary Title of the Consolidated Text of Law No. 27444 - General Administrative Procedure Law, approved by Supreme Decree 004-2019-JUS.

In token of conformity, I sign this document.

Date ____/____/____ - Time:

_____

Legal Representative (item 2.3)

NOTE:

- All documents must be paginated, submitted to the National Institute of Health in a folder or filing cabinet, and organized according to the requirements, indicating the names of each document using dividers.