	FORM	FOR-OGIT-036
	REQUEST FOR EXPANSION OF THE NUMBER OF CENTERS INVESTIGATION	Edition No. 02

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

1. SPONSOR INFORMATION

Foreign ☐ **National** ☐

1.1.PERSONA NATURAL ☐

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

1.2. LEGAL PERSON ☐

SPONSOR REPRESENTATIVE IN PERU

(Data of the representative who channels all communication with the INS OGITT during the execution of the study)

FILIAL ☐ **BRANCH** ☐ **OIC** ☐ **OTHER:** …… ☐

RUC:		Business name: *(Add details of your legal representative in sections 1.2.1 and 1.2.2)*	
Tradename:		Telephone and annex:	

1.2.1. 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, the person must have the special power. which must expressly indicate it 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 you are a public entity and detail the full name of the resolution)*		Date: *(Day, month and year)*	
Email:		Telephone and annex:	

1.2.2. ADDRESS OF THE LEGAL REPRESENTATIVE

Address:		District:	
Province:		Department:	

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

2. GENERAL INFORMATION OF THE CLINICAL TRIAL	
Clinical Trial Title: *(Enter as it appears in the REPEC)*	
N° EC INS:	
Expiration Date **Insurance policy:**	

3. 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.*	
3.2 Research center data to be expanded	
Name of the Center Investigation:	
RCI No.:	
3.3. Data from the Institutional Research Ethics Committee (CIEI)	
Name of the CIEI	
RCEI N°	
3.4.Principal researcher of the Research Center	
Names	
Surnames	

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 format(s) (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

5. REQUIREMENTS FOR THE REQUEST FOR AN EXPANSION OF THE NUMBER OF RESEARCH CENTERS	
to. Request to expand the number of research centers, justifying the reasons for the extension, includes information on payment receipt No……..of date ……./……./……. (FOR-OGITT-036)	☐
b. 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 Manual of Clinical Trials Procedures, for the additional research center	☐
c. Copy of the approval document of the research protocol and the informed consent form(s) issued by the respective CIEI accredited by the INS, according to the model established in the Manual of Clinical Trials Procedures, for the additional research center .	☐
d. Informed consent format(s) according to Annex 4 of these regulations, approved(s) 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 OGITT-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 Trial Procedures Manual. (FOR OGITT-064)	☐
g. Updated undocumented curriculum vitae of the entire research team of each research center, according to the model established in the Manual of Clinical Trials Procedures, attaching a copy of the documents that accredit training in Good Clinical Practices of the entire research team, with a validity of no more than three (3) years old. (FOR OGITT-031)	☐

6. COMPANY

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 paragraph 1.7 of article IV of the Preliminary Title of the Single Text Ordered from 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 1.2.1)

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