
	FORM	FOR-OGIT-044
	REQUEST FOR AUTHORIZATION OF REPORT OF AMENDMENT TO THE CLINICAL TRIAL	Edition No. 02

RNE code: <i>(Automatically generated during electronic registration in REPEC)</i>			
1. SPONSOR INFORMATION		Foreign <input type="checkbox"/>	National <input type="checkbox"/>
1.1. PERSONA NATURAL <input type="checkbox"/>			
Last name:		Mother's last name:	
Names:		DAYS/CE:	
Email:		Telephone and annex	
Legal domicile: <i>(District, Province and Department)</i>			
1.2. LEGAL PERSON <input type="checkbox"/>			
SPONSOR REPRESENTATIVE IN PERU <i>(Data of the representative who channels all communication with the INS OGITT during the execution of the study)</i>			
FILIAL <input type="checkbox"/>	BRANCH <input type="checkbox"/>	OIC <input type="checkbox"/>	OTHER: <input type="checkbox"/>
RUC:		Business name: <i>(Add details of your legal representative in sections 1.2.1 and 1.2.2)</i>	
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): <i>(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)</i>			
Last name:		Mother's last name:	
Names:		DAYS/CE:	
Power registered in the Office Registry - SUNARP: <i>(Complete if you are from Lima or province)</i>		Cargo:	
Electronic item No.:		Seat No.:	
Resolution No. designating it: <i>(Complete this item only if you are a public entity and detail the full name of the resolution)</i>		Date: <i>(Day, month and year)</i>	
Email:		Telephone and annex:	
1.2.2. ADDRESS OF THE LEGAL REPRESENTATIVE			
Address:		District:	

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B. Amendment to the Informed Consent Form(s):

Document name, version and date	Nº the RCI	Research Center where it will be applied	CIEI that approves the amendment	Close of approval by CIEI

Note: The information you enter will be used verbatim to generate the amendment report authorization letter.

4. REQUIREMENTS FOR THE REQUEST FOR AUTHORIZATION OF AN AMENDMENT REPORT

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|---|--|
| <p>to. Request for an amendment report that includes the list of documents to be amended (document, version and date), includes payment receipt information
No.....of closing/...../..... (FOR-OGITT-044)</p> <p>b. Justification of the proposed changes.</p> <p>c. Protocol and/or Informed Consent Form(s) with change control in Spanish version and also in original language if it is different from Spanish. These documents are presented electronically (PDF format to copyable text).</p> <p>d. Research protocol with the amendment integrated in the Spanish version and in the original language if it is different from Spanish and/or final Informed Consent Form(s), also attaching a copy of the document approving the amendment to the research protocol and/or informed consent form(s) issued by a CIEI accredited by the INS. These documents are presented electronically (PDF format to copyable text).</p> | <input type="checkbox"/>

<input type="checkbox"/> |
|---|--|

5. 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 numeral 1.7 of article IV of the Preliminary Title of the Single Ordered Text of Law No. 27444 - Law of General Administrative Procedure, 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 (item 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.