	FORM	FOR-OGIT-053
	NOTIFICATION OF DEVIATIONS TO THE PROTOCOL	Edition No. 01

Instructions: *Dear User, remember that the application must be filled out through the electronic form available in the Peruvian Registry of Clinical Trials (REPEC) at: http:// www.ensayosclinicos-repec.ins.gob.pe*

RNE code: *(Generated automatically during electronic registration in the REPEC)*

1. NOTIFYING INSTITUTION

Name of the Institution :	*(Automatically generated during electronic registration in REPEC)*		
Legal representative			
Last name:		**document Identity:**	
Mother's last name:		**Telephone:**	
Names:		**Email:**	

2. GENERAL INFORMATION OF THE CLINICAL TRIAL

EC INS N°: *(Generated automatically during electronic registration in REPEC)*

Clinical Trial Title:

Sponsor:	**Institution that legally represents the sponsor in the country:**

Note: If there is more than one company/ institution/ other with delegation of responsibilities, add the necessary spaces

Clinical Phase from the study: ☐ I ☐ II ☐ III ☐ IV ☐ Does not apply	**Protocol Code:**
Insurance Policy Expiration Date	

3. IDENTIFICATION OF THE NOTIFICATION

3.1 Type of deviation	☐ Critical or very serious ☐ Major or serious		
3.2 Research Institution:			
3.3 Research center		**3.4 RCI No.**	
3.5 Principal Investigator			

If the impact of the deviation affects all research centers in the country, the following must be selected:

☐ All authorized research centers

3.6 Date of occurrence of the deflection (dd/mm/aaaa)		**3.7 Date of taking cognizance by the sponsor / OIC (dd/ mm/aaaa)**	
3.8 Date of notification Ethics Committee (dd/mm/yyyy)			

4. INFORMATION ABOUT THE DEVIATION TO THE PROTOCOL

Has or may have an impact on (check all that apply):	☐ Safety of research subjects ☐ Research product ☐ Scientific value/data integrity ☐ Confidentiality/informed consent ☐ Others (specify:		
Detailed description of the deviation:			
Did the deviation result in a serious adverse event?	☐ And ☐ No	**If the answer is YES, indicate:**	
		Notification date of EAS	
		EAS No. (according to REAS-Net)	
Is the subject continuing in the study?	☐ And ☐ No		

Detailed description of actions taken

Must include:

a) The corrective actions carried out must be included as well as the preventive actions to be implemented to ensure that the deviation does not occur again

b) For each corrective or preventive action you must indicate:

- *Type of action: corrective or preventive*
- *Action or measure to be implemented*
- *Date of compliance of the measure (executed or estimated)*
- *Personnel involved or responsible for its application*

c) Attach the information indicated in this section as an attachment.

INS notification date:	*(Generated automatically upon completion of registration)*

Form approved by RD No. 585 -2017-OGITT-OPE/INS **Date: 04 - 10 - 2017**

4. AUTHORIZED LEGAL REPRESENTATIVE

By signing this application, I certify that the information contained herein is true and accurate.

_____

Signature of Authorized Legal Representative

Surnames and names:

Date: / /