"Year of Good Citizen Service"

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The National Institute of Health, through the General Office of Research and Technology Transfer, as the regulatory authority in Clinical Trials, is in charge at the national level of ensuring compliance with the Clinical Trials Regulation and the related regulations that govern the authorization and execution of clinical trials, as well as dictate the complementary provisions required for their application.

The Clinical Trials Regulations approved with Supreme Decree N°021-2017-SA and Errata
Supreme Decree N°021-2017-SA Regulation of Clinical Trials dated July 21, 2017, in **Article 40,** among other responsibilities, establishes that the Sponsor is responsible for:

"n) Notify critical or very serious and major or serious deviations from the clinical trial protocol within a maximum period of seven (7) calendar days from when the sponsor or OIC becomes aware of them."

In this context, the OGITT-INS has developed the electronic form FOR-OGITT-053 "Notification of Deviations to the Protocol", which is available in the Peruvian Registry of Clinical Trials – REPEC.

The Sponsor or its legal representative in the country, to notify the OGITT-INS of deviations from the clinical trial protocol, in accordance with the Manual of Clinical Trial Procedures approved with Chief Resolution No. 279-2017-J-OPE/INS, must :

1. Enter REPEC with the user account and password provided.
2. Complete all the fields of the FOR-OGITT-053 form "Notification of Deviations to the Protocol" and print it.
3. Submit the signed form in the Documentary Processing Area, within the maximum period established.