"Year of Good Citizen Service"

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NOTIFICATION OF DEVIATIONS TO THE INS OGITT

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Within the framework of the implementation of the Clinical Trials Regulations (DS N°021-2017-SA) and with the aim of regulating the reporting of deviations from the protocol, the General Office of Research and Technology Transfer of the National Institute of Health informs the guidelines established for notification:

1. For the purposes of this communication, the definitions established by regulatory agencies with high health surveillance will be taken into account, which will allow the characterization of the deviations subject to being reported:

   Critical or very serious deviations: procedures or practices that negatively affect the rights, safety or well-being of research subjects and/or the quality and integrity of the data

   Major or serious deviations: procedures or practices that could negatively affect the rights, safety or well-being of research subjects and/or the quality and integrity of the data.

   Minor or slight deviations: procedures or practices that are not expected to affect adversely affects the rights, safety or well-being of the subjects and/or the quality and integrity of the data.

2. It should be noted that according to the provisions of articles 40 literal h) and 108 literal h) of the Clinical Trials Regulations (DS N°021-2017-SA), it is the responsibility of the sponsor or OIC to report critical deviations from the clinical trial protocol. or very serious, and major or serious within a maximum period of seven (7) calendar days. For said notification you must use the Deviation Report Form and present it at the INS Document Processing Office. Later this form will be available as an electronic form in the Peruvian Registry of Clinical Trials – REPEC.

3. Minor or slight deviations must be notified to the OGITT in the progress reports of each research center in the respective section of the form.

Note

For inquiries about Clinical Trials, contact telephone number 51(1) 748-1111, annex 2191 or email consultaensayos@ins.gob.pe.