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Regarding the notification of reports and deviations in clinical trials through the platform REPEC

The Clinical Trials Sub-Directorate (SUDEC) of the Research and Innovation Directorate in The Department of Health (DIIS) of the National Institute of Health (INS), within the framework established in the Regulation of Clinical Trials of Peru, approved by Supreme Decree No. 021-2017-SA, communicates the following to sponsors, contract research organizations, researchers and other actors linked to clinical research:

- In accordance with Articles 40(n), 104 and 105 of the REC, the Sponsor is responsible for reporting, on its own behalf or through an OIC, progress reports, final reports and results reports, as well as deviations that occurred in clinical trials;

- The notification of reports and deviations must be managed through the Peruvian Clinical Trials Registry (REPEC) platform and formalized through the Digital Document Desk (MPD) of the INS.

- Therefore, those responsible are urged to make such notifications through the REPEC and to carry out the corresponding follow-up, since the results of the evaluation of the same and their consequent acceptance or rejection, as well as any possible requests for clarification, will be communicated exclusively through said platform.

Deputy Directorate of Clinical Trials
Directorate of Research and Innovation in Health – DIIS
National Institute of Health