COMMUNICATION N° 002 -2023-OGITT/INS

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The General Office of Research and Technology Transfer – OGITT informs the Sponsors and Contract Research Organizations that the process of **Migration of information** from the REPECV1 System to REPECv2 has begun, with the objective of receiving and managing the information of the clinical trials on a single platform. Along these lines, we request that starting **Monday, May 22, 2023,** all new requests for clinical trial procedures be entered through the **REPECv2 platform** https://repec.ins.gob.pe/

Likewise, it is important to take into account the following:

- Requests for clinical trials that are in progress and have been entered through REPEC v1 will not be migrated to REPEC v2 until the procedure is concluded.
- Progress reports, center final reports, national final reports and international final reports will not be migrated at this stage. Therefore, we request that these documents continue to be entered through the REPEC v1 platform for authorized clinical trials until 2020.
- Reports of serious adverse events (REAS) and deviations can be entered starting Monday, May 22 through the REPEC v2 platform, regardless of the year of authorization of the clinical trial. The REAS and deviations that have been submitted through REPEC v1 will not be migrated to REPEC v2 at this stage, but will remain in REPEC v1 for consultation, if required.

Finally, you are reminded that all requests must be registered through the Peruvian Registry of Clinical Trials – REPEC and notified by the Virtual Parties Table (MPV) which is the official channel for receiving documents and will allow you to track your procedures.

Applications that can be submitted from 05/22/2023

AMENDMENTS

- o Expansion or Modification of Supplies
- o Extension of the IC Number
- o EC Realization Time Extension
- o Change of Principal Investigator
- o Change of Sponsor or OIC
- o Closure of a Research Center for EC
- o Suspension of an EC
- o Cancellation of an EC
- o Change of Title of an EC
- o Authorization of Clinical Trial Amendment Report
- o Other Relevant Notifications

NOTIFICATIONS

- o Serious Adverse Event Report
- o Deviations
- o Pregnant Notification



If you have any questions or problems about the REPECv2 System, you can contact Engineer Jenny Parillo at Telephone (51 1) 748 0000 annex 2616 or at Cell 984108368, email jparillo@ins.gob.pe

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