



“Decade of Equal Opportunities for women and men”
“Year of the fight against corruption and impunity”

COMMUNICATION No. 001-2019-OGITT/INS

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The Clinical Trials Regulations (REC) approved by DS N°021-2017-SA), in its article 7, establishes that the National Institute of Health (INS) is the authority in charge at the national level of ensuring compliance with the aforementioned **Regulations, and the related regulations** that govern the certification and execution of clinical trials, as well as dictate the complementary provisions required for their application.

The INS, through the General Office of Research and Technology Transfer (OGITT), is in charge at the national level of ensuring compliance with the REC, whose purpose is to protect the rights, safety, and well-being of research subjects, determine the obligations of the people and entities that participate in the approval and execution of clinical trials.

In this context, and considering the relevance and importance of the current regulations that regulate procedures in the Public Administration, it should be noted that article 64 of the Single Ordered Text of Law No. 27444 Law of General Administrative Procedure approved by Supreme Decree No. 004-2019 JUS, establishes that *“Legal entities can intervene in the procedure through their **legal representatives, who act armed with the respective powers.**”*

In light of the aforementioned, if the legal representative or attorney-in-fact of the foreign Sponsor delegates to a third person the management of its Sponsor Registration in the Peruvian Registry of Clinical Trials (REPEC), must present, in addition to the requirements requested in section 7.1 of the Manual of Clinical Trials Procedures approved with Chief Resolution No. 279- 2017-J-OPE/INS:

- Copy of the legal document authenticated with the Hague Apostille or legalized by the Consulate of Peru in their country with the respective translation, through which the legal representative of the foreign sponsor explicitly authorizes their representative in Peru to request the registration of the Sponsor in the REPEC of the INS. Likewise, the aforementioned document must not be older than ninety (90) calendar days.

The grantor of the foreign power must be duly empowered in accordance with the statute of the legal entity and the laws of the country in which it was incorporated, to act as its representative and grant powers in its name, in the terms established in the subject title. of inscription.

¹ “Regulations for Registration of the Registry of Legal Entities” has been tested with the Resolution of the National Superintendent of Public Registries No. 038-2013-SUNARP/SN, paragraph b) of article 91. Registration of powers granted by legal entities incorporated and domiciled abroad .

Note

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