



**COMMUNICATION No. 005-2018-OGITT/INS**

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In order to ensure the proper application of **Article 35** of the Clinical Trials Regulations, which establishes: *"Research subjects may receive reasonable compensation from the sponsor for the extraordinary expenses incurred and loss of productivity arising from their participation, which will be specified in the informed consent. The CIEI will evaluate said compensation on a case-by-case basis; and will evaluate that it does not unduly influence the research subject."* The OGITT communicates the following:

1. Research subjects may receive compensation in order to reimburse them for expenses (for example: transportation costs, accommodation, communication, food) and/or compensate for the loss of productivity, time, among others, that may arise. of their participation. Any compensation to research subjects must be reasonable and proportional and, in no case, may constitute undue influence.
2. The OGITT has verified that compensation for transportation and accommodation is not being adequately reimbursed in cases where research subjects incur greater expenses due to distance issues (for example, research subjects who live in the provinces); thus harming their well-being and violating the principle of justice.
3. That in order to safeguard the rights of research subjects, researchers and sponsors must take into account the personal and specific considerations of each research subject when calculating compensation for the expenses incurred resulting from their participation and ,
4. The Institutional Research Ethics Committees must evaluate with special attention the information provided regarding the compensations that appear in the informed consent forms in order to ensure that the established compensations consider the possible conditions of each research subject.

Note

For inquiries about Clinical Trials, call 51(1) 748-1111, annex 2191  
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