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Through this statement, the Directorate of Health Research and Innovation - DIIS informs the Research Centers, Research Institutions, Sponsors, Contract Research Organizations - OIC and Ethics Committees, that the criteria that has been applied to establish the Validity of the Record of Registration of Research Centers is the one described in DL No. 1452 of September 16, 2018, which modifies Law No. 27444, Law of General Administrative Procedure, in its article 36-B "Indeterminate validity of the enabling titles", where it mentions that: "The enabling titles issued are **valid indefinitely,** unless a specific period of validity is established by law or legislative decree" (...) "When the authority verifies the change in the conditions essential for obtaining them, "After inspection, the authorizing title may be revoked."

Due to the above, any Research Center Registration Certificate that is valid as of September 16, 2018 and all those issued subsequently, are already valid for an indefinite period, and therefore, are exempt from the Registry Renewal process indicated in article 54 of the current REC. Without prejudice to the foregoing, the authority

The regulatory authority may carry out subsequent audits, whether audited or unexpected, in accordance with its jurisdiction.

Health Research and Innovation Directorate

National Institute of Health