Cuban regulations

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- Resolution 14-2018: Approves the Implementation Procedure of the Regulation of Clinical Trials in Cuba, put into effect by Resolution No.435/17 of the Ministry of Public Health (MINSAP). [1]
- Regulation 21-2008: Requirements for the request for authorization and modification of Clinical Trials. Center for the State Control of Medicines, Equipment and Medical Devices (CECMED). [2]
- Guidelines for Good Clinical Practices 2000. Center for the State Control of Medicines, Equipment and Medical Devices (CECMED). [3]
- Regulation 27/00: Requirements for phase I and II clinical trials with research products for the treatment of Cancer and AIDS. Center for the State Control of Medicines, Equipment and Medical Devices (CECMED). [4]
- Resolution 40-2011: MINSAP Resolution No. 40/2014: Creates a MINSAP commission to attend to the Ethics and Investigation Committees, their objectives, structure and functions, and order their approval by the directors of the corresponding instances (MINSAP). [5]
- Regulation 45-2007: Requirements for notification and reporting of serious and unexpected adverse events in authorized clinical trials. Center for the State Control of Medicines, Equipment and Medical Devices (CECMED). [6]
- Regulation 52-2008: Requirements for the certification of Good Clinical Practices. Center for the State Control of Medicines, Equipment and Medical Devices (CECMED). [7]
- Regulation 70-2014: Requirements for the request for authorization and modification of Clinical Trials. Evidence of the application process for registration in the public registry of clinical trials Center for the State Control of Medicines, Equipment and Medical Devices (CECMED). [8]
- Resolution 435-2017: Approves the "Regulation of Clinical Trials in Cuba" (MINSAP). [9]
- [10]

For more information visit the website of the Center for the State Control of Medicines, Equipment and Medical Devices (CECMED) (CECMED) [11]

Calle 5ta A Edificio CECMED-CENCEC 2do piso e/ 60 y 62 Miramar, Playa.CP 11300. La Habana, Cuba
Telef: (537) 216-4126 | (537) 216-4212 | (537) 216-4218.
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Links:
[1] http://instituciones.sld.cu/cencec/files/2018/11/Resolución-para-la-Implementación-del-Reglamento-de-EC-en-el-SNS-Versión-Final-Firmada.pdf
[2] https://www.cecmed.cu/sites/default/files/adjuntos/Reglamentacion/Reg_21-08.pdf#overlay-context=reglamentacion/aprobadas?page=9
[3] https://www.cecmed.cu/sites/default/files/adjuntos/ambitor/ambreg-18.pdf
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[9] http://instituciones.sld.cu/cencec/files/2017/12/Resolución-435-del-MINSAP-Reglamento-de-los-Ensayos-Clínicos-en-Cuba.pdf
[10] https://rpcec.sld.cu/en/cuban%20regulations
[11] http://www.cecmed.cu