



Ministry of Health  
executive Secretary

Department of Interfederative and Participatory Management  
Executive Secretariat of the National Health Council  
National Research Ethics Commission

## CLARIFICATION NOTE

To the Coordinators, members and administrative employees of  
Research Ethics Committees - CEPs.

**Subject: Clarification note on Circular Letter No.**

**24/2022/CONEP/SECNS/DGIP/SE/MS, which presents general guidelines  
for conducting clinical trials.**

1. For the best protection of the research participant, in accordance with the letter h, item III.1, of CNS Resolution N. 466/2012, the ethics of the research implies having researcher(s) who have professional capacity suitable to develop its role in the proposed project. Therefore, researchers from any professional category can submit research protocols clinical trial for the CEP/Conep System.

2. item N<sup>o</sup> O 5 do Craft Circular

24/2022/CONEP/SECNS/DGIP/SE/MS establishes that: "clinical trials must have a qualified professional (doctor or dentist) who is a researcher or study sub-investigator, as responsible for all medical decisions or dental, related to the test." Therefore, to clarify the understanding of this item, the following is ratified:

3. The [Craft Circular N<sup>o</sup>](#)

[24/2022/CONEP/SECNS/DGIP/SE/MS](#) only establishes that, in tests clinicians, all decisions related to research and related activities medical or dental professionals, must be responsible for this activity, a doctor or a dentist, respectively.

4. In protocols where this type of decision is necessary, these researchers must be included in the research team.

5. The researcher responsible for the research protocol, in submission to the CEP/Conep System, does not necessarily need to be one of these professional categories.

Yours sincerely,

LAÍS ALVES DE SOUZA BONILHA

Coordinator of the National Research Ethics Commission



Document signed electronically by **Lais Alves de Souza Bonilha, Coordinator of the National Research Ethics Commission**, on 10/26/2022, at 7:10 pm, according to official Brasília time, based on § 3 of art. 4th, of [Decree No. 10,543, of November 13, 2020](#); and art. 8th, of [Ordinance No. 900 of March 31, 2017](#).

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