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

CIRCULAR LETTER No. 24/2022/CONEP/SECNS/DGIP/SE/MS

Brasília, October 17, 2022.

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

Subject: General guidelines for conducting clinical trials.

Dear,

The National Research Ethics Commission (Conep), with the objective 1. of clarifying and standardizing clinical trial submissions in the CEP/Conep system, establishes the following guidelines for researchers and Research Ethics Committees.

A clinical trial is a research activity, developed, 2. initially, to evaluate the safety and efficacy or effectiveness of an experimental drug administered to human beings. This definition can include everything from a first test of a drug, without any control, to a rigorously designed randomized clinical trial (1). Currently, this definition has been extended to include – in a virtual or non-virtual environment – biological therapies, medical devices, surgical procedures, vaccines, as well as nutritional, cognitive, behavioral, psychological and public health interventions (2).

Conep's guidelines apply not only to “traditional” clinical trials, but also – where appropriate – to clinical trials with other designs: adaptive, sequential, basket *trials,* platform *trials. ,* umbrella trials , human challenge *trials,* decentralized, pragmatic, real life, mechanistic, quasi-experimental, among others.

4. Clinical trials must be registered, preferably, in the Brazilian Clinical Trials Registry (Rebec) database (3).

Clinical trials must have a qualified professional (physician or dentist) who is a researcher or sub-researcher of the study, responsible for all medical or dental decisions relating to the study.

test (4).

6. Clinical trial protocols must include, when submission to the CEP/Conep System:

I - Rationale for the study based on clinical evidence, laboratory or experimental (5);

II - Justification of the sample size, when applicable (2);

III - Detailed description of the inclusion and exclusion criteria, presented in accordance with the requirements of the method to be used (6);

IV - Detailed description of the risks and possible benefits (6)

V - Monitoring plan and analysis of adverse events, with the rating system and evaluation criteria used, when it fits (7);

VI - Independent Safety Monitoring Committee, with the description of its composition and the activity plan, when fit (2);

VII - Interim analysis plan, when applicable (2);

VIII - Criteria for closing or suspending the research explained, when applicable (6);

IX - Information about the registration status of the product or device, at Anvisa, when applicable (8).

Yours sincerely,

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Coordinator of the National Research Ethics Commission

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Document signed electronically by **Laís Alves de Souza Bonilha, Coordinator of the National Research Ethics Commission,** on 10/17/2022, at 6:01 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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