



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. 12/2023/CONEP/SECNS/DGIP/SE/MS

Brasília, July 27, 2023.

To the Coordinators, members, administrative staff of Research Ethics Committees (CEP) and researchers.

Subject: Guidelines for the implementation of article 26 of CNS Resolution No. 674 of May 6, 2022, which provides for the classification of research and the processing of research protocols in the CEP/Conep System.

The National Research Ethics Commission (Conep) hereby provides guidance, through this Circular Letter 1, specifically regarding the implementation of article 26 of CNS Resolution No. 674 of May 6, 2022, which addresses research exempt from ethical assessment by the System CEP/Conep. In that regard:

This guidance is applicable to research protocols whose procedures
2. fall within one or more sections of article 26 of CNS Resolution No. 674/2022.

3. Considering the provisions of CNS Resolution No. 510 of April 7, 2016, in Circular Letter No. 17 of 2022 and in article 26 of CNS Resolution No. 674/2022, research that falls exclusively within the in the following situations:

I - Public opinion research with non-identifiable participants;

In accordance with Circular Letter No. 17/2022/CONEP/SECNS/MS, of July 2022.

II - Research that uses publicly accessible information, under the terms of Law No. 12,527, of November 18, 2011;

In accordance with Circular Letter No. 17/2022/CONEP/SECNS/MS, of July 2022.

III - Research that uses public domain information;

In accordance with Circular Letter No. 17/2022/CONEP/SECNS/MS, of July 2022.

IV - Census research carried out by government bodies;

The wording of this section incorporated, in CNS Resolution No. 674/2022, the addition "carried out by government bodies". Compatible with the comment in Circular Letter No. 17/2022/CONEP/SECNS/MS, of July 2022.

V - Research carried out exclusively with information or data already available in an aggregated form, without the possibility of individual identification;

This wording, corresponding to item V of CNS Resolution No. 510/2016, which was adjusted to better clarify what information or data is

presented in aggregate form. Compatible with the comment in Circular Letter No. 17/2022/CONEP/SECNS/MS, of July 2022.

VI - Research carried out exclusively with scientific texts to review scientific literature;

In accordance with Circular Letter No. 17/2022/CONEP/SECNS/MS, of July 2022.

VII - Research that aims to deepen the theory of situations that emerge spontaneously and contingently in professional practice, as long as they do not reveal data that could identify the individual;

In accordance with Circular Letter No. 17/2022/CONEP/SECNS/MS, of July 2022.

VIII - Activity carried out for the exclusive purpose of education, teaching, extension or training, without the purpose of scientific research, of undergraduate students, technical courses, or professionals in specialization:

a) Completion Course Works do not fall under the preceding section.

Graduation, Master's Dissertations, Doctoral Theses, Monographs and similar, and in these cases, the research protocol must be submitted to the CEP/Conep System;

b) if, during the planning or execution of the education, teaching, extension or training activity, the intention arises to incorporate the results of these activities into a research project, the research protocol must be obligatorily presented to the CEP/Conep System.

The wording of this section, presented in CNS Resolution No. 510/2016, was appropriate to include extension activities. The letter "a" also included completion of work at different levels of education. Compatible with the comment in Circular Letter No. 17/2022/CONEP/SECNS/MS, of July 2022.

IX - Market research;

Refers to research of an exclusively marketing nature. For example, surveys that ask consumers about the quality of a product or service, without identifying the participant from the moment of data collection and without an academic nature.

X - scientific research carried out with cells, tissues, organs and bodies of non -human origin, including their biological products, provided that there is no interaction with research participants or implies the collection or use of human biological material to obtain them;

Refers to research in which the biological material analyzed is not human, such as bacteria, viruses and fungi, and in which there is no prospective collection or interaction with research participants to obtain this material. When human biological material previously stored in biobanks or biorepositories is used, those responsible must maintain a record of the research, for reporting purposes to the CEP/Conep System and bank management.

XI - Activity whose purpose is to describe or analyze the production or administrative process for the exclusive purpose of organizational development.

Refers to research in which information related to the production or administrative process is collected, without recording data, opinions or perceptions of people. For example, studies that analyze the industrial process and its stages, without collecting individual information (in the form of opinions, data or others), only that related to the process under study.

4. The implementation of these guidelines comes into force from this date.

Cordially,

LAIS ALVES DE SOUZA BONILHA
Coordinator of the National Research Ethics Commission



Document signed electronically by **Laís Alves de Souza Bonilha, Coordinator of the National Research Ethics Commission**, on 7/27/2023, at 7:06 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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