

Ministry of Health Executive Secretary

Department of Interfederative and Participatory Management Executive Secretary of the National Health Council National Research Ethics Committee

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 typification of research and the processing of research protocols in the CEP/Conep System.

The National Commission for Ethics in Research (Conep) comes through this Circular Letter 1. to provide specific guidance regarding the implementation of article 26 of CNS Resolution No. 674 of May 6, 2022, which addresses research exempted from ethical appreciation by the System CEP/Conep. In that regard:

This guideline is applicable to research protocols whose procedures 2. fully comply with one or more items of article 26 of CNS Resolution No. 674/2022.

3. Considering the provisions of CNS Resolution No. 510 of April 07, 2016, Circular Letter No. 17 of 2022 and Article 26 of CNS Resolution No. 674/2022, the CEP/Conep System does not require ethical assessment for research that falls exclusively within in the following situations:

I - Public opinion survey with unidentifiable participants;

According to Circular Letter No. 17/2022/CONEP/SECNS/MS, of July 2022.

II - Research that uses publicly accessible information, pursuant to Law No. 12,527, of November 18, 2011;

According to Circular Letter No. 17/2022/CONEP/SECNS/MS, of July 2022.

III - Research that uses public domain information;

According to Circular Letter No. 17/2022/CONEP/SECNS/MS, of July 2022.

IV - Census research carried out by government agencies;

The wording of this item incorporated, in CNS Resolution No. 674/2022, the complement "performed by government agencies". Compatible with the comment of Circular Letter No. 17/2022/ CONEP/SECNS/MS, of July 2022.

V - Research carried out exclusively with information or data already available in aggregate 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 of Circular Letter No. 17/2022/ CONEP/SECNS/MS, of July 2022.

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

According to Circular Letter No. 17/2022/CONEP/SECNS/MS, of July 2022.

VII - Research that aims at the theoretical deepening of situations that emerge spontaneously and contingently in professional practice, as long as they do not reveal data that can identify the individual;

According to Circular Letter No. 17/2022/CONEP/SECNS/MS, of July 2022.

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

a) the Completion Course Works of

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 there is an intention to incorporate the results of these activities into a research project, the research protocol must be presented to the CEP/Conep System.

The wording of this item, presented in CNS Resolution No. 510/2016, was adapted to include extension activities. Also included in letter "a" are final works from different levels of education. Compatible with the comment of Circular Letter No. 17/2022/CONEP/ SECNS/MS, of July 2022.

IX - Market research;

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

X - Scientific research carried out with cells, tissues, organs and organisms of nonhuman origin, including their biological products, provided there is no interaction with research participants or imply 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 where there is no prospective collection or interaction with research participants to obtain this material. When using human biological material previously stored in biobanks or biorepositories, the research record must be kept by those responsible for reporting to the CEP/Conep System and bank management.

XI - Activity whose purpose is to describe or analyze the productive or administrative process exclusively for organizational development purposes.

Refers to surveys 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 those related to the process under study.

The implementation of these guidelines is effective from this date.

Cordially,

LAIS ALVES DE SOUZA BONILHA

Coordinator of the National Research Ethics Commission



Document electronically signed by Laís Alves de Souza Bonilha, Coordinator of the National Research Ethics Commission, on 07/27/2023, at 7:06 pm, according to official Brasília time, based on § 3, of art. 4, of Decree No. 10,543, of November 13, 2020; and art. 8, of Ordinance No. 900 of March 31, 2017.



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