



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. 29/2023/CONEP/SECNS/DGIP/SE/MS

Brasília, December 22, 2023.

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

Subject: Guidelines for forwarding appeals to the CEP/Conep System instances.

1. **GENERAL PROVISIONS:**

1.1. The National Research Ethics Commission (Conep), under the terms of section XI, art. 16 da CNS Resolution No. 446 of August 11, 2011, informs the CEP/Conep System about the procedures to file an appeal against decisions made, with the purpose of standardizing and guiding regarding the actions to be adopted in these situations.

1.2. For the purposes of these guidelines, the following terms and definitions are adopted:

- I Appeal to the CEP/Conep System: this is the request in which the researcher - requests the review (total or partial) of the opinion substantiated as "non-approval" of the research protocol issued by the CEP/Conep System;
- II "Not approved" opinion: is one in which the decision considers that the obstacles - ethics of the protocol are of such gravity that they cannot be overcome by the procedure in "pending", according to letter g, 3, item 2.1, of CNS Operational Standard No. 001 of 2013.
- III Conflict of interest: situation generated by the clash between public interests - and private, which may compromise the collective interest or influence, in a improper, the performance of activities in the CEP/Conep System.

2. **APPEAL ADMISSIBILITY REQUIREMENTS IN THE CEP/Conep SYSTEM:**

2.1. The appeal submitted to the CEP/Conep System will be initially examined regarding the adequacy to the requirements for its proposal, and, if relevant, its merit will be evaluated.

2.2. The requirements for receiving an appeal submitted to the CEP/Conep System, through of Plataforma Brasil, are:

- I Only the researcher responsible for the protocol can submit the resource - research, which had a substantiated opinion of non-approval;
- II - The appeal must be filed within 30 (thirty) calendar days, counting from from the first day following the issuance of the substantiated opinion of non approval;

- III Appeals containing the presentation of justification will be accepted.
 - based on the substantiated opinion of non-approval.

3. **APPEAL SUBMITTED TO THE INSTANCE OF THE RESEARCH ETHICS COMMITTEE (CEP):**

3.1. The Research Ethics Committee (CEP), in the event of non-approval of a research protocol, research, must clearly identify in the opinion the reason for non-approval, providing the justifications and normative provisions that were not met by the researcher.

3.2. The CEP, upon receiving the researcher's appeal, must observe:

- I Adequacy to the requirements for receiving resources, set out in item 2
 - of this guidance;
- II - The justification and arguments presented by the researcher.

3.3. If the CEP considers the requirements and justifications presented in the appeal to be appropriate, the In order to continue the ethical analysis, the following opinion must be issued:

- I - Approved: if from the resource it is identified that the research includes all necessary ethical precepts;
- II - Pending: if the need for adjustments to the research protocol documents, for ethical assessment.

3.4. If the CEP does not consider the requirements and justifications presented in the appeal, must issue an opinion of non-approval, justifying the reasons for the decision, indicating the possibility of appeals and the deadline, in the substantiated opinion, issued via Plataforma Brasil.

3.5. The CEP's opinion must set out, in a clear and well-founded manner, the aspects that were relevant in the analysis of the resource.

3.6. CEP has a deadline of up to 30 (thirty) calendar days after receipt of the appeal submitted by the researcher, to issue a substantiated opinion on the analysis of the resource.

3.7. The researcher, when submitting the resource to the CEP, must observe the requirements contained in the item 2 of this guideline, and it is essential to present justifications based on with the normative provisions that, from their perspective, were not considered in the opinion issued by the

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3.8. The researcher, upon the opinion of non-approval of the resource at the CEP, may file a appeal to Conep, according to letter I, item 2.2 of CNS Operational Standard No. 001/2013 and CNS Resolution Nº 674/2022.

4. **OF THE RESOURCES SUBMITTED TO THE NATIONAL RESEARCH ETHICS COMMISSION (Conep):**

4.1. Conep, when evaluating the appeal in relation to the substantiated opinion issued by the CEP, you should consider:

- I - Adequacy to the requirements for receiving resources, set out in item 2
 - of this guidance;
- II - The justification and arguments presented by the researcher;
- III - The processing process in the zip code of origin;

4.1.1. If Conep considers the requirements and justifications presented in the appeal, in order to continue the ethical analysis, must issue the opinion:

- I - Approved: if from the resource it is identified that the research includes all necessary ethical precepts;
- II - Pending: if the need for adjustments to the research protocol documents, for ethical assessment.

- 4.1.2. If Conep does not consider the requirements and justifications presented in the appeal, must issue an opinion of non-approval, justifying the reasons for the decision in the opinion substantiated, issued via Plataforma Brasil.
- 4.1.3. Conep's opinion must set out, in a clear and well-founded manner, the aspects that were relevant in the analysis of the resource.
- 4.1.4. Conep has a deadline of up to 45 (forty-five) days, after receiving the appeal from the researcher, to issue a substantiated opinion on the resource.
- 4.1.5. The researcher, upon receiving Conep's opinion of non-approval, may file an appeal - to Conep itself -, according to letter G, item 2.2 of CNS Operational Standard No. 001/2013 and CNS Resolution N° 674/2022.
- 4.2. Conep, when evaluating the resource, observing item 4.1.5, must consider:
- I - Adequacy to the requirements for receiving resources, set out in item 2 of this guidance;
 - II - The justification and arguments presented by the researcher.

5. DECISIONS AFTER RESOURCE ANALYSIS

- 5.1. From the analysis of the resources submitted to the CEP and/or Conep, after deliberation, it will be decision given:
- I - Approved;
 - II - Pending;
 - III - Not approved.
- 5.2. From the analysis of the resources submitted to Conep, an opinion of "Approved with Recommendation" to the CEP, when applicable.
- 5.3. In the case of Conep's decision not to approve the appeal, the processing will be terminated. of the same, with the research protocol being archived [1] , with no other instance of appeal, as per provided for in item IV, letter G, subitem 2, item 2.3, of Operational Standard No. 001/2013 and art. 24 da CNS Resolution No. 674/2

6. FINAL PROVISIONS

- 6.1. Circular Letter No. 060/2011 Conep/CNS/MS, dated July 14, 2011, is hereby revoked.
- 6.2. Any omitted cases will be evaluated and deliberated by the Conep Plenary.
- 6.3. This guidance comes into force on the date of its publication.

Cordially,

LAÍS ALVES DE SOUZA BONILHA

Coordinator of the National Research Ethics Commission

[1] Definitive conclusion of the analysis of the research protocol, with no new appeal possible.



Document signed electronically by **Laís Alves de Souza Bonilha, Coordinator of the Commission National Research Ethics Committee**, on 12/26/2023, at 3:52 pm, according to official Brasília time, with based on § 3 of art. 4th, of [Decree No. 10,543, of November 13, 2020](#); and art. 8th, from [Ordinance No. 900 of March 31, 2017](#).



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