

OFFICIAL DIARY OF THE UNION

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Page: 76 **Body: Ministry of Health/National Health Council**

RESOLUTION No. 706, OF FEBRUARY 16, 2023 (*)

Provides for registration, accreditation, renewal, alteration, suspension and cancellation of registration of Research Ethics Committees (CEPs) with the CEP/Conep System, among other provisions.

The Plenary of the National Health Council (CNS), at its Three Hundred and Thirty-ninth Ordinary Meeting, held on February 15 and 16, 2023, and in the use of its regulatory powers and attributions conferred by Law No. 8.080, of September 19, nineteen ninety; by Law No. 8,142, of December 28, 1990; by Complementary Law No. 141, of January 13, 2012; by Decree No. 5,839, of July 11, 2006, and complying with the provisions of the 1988 Constitution of the Federative Republic of Brazil and related Brazilian legislation; It is

Considering the need to minimize conflicts of interest when judging projects research involving human beings, within the scope of the CEP/Conep System;

Considering the attributions of the Research Ethics Committees (CEPs) defined in item VIII, items VIII.1, VIII.2 and VIII.3 of CNS Resolution No. 466, of December 12, 2012; It is

Considering the need to regulate the creation, functioning and monitoring of Research Ethics Committees within the scope of the CEP/Conep System, in compliance with the provisions of item IX.3 of CNS Resolution No. 466, of December 12, 2012, resolves :

Regulate the criteria for registration, accreditation, renewal, alteration, suspension and cancellation of the registration of Research Ethics Committees, as well as the forms of monitoring the accreditations granted within the scope of the CEP/Conep System.

CHAPTER I

PRELIMINARY PROVISIONS

Art. 1 It is up to the CEP to act in accordance with the norms established by the National Health Council (CNS), pertinent to ethics in research, involving human beings.

Art. 2 To operate in the CEP/Conep System, the CEP must be duly registered with Conep, with current accreditation, in compliance with the rules set forth in this Resolution.

Art. 3rd It is up to the Conep collegiate to grant or reject the registration, accreditation, renewal, alteration of data, suspension and cancellation of CEPs, in accordance with the provisions of item II, art. 16 of CNS Resolution No. 446, of August 11, 2011.

CHAPTER II

TERMS AND DEFINITIONS

Art. 4 For the purposes of this Resolution, the following terms and definitions are adopted:

I - registration: registration act of the CEP to work with the CEP/Conep System;

II - accreditation: act of approval by the CEP to work with the CEP/Conep System;

III - renewal of registration and accreditation: act of updating the registration and CEP accreditation;

IV - suspension of CEP accreditation: temporary and preventive suspension of accreditation, decided by the Conep plenary, which determines the interruption of receiving new protocols for ethical assessment;

V - Cancellation of CEP registration and accreditation: irrevocable, deliberate act by the Conep plenary, which determines the disqualification and cancels the registration of the CEP;

VI - alteration of registration data: any modification of information referring to CEP registration;

VII - minimum operating conditions: requirements necessary to carry out activities CEP, required for registration maintenance and accreditation;

VIII - internal regulations: document that provides for the composition, attributions and rules CEP functioning;

IX - sponsoring institution: institution that requests the registration and accreditation of the CEP, being responsible for guaranteeing the minimum conditions for its operation;

X - designation act: formal document for the appointment of CEP members, issued by the sponsoring institution, containing the functions performed by the members in the CEP, as well as the positions they hold in the institution, when applicable;

XI - conflict of interest: situation generated by the confrontation between public and private interests, which may compromise the collective interest or improperly influence the performance in the exercise of activities in the CEP/Conep system. It configures, conflict of interest, the existence of a relationship of trust or subordination with the interested party in the decision of the Collegiate;

XII - Representative Organization of Clinical Research (ORPC): company, regularly installed in the national territory, contracted by the sponsor or by the investigator, which assumes, partially or totally, the attributions of the clinical research sponsor; It is

XIII - proposing institution: organization, public or private, legitimately constituted and qualified, to which the responsible researcher is linked.

CHAPTER III

REGISTRATION AND ACCREDITATION

Art. 5 CEP registration and accreditation may only be requested by health or teaching or research institutions, headquartered in the national territory, without potential conflict of interest and in good standing with the competent bodies.

Single paragraph. It is forbidden to grant CEP registration and accreditation to:

I - Research centers maintained or linked to Representative Research Organizations Clinic (ORPCs); It is

II - Professional category associations.

Art. 6 The registration and accreditation of the CEP, as well as its renewal, will be carried out by submitting the following documents:

I - application sent by the sponsoring institution, signed by its legal guardian, containing the description of that institution and the commitment to ensure the minimum conditions for the functioning of the CEP;

II - proof of the minimum functioning requirements of the sponsoring institution, of according to specific norm;

III - request form, according to the model provided by Conep;

IV - nomination letters from Research Participant Representatives (RPPs), in accordance with the specific resolution;

V - act of designation of the CEP Collegiate; It is

VI - internal regulation of the CEP.

§1 In order to start activities, the CEP must, within 90 (ninety) days, after the communication of approval of registration and accreditation, prove the adequate training of its members, observing the requirements described in a specific rule.

§2 The approval of the registration and accreditation of the CEP that does not initiate the its activities, within 120 (one hundred and twenty) days, after approval of its registration.

Art. 7 CEP accreditation is valid for four years.

Single paragraph. In order to maintain the regular functioning of the CEP, the sponsoring institution must submit an application for renewal of accreditation.

Art. 8 Renewal of CEP accreditation must be completed by the closing date of expiration of its term.

§1 The request for renewal must be initiated from 90 (ninety) days before the date of expiration of its term.

§2 The extension of the period for renewal may be requested, only once, for the period maximum of 90 (ninety) days, upon justification.

§3 The renewal will not be carried out, if there is a pendency in the sending of the annual reports referring to the last period of validity of the CEP registration.

Art. 9 The CEP accreditation renewal request must comply with the requirements additional provisions provided for in a specific rule.

§1 Non-compliance with the requirements for renewing CEP accreditation will result in its suspension.

§ 2 The absence of any of the requirements set forth in the specific norm or their inadequacy will give rise to the issuance of pendencies to be fulfilled by the CEP, in order to proceed with the accreditation renewal process.

§ 3 The pendencies listed to the CEP must be fulfilled within a maximum period of 30 (thirty) days.

§ 4 Non-compliance with the pendencies listed, within the period granted, will result in the CEP suspension, which may lead to its cancellation.

Art. 10 The maintenance of CEP registration and accreditation may be assessed at any time by Conep and are subject to compliance with the operating requirements described in chapter V of this Resolution, complemented by a specific rule.

CHAPTER IV

CEP COMPOSITION

Art. 11 The CEP Collegiate must be composed of at least nine members with at least two RPPs.

§1 The proportionality for RPP members must be respected, according to a specific rule.

§2 At least 50% of the members must prove to have experience in research.

§3 The Collegiate referred to in the caput of this article will always have a multidisciplinary nature, with no more than half of the members belonging to the same professional category, observing gender balance.

§4 The CEP may rely on ad hoc consultants, external to the Collegiate, with the purpose of provide technical support.

Art. 12 The term of office of the members lasts for four years, and may be reappointed, at CEP criteria.

§1 The term of office of the Coordination lasts for four years, with the possibility of reappointment, at the discretion of the CEP, according to the Internal Regulations.

§2 The term of office of the RPP will be governed by a specific Resolution.

Art. 13 At the end of the mandate, the member can remain in his function, for a period that does not exceed 90 (ninety) days, until the effectiveness of its replacement or reappointment.

CHAPTER V

MINIMUM CONDITIONS FOR CEP OPERATION

Art. 14 It is incumbent upon the sponsoring institution to ensure, at least, the following conditions:

I - ratify the election of the CEP Coordination;

II - maintain the proper composition;

III - ensure the participation of the RPPs;

IV - designate an administrative employee, exclusively for the CEP, during the period of its operation;

V - ensure that members with experience in research involving human subjects;

VI - maintain adequate infrastructure and physical space for the exclusive use of the CEP;

VII - make available an exclusive page for the CEP on the institutional website;

VIII - provide institutional e-mail and telephone (or extension) for the exclusive use of the CEP; IX - Encourage, promote and support the implementation of CEP educational activities;

X - ensure the autonomy of the CEP in the exercise of its activities and deliberations; It is

XI - submit a project demand forecast that justifies CEP activity.

Art. 15 It is incumbent upon the CEP:

I - maintain the proper composition;

II - choose, for coordination, a member of the CEP that does not present a potential conflict of rights interest, by voting of the absolute majority (50% plus one) of the total number of full members;

III - issue opinions within the regulatory deadlines;

IV - send to Conep the reports of its activities, within the normative deadlines;

V - guarantee and maintain a quorum for deliberative activities in the meetings of the Collegiate;

VI - maintain confidentiality of all information regarding research protocols and content of the Collegiate meetings;

VII - prepare the Internal Regulations;

VIII - analyze research protocols of Proposing Institutions, located only in the same Federative Unit of CEP registration;

IX - ensure periodic training of its members, through a Training Plan

Permanent on ethics in research involving human subjects, including content targeted and accessible to RPPs;

X - promote educational activities, in the area of ethics in research involving human beings, with its members and the community in general;

XI - receive and evaluate, from an ethical point of view, the research protocols indicated by Conep;

XII - maintain regular and effective communication with Conep; It is

XIII - receive complaints and investigate ethical infractions, especially those that imply risks to research participants, communicating the facts to the competent authorities for investigation and, when appropriate, to the Public Prosecutor's Office.

§1 The CEP may refuse the ethical assessment of research protocols indicated by Conep, upon justification.

§2 The CEP is prohibited from charging any fees for analysis of research protocols.

CHAPTER VI

SUSPENSION OF CEP REGISTRATION AND ACCREDITATION

Art. 16 The suspension of CEP accreditation consists of the temporary interruption of receiving new research protocols for ethical appreciation.

§1º The suspended CEP must monitor the protocols under its responsibility, approved or in process, while the suspension remains.

§2 New protocols, submitted to the suspended CEP for consideration, will be directed to another CEP, as indicated by Conep.

Art. 17 The suspension will be applied in the following cases:

I - whenever non-compliance with the minimum requirements for the operation of the

POCKET;

II - on a precautionary basis, when necessary for the investigation of irregularities and complaints about the exercise of CEP activities;

III - when, after expiry of the validity period, the renewal process of the registration and accreditation of the CEP, observing the provisions of art. 8th, §2nd; It is

IV - when, repeatedly and without justification, CEP refuses to receive protocols indicated by Conep.

Art. 18 The precautionary suspension, for the investigation of irregularities and denouncements, can only be interrupted by Conep, after verification and reasoned decision.

Art. 19 Suspension, at the request of the CEP or the sponsoring institution, may be granted, for a maximum period of 90 (ninety) days, upon reasoned justification, and may be extended once, for the same period.

Single paragraph. The request will be assessed upon request addressed to Conep's Coordination, containing the reasons for your request.

Art. 20 The suspension may be revoked, at any time, ex officio by Conep or the request from the interested party.

Single paragraph. The request for revocation of the suspension must be accompanied by justification and supporting documentation that the reasons that led to the suspension have been remedied.

Art. 21 The decision to suspend CEP accreditation may be appealed to Conep, within the deadline of 30 (thirty) days.

Single paragraph. An extension of the deadline for appeal may be requested, only once, by the maximum period of 30 (thirty) days, upon justification.

CHAPTER VII

CEP REGISTRATION CANCELLATION

Art. 22 The cancellation consists of the revocation of the registration and extinction of the CEP in the System CEP/Conep.

Single paragraph. In the event of cancellation, Conep will transfer the protocols to another CEP, for proper follow-up.

Art. 23 The cancellation will occur in the following cases:

I - when, after the validity period has expired, the CEP has not completed the renewal process in 180 (one hundred and eighty) days.

II - when, once the CEP is suspended, it is not possible to remedy the irregularities that demanded the suspension;

III - when, definitively, the sponsoring institution does not promote the minimum conditions CEP functioning; It is

IV - at the request of the sponsoring institution, with reasoned justification.

Art. 24 Cancellation, at the request of the sponsoring institution, will be appreciated, upon request addressed to Conep's Coordination, containing the reasons for your request.

Art. 25 The cancellation decision may be appealed to Conep, within a period of 30 (thirty) days.

Single paragraph. An extension of the deadline for appeal may be requested, only once, by the maximum period of 30 (thirty) days, upon justification.

Art. 26 In case of cancellation, the institution cannot request a new registration maintainer, within 12 months.

Single paragraph. The request for a new registration must be accompanied by a formal commitment of the institution that maintains the resolution of the problems that led to the cancellation of the CEP.

CHAPTER VIII

DATA CHANGE

Art. 27 Any alterations to the infrastructure, composition of the members or administrative employee(s) of the CEP must be communicated to Conep.

§1 When there is a change in the composition of CEP members, at least one third of members of the previous composition must be maintained.

§2 Any change in the CEP Coordination must be communicated and approved by the Conep, upon reasoned justification and in compliance with item II, art. 15 of this Resolution.

§3 In the event of vacancy of the RPP member, the CEP must provide for its replacement, observing the provisions contained in a specific Resolution.

Art. 28 The alteration of registration data of the maintaining institution must be communicated to the Conep.

CHAPTER IX

FINAL DISPOSITIONS

Art. 29 The provisions contained in this Resolution apply to Accredited CEPs, without prejudice of the regulations provided for in CNS Resolution No. 506, of February 3, 2016.

Art. 30 For purposes of compliance with the provisions of art. 10, Conep may carry out a local inspection of the CEP, at any time, mainly when requesting a new registration, accreditation or to investigate complaints and irregularities.

Art. 31 This Resolution will be complemented by a specific rule, to regulate the activities of the CEP and its members.

Art. 32 The omissions in this Resolution will be evaluated and deliberated by the Collegiate of the Conep.

Art. 33 For CEPs with current accreditation, the norms of Sections III and IV of this present Resolution must be complied with when requesting renewal of accreditation.

Art. 34 The CEPs that request renewal of accreditation, within 120 (one hundred and twenty) days after the date of publication of this Resolution, must adapt to the changes promoted by this Resolution, within a period of up to 180 (one hundred and eighty) days.

Art. 35 CNS Resolution No. 370 of March 8, 2007 and items 2.2.B and 2.2.C of Operational Standard 001 of September 30, 2013.

Art. 36 This Resolution will come into force from the date of its publication.

FERNANDO ZASSO PIGATTO

Board Chairman

I ratify CNS Resolution No. 706, of February 16, 2023, pursuant to Law No. 8142, of December 28, 1990.

NÍSIA TRINDADE LIMA

Minister of State for Health

Republished due to its publication, in DOU nº 102, of 5-30-2023, Section 1, p. 65, incorrect in the original.

This content does not replace the one published in the certified version.