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**Agency: Ministry of Health/National Health Council**

# RESOLUTION No. 506, OF FEBRUARY 3, 2016

The Plenary of the National Health Council, at its Two Hundred and Seventy-Seventh Ordinary Meeting, held on January 2nd and 3rd, 2016, in the exercise of its regulatory powers and attributions conferred by Law No. 8,080, of September 19, 1990, by Law No. 8,142, of December 28, 1990, by Decree No. 5,839, of July 11, 2006, and complying with the provisions of the Constitution of the Federative Republic of Brazil of 1988 and related Brazilian legislation; and considering the provisions of CNS Resolution No. 466, of 2012, in its items XIII.1 and XIII.2; resolves:

To approve the following Resolution regarding the accreditation process for Research Ethics Committees (RECs) which They comprise the CEP/Conep System.

## Chapter I

## PRELIMINARY PROVISIONS

Article 1. This Resolution establishes the criteria for the accreditation process of Ethics Committees (CEP) within the CEP/Conep System, in public and private institutions. The processing of the protocol will be based on the gradation and classification of risks defined in specific regulations, with criteria established by the National Ethics Committee in Research (Conep), arising from research activities involving human beings.

Article 2. The accreditation process aims to reinforce the decentralization of the CEP/Conep System, while maintaining the uniformity of the analysis criteria established by the CNS, in accordance with its current regulations.

Article 3. It is the responsibility of CONEP to evaluate, deliberate on, and grant accreditation to CEPs, in accordance with the provisions of this Resolution.

## Chapter II

## TERMS AND DEFINITIONS

Article 4. This Resolution adopts the following definitions:

I. ACCREDITATION: a voluntary conformity assessment process aimed at granting certification. by Conep to the CEP for the ethical analysis of high-risk protocols involving human beings;

II. ACCREDITATION CERTIFICATE: a document granted by CONEP that formalizes the status of an accredited Ethics Committee (CEP) to a committee whose accreditation proposal has been selected and which has demonstrated satisfactory performance during the pre-accreditation period;

III ACCREDITED RESEARCH ETHICS COMMITTEE: A research ethics committee that, in addition to being accredited by the CEP/Conep System, is certified by Conep for the analysis of high-risk protocols;

IV. ACCREDITED RESEARCH ETHICS COMMITTEE: A Research Ethics Committee (CEP) that meets the operating conditions established in the guidelines of the CEP/Conep System and has its registration granted by Conep. It can act as a CEP for a proposing, participating, or co-participating institution;

V. RESEARCH RISK CLASSIFICATION: classification of a research project into one of the risk levels established in own rule;

VI. REPORT: evaluation of the protocol carried out by a rapporteur, in accordance with the CNS Resolutions and relevant Brazilian regulations;

VII. INSTITUTIONAL RESPONSIBLE: the person with the highest authority in the institution or, if this is not possible, someone who represent officially; and

VIII. RESEARCH RISK CLASSIFICATION: the process by which the degree of risk of a research project is defined. It is based on the possibility of resulting harm, the magnitude of that harm, and the consequences for the integrity of research participants in all its dimensions.

Chapter III

STEPS FOR THE ACCREDITATION OF RESEARCH ETHICS COMMITTEES

Article 5. The accreditation process consists of three distinct and sequential stages:

I. Selection of proposals: The Executive Secretariat of CONEP will issue a public call containing the selection and evaluation criteria, according to the needs identified by CONEP and their respective regional specificities. Ethics Committees accredited in the CEP/CONEP System may apply for the accreditation process, according to the specifications of each call.

II. Pre-accreditation: The number of Ethics Committees (CEPs) selected for the pre-accreditation phase will be defined in the public call for proposals. The CEP whose proposal is selected will undergo a pre-accreditation period lasting 6 months, which may be extended for another 6 months if necessary. During this stage, the CEP's activities will be monitored and evaluated by CONEP. The CEP will not be accredited unless it fulfills the requirements established in this Resolution and in the current public call for proposals; and

III. Accreditation: Once the pre-accreditation period is completed, the CEP that meets the requirements, according to the criteria...
Established by CONEP, you will receive the Accreditation Certificate.

Chapter IV

FROM THE SELECTION OF PROPOSALS FOR ACCREDITATION

Article 6. The selection of proposals will be carried out through analysis of the documents required in this Resolution, in addition to those eventually requested by the current public call for proposals. This analysis will be carried out by CONEP.

Article 7. The accreditation proposal shall be accompanied by a declaration issued by the institutional representative, ensuring a commitment to analyze high-risk protocols, which may be from the institution itself as well as from other institutions not linked to the one that houses the Ethics Committee, when forwarded by CONEP through the Brazil Platform.

Article 8. The institutional representative must submit a document describing, in detail, the institution's policy for:

I provide financial resources for the maintenance and continuous investment in the Ethics Committee, encompassing training and improvement of human resources (board and secretariat), secretariat and infrastructure, aiming to guarantee quality in the ethical evaluation of protocols involving human beings;

II. To guarantee the members of the Ethics Committee (CEP) total independence in decision-making when performing their ethical analysis functions, without suffering any form of pressure or interference from institutional managers, their hierarchical superiors, or those interested in a particular research project;

III. To guarantee that CEP members are excused from their institutional activities during meetings or other events.
related to postal codes, without prejudice to their remuneration; and

IV. To guarantee to the members of the Ethics Committee the reimbursement of expenses incurred due to participation in meetings or
other events related to the postal code.

Article 9. The accreditation proposal must also be accompanied by documentation issued by the Ethics Committee, signed by
your coordinator with the knowledge of the institutional representative, which should include:

I. A formal request justifying the application for CEP accreditation;

II Current Internal Regulations of the CEP;

III. Description of the current operation and infrastructure of the EP;

IV. Proposal for the minimum number of high-risk protocols from other institutions that the Ethics Committee commits to.
to be evaluated monthly, after obtaining the Accreditation Certificate;

V. Report on the activities of the Ethics Committee (CEP) for the three years prior to the date of publication of the public call for proposals, in which
It must include, at a minimum:

a) total number of substantiated opinions issued, highlighting quantitatively those that were forwarded for analysis by CONEP or an accredited CEP;

b) description of the training and capacity-building activities of its members;

c) Description of activities for disseminating knowledge of ethics in research to users, researchers, and the community.
between others;

d) composition of the CEP board in the last three years;

e) frequency of holding meetings for ethical deliberation of research protocols through presentation of
respective minutes; and

f) attendance of each member of the Ethics Committee at meetings for ethical deliberation and compliance with the minimum quorum.

Article 10. Proposals that present the documentation required by Articles 7, 8, and 9, and that meet the eligibility requirements of the current public call for proposals, will be eligible. The proposals will be evaluated through document analysis, and the...
Postal Code:

I demonstrate the ability to evaluate and issue substantiated opinions regarding high-risk protocols, in a number not less than a minimum defined in the current public call, within the deadlines stipulated by the System's regulations.
CEP/Conep;

II. It must have a multidisciplinary composition, with no more than half of its members belonging to the same professional category, and including people of both sexes. The Ethics Committee should preferably have at least one member with curricular experience in the area of bioethics or research ethics. Curricular experience is understood to mean an individual who has training in bioethics or ethics (postgraduate degree, either lato or stricto sensu); or who is a professor in the area of bioethics or research ethics; or who has publications in the area of bioethics or research ethics;

III. To demonstrate the effective and continuous participation of user representatives in the three years prior to the date of
Public notice published;

IV. to have obtained at least one registration renewal with CONEP, totaling an uninterrupted operating period of,
at least four years; and

V. Not having a history of suspension or of practices inconsistent with the guidelines of the CEP/Conep System, as determined.
Complaint or other means of reporting the fact, in the six years prior to the date of publication of the public notice.

Chapter V

FROM PRE-ACCREDITATION

Article 11. The pre-accreditation phase will include activities related to on-site visits, training, and monitoring of...
CEP activities by Conep.

The on-site visit aims to assess the CEP's infrastructure and confirm institutional commitments and guarantees, in addition to...
other information contained in the proposal submitted during the current public call for proposals;

II. The training aims to harmonize the ethical analysis between the substantiated opinions of the Ethics Committee (CEP) and the National Ethics Committee (CONEP).
considering compliance with the Resolutions and other regulations of the CNS;

III. Monitoring of the CEP's activities will be carried out with the objective of improving and correcting them.
any inadequacies identified by Conep; and

IV. During this stage, the CEP accreditation body may request access to the Technical Notes prepared by CONEP for the high-risk protocols it is analyzing.

Article 12. During the training and monitoring period, there will be:

I. Simultaneous and distinct ethical analysis by the Ethics Committee in accreditation and by CONEP. Only the opinion of CONEP will be valid.
issued to the researcher during the pre-accreditation period; and

II. Qualitative analysis by CONEP, through comparison, of the corresponding substantiated opinions of CONEP and of
CEP accreditation, in accordance with CNS regulations.

Chapter VI

FROM ACCREDITATION

Article 13. The Accreditation Certificate, when granted, will be valid for three years and may be renewed upon request from the Ethics Committee itself and evaluation by CONEP.

§ 1 The CEP registration will be renewed concurrently with the issuance or renewal of the Accreditation Certificate.

§ 2 The renewal of the CEP Accreditation Certificate must be requested from 60 days before to 60 days after the certificate's expiration date, and will be effective upon presentation and evaluation by CONEP of the documents listed in Article 9, item V (subparagraphs "a" to "f") of this Resolution.

§ 3 After the deadline has passed, and if renewal has not been requested, the Accreditation Certificate will be cancelled.
automatically.

§4 The Accreditation Certificate may be cancelled at any time at the request of the CEP, upon presentation
Justification in writing, without prejudice to the loss of your registration.

§ 5. If the current CNS regulations are not met, CONEP will cancel the Accreditation Certificate, substantiating its decision in an opinion.

§ 6 In the event of cancellation of accreditation by CONEP, the CEP may appeal. During the appeal review period, the accredited CEP will retain the prerogatives conferred by the Accreditation Certificate.

Article 14. Upon granting the Accreditation Certificate, the Ethics Committee will ensure, through a document signed by its coordinator, a commitment to evaluate high-risk protocols in a number at least equal to the number of proposals submitted, complying with the deadlines defined in the current operational standard and the ethical criteria established in the CNS Resolutions.

Article 15. During the period of validity of the accreditation, there will be:

I. Issuance of the substantiated opinion by the accredited Ethics Committee to the principal investigator;

II. Periodic monitoring by CONEP of the substantiated opinions issued by the accredited CEP, in accordance with
in accordance with CNS regulations; and

III inspection visits to the accredited CEP.

Chapter VII

Regarding the responsibilities of the Research Ethics Committees of CONEP in the analysis of protocols.
HIGH RISK

Article 16. The accredited Ethics Committee will analyze the high-risk protocols.

§ 1 The high-risk protocols will be distributed by Conep among the accredited CEPs.

§ 2. High-risk protocols will preferably be analyzed by the accredited Ethics Committee of the proposing institution itself.

§3 In the event that there is no accredited CEP available for the analysis of a high-risk protocol, it will be up to
Conepesta responsibility.

Article 17. The processing of high-risk protocols in the CEP/Conep System will occur as follows:

The protocol will be forwarded to the accredited Ethics Committee after submission by the researcher on the Brazil Platform. After approval by the accredited Ethics Committee, the protocol will be forwarded for evaluation by the Ethics Committees of the proposing, participating, or co-participating institutions, when applicable;

II. The document verification process will be carried out by the accredited Ethics Committee;

III. Once the documentation has been checked and deemed satisfactory, an ethical review of the protocol will be conducted.
by accredited CEP;

IV. During the protocol analysis period by the accredited CEP, all related documentation will be available for verification, without the possibility of editing, to the CEPs linked to the proposing institution, participant(s) and co-participant(s), if any. In the case of multicenter studies, it will also be available to the other CEPs involved;

After the protocol is approved by the accredited Ethics Committee, it will be evaluated simultaneously by the Ethics Committee linked to the proposing institution and other Ethics Committees involved with the protocol;

VI. The accredited CEPs involved with the protocol will assess local aspects relevant to Research at the institution, which includes:

a) analysis of local documents;

b) local adaptations of the Free and Informed Consent Form, in the fields where editing is permitted (data of researcher, from the institution and the Ethics Committee);

c) analysis of the institutional conditions and the competence of the principal investigator at the institution;

d) Questions that may generate pending issues indicating a need for further clarification. However, these pending issues cannot determine changes to the detailed project or to the fields in the Informed Consent Form where editing is not permitted. If the pending issue is not clarified satisfactorily and if the Ethics Committee considers it relevant, it may not approve the protocol's implementation at the affiliated institution;

VII. Accredited Ethics Committees (CEPs) have the prerogative to approve or reject the protocol at their institution, even if approved by the accredited CEP. In case of non-approval by the accredited CEP, the research cannot be carried out at the institution linked to that CEP, and the substantiated opinion will be sent to the accredited CEP and also to CONEP;

VIII. It is the responsibility of the accredited Ethics Committees involved with the protocol to communicate to the accredited Ethics Committee any information they may have. potential impact on the safety and well-being of research participants;

IX. The handling of complaints, doubts, and grievances is the responsibility of all those involved in the CEP/Conep System;

X the deadlines for document verification, issuance of a substantiated opinion, researcher's response, and request. Resource allocation will be defined in a specific operational standard; and

XI. Amendments and notifications of high-risk protocols will begin processing through the accredited Ethics Committee.

Article 18. The first instance of appeal will be the Ethics Committee (CEP) where the protocol was not approved. The National Ethics Committee (CONEP) will be the next. final appeal instance.

Art. 19. Once the operational capacity of the accredited CEPs is exceeded, Conep will be responsible for analyzing the high-risk protocols in excess.

Chapter VIII

TRANSITIONAL PROVISIONS

Article 20. For the purposes of this Resolution, protocols that fall within the areas foreseen in item IX.4 of CNS Resolution No. 466 of 2012 will be considered high risk until the publication of the standard related to the classification and gradation of research risk.

Article 21. After the publication of this Resolution, and while there are no accredited Ethics Committees in the System, CONEP will be responsible for the ethical evaluation of high-risk protocols.

Article 22. The aspects related to the necessary modifications to the Brazil Platform will come into effect when... updating this electronic system.

Article 23. An instance established within the scope of CONEP will carry out the implementation and monitoring of the accreditation process. of the CEPs and the proposal for a continuing education program.

Chapter IX

FINAL PROVISIONS

Article 24. Any omissions will be resolved by CONEP.

Article 25. This Resolution shall enter into force on the date of its publication.

RONALD FERREIRA DOS SANTOS
President of the National Health Council

I approve CNS Resolution No. 506, of February 3, 2016, pursuant to the Decree of Delegation of Competence of November 12, 1991.

MARCELO CASTRO
Minister of State for Health