RESOLUTION No. 506, DATED FEBRUARY 03, 2016.

The Plenary of the Brazilian National Board of Health, at its Two hundred and Seventy-seventh Ordinary Meeting, held on January 2 and 3, 2016, in the use of its regimental powers and attributions conferred by Law No. 8.080, dated September 19, 1990, by Law No. 8.142, dated December 28, 1990, by Decree No. 5.839, dated July 11, 2006, and in compliance 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 dated 2012, in items XIII.1 and XIII.2;

RESOLVES to:

Approve the following Resolution regarding the accreditation process of Research Ethics Committees (REC) that make up the REC/Conep System.

Chapter I
PRELIMINARY PROVISIONS

Art. 1. This Resolution establishes the criteria for the REC accreditation process of the REC/Conep System, in public and private institutions. The protocol processing will be based on the gradation and classification of risks defined in a specific standard, with criteria established by the Brazilian National Research Ethics Committee (Conep), resulting from research activities involving human beings.

Art. 2. The accreditation process aims to reinforce the decentralization of the REC/Conep System, maintaining the uniformity of the analysis criteria established by the CNS, in compliance with its regulations in force.

Art. 3. Conep is responsible for evaluating, deciding, and granting accreditation to the RECs, in accordance with the provisions of this Resolution.

Chapter II
TERMS AND DEFINITIONS

Art. 4. This Resolution adopts the following definitions:

I. ACCREDITATION: voluntary-based compliance evaluation process, with a view to certification granted by Conep to RECs for the ethical analysis of high-risk protocols involving human beings.

II. ACCREDITATION CERTIFICATE: document granted by Conep formalizing the condition of accredited REC to the committee that has its accreditation proposal selected and presenting with a performance considered satisfactory in the pre-accreditation period.

III. ACCREDITED RESEARCH ETHICS COMMITTEE: REC that, in addition to being accredited in the REC/Conep System, is certified by Conep for the analysis of high-risk protocols.

IV. ACCREDITED RESEARCH ETHICS COMMITTEE: REC meeting the operating conditions established in the REC/Conep System guidelines and has its registration granted by Conep. It can act as the REC of a proposing, participating, or co-participating institution.

V. RESEARCH RISK GRADATION: classification of a research in one of the risk degrees established in a specific standard.

VI. REPORTING: evaluation of the protocol carried out by the reporter, in accordance with the CNS Resolutions and relevant Brazilian regulations.

VII. INSTITUTIONAL PERSON IN CHARGE: person with high authority in the institution or, if this is not possible, a person who officially represents him/her.

VIII. RESEARCH RISK TYPIFICATION: a process by which the risk degree of the research is defined. It is based on the possibility of occurrence of damages resulting from it, on the magnitude of these and on the consequences to the integrity of research participants in all its dimensions.

Chapter III
STEPS FOR ACCREDITATION OF RESEARCH ETHICS COMMITTEES

Art. 5. The accreditation process consists of three distinct and sequential steps:

I. Selection of proposals: Conep's Executive Secretariat will launch a public call containing the selection and evaluation criteria, according to the needs identified by Conep and respective regional specificities. RECs accredited in the REC/Conep System may apply for the accreditation process, according to the specifications of each call;

II. Pre-accreditation: The number of RECs selected for the pre-accreditation phase will be defined in the public call. The REC that has its proposal selected will undergo a 6-month pre-accreditation period, which can be extended for another 6 months, if necessary. At this stage, the REC will have its activities monitored and evaluated by Conep. The REC will not be accredited if it does not fulfill the requirements established in this Resolution and in the current public call;

III. Accreditation: Upon completion of the pre-accreditation period, the REC that fulfills the requirements, according to the criteria established by Conep, will receive the Accreditation Certificate.

Chapter IV
SELECTION OF PROPOSALS FOR ACCREDITATION

Art. 6. The selection of proposals will be conducted by analyzing the documents required in this Resolution, in addition to those eventually requested by the current public call. This analysis will be carried out by Conep.

Art. 7. The accreditation proposal will be accompanied by a statement issued by the institutional responsible, which ensures the commitment of reviewing high-risk protocols, which may be from the institution itself as well as from other institutions not linked to the institution with the REC, when forwarded by Conep, through Plataforma Brasil.

Art. 8. The institutional responsible must present a document describing, in detail, the institution's policy for:

I. Providing financial resources for the maintenance and continuous investment in the REC, covering training and improvement of human resources (collegiate and secretariat), secretariat and infrastructure, aiming to guarantee quality in the ethical evaluation of protocols involving human beings;

II. Ensuring REC members total independence in decision-making in the exercise of their ethical analysis functions, without suffering any form of pressure or interference from institutional managers, their hierarchical supervisors or those interested in a given research;

III. Ensuring REC members a dismissal from their institutional activities during meetings or other events related to the REC, without prejudice to their remuneration;

IV. Ensuring REC members costing related to expenses incurred as a result of participation in meetings or other events related to the REC.

Art. 9. The accreditation proposal shall also be accompanied by documentation issued by the REC, signed by its coordinator and with the awareness of the institutional responsible, which includes:

I. Formal requirement justifying the REC accreditation request;

II. Current Internal Regulations of the REC;

III. Description of the current functioning and infrastructure of the REC;

IV. Proposal of the minimum number of high-risk protocols from other institutions that the REC is responsible for evaluating monthly, after obtaining the Accreditation Certificate;

V. REC activity report for the three years prior to the date of publication of the public call, which includes, at least:

a) Total number of opinion letters issued, quantitatively highlighting those that were sent for analysis by Conep or an accredited REC;

b) Description of the training and qualification activities of its members;

c) Description of activities to disseminate awareness of research ethics to users, researchers, the community, among others;

d) Composition of the REC collegiate in the last three years;

e) Frequency of holding meetings for ethical deliberation of research protocols through the presentation of the respective minutes;

f) Frequency of each REC member at meetings for ethical deliberation and the minimum quorum.

Art. 10. Proposals presenting the documentation of articles 7, 8, and 9, and meeting the eligibility requirements of the current public call, will be eligible. Through document analysis, the proposals will be evaluated, and the REC shall:

I. Show the ability to evaluate and issue opinion letters regarding high-risk protocols, in a number not less than a minimum defined in the current public call, within the deadlines stipulated by the regulations of the REC/Conep System;

II. Present a multidisciplinary composition, with no more than half of its members belonging to the same professional category, with people of both sexes participating. The REC must preferably have at least one member with curricular experience in the area of bioethics or research ethics. Curricular experience is known as the individual who has a degree in bioethics or ethics (*latu* or *stricto sensu* postgraduate studies); or who is a Professor in Bioethics or Research Ethics area; or who has a publication in Bioethics or Research Ethics area;

III. Prove the effective and continuous participation of a user representative in the three years prior to the date of publication of the public call;

IV. Have obtained at least one renewal of registration with Conep, totaling a period of uninterrupted operation of at least four years;

V. Not having a history of suspension or a practice in disagreement with the guidelines of the REC/Conep System according to the investigation of the complaint or other means of information of the fact, in the six years prior to the date of publication of the public call.

Chapter V
PRE-ACCREDITATION

Art. 11. The pre-accreditation stage shall include activities related to the on-site visit, training, and monitoring of the REC activities by Conep.

I. The on-site visit aims to assess the infrastructure of the REC, and confirm the commitments and institutional guarantees, in addition to other information contained in the proposal submitted at the time of the current public call;

II. The training aims at harmonizing the ethical analysis between the REC and Conep's opinion letters, considering compliance with the Resolutions and other CNS regulations;

III. The follow-up of REC activities will be carried out with the aim of improving and correcting any inadequacies identified by Conep.

IV. During this stage, the REC in accreditation may request access to the Technical Notes prepared by Conep for the high-risk protocols it is reviewing.

Art. 12. During the training and follow-up period, there will be:

I. Simultaneous and distinct ethical analysis by the REC in accreditation and by Conep. Only Conep's opinion will be valid and issued to the investigator during the pre-accreditation period;

II. Qualitative analysis by Conep, by comparison, of the corresponding opinion letters of Conep and REC in accreditation, in compliance with CNS regulations.

Chapter VI
ACCREDITATION

Art. 13. The Accreditation Certificate, when granted, shall be valid for three years, and may be renewed upon request by the REC itself and evaluation by Conep.

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

Paragraph 2. The renewal of the REC Accreditation Certificate must be requested from 60 days before, until 60 days after the certificate's expiration date, and shall be in force upon presentation, and evaluation by Conep, of the documents listed in Art. 9, item V (items "a" to "f") of this Resolution.

Paragraph 3. After the deadline, and with no request for the renewal, the Accreditation Certificate will be automatically cancelled.

Paragraph 4. The Accreditation Certificate may be canceled, at any time, at the request of the REC, upon presentation of a written justification, without prejudice to the loss of its registration.

Paragraph 5. If there is no compliance with the current regulations of the CNS, Conep shall cancel the Accreditation Certificate, with its decision stated in an opinion letter.

Paragraph 6. In the case of cancellation of accreditation by Conep, the REC may appeal. During the appeal review period, the accredited REC will maintain the prerogatives conferred by the Accreditation Certificate.

Art. 14. Upon granting the Accreditation Certificate, the REC will ensure, through a document signed by its coordinator, the commitment to evaluate high-risk protocols in a number at least equal to the proposal presented, fulfilling the deadlines defined in the current operational standard and the ethical criteria established in the CNS Resolutions.

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

I. Issuance of the opinion letter by the accredited REC to the investigator in charge;

II. Periodic monitoring by Conep of the opinion letters issued by the accredited REC, in accordance with CNS regulations;

III. Inspection visits to the accredited REC.

Chapter VII
ATTRIBUTIONS OF THE RESEARCH ETHIC COMMITTEES AND CONEP IN THE ANALYSIS OF HIGH-RISK PROTOCOLS

Art. 16. The accredited REC will review high-risk protocols.

Paragraph 1. High-risk protocols will be distributed by Conep among the accredited RECs.

Paragraph 2. High-risk protocols will preferably be reviewed by the accredited REC of the proposing institution.

Paragraph 3. If there is no availability of an accredited REC for the analysis of a high-risk protocol, Conep shall be responsible for this.

Art. 17. The processing of high-risk protocols in the REC/Conep System will take place as follows:

I. The protocol will be forwarded to the accredited REC, after submission by the investigator via Plataforma Brasil. After approval by the accredited REC, the protocol will be forwarded for appreciation by the RECs of the proposing institutions, participant(s) or co-participants, if any.

II. The document verification process shall be carried out by the accredited REC;

III. Once the documentation has been checked and it is considered satisfactory, the ethical analysis of the protocol will be carried out by the accredited REC;

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

V. After approval of the protocol by the accredited REC, it will be evaluated, simultaneously, by the REC linked to the proposing institution and other RECs involved with the protocol;

VI. Accredited RECs involved with the protocol shall appreciate local aspects relevant to research at the institution, which include:

a) analysis of local documents;

b) local adaptations of the Informed Consent Form, in the fields where editing is allowed (investigator, institution, and REC data);

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

d) questions that may generate a pending issue indicating the need for further clarification. However, these pending issues will not be able to determine changes in the detailed project or in the fields in which editing in the Informed Consent Form is not allowed. If the pending issue is not satisfactorily clarified and if the REC considers it relevant, it may not approve the conduction of the protocol in the linked institution;

VII. Accredited RECs have the prerogative to approve or not the protocol in their institution, even if approved by the accredited REC. In case of non-approval by the accredited REC, the research cannot be carried out in the institution linked to that REC, and the opinion letter shall be sent to the accredited REC and also to Conep;

VIII. It is up to the accredited RECs involved with the protocol to communicate to the accredited REC information that has a possible impact on the safety and well-being of research participants;

IX. The reception of reports, questions, and complaints is the responsibility of all those involved in the REC/Conep System;

X. The deadlines for document checking, issuance of an opinion letter, investigator's response, and appeal request shall be defined in an operational standard;

XI. Amendments and notifications for high-risk protocols shall begin processing by the accredited REC.

Art. 18. The first instance appeal shall be the REC in which the protocol is not approved. Conep will be the next and last instance appeal.

Art. 19. Once the operational capacity of the accredited RECs is exceeded, Conep shall be responsible for reviewing the excess high-risk protocols.

Chapter VIII
TEMPORARY PROVISIONS

Art. 20. For the purposes of this Resolution, the protocols that fall into the areas provided for in item IX.4 of CNS Resolution No. 466 dated 2012 will be considered of high risk, until the publication of the standard related to the typification and gradation of research risk.

Art. 21. After the publication of this Resolution, and while there are no RECs accredited in the System, Conep shall be responsible for the ethical evaluation of high-risk protocols.

Art. 22. The aspects related to the necessary changes at Plataforma Brasil shall come into effect when this electronic system is updated.

Art. 23. Instance established within the scope of Conep will carry out the implementation and follow-up of the REC accreditation process and the proposal of a continuing education program.

Chapter IX
FINAL PROVISIONS

Art. 24. Cases not covered shall be resolved by Conep.

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

RONALD FERREIRA DOS SANTOS
President of the Brazilian National Board of Health

I hereby ratify CNS Resolution No. 506, dated February 03, 2016, pursuant to the Competence Delegation Decree dated November 12, 1991.

MARCELO COSTA E CASTRO
Minister of State for Health