MINISTRY OF HEALTH
National Health Council

PROCEDURES STANDARD No. 006

EVALUATION OF RESEARCH ETHICS COMMITTEES

Objectives: This Operational Standard provides for the Assessment of Research Ethics Committees – CEP, accredited by the CEP/CONEP System, considering CNS Res. 196/96 and the provisions of items III and III.1 of CNS Res. 370/07 , and details the procedures to be developed for the
establishment of an evaluation standard capable of promoting
strengthening the performance of the CEP/CONEP System.

Justification: The CEP/CONEP system, created by Res. CNS 196/96, currently has 602 accredited research ethics committees. In 2007, with the approval of Res. CNS 370, new requirements for the
accreditation and re-accreditation of these committees, with the CNS stating in this resolution that the evaluation of the CEP may be carried out at any time, at the discretion of CONEP and that, if the CEP does not meet the conditions of
operation, a period of 60 days will be given for measures to be taken.
appropriate measures and communication to CONEP. If there is no response or it is not possible to meet the operating criteria, the CEP registration will be cancelled. Although some of these assessment items are
set out in the aforementioned resolution, through evaluations carried out during 2008, one year after its approval, CONEP verified that the committees have many doubts in their operational procedures, as well as lacking greater detail regarding their conduct in relation to the process of permanent qualitative assessment. In this way, the present proposal is justified, in order to expand the understanding of ethics committees about the need to adapt to an organizational, qualitative and relationship standard

with the CEP/CONEP System, to remain accredited or not, by the CNS.

Evaluation Guide for Research Ethics Committees

1. First accreditation process for an Ethics Committee in Search

1.1. Documentary verification for the accreditation process of a research ethics committee is carried out first by the Executive Secretariat of CONEP, and begins upon the **request from the proposing Institution,** duly signed by its legal representative.

1.2. All documents proving compliance with the requirements of Res. CNS 370/07 must be verified.

1.3. If compliance with the requirements in your entirety, the request as well as all its attachments documents will be filed in a separate folder, and the claim will be granted.

1.4. If the requirements of Res. CNS 370/07 are not met, the proposing Institution will receive a letter from CONEP, through its coordination, specifying the reasons for the pendency or rejection of the claim.

2. Process of first re-accreditation of the Ethics Committee in Search

2.1. The re-accreditation process must always begin 90 days before the expiration of the previous operating license, when the CONEP Executive Secretariat must issue a letter acknowledging the need to request renewal within 60 days before its expiration and must not exceed 90 days

after the registration expiration date, considering the fulfillment of pending issues and procedures via mail, observing the provisions of item II.1 of CNS Res. 370/07.

2.2. If the CEP does not respond within 60 days after the expiration of the previous registration, it will be canceled by means of an official letter. cancellation without any prior notice.

2.3. In the period of 90 days that exceeds the previous registration, the CEP is still considered regular and remains the CEP with all its rights and duties preserved, as long as you have requested its renewal is in progress.

2.4. If communication with CONEP during the handling pending renewal issues interrupted by the CEP for more than 60 days, its registration will be automatically canceled and the CEP will be communicated by letter.

3. **From local inspections.**

Local inspections of CEPs will be carried out at any time, considering the process of permanent qualitative assessment of the system or, in particular, upon request for re-accreditation, reporting situations, irregularities in the opinions sent to the CONEP, difficulties expressed by the CEPs themselves, or demands arising from the local community.

3. 1 The inspection visit will always be carried out with the presence of a CONEP member, accompanied by employees specially trained for this purpose, in addition to advisors from the National Health Council who live close to the location where the CEP is established.

3.2 The inspection committee will have the participation of at least 03 people.

3.3 The ethics committee may be inspected without the need for prior notice, at any time, and must keep its documentary files permanently organized in the CEP itself, as well as its secretariat.

3.4 If necessary, the presence of the CEP coordinator, user representation and/or director of Institution to monitor the visit.

3.5 Any of the CEP members may be invited to accompany the inspection, at the discretion of the inspection committee.

3.6 There is no deadline set in advance for the inspection, and it must be occur in a way that understands the natural routine of the committee, the one that would be encountered by a research subject, for example.

3.7 The inspection time cannot be determined in advance, depending on each case and its complexity, the inspection committee inspection will justify your stay on site.

3.8 The inspection team will prepare a report to be presented to CONEP/CNS at an ordinary meeting, when any decision on the registration of the CEP will be taken collectively.

3.9 The report prepared must be sent to the CEP, for information, after analysis by CONEP/CNS.

3.10 After receiving the report and the considerations attached by CONEP, the CEP will have a maximum period of 30 days to manifestation.

3.11 Upon the CEP's manifestation, CONEP will issue a final assessment opinion on the CEP, establishing its activity condition.

3.12 Cases that require new monitoring visits for adjustments must already be specified by the inspection committee at the time of their initial report.

3.13 The members of the inspection committee must accuse any possible conflict of interest in carrying out the role, so that, if necessary, they can be replaced.

4 Inspection items

4.1 **Administrative and operational aspects of the functioning of the CEP:**

4.1.1 Does the institution that houses the CEP have a research center? If yes: Do you have a health license from ANVISA? Has it already been inspected by ANVISA? What is the research area of this center? Public or private? How do you maintain your zip code?

4.1.2 Organization of CEP documentation;

4.1.3 Is the CEP accessible and its location well publicized within the Institution? Describe the CEP's facilities and equipment (furnished meeting room with guaranteed privacy for meetings);

4.1.4 Computer and printer exclusive to the CEP, with internet access, telephone/fax exclusive to the CEP; 4.1.5 File with key, to guarantee confidentiality for protocols and opinions;

4.1.6 Proof of a specific structure for the secretariat, in addition to a professional specifically hired to act as the CEP secretariat;

4.1.7 Minutes of ordinary and extraordinary meetings of the last three years;

4.1.8 Attendance list of members corresponding to each the meetings of the last three years;

4.1.9 List of research analyzed by CEP in the last three years;

4.1.10 Calendar of meetings for the current year, duly displayed;

4.2 Qualitative aspects of CEP's action in protecting subjects of researches:

Five research protocols from each of the last three years will be randomly drawn to verify the following qualitative aspects:

4.2.1 Does it follow a question guide or is it descriptive of the project?

4.2.2 Is it signed by the CEP coordinator?

4.2.3 Is it organized according to the CONEP opinion script?

4.2.4 There was a quorum at the meeting that analyzed it (check list of presence of the meeting)?

4.2.5 Provides the researcher with the necessary guidelines in favor of the research subjects (analyze the merit of the opinion), concluding with a position compatible with the System's standards CEP/CONEP?

4.2.6 Were the due partial reports submitted?

4.2.7 Were these reports evaluated by the CEP? There is an opinion on the same?

4.2.8 Are the opinions on the reports substantiated and were they sent to CONEP with the appropriate frequency?

4.2.9 Were adverse events observed in the studies being monitored properly communicated to CONEP? They were taken immediate measures to protect research subjects?

4.2.10 Does the CEP collaborate with the CEP/CONEP System by analyzing projects from other Institutions?

4.2.11 Are there possible identifiable conflicts of interest between committee members and the role they must perform? (Small institution, with researchers who make up the CEP and analyze projects of their own interest?)

4.3 Aspects of monitoring approved research:

4.3.1 Is there any mechanism provided by the CEP for the monitoring of analyzed projects, in addition to reports presented by the researchers? If positive, describe.

4.3.2 Has there ever been any case of interruption of studies by the committee?

4.3.3 Has there ever been a case of research participants reporting to the CEP? If yes, how was your inquiry?

4.3.4 The CEP carries out some type of educational work for research participants or researchers, aiming to expand their autonomy in proposing and carrying out ethical research?

4.3.5 In cases of violations against the rights of subjects of research, what action does the CEP deem to be relevant (interruption of research in courses without justification, denial of assistance, failure to guarantee access to drugs being tested after the study, among other violations)?

4.4 Aspects of the relationship with the CEP/CONEP System

4.4.1 The CEP is accredited in the current registration system (SISNEP or other)?

4.4.2 Did you request renewal within the deadline set by the CEP/CONEP System?

4.4.3 Keeps CONEP registration updated, communicating all changes in the composition of the CEP?

4.4.4 Do you request guidance from CONEP in case of doubts? If positive, How have you been treated?

4.4.5 Do you have a training plan for new members?

4.4.6 Issuing a certificate of participation in the CEP for rapporteurs?

4.4.7 Do you have any incentive plan for participating in the CEP?

4.4.8 Do you have an ethics training plan for the entity that hosts you and the community as a whole?

4.4.9 Relates to other CEPs to organize meetings or thematic discussions?

4.4.10 Did the CEP participate in the last ENCEP? If so, what was the member who participated? What is your assessment? Detail.

4.4.11 Have members already participated in any in-person or distance learning course offered by the CNS or the Ministry of Health on research ethics? Detail.

4.4.12 Have CEP members participated in any other training initiative in ethics in research involving human beings? Detail.

4.5 Participation aspects of user representation in the CEP

4.5.1 How many members represent users in the composition from the CEP?

4.5.2 What form of indication of user representation is used by the POCKET?

4.5.3 What is the frequency of the user representative member in the last again?

4.5.4. Assign a value from 0 to 5 to the user member's level of participation in CEP activities.

4.5.5 Is there a link between the user representative and Social Control within the Municipality?

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