

# CHARACTERIZATION OF ETHICS COMMITTEES IN RESEARCH OF A MUNICIPALITY OF BAHIA

## CARACTERIZAÇÃO DE COMITÊS DE ÉTICA EM PESQUISA DE UM MUNICÍPIO BAIANO

## CARACTERIZACIÓN DE COMITÉS DE ÉTICA EN INVESTIGACIÓN DE UN MUNICIPIO DE BAHÍA

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**Objective:** to characterize the profile of the Research Ethics Committees of a municipality of Bahia. **Method:** quantitative approach study, with descriptive analysis of the results, conducted in five Research Ethics Committees. **Data collection** was based on a self-administered questionnaire on the Google Forms Platform. **Results:** a majority of male members were evidenced, with stricto sensu graduate course, invitation admission and prior training to work in the Committees. They were implanted more than 8 years ago; composition ranges from 8 to 25 full members; the use of the website in the communicative process predominates. The projects evaluated are multidisciplinary, distributed for consideration considering the area of training, profile, and expertise of the member. **Conclusion:** the Research Ethics Committees studied had been active for more than eight years, which demonstrates consolidated experience in research. The renewal of the mandate contributes to the deepening of discussions, training of new members and strengthening of the system (CEP/CONEP in Portuguese).

**Descriptors:** Research Ethics Committees. Ethics in Research. Ethics Review. Human. Bioethics.

*Objetivo:* caracterizar o perfil dos Comitês de Ética em Pesquisa de um município baiano. *Método:* estudo de abordagem quantitativa, com análise descritiva dos resultados, realizado em cinco Comitês de Ética em Pesquisa. A coleta de dados deu-se por questionário autoaplicado na Plataforma Google Forms. *Resultados:* evidenciou-se maioria de membros do gênero masculino, com curso de pós-graduação stricto sensu, ingresso por convite e capacitação prévia para atuarem nos Comitês. Foram implantados há mais de 8 anos; composição varia de 8 a 25 membros efetivos; predomina a utilização da página eletrônica no processo comunicativo. Os projetos avaliados são multidisciplinares, distribuídos para apreciação considerando a área de formação, perfil, e expertise do membro. *Conclusão:* os Comitês de Ética em Pesquisa estudados possuem atuação há mais de oito anos, o que demonstra experiência consolidada em pesquisa. A recondução do mandato contribui para o aprofundamento das discussões, capacitação de novos membros e fortalecimento do sistema CEP/CONEP.

*Descritores:* Comitês de Ética em Pesquisa. Ética em Pesquisa. Revisão Ética. Humanos. Bioética.

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*Objetivo: caracterizar el perfil de los Comités de Ética en Investigación de un municipio de Bahía. Método: estudio de aproximación cuantitativa, con análisis descriptivo de los resultados, realizado en cinco Comités de Ética en Investigación. La recolección de datos se basó en un cuestionario autoadministrado en Google Forms Platform. Resultados: se evidenció la mayoría de los miembros varones, con curso de posgrado stricto sensu, admisión por invitación y capacitación previa para trabajar en los Comités. Fueron implantados hace más de 8 años; la composición oscila entre 8 y 25 miembros de pleno derecho; predomina el uso del sitio web en el proceso comunicativo. Los proyectos evaluados son multidisciplinarios, distribuidos para su consideración considerando el área de capacitación, perfil y experiencia del miembro. Conclusión: los Comités de Ética en Investigación estudiados llevaban más de ocho años activos, lo que demuestra una experiencia consolidada en investigación. La renovación del mandato contribuye a la profundización de los debates, la capacitación de nuevos miembros y el fortalecimiento del sistema (CEP/CONEP en Portugués).*

*Descriptor: Comités de Ética en Investigación. Ética en la Investigación. Revisión Ética. Humano. Bioética.*

## Introduction

The Research Ethics Committees (CEPs in Portuguese) are bodies responsible for the assessment of research protocols involving human beings submitted to the Brazil Platform, from public and private institutions, with the purpose of defending and protecting the rights of research participants<sup>(1)</sup>. Thus, CEPs are mandatory consultation bodies so that scientific research involving human beings can be initiated.

In this sense, the CEPs contribute to the quality of research and to the discussion of the social function they exercise in the institutions where they are developed and for the community in general. Consequently, they value and defend the interests of the participant and the researcher, because once approved, the research protocol will be validated as an appropriate proposal from an ethical point of view<sup>(2)</sup>. For this reason, researchers need to guide their research according to the ethical requirements defined in the documents and regulations of research involving human beings whose main focus is related to respect for human rights and the dignity of the human person<sup>(3)</sup>.

Moreover, the CEPs perform the ethical review of the research protocols while associating this review with scientific analysis and keeping the information known on a strictly confidential basis<sup>(4)</sup>. In decision-making, each Research Ethics Committee should have full independence and prioritize the assessment of protocols of public relevance and strategic interest of the agenda of priorities of the Unified Health System (SUS in

Portuguese). Moreover, the CEP should issue an opinion of the research protocols submitted to it within the deadlines established by the specific operational standard<sup>(5)</sup>. In addition to the function of conducting the ethical review of research projects, the CEPs Codes have an educational, consultative and deliberative function<sup>(2)</sup>.

The implementation of a CEP is done in the form of a multidisciplinary and independent collegiate, to analyze and decide on research protocols involving human beings<sup>(6)</sup>. Because it is collegiate, each CEP must be formed by at least seven members and registered with the National Research Ethics Commission (CONEP in Portuguese), the body charged with analyzing the documentation and request for this registration. In addition, the CEP must prove that at least 50% of its members have research experience. However, there may be variation in this composition, depending on the specificity of each institution and the research themes analyzed<sup>(7)</sup>.

In the distribution of the members of each CEP, according to the orientation of CONEP, the principle of proportionality in relation to the professional category and the participation of both genders should be respected. In this sense, these members must belong to different areas of knowledge and professional categories, to meet the multidisciplinary and multidisciplinary aspects necessary for the composition of the CEP and there must be at least one representative of the users. Allied to this, to contemplate the profile of

multidisciplinarity, people from other institutions and areas of knowledge may be invited as effective members and should include bioethics scholars<sup>(2)</sup>. The aspects of multidisciplinarity and proportionality should be described in their own form, with the information of the full name of each member, their attribution in the CEP, gender, professional training, the area of knowledge and current schooling<sup>(8)</sup>.

The term of the member mandate is three years, but there may be re-renewal for an equal period. It is up to each Committee to define the way members enter the CEP, which can be, for example, through election, edict, nomination and invitation. Once the form of entry of the members has been defined, it must be included in their bylaws (IR in Portuguese)<sup>(2)</sup>. On the other hand, the entry of the member representing users in the CEP is done by indication, preferably, by the Municipal or State Health Councils, by social movements and representative entities of users<sup>(7)</sup>.

Studying the way the CEP operates is considered a priority by the National Agenda of Health Research Priorities (ANPPS in Portuguese)<sup>(9)</sup>, as it enables, among other aspects, to highlight the need for training actions of its members to deepen the themes appreciated in research projects. In addition, the CEPs are organs of public relevance in the social control of the research<sup>(10)</sup>.

Knowing these committees can help researchers from all areas of knowledge understand why they need to develop their research according to aspects that generate safety and protection for individuals<sup>(11)</sup>. Consequently, they bring benefit to society, as is the case of research whose results are used in the area of health. Therefore, the aim of this study is to characterize the profile of CEPs of a municipality in Bahia.

## **Method**

Study of quantitative approach and descriptive analysis of the results. Data were collected through a self-applied questionnaire on the Google Forms Platform from September 10 to

October 13, 2020. Sociodemographic variables (gender, color, marital status and education) were studied; structural variables of the CEPs (time of existence, number of members, formation of members, duration of mandates, renewal of members, forms of relationship of the CEP with the public and with other CEPs); and variables that make up the distribution process, quantity and thematic areas of the projects appreciated in the CEP.

The study involved five CEPs implanted in public institutions, located in a municipality of Bahia as distributed as well: four CEPs implanted in higher education institutions (HEIs), with predominance of CEP in the health area; cep implanted in a hospital. The participants were four coordinators and one deputy coordinator. It was adopted as inclusion criterion to be responsible for the assessment of research projects and away for any reason.

It should be noted that, of the total of 39 CEPs existing in the municipality at the date of collection<sup>(12)</sup>, ten CEPs were selected for convenience, however only five CEPs agreed to answer the characterization questions. For the characterization of the cep profile and in order to avoid the repetition and/or duplication of data collection, the questionnaire was inserted that only the coordinators and/or person indicated by him could answer the questionnaire. The participants' contacts were made available by the respective CEPs via e-mail. Ethical aspects related to research involving human beings were observed, according to Resolution n. 466/2012 of the National Health Council, especially with regard to free and informed consent, confidentiality and anonymity of the participants. In this sense, the Free and Informed Consent Form (TCLE in Portuguese) was made available through a link inserted in the questionnaire with the possibility of downloading by the participants and virtual signature of the Informed Consent as they agreed to answer the questionnaire. The collected data were organized by CEP, in excel spreadsheet, and received specific coding to avoid the identification of the participants and their respective CEPs.

This study was approved by the CEP of the School of Nursing of the Universidade Federal da Bahia, under Opinion n. 4,255,337 and Certificate of Presentation of Ethical Appreciation (CAAE) 36248120.7.0000.5531 and is part of the dissertation research project entitled “Moral and/or ethical problems experienced by members of Ethics and

Research Committees”.

## Results

Of the five study participants, four were CEP coordinators and one was vice-coordinator (CEP 5), as described in Chart 1, below.

**Chart 1** – Distribution of coordinators and vice-coordinator by the Research Ethics Committee regarding sociodemographic characteristics.

CEP	Gender	Self-declared skin color	Marital status	Major schooling	Religion
A*	Male	Black	Divorced	Master	Christianity (without specifying)
B	Female	White	Married	Doctor	Catholic
C	Male	White	Married	Doctor	Catholic
D	Male	White	Married	Postgraduate in Psychology (without specifying)	Catholic
E	Male	Black	Married	Postgraduate in Anthropology (without specifying)	Candomblé

Source: Created by the authors.

Subtitle:

\* Vice coordinator; CEP Research Ethics Committee (in Portuguese)

In relation to undergraduate courses and professional category of coordinators of the CEPs, the same proportion of professionals in the areas of Health and Humanities was verified. Thus, regarding the training courses were mentioned: dentistry, pharmacy, administration, psychology and philosophy. The professional categories of the participants were: dentist, pharmacist, administrator, psychologist and anthropologist. There was no duplicate of undergraduate and/or professional category.

The participants expressed their role in the CEP of the institution in which they worked with a working time ranging from 1.5 to 10 years. All reported having received initial training to be a member and continued training, which can

occur every thirty days and even between one and two years. The majority (3) of the members reported no incentives to work in the CEP.

Chart 2 summarizes the information about the time of implantation (existence) of the study's CEPs, a quantity of effective members, a form of entry into the respective CEP, the form of communication used by the CEPs for relationships with the public/researchers, with other CEPs and CONEP, and changes in the forms and relationships due to Covid-19. It should be emphasized that, due to the pandemic caused by Covid-19, most of them described that the face-to-face relationship was suspended and replaced by telephone contacts and videoconferences.

**Chart 2** – Structural variables of the Research Ethics Committees.

(continued)

Variables	Research Ethics Committees				
	A	B	C	D	E
Time of existence (years)	Not answered	8	16	Could not inform	15
Number of effective members	25	8	8	9	9

**Chart 2** – Structural variables of the Research Ethics Committees.

(conclusion)

Variables	Research Ethics Committees				
	A	B	C	D	E
User representative login form	Nomination of an institution /civil community association	Invitation	Not informed	Indication of an institution /civil community association	Indication (without specifying)
Form of entry of other effective members	Election	Invitation	Invitation	Invitation	Edictal
Term of office of members (years)	3	3	3	2	3
Renewal of members	Yes	Yes	Yes	Yes	Yes
Forms of relationship between CEP and the public and/or researchers	Website; Speak conoso; In person	Website	Website; Face-to-face; email; phone number; Intranet page	Website	Website
Forms of CEP relationship with other CEPs and CONEP	Website; Contact us; In person	Not aswered	Contact us; Brazil Platform; WhatsApp.	Website; WhatsApp Group	Website; Contact us
Change in relationship forms due to Covid-19	Yes	Yes	Yes	Yes	No

Source: Created by the authors.

Subtitle: CEP Research Ethics Committee; CONEP National Research Ethics Commission (both initials in Portuguese)

The process of distribution of research projects in the CEPs takes place in different ways including for the same CEP. The thematic areas of the most frequently analyzed projects are new

drugs. Only one CEP reported the participation of the ad hoc. There are CEPs with more than one way to meet to deliberate on the research protocols (Table 1).

**Table 1** – Distribution process, quantity and thematic areas of the projects evaluated, ad hoc participation. Bahia, Brazil, 2020. (N = 5)

(continued)

Variables	Research Ethics Committee				
	A	B	C	D	E
<b>Project distribution process</b>					
Based on the member's training area	1	1	-	-	-
Based on the member's profile	1	-	-	-	-
Based on expertise	1	-	-	1	-
Availability for learning	1	-	-	-	-
Consider the volume the rapporteur already has to analyse	-	-	1	-	-
On meeting	-	-	-	-	1

**Table 1** – Distribution process, quantity and thematic areas of the projects evaluated, ad hoc participation. Bahia, Brazil, 2020. (N = 5) (conclusion)

Variables	Research Ethics Committee				
	A	B	C	D	E
<b>Approximate number of projects analyzed/month</b>	150	10	15	15	15
<b>Thematic areas of the projects analyzed by the Research Ethics Committee</b>					
New Equipment	-	-	1	-	-
Inputs	-	-	1	-	-
Health devices	-	-	1	-	-
New Drugs	-	-	1	-	-
Human Reproduction	-	-	1	-	-
Other	1	1	1	1	1
<b>Thematic areas of the projects analyzed by the Research Ethics Committee/ more frequently</b>					
New Drugs	-	-	1	-	-
Other	1	-	-	1	1
No answer	-	1	-	-	-
<b>Participation of ad hoc consultant</b>	1	No answer	No answer	No answer	No answer
<b>Topics consulted to the ad hoc</b>					
Information system	1	-	-	-	-
Anthropology	1	-	-	-	-
Psychology	1	-	-	-	-
Theology	1	-	-	-	-
<b>Periodicity of meetings to deliberate on the projects</b>					
Biweekly	1	-	1	-	-
Monthly	-	1	-	1	1
Online Meetings/Projects of Relevance of the Unified Health System	-	-	1	1	-
<b>Form of meetings to deliberate on projects</b>					
Presential	-	-	1	1	-
Video conferencing	1	1	1	1	1
No answer	-	-	-	-	-

Source: Created by the authors.

Note: Conventional signal used:

- Numeric data equal to zero not resulting from rounding.

As for the other thematic areas of the projects analyzed by the CEP, the following were described: CEP A, interdisciplinary (without specifying which ones); CEP B, clinical studies; CEP C, qualitative studies, human sciences, psychology, nutrition, diagnostics, evaluation of health techniques and procedures; CEP D, human behavior; and CEP E, food, Health, Social sciences and Humanities. In relation to the other thematic areas of the projects most frequently analyzed by the CEP, they were described, generically, as other areas: CEP A, educational sciences, humanities and health; CEP B did not respond; CEP C, qualitative studies, human

sciences, psychology, nutrition, diagnostics, evaluation of health techniques and procedures; CEP D, human behavior; and CEP E, food.

## Discussion

The sociodemographic data of the study participants point to a majority of male CEP members and training in different areas of knowledge, although with a predominance of the health area, which suggests the existence of unbalanced composition of the limbs. These data corroborate studies on the theme and which also indicated an imbalance in the composition

of CEP in terms of gender and professional category<sup>(1,13-14)</sup>.

It should be noted that the balanced distribution of gender, training and professional category in the composition of CEP is a requirement of CONEP for the registration of these committees. The relevance of people in different areas of training and professional categories contribute to the aspect of multidisciplinary and multiprofessionalism in the composition of the CEPs<sup>(8,15)</sup>.

Besides, the existence of people from different areas may favor further discussions and analysis of projects<sup>(16-17)</sup>. To make this aspect, people from different institutions can be invited when there are no professionals from the institution itself<sup>(2)</sup>.

On the other hand, when dealing with the balanced distribution of gender, the Operational Manual for CEP refers to men and women. Similarly, The Operational Standard (NOP in Portuguese) n. 001, of 2013<sup>(7)</sup>, when defining the composition of the CEP, determines that there must be people of both sexes, that is, it does not use the term gender, but maintains the idea of man and woman<sup>(2,7)</sup>. However, the use of the term gender as a binary factor (female and male) has been criticized, because the reference to gender binary does not meet the current conception of the theme<sup>(18-19)</sup>.

The participants of this study expressed the existence of initial training activities to be a member of the CEP and continued training, which were also reported in another study on CEPs<sup>(14)</sup>. Activities for initial training and continued training are mandatory in the operationalization of the CEP as determined by CONEP<sup>(7)</sup>.

Initial training activities are relevant so that new members can be trained in ethical and bioethical aspects and to know the regulations of research involving human beings. These activities should include, among others, discussion about the function of the CEP, presentations of norms regarding research involving human beings, indication of theoretical references on ethics in research, reading of resolutions on ethics in research and RI of the respective CEP<sup>(2,20-21)</sup>.

On the other hand, continuous training can occur, among other means, through the

continuous analysis of research protocols, as well as through extension, undergraduate and graduate courses<sup>(14)</sup>. Both initial training and initial training allow better perception and understanding of the research protocols discussed and, consequently, that ethical assessment is carried out in an agile and adequate manner<sup>(17)</sup>. Therefore, initial training and continued training, as integral parts of the CEP educational function, ratify education as a means capable of preparing people for critical decision-making and the proper application of ethical values<sup>(22)</sup>.

When asked about incentives provided by the CEPs to act as members, the majority of the participants in this study expressed no such incentives. However, CONEP orientation is that the institution in which the CEP is implanted develops means for stimulating and recognizing this action, as is the case of specific workload, score to evaluate academic productivity and functional progression. Moreover, once the expenses incurred by cep members for cep activities are proven, the amounts spent should be reimbursed<sup>(2)</sup>.

Thus, it becomes relevant that there is financial, material and human assistance from the place where each CEP is implemented and that its members are encouraged, as a way of valuing and recognizing the voluntary work of these people. For this reason, the accounting of the hours of activities in the CEP for the effective work effect in the institution, the institutional and curricular recognition of the work of its members as a score for functional progression are pointed out as possible alternatives to mitigate the limitations of this system and stimulate the participation of CEP members<sup>(23)</sup>.

The information in the present study on the time of implementation of the CEPs shows that these Committees have long experience in the assessment of projects involving research with human beings, but there is a contrast when it is verified that the members remain in office between two and three years, with the right only to a re-leadership to the position. Similarly, a study that analyzes the characteristics of the CEP distributed in The Brazilian territory points to the short length of stay of the members, which

reveals high turnover in the position and little experience. However, research experience is essential for strengthening the CEP/CONEP System and for members of the CEPs to perform the ethical review of protocols in an appropriate manner, which, among other requirements, requires time and experience<sup>(17)</sup>.

The experience of the members of CEPs occurs to the extent that they are returned to office, which promotes the acquisition of new knowledge and improvement of the experience through the continuous ethical analysis of research. Thus, the renewal of the mandate allows the permanence of experienced members in the CEP, and, consequently, favors the deepening of discussions and the training of new members regarding the knowledge necessary for the evaluation of projects.

The CEPs of this study maintain relationships with the public/researchers, with other CEPs and with CONEP, with emphasis on the website. A study<sup>(24)</sup> points out the importance of this relationship in the measure that provides protection of the freedom and well-being of the participants and the promotion of public trust in the research. Especially in relation to CEPs, through this relationship it is possible to exchange experiences and information to support the solution of similar cases. Together with this, the exchange of experiences, as well as the activities for initial training and continuous training, are in line with the educational function of the CEP, to enable its members to develop the capacity for reflection and make ethical decisions, with a view to the defense and protection of research participants<sup>(17,25)</sup>.

The existence of different forms of distribution of research protocols among the members of the CEPs seen in this study, among which, the areas of activity and training of each of its members, the expertise, profile and availability of the member to learn, contributes to stimulate the learning of the members and enable their insertion in the study of the different themes of the research protocols submitted for evaluation. If there is difficulty in analyzing a particular research protocol, it can be resolved by the participation

of the ad hoc member who specializes in the topic under discussion.

This diversification was also seen in a study<sup>(26)</sup> conducted in Minas Gerais regarding the CEP experience, which highlights the analysis of research projects in the various areas of knowledge with emphasis on health sciences. It should be emphasized that this diversity of research projects reinforces the need to think about the distribution of projects in order not only to provide opportunities for the rotation scheme suggested by CONEP, but to enable the knowledge of the members to be expanded, since the promotion of learning should also be part of the educational role of each CEP.

Among the limitations of the study, we mention the low adhering of the coordinating members of the CEP. However, this study has scientific relevance in being able to characterize the professionals who compose the Committees in their work process and, above all, presents to the academic community the organizational, institutional and structural challenges of research ethics committees based on the sampling of a large municipality in Bahia.

## Conclusion

The research made it possible to characterize the study's CEPs, with emphasis on the fact that all have been active for more than eight years and a re-mandate, which demonstrates consolidated experience in research. Thus, the renewal of the mandate allows the more experienced members to remain in the CEP contributing to the deepening of discussions during the assessment of research protocols, as well as to the training of new members. Moreover, this experience represents an essential gain for the CEP/CONEP system to be strengthened in the processes of ethical assessment.

The contributions of this study encompass the academic fields and professionals who are dedicated to research involving human beings. It is important to know the CEPs, their composition, their role and how they act in the appreciation of research projects for the



relevance that these committees have in terms of social control of research, as well as to subsidize public policies aimed at strengthening the CEP/CONEP System, so that its members continue to work in favor of the protection of the rights of research participants. Therefore, it is necessary to encourage for the academic community the existence and performance of the CEPs in specific disciplines, as well as by reading scientific texts. Similarly, in the professional field, it is relevant to promote publications related to the CEPs as a way to ratify research projects appreciated by agencies committed to the promotion of ethical assessment of projects, with a view to full protection of research participants and protection of the researcher when validating research projects as an appropriate ethical proposal.

### Collaborations:

1 – conception, design, analysis and interpretation of data: Rosinete Souza Barata, Karla Ferraz dos Anjos, Alciene Pereira da Silva and Darci de Oliveira Santa Rosa;

2 – writing of the article and relevant critical review of the intellectual content: Rosinete Souza Barata, Karla Ferraz dos Anjos, Alciene Pereira da Silva, Julia Barbosa de Magalhães and Darci de Oliveira Santa Rosa;

3 – final approval of the version to be published: Rosinete Souza Barata, Karla Ferraz dos Anjos, Alciene Pereira da Silva, Julia Barbosa de Magalhães and Darci de Oliveira Santa Rosa.

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