




## CONTINUING EDUCATION FOR EMPLOYEES OF THE ETHICS COMMITTEE

 [https://doi.org/ 10.56238/isevmjv4n2-018](https://doi.org/10.56238/isevmjv4n2-018)

Receipt of originals: 10/03/2025

Acceptance for publication: 10/04/2025

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## **ABSTRACT**

Since 2000, the Gaspar Vianna Hospital de Clínicas Foundation has implemented a continuing education program for the members of the Research Ethics Committee. In 2024, the annual action plan was updated in accordance with operational standard 001/2013. Objective To train the members of the Committee in order to improve the quality of the rapporteurships. Experience report on the creation of a hybrid course with one-hour monthly classes, started in February and scheduled to end in December 2024. So far, four classes have been held, addressing topics such as research ethics, pending Resolutions No. 466/2012 and 510/2016, and protocol documentation. Final thoughts: Feedback from attendees has been positive, highlighting the interaction and quality of the content. Continuing education proves to be a successful experience, contributing to the protection of research participants and the improvement of reporting.

**Keywords:** Teaching and Research. Zip code. Training. Continuing Education.

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## INTRODUCTION

The Gaspar Vianna Hospital de Clínicas Foundation (FHCGV) is a public institution that is part of the Unified Health System (SUS), with specializations in cardiology, psychiatry and nephrology. In 2013, it was recognized by the Ministry of Education and Culture (MEC) as a Teaching and Research Hospital through Ordinance 167/2013, which establishes guidelines and criteria for hospitals that carry out teaching and research activities in health, contributing to the training of professionals and the improvement of clinical and scientific practices<sup>1</sup>.

The FHCGV Research Ethics Committee (CEP) is responsible for evaluating and monitoring research involving human beings, ensuring that they are carried out ethically and legally. It protects the rights and well-being of participants by ensuring that research takes place in a transparent and accountable manner, minimizing risk and optimizing scientific benefits<sup>2</sup>.

According to Gontijo (2017), the members of the CEP must be trained to perform the function. The CEP aims to develop educational and consecutive activities, polishing their bioethical knowledge, to be able to carry out ethical reflections in the projects they evaluate. Improved knowledge is essential for a good evaluation, ensuring confidentiality and protection for participants<sup>1</sup>.

The continuing education program of the Research Ethics Committee (CEP) of the FHCGV, implemented in 2000, is part of the institution's long-term action plan. It provides for the participation of CEP members in courses offered by the National Research Ethics Commission and other specialized institutions <sup>3,6,6,8,11,12,15,17</sup>.

In 2024, the annual action plan of the Research Ethics Committee (CEP) was updated, in line with operational standard 001/2013, which establishes guidelines for the organization, structure, and functioning of RECs in Brazil. This update highlighted aspects such as the composition of the committee, roles and responsibilities, documentation and reporting, as well as training, continuing education, monitoring and evaluation, among others <sup>1,3,5,7,8,9,10,12,15,18</sup>.

Salgueiro et al. (2018) highlighted that, in 2017, the members of the Research Ethics Committee (CEP) of the Sérgio Arouca National School of Public Health participated in a continuing education program focused on topics such as CNS Resolution 510/16, preparation of ethical opinions, and issues related to the payment and reimbursement of participants, in addition to studies in virtual environments. This training



was initiated in response to Senate Bill No. 200, which emphasizes ethics in research with human subjects, biobanks, and the vulnerability of participants. The events were fundamental to clarify doubts, encourage previous readings and enrich the analysis of projects, contributing significantly to the continuous training of the CEP team and improving research ethics <sup>2, 3,4, 6, 7</sup>.

## OBJECTIVE

To train members of the Ethics and Research Committee in order to improve the quality of bioethical assessments.

## METHODOLOGY

This was an experience report type study, descriptive, qualitative, prospective, with compliance with a training program. This training in continuing education for members of the Research Ethics Committee (CEP) of the Gaspar Vianna Hospital Clínicas Foundation began in February 2024, and is scheduled to end in December of the same year, totaling 11 monthly meetings of 60 minutes. The course adopted a hybrid and integrative format, which combines several psychopedagogical approaches to promote effective and lasting learning, valuing the relationship between the topic addressed and the participants. In addition, the use of visual content facilitated the absorption and memorization of the topics, contributing to the quality of learning. Reporting members, full members, alternates and representatives of research participants were involved in this training process.

## RESULTS

Between February and May 2024, the CEP team taught four classes addressing different themes, arranged below:

- **Introduction to Research Ethics:** Research ethics is a fundamental component that ensures the protection of participants and the integrity of scientific investigations, incorporating essential principles such as respect, fairness, and responsibility at all stages of the study. One of the pillars of this ethic is informed consent, which requires participants to be fully informed about the study's objectives, procedures, risks, and benefits before deciding to participate. This practice not only respects the autonomy of individuals but also strengthens trust in research practices, creating an environment of



transparency and mutual respect. In addition, research ethics addresses the issue of confidentiality, ensuring that participants' data is protected and used exclusively for the agreed purposes, avoiding any misuse that could compromise their privacy. Codes of ethics and guidelines play a crucial role in guiding researchers in implementing these ethical principles, promoting responsible practices, and ensuring that investigations are conducted ethically. Organizations such as the National Research Ethics Commission (CONEP) offer specific regulations and guidelines, ensuring that research complies with international standards and contributing to a safer and more respectful academic and scientific environment. In this way, research ethics not only protects the participants, but also raises the quality and credibility of science as a whole.

- **Resolution No. 466/2012:** Issued by the Regional Health Council on December 12, 2012, the resolution emphasizes the guidelines and standards for research with human beings, incorporating bioethical principles such as autonomy, non-maleficence, beneficence, justice and equity. These principles ensure the rights and duties of the participants, respecting human and social dignity. The resolution defines essential concepts, such as:

- ❖ Research findings: which are relevant information for the participants;
- ❖ Immediate and Comprehensive Assistance: which covers emergency care;
- ❖ Benefits of the Survey: refer to the gains for the participants and their communities;
- ❖ Informed Consent and Informed Consent: ensure that participants, or their legal representatives, are well informed and voluntarily in accordance with the research.
- ❖ Informed Consent Form (ICF): it is the formal document that records this consent. The resolution highlights the importance of ethics in the protection of participants in scientific studies, underlining the need for approval by the CEP for the start of research, in addition to ensuring the reliability and privacy of data and the consent of those involved.

- **Resolution No. 510/2016:** Revising Resolution 196/1996 was issued by the National Health Council on April 7, 2016, in which it introduces new guidelines and regulations to ensure ethics and the participation of research participants with respect and human dignity, ensuring the protection of the rights of collaborators in scientific research and ethics, providing clear information about the research, risks and benefits,



reinforcing the protection of participants and the confidentiality of data used. Thus, the REC must be composed of specialized professionals with ethical knowledge so that there is monitoring and evaluation throughout the research process, ensuring ethics.

- **Harmonization and Technical Notes:** Harmonization in the Research Ethics Committee (REC) is essential to ensure the impersonality and integrity of the review process, implementing uniform guidelines and procedures that ensure a consistent and objective evaluation of the protocols. The application of standardized criteria is essential to create a transparent environment, minimizing bias and ensuring that all researchers are treated fairly.

Technical notes play a crucial role, offering detailed guidance that ensures rigorous analysis that is in line with ethical and scientific best practices. Additionally, effective communication with researchers is vital, as providing clear and constructive feedback allows them to understand the CEP's expectations and make necessary corrections efficiently. This open dialogue contributes to the quality and credibility of the opinions issued, strengthening trust in the ethical research process.

- **The Functioning of the CEP:** The flow begins with the submission of a research protocol by the researcher, which details the study plan, including objectives, methods and ethical considerations. After submission, the Committee conducts a rigorous analysis of the protocol to ensure that the research is conducted in accordance with ethical principles, such as the protection of participants and the minimization of risks.

The committee evaluates aspects such as informed consent, data confidentiality, and the scientific validity of the research. Based on this review, the REC can approve the protocol, request modifications, or reject it, thus ensuring that all studies meet established ethical and scientific standards. The decision of the REC is crucial to ensure the integrity and ethics of the research, promoting the protection of the subjects involved and the quality of the results obtained.

- **The Routine of the CEP:** After the judgment, the researcher submits the research protocol, which can be accepted within ten days. If the documentation needs correction, it is returned to the researcher; otherwise, it is received by the coordinator, who designates a rapporteur to evaluate. The rapporteur issues an opinion, which is reviewed by the collegiate before the preparation of the opinion substantiated by the coordinator, to be issued within 30 days. If favorable, the protocol is approved for execution; If not, the researcher has 30 days to respond to the pending issues. In case of failure, it is possible

to appeal to the Research Ethics Committee or to CONEP. The final approval of the protocol depends on validation by the CEP and, if necessary, by CONEP, ensuring compliance with ethical standards. If the protocol is withdrawn at any stage, the Platform is closed, ensuring the quality of ethical studies.

- **The documents used for the research protocol:** A research protocol includes documents that are essential to ensure ethical compliance and the quality of the study. It must be presented in Doc or PDF format, detailing objectives, methods and justifications. Terms such as the Informed Consent Form (ICF) and the Data Use Commitment Agreement (TCUD) ensure that participants are informed and consent to the research, except in previously approved situations. The researchers' Lattes curricula are required to assess their qualifications, and the protocol must contain a cover page with the stamp of the principal investigator and the institution, as well as a declaration of institutional acceptance that confirms the approval of the project. A term of commitment for the delivery of reports is also required, which guarantees the presentation of the results in accordance with the requirements of the Ethics Committee. These documents are fundamental for ethical and administrative review, ensuring the integrity and transparency of the research process.

**Table 01** - Continued Training Plan - February to May, 2024.

MONTH	SUBJECT	TARGET AUDIENCE
February	Introduction to ethics and research.	All members and administrative staff.
March	Operation and routines of the CEP and documents that make up the research protocol.	General training of new members, retraining of permanent members and administrative staff

April	Drafting of opinion I (Resolutions 466/2012 and 510/2016)	General training of new members, retraining of permanent members and administrative staff.
May	Preparation of opinion II (Resolution 466/2012 and 510/2016)	General training of new members, retraining of permanent members and administrative staff.

**SOURCE:** Authors, 2024.

## DISCUSSION

This study presents the experience of continuing education carried out by the Research Ethics Committee (CEP) of the Gaspar Vianna Clinical Hospital. Since 2000, the program has aimed to train committee members to strengthen the ethical quality of rapporteurships and ensure the protection of research participants <sup>1,4,5,10,12</sup>.

Updated in 2024, the hybrid course included monthly classes focused on ethics and essential regulations, such as resolutions No. 466/2012 and 510/2016. The approach highlighted principles such as autonomy, justice, and respect for human rights, which are fundamental for the rigor of the analyses and the responsible conduct of research <sup>2,3,4,6</sup>.

Every educational process needs to evaluate the result through the responses of those involved, which is called feedback, which is positive, and training is valued for the interaction and relevance of the contents, promoting a continuous learning environment <sup>5,8,11,13,17</sup>.

This experience of in-service training of the CEP contributed to the improvement of bioethical assessments, making them more efficient and effective. In summary, the



continuing education program strengthens research ethics and trust in the scientific process, benefiting both the professionals involved and the participants, and reinforces the institution's commitment to quality and responsibility in research practices

6,7,9,12,13,14,15,18

## **FINAL CONSIDERATIONS**

The initiative of reserving time at the end of each class to resolve doubts, welcome praise and criticism, and discuss positions proved to be highly effective, promoting an enriching learning environment and strengthening continuous feedback. The positive consensus among the participants highlighted the success of this approach, which contributed to the improvement of reporting skills, resulting in a more qualitative feedback to researchers. In addition, the continuing education experience raised the quality of evaluations and reports, ensuring greater protection for research participants. With a deeper understanding of ethical and normative practices, Research Participant Representatives will be better prepared to advocate for the rights and well-being of those involved, ensuring that research is conducted responsibly and with integrity. This initiative represented a fundamental step towards advancing research ethics and strengthening trust in the scientific community.



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