




PERFORMANCE OF RAPORTEURSHIPS IN THE RESEARCH ETHICS COMMITTEE

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Aldair da Silva Guterres¹, Marly Lobato Maciel², Gianne de La-Rocque Barros Warken³, Dilma do Socorro Moraes de Souza⁴, Fabiola Santana de Oliveira Costa⁵, Milene de Andrade Goveia Tyll⁶, Xaene Maria Fernandes Duarte⁷, Anne Caroline Gonçalves Lima⁸, Lilian Pereira da Silva Costa⁹, Rosileide de Souza Torres¹⁰, Patricia Bentes Diniz¹¹, Ingrid Magali de Souza Pimentel¹²

¹Nutritionist

State Public Foundation Hospital de Clínicas Gaspar Vianna, FHCGV
E-mail: aldair.guterres@gasparvianna.pa.gov.br

²Occupational Therapist

State Public Foundation Hospital de Clínicas Gaspar Vianna, FHCGV
Email: marlylobato@gmail.com

³Physical therapist

State Public Foundation Hospital de Clínicas Gaspar Vianna, FHCGV
E-mail: giannedelarocque@gmail.com

⁴Medical

State Public Foundation Hospital de Clínicas Gaspar Vianna, FHCGV
E-mail: dsouza@cardiol.br

⁵Nurse

State Public Foundation Hospital de Clínicas Gaspar Vianna, FHCGV
E-mail: fabiolacosta.enf@gmail.com

⁶Nurse

State Public Foundation Hospital de Clínicas Gaspar Vianna, FHCGV
E-mail: milene.tyll@gasparvianna.pa.gov.br

⁷Nutritionist

State Public Foundation Hospital de Clínicas Gaspar Vianna, FHCGV
E-mail: xaenemaria@gmail.com

⁸Nurse

State Public Foundation Hospital de Clínicas Gaspar Vianna, FHCGV
Email: annecglima@outlook.com

⁹Nutritionist

State Public Foundation Hospital de Clínicas Gaspar Vianna, FHCGV
E-mail: lilianpereirasc@yahoo.com.br

¹⁰Nutritionist

State Public Foundation Hospital de Clínicas Gaspar Vianna, FHCGV
E-mail: rosileide2@gmail.com

¹¹Psychologist

State Public Foundation Hospital de Clínicas Gaspar Vianna, FHCGV
Email: patriciabentesdiniz10@gmail.com

¹²Nurse

State Public Foundation Hospital de Clínicas Gaspar Vianna, FHCGV
Email: Ingrid.magali@uepa.br



Aliny Silva dos Santos¹³, Kariny Vieira Rebelo¹⁴, Maria Eduarda Ferreira da Conceição¹⁵, Myreya Naomi Pereira da Silva¹⁶ and Eloiza de Sena Almeida¹⁷

ABSTRACT

The research on the quantitative advancement of reports carried out by the members of the Research Ethics Committee of the Gaspar Vianna Hospital de Clínicas Foundation during the years 2020 until May 2024, allowed the projection of techniques aimed at advancing in the increase in productivity of the number of reports by the members. The investigation took place through an analysis of the increases in the number of reports in the aforementioned period. From the analysis, gradual increases in the number of rapporteurships were demonstrated. Having as possible triggering factors, the increase in incentive for scientific production, the encouragement of members for the greatest possible agility in carrying out the reports of the projects now submitted to the Committee, better distribution of projects to the 14 members of the Committee in the most equal way possible, in order not to cause overload to any of the members. Thus, supporting the data, in 2020 96 rapporteurships were carried out, in 2021 there were 124, 2022 there were 149, in 2023 there were 174 and from January to May 2024 they have already reached the level of 85 rapporteurships. In view of the above, it is possible to see that it is extremely important to observe this growth in the number of reports to our Committee, since this will have a favorable impact on the future achievement of the CEP/FHCGV accreditation. For the institution, this characteristic is of paramount importance, since it is a hospital with the mission of teaching, research and assistance. With the responsibility of training trained and ethically committed professionals.

Keywords: Scientific production. Ethics Committee. Researchers.

¹³Pedagogue

State Public Foundation Hospital de Clínicas Gaspar Vianna, FHCGV
E-mail: alinysilvados_santos@hotmail.com

¹⁴Pedagogue

State Public Foundation Hospital de Clínicas Gaspar Vianna, FHCGV,
Email: karinyrebelo93@gmail.com

¹⁵Nutritionist

State Public Foundation Hospital de Clínicas Gaspar Vianna, FHCGV
Email: nutrii.mariaeduarda@gmail.com

¹⁶Nursing Student

State Public Foundation Hospital de Clínicas Gaspar Vianna, FHCGV
Email: Naomymyreya25@gmail.com

¹⁷Nutritionist

State Public Foundation Hospital de Clínicas Gaspar Vianna, FHCGV
Email: almeidaeloiza25@gmail.com



INTRODUCTION

The Research Ethics Committee (CEP) is a body linked to the National Research Ethics Committee (CONEP) of the Ministry of Health, and is responsible for evaluating and ensuring that research involving human beings is conducted in accordance with ethical principles, considering that development and ethical engagement are inherent to scientific and technological development^{1, 2,3,4}.

The main function of the REC is to protect the rights and well-being of research participants and to ensure the rights and duties of those involved, the scientific community and the State².

However, with the advent of Bill No. 6007/2023 that is being processed in the Senate, the magnitude of this work has been questioned, one of the requirements proposed by the PL is the creation of independent RECs, in its justifications for this fact, the document discusses the time of delay for the release of opinions analyzed by CONEP and proposes the development of the autonomy of the RECs so that they adopt new management measures to reduce this term slowly and gradually^{1,2,3,4}.

It is worth considering that today 93% of the opinions analyzed by CONEP are carried out in a timely manner in the regulation, data compatible with reference countries in research, such as the United States, the United Kingdom and Germany^{1,2}.

CONEP also has the support of Accredited RECs, which are authorized to carry out together with CONEP the protocols of greatest risk for research participants, emphasizing that the deadline for the release of this opinion includes the period of analysis of the projects and also the periods for researchers to resolve the pending issues identified^{1, 2,3,4}.

Currently, the main functions regarding the ethical analysis of the CEP according to the guidelines of resolution No. 466, of December 12, 2012. Include²:

"VIII.1 - evaluate research protocols involving human beings, with priority in themes of public relevance and strategic interest of the SUS priority agenda, based on epidemiological indicators, issuing an opinion, duly justified, always guided, among others, by the principles of impersonality, transparency, reasonableness, proportionality and efficiency, within the deadlines established in operational rules, avoiding redundancies that result in delays in the analysis."²

In order to comply with what is stated in Resolution No. 466, the REC has important criteria to be used by the rapporteur when carrying out a project analysis, namely^{2,3}:

1. Ethical evaluation, with the purpose of examining research projects to ensure that they comply with established ethical standards, considering aspects such as informed consent, privacy, and risks and benefits for participants;
2. Informed consent, a mandatory document to conduct research with human beings, is used to verify that participants are adequately informed about the study, including its objectives, procedures, risks and benefits, and that consent is obtained in a voluntary and informed manner;
3. The protection of participants seeks to ensure that the rights and dignity of participants are respected, and that measures are taken to minimize risks and discomfort;
4. Regulatory Compliance, an analysis that aims to ensure that research complies with local, national, and international laws and regulations related to research with human subjects.

Allied to these criteria, continuous monitoring is also sought, through partial and final reports, which, despite appearing in the resolution as being necessary, are not included as mandatory documents, which makes it difficult for the CEP to follow up. Considering that this action ensures that the research continues to follow the ethical guidelines established to review and evaluate any ethical problems that arise during the study^{5,6,7,8}.

Therefore, RECs are essential in academic environments and health institutions, which develop scientific research with human beings, such a device serves to ensure that scientific research is conducted in an ethical and responsible manner, promoting integrity and trust in science. To this end, the management of RECs carried out by CONEP, in an integrated system, although it presents some fragility that needs to be reviewed, favors the qualification of the work in a systematic way and the rapid response, with safety^{1,2,3,4}.

With regard to the reports linked to the guidelines of ethical analysis supported by the current standards, they support the existence of the CEP, as they play a crucial role in the documentation, monitoring and evaluation of the activities of a given research



project. They are essential for the integrity and effectiveness of the research participant and ensure that the committee's practices are documented, transparent, and that they comply with ethical standards, in addition to supporting continuous improvement and accountability through a biannual report with CONEP^{1,2,3,4}.

Rapporteurships provide a detailed record of the REC's discussions and decisions, including the evaluation of research projects and the reasons for approval or rejection, ensure transparency in the ethical review process, allow other stakeholders (such as researchers and regulators) to understand the reasoning behind the committee's decisions, and promote some ease in assessing compliance with ethical guidelines and regulations when reviewing progress reports and events adverse events reported by the researchers. The rapporteurships also ensure that the REC is acting in accordance with its responsibilities at the state, national and international levels and that decisions are well-founded, providing a basis for accountability to research participants and other actors involved, demonstrating that the REC is committed to research ethics, also allowing the review of practices and their processes, helping to identify areas for improvement, ensuring efficiency and effectiveness in ethical review, serving as reference material for the training of new CEP members and for the ongoing training of current members. The rapporteurships keep the CEP with a watchful eye, facilitating auditing and inspections that aim to improve and adjust any inadequacies identified by CONEP and regulatory bodies, providing documented evidence of compliance with ethical standards^{5,6,7,8}.

The quantitative advance of rapporteurships carried out by the members of the CEP/FHCGV, during the years 2020 until May 2024, generated curiosity and the need to draw up future strategic plans to monitor the demands and qualities of the rapporteurships.

The objective of this work was to report the experience lived by the CEP/FHCGV, in order to show the progress in the increase in productivity of the number of reports by the members of the CEP, even obeying the current standards.

METHODOLOGY

This study is an observational, descriptive and retrospective experience report, with qualitative and quantitative descriptions, in order to show and analyze the possible drivers for the increase in the number of reports in the period from 2020 to May 2024.

The study site was the CEP/FHCGV, which operates on the first floor of the hospital, and is located in the city of Belém, state of Pará, Brazil

RESULTS

Between 2020 and May 2024, the CEP/FHCGV experienced a notable increase in the number and efficiency of its reporting, reflecting a significant percentage growth in the number of documents processed and a substantial reduction in the average review time. This progress has been achieved through streamlining workflows and ongoing member empowerment. However, it faced challenges such as work overload and resource limitations. To sustain and expand these advancements, the committee plans to expand its staff, invest in new technology tools, and seek partnerships to share best practices and resources. This progress demonstrates a strong commitment to integrity and efficiency in ethical research review.

From the analysis, gradual increases in the number of rapporteurships were demonstrated. Having as possible triggering factors the encouragement of the members for the greatest possible agility in carrying out the reports of the projects now submitted to the CEP, better distribution of the projects to the 14 component members in the most equal way possible, in order not to cause overload to any of the members. In order to meet the deadlines of the regulations that guide the processing processes, this CEP aims to achieve future Accreditation and for this, it uses the deadlines not as a goal for the return of reports, but as a margin of allowed period, always valuing the quality in its ethical opinions carried out with the greatest possible agility, which allows the rapporteur to receive more than 3 projects when necessary.

Thus, we can say that after the survey carried out, through the counting of rapporteurships and supporting the data found, we had 96 rapporteurships carried out in 2020, in 2021 there were 124, 2022 there were 149, in 2023 there were 174 and from January to May 2024 they have already reached the level of 85 rapporteurships. The data, if compared to the initial year of the survey, are presented as follows:

Table 01 - Statement of the number of rapporteurships per year:

Years	Number of reports	Percentage increase
2020	96	100%
2021	124	+24%
2022	149	+50%
2023	174	+82%
2024 (Jan to May)	85	+92%



DISCUSSION

Justifiable movements for this significant increase in reports are directly related to the demands of scientific research production, among the observable aspects we have the existence of financial incentives for which FHCGV researchers seek; such as the Institutional Program of Scientific Initiation Scholarships (PIBIC) which currently has scholarships of R\$ 700.00 having in its mandatory criteria, the presentation of scientific production in the form of an abstract/presentation; Integration In the internship selection process provided by the Euvaldo Lodi Institute (IEL) that brings university students and technical courses closer to the job market, indicating talents to fill vacancies available at the Foundation with an incentive in the average amount of R\$ 600.00, in addition to the multiprofessional residencies subsidized by the National Plan for the Strengthening of Health Residencies, that offer the incentive of R\$ 4,106.09 and fosters the vision of how the Federal Government has perceived residency as a way to specialize the professional, valuing continuing education as an essential step for the sustainability and improvement of the Unified Health System (SUS), in this aspect; The residency also promotes the obligation of scientific production. For the assistance, monitoring and supervision of the aforementioned actors, the Foundation, through financial resources from the Ministry of Health, also has an incentive for preceptors in the amount of R\$ 700.00, as they indirectly stimulate research within the scope of the SUS, since their follow-up with Trainees, Interns and residents makes scientific production more palpable^{9, 10, 11, 12, 13, 14}.

To stimulate these incentives that reach the population of researchers present at the Foundation, we have the existence of Law No. 9,319, which instituted the Qualifica Health Program, sanctioned by Governor Helder Barbalho of the State of Pará in 2021, it combines the State Department of Public Health (SESPA) and the State University of Pará (UEPA) to promote the qualification and appreciation of health professionals who work in the State, achieving in this way; medium and high complexity care, encouraging teaching, research and extension activities of medical residency programs and/or equivalent medical specialization programs, a multiprofessional residency that is already a reality at the Foundation and currently serves about 27 health professionals^{15, 16, 17, 18, 19, 20}.

It is also worth considering that the FHCGV has a group of multiprofessionals who volunteer to join research groups, we emphasize that although there is no data on



productions carried out only by volunteers, the research protocols subsidized to this committee commonly have at least 1 volunteer author involved. In addition to also considering physicians, physiotherapists, nurses, among other professionals in the clinical care of this Hospital who value movements in their daily work and seek to convert them into scientific productions, developing writings for publication in scientific journals and journals, strengthening the researcher aspect in their personal profile^{21,22,23,24,25}.

However, in order for the perception of all researchers to be welcomed and developed at the institution, it is necessary to permanently train employees linked to the Teaching and Research sector for the instruction, processing and monitoring of their respective researches, valuing, stimulating and monitoring each protocol, respecting its particularities. To this end, the Foundation, in the role of strengthening its function as a teaching and research hospital, holds events; such as the Teaching and Research Journey in order to value existing productions and stimulate the emergence of new perspectives for scientific production, providing the debate of various issues of social and educational relevance to the health field, promoting preparatory courses on important themes for the community, in addition to awarding, highlighting the most relevant productions, registered in the event^{21.22.23.24.25..}

Favoring this long-term view, this committee has new goals, which were generated from the results collected within this analysis of the quantitative advances of rapporteurships, to be achieved in the coming months. These goals are related to the monitoring of the protocols received in the last 2 years, aiming to categorize the field of action of each researcher, categorize their main doubts so that it is then possible to build events together with the Teaching and Research team to promote research. In this sense, for the institution, this characteristic is of paramount importance, since as it is a hospital with the mission of teaching, research and care, it values training trained and ethically committed professionals and for this REC, it is valuable to be able to contribute directly or indirectly so that this training occurs satisfactorily, within the parameters established by the CONEP^{26, 27,28,29,30}.

CONCLUSION

In view of the above, it is possible to see that it is extremely important to observe this growth in the number of reports for the CEP/FHGCV, since this will have a



favorable impact on the future obtaining of accreditation with CONEP. The predictability of the factors that move the number of reports linked to this committee, allows the team linked to Teaching and Research to have a perception of the research groups that present a greater result with regard to scientific production, in addition to allowing a glimpse of weaknesses, such as the absence of relevant themes with the possibility of being developed within the Foundation, generating content based on future projections to encourage research.



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