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The CEP-Conep System in 2020: confronting COVID-19, challenges and lessons learned

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Abstract *This paper presents the structuring dimensions of the CEP-Conep System in order to understand the actions promoted by the National Research Ethics Commission in response to demands for the processing and ethical analysis of research protocols related to COVID-19 in 2020. Based on CEP-Conep System public documents, an assessment of legislation, from 1988 to 2020, and its extension in terms of the number of Committees, users, and protocols, from 2012 to 2020 was presented. The minutes of Conep's Ordinary Meetings (RO), for 2020, of a confidential nature, were analyzed, to verify adaptations to the pandemic. At the end of 2020, the System had 844 Committees, 854,741 users, and 701,791 analyzed protocols. The Commission centralized the analysis of COVID-19 protocols, in January 2020, and promoted three decentralizations, as more knowledge was generated, with vaccine protocols for COVID-19 remaining centralized. The history of the CEP-Conep System provided ballast for the adoption of management, educational and communication measures that accelerated the approval of protocols and made the process transparent. The absence of indicators made it impossible to evaluate the performance in 2020, which was apparently satisfactory.*

Key words *Research ethics, Research ethics committees, COVID-19*

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Introduction

The protection of people who participate in research is the primary mission of the Research Ethics Committees (RECs). Ethics in research involving human beings was regulated, in Brazil, by the National Health Council (CNS) from 1988, and composed of various norms, the backbone of the current CEP-Conep System[1-3].

According to the CNS/MS Resolution No. 466/2012, data collection in research with human subjects can only begin after formal approval by the CEP-Conep System, ensuring that ethical requirements are followed from the outset[4]. Internationally, the use of indicators is recommended to monitor the ethical review and supervision process, from submission to completion of studies[5,6]. The year of 2020 saw the onset of COVID-19. On January 30, 2020, the World Health Organization (WHO) declared the disease a global public health emergency and, on March 11, 2020, a pandemic. At the end of 2020, Brazil had 7,714.819 cases and 195,742 deaths from COVID-19[7].

The period was marked by the search for cures or treatments, whether in the repositioning (new indication) of known drugs, the development of new therapeutic alternatives or the development of vaccines[8,9]. In all cases, clinical studies are key to providing the necessary proof of efficacy and safety.

Although the CEP-Conep System had already been consolidated, the health emergency resulting from the COVID-19 pandemic subjected it to the challenge of meeting the demand for ethical analysis of specific research protocols, and with unprecedented urgency.

The article presents structuring dimensions of the CEP-Conep System in order to understand the actions promoted by the National Research Ethics Committee in responding to demands for the processing and ethical analysis of research protocols related to COVID-19 in 2020.

Method

The method followed a case study design, using documentary and historiographical research. The theoretical foundation of the case study is based on the analysis of events within their real-life contexts, when the focus of the research question is the "how" and "why" of a situation, which does not require control on the part of the investigator. The case study focuses on contemporary events and aims to deepen the understanding of complex social phenomena[10,11].

The process of historiographical research involves gathering data by identifying, recording and organizing documents that answer the research question, and which can be classified chronologically and thematically[12]. Content analysis techniques applied to documents help to identify the core of meaning and key terms that elucidate the object of investigation. The content is then categorized and interpreted in a way that allows for relevant inferences[13].

Information was compiled in stages, forming two structuring dimensions of the System. The first described the normative path of the CEP-Conep System. Resolutions and other documents issued by the National Health Council regarding research ethics and CONEP were identified from 1988, the year of the first CNS Resolution, until 2020, by consulting http://conselho.saude.gov.br/resolucoes-cns and https://plataformabrasil.saude.gov.br/login.isf. The regulations were organized in the form of a timeline, with the number, issue year and enforcement period of the norm.

In the second dimension, related to aspects of the structure of the CEP-Conep System, data extracted from documents made it possible to identify, year by year, the number of CEPs, protocols approved by the System and number of users/researchers, from 2012 to 2020. The data was organized in a table to show the variation in these dimensions over time.

In order to investigate the adaptations implemented by the System to the demand for research protocols related to COVID-19, the minutes of Conep's ordinary meetings (RO) were analyzed for the year 2020, chosen because it was the first calendar year of the pandemic. The minutes were read first across the board and then in depth, trying to identify key expressions, cores of meaning and relevant thematic clusters[14]. This analytical reading led to the emergence of analytical categories related to Conep's activities in the examination of protocols, namely (i) centralization and decentralization of the protocol processing flow, (ii) adaptation of work processes, and (iii) Conep's normative, educational and informative measures. The information from the minutes was complemented, where necessary, with other documentary and/or bibliographic information, in an attempt to form a historical perspective. The data were presented as text, with identified and coded highlights of interest from the minutes.

Conep's normative changes in 2020 were organized in the form of a timeline to visualize the chronological sequence of adaptations.

The research was submitted to the CEP of the Sérgio Arouca National School of Public Health (ENSP) and approved, with the Certificate of Presentation for Ethical Appreciation (CAAE) number 5008.1521.0.0000.5240. The study protocol submitted to CEP- ENSP was complemented by authorizations for access to the Commission's documents and use for research purposes and resulting publications, signed by the Conep Coordinator: the Institutional Consent Term (TAI) and the Data Use Commitment Term (TCUD). The original documents are held by main author. The research only began after all the authorizations had been obtained.

Results

To demonstrate the first of the two dimensions of the CEP-Conep System, the historical series of CNS/MS resolutions was detailed in Figure 1.

Three rules stand out due to their nature, as mentioned above: 1/88, 196/96 and 466/12. Under Resolution 196/96, the CNS approved 13 other additional resolutions related to research ethics. In 2012, the CNS approved Resolution 466/2012, revoking Resolutions 196/199, 303/2000 and 404/2008. Among the innovations, Resolution 466/2012 established the "Plataforma Brasil" (Brazil Platform) as the exclusive means of processing research protocols and defined subsequent complementary resolutions. In 2016 and 2018, three of the complementary resolutions stated in the norm were approved: accreditation of CEP (506/2016); standardization of protocol analyses in the area of Human and Social Sciences (CHS) (510/2016); and regarding detailing of research of strategic interest to SUS (580/2018). Res. 647/2020 defines rules for the appointment and performance of CEP members as representatives of research participants[15].

The CEP-Conep System is also structured by two Operational Norms (NO). NO 1/2012 addresses and details the flows for multicenter protocols and creates a single flow for reporting adverse events. NO 1/2013 explains the issues of conflicts of interest, confidentiality in the assessment of protocols, regulates the processing of amendments and extensions, the processing of notifications of serious adverse events, the receipt of complaints and issues regarding ethical infringement, among other aspects. In addition to the NO, there are three manuals, which guide the organization of the CEP, instruct researchers on how to submit studies onto the Plataforma Brasil, and pedagogically explain, the most frequent pending issues in clinical research[15].

In the Plataforma Brasil, from January 2012 to December 2020, there were 854,741 registered researchers/users and 701,791 registered research protocols (Table 1). At the end of 2020, there were 844 approved CEPs in the country. During this period, there was a 780% increase in number of users, a 1,250% increase in number of submitted protocols and a 28% increase in number of CEPs. In 2020, there was a reduction of around 18% in both the number of new users and of new protocols, and practically stability in the number of new CEPs[15].

To deal with the COVID-19 pandemic and the speed required for Conep actions, the system was restructured. The minutes of the 2020 ordinary meetings present different aspects that proved necessary for this turn of events, and their contents were analyzed according to categories, relating to the most outstanding characteristics of the System, and described below.

Centralization and decentralization of protocol processing flows

On January 31, 2020, Conep decided that the examination of all protocols related to COVID-19 would be centralized and timely, and for that the CEPs should abstain from analyzing them. The centralization was recorded in the minutes of the Ordinary Meeting (RO) in January:

Conep authorized the speedy processing of protocols on this subject [COVID-19] [...] even though they do not fall within the areas of mandatory ethical analysis [of Conep], guiding the CEPs not to analyze them[16].

Conep announced the decision to centralize through two documents, issued on 01/31/2020: (i) the Report to Research Ethics Committees, identified as I Report, and (ii) the Report to Society (Figure 2). Circular Letter No. 4/2020, dated 02/10/2020, disclosed what was defined in the RO and also advised that

[...] within the scope of the CEP, Consubstantiated Opinions should be issued with the "Approved" status, and it is up to Conep to decide on such research protocols under a special processing regime[17].

Due to the growing number of protocols, the overload on technical advisors and reviewers and a better understanding of the disease, an oppo-

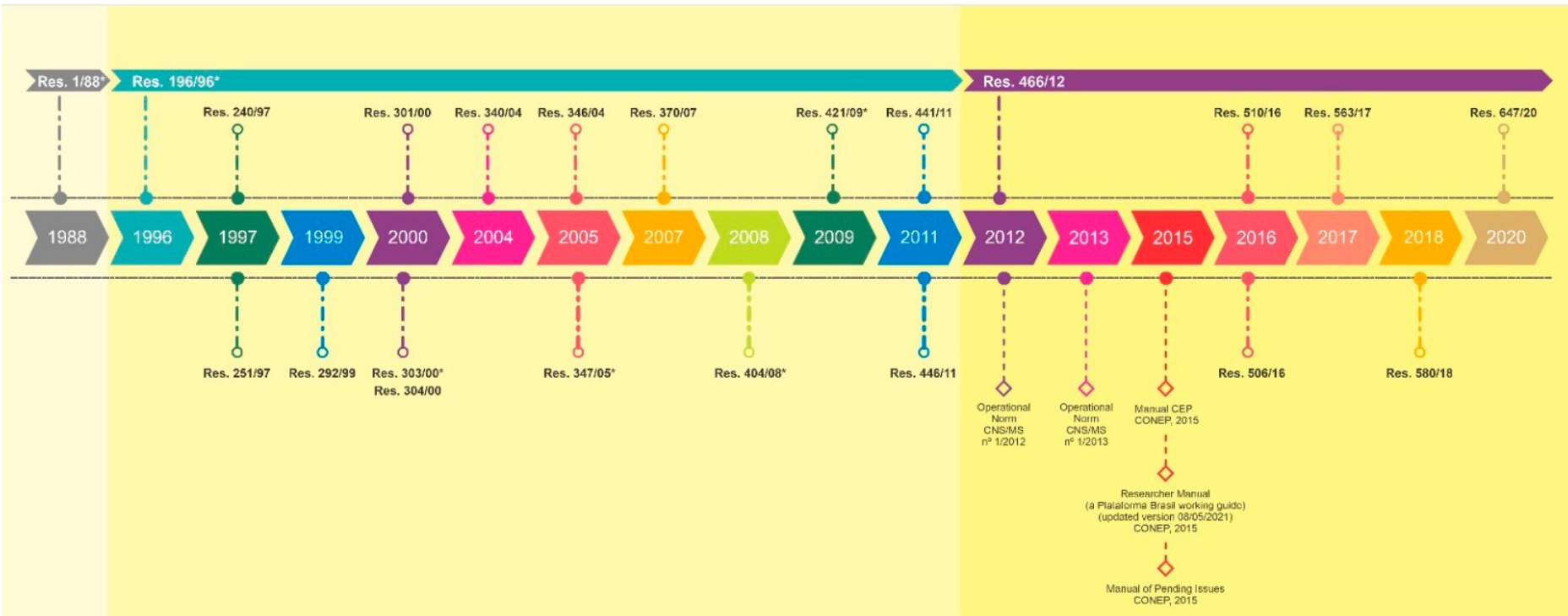

Figure 1. History of the structuring norms of the CEP-Conep System, from 1988 to 2020.

Source: Authors based on information gathered from references, with emphasis on the Conep/MS website – Plataforma Brasil15. (*) Repealed resolutions. Acronyms: Conep - National Research Ethics Committee; CNS - National Health Council; MS - Ministry of Health; Res. - CNS/MS Resolution.

Table 1. Number of users/researchers, protocols and CEP of the CEP-Conep System, from 2012 to 2020.

Year	Users/researchers		Protocols		CEP - total number per year	
	N	Difference % compared to previous year	N	Difference % compared to previous year	N	Difference % compared to previous year
2012	97,505	-	52,079	-	661	-
2013	88,167	-9.6	64,298	23.5	670	1.4
2014	83,704	-5.1	69,138	7.5	691	3.1
2015	85,080	1.6	73,819	6.8	711	2.9
2016	93,177	9.5	79,419	7.6	731	2.8
2017	94,248	1.1	88,372	11.3	791	8.2
2018	108,166	14.8	94,856	7.3	842	6.4
2019	112,426	3.9	98,856	4.2	847	0.6
2020	92,268	-17.9	80,954	-18.1	844	-0.4
Total	854,741	-	701,791	-	n.a.	-

n.a. - not applicable.

Source: Conep/MS, 2022; authors' calculations15.

site path to centralization was taken. Happening was gradual, in April, June and November 2020 (Figure 2), and, at the end of the period, the flow established by the regulations prior to the occurrence of COVID-19[4] was reinstated, with the addition of the centralization of vaccine clinical trial protocols for COVID-19[18-20]:

ITEM 3. [...] The proposed measures are to send the CEP the protocols they normally already receive and we would keep at Conep the special thematic areas and vaccine protocols [for COVID-19][20].

Adapting the work processes

On March 16, 2020, due to the inexorability of the pandemic and the requirement of social distancing, the CEPs´ were authorized to hold virtual meetings, on an exceptional basis[20], safeguarding all ethical precautions, maintaining confidentiality and privacy in relation to processed information during all meetings. In April and May, it was recommended that opinions on COVID-19 be assessed and released within seven calendar days and that the CEPs operate through virtual technical chambers, with at least five reporting members[21-22].

For Conep, virtual plenary meetings were discussed and approved by consensus at the April RO and the need for members to adapt to the virtual format was emphasized. The process of holding meetings of the technical chambers was also intense, and they became daily endeavours, happening seven days a week and, to this end, the functioning of Conep involved the opening of four continuously working chambers . The II Report, of the same month, requested that the opinions be issued within seven days, that the results related to COVID-19 be dealt with urgently and prioritized, while maintaining the ethical standards in force [18].

The minutes of the September 2020 RO recorded the proposal to increase the number of members of the technical chambers, inviting *ad hoc* reviewers, in order to increase the capacity to examine protocols[23]. At the December meeting, Conep took stock of its activities in dealing with the pandemic and reported that there had been 327 extraordinary chambers on COVID-19 throughout the year, with more than 9,000 protocols in progress, more than 4,000 of which were on COVID-19[24]. The need for the participation of *ad hoc* reviewers was reiterated[15].

Conep's normative, educational and informative measures

Conep adopted complementary regulations to the standards described above (Figure 2), seeking to adapt the CEP-Conep System to the new emerging reality. These included the relaxation of the registration of signed consent, with alternative forms being accepted, such as digital signatures and recorded consent; the relaxation or suspension of the need for signatures on protocol documents; the concurrent processing of amendments

with the adoption of the new procedure; and the exceptional interruption of the CEPs' operations, in view of the need for social distancing[23].

As a result of the requirements of the pandemic, regular regional face-to-face training for the CEP-Conep System was suspended in 2020, by means of Circular Letter No. 11/2020, of April 28, 2020.[26] On the other hand, distance-learning courses were strengthened that year, and seven courses were offered, for which content ranged from basic ("Basic methodological principles and ethical issues"), to more specific ("Biobanks and Biorepositories"), totaling more than 17.000 participant registrations[27,28].

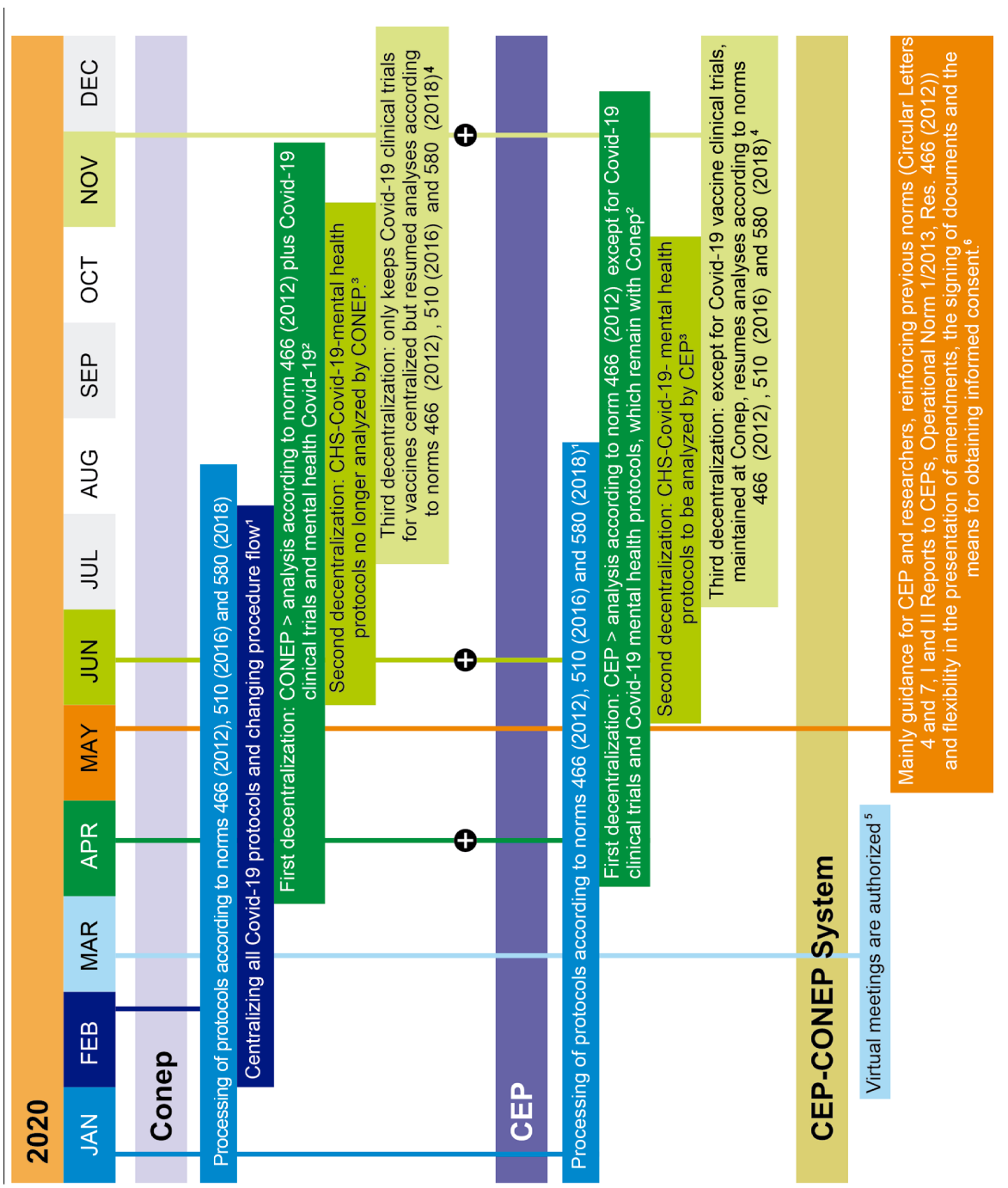

Figure 2. Changes in the processing of COVID-19 protocols – CEP-Conep System, 2020.

Sources: Ministério da Saúde[17,18,20-23].

Another important initiative was the innovation in Conep communication, using social media. During the first year of the pandemic, five different apps were used: Facebook, Instagram, LinkedIn, Twitter and YouTube. In addition, a different innovation emerged with the "Research Ethics Report - COVID-19 Special Edition". In 2020, there were 53 editions, publicizing the 783 approved protocols related to COVID-19. The public data of these protocols was made available on the *website* of the Observatory of Scientific Research Registered on Plataforma Brasil (OPB)[27,28].

At the end of 2020, the National CEP Meeting (ENCEP) was held remotely, with more than 3,500 registered participants[29].

Discussion

Assessing how the CEP-Conep System was regulated and structured, and whether, in fact, this structuring provided support for the challenges of the pandemic year was a first step to understand which changes were necessary to adapt to the new demand for assessing research protocols due to the COVID-19 pandemic.

The three main structuring norms of the System, 1/88, 196/96 and 466/12, stand out, not only because they accommodate the various other complementary or additive norms that emerged during the period, but also because they show the capacity for normative improvement, which would be essential in facing the pandemic.

Of note is the fact that norm 1/88 changed the hierarchical link from an administrative body (Secretariat of the Ministry of Health) to a social representation body (CNS), recommending, monitoring and overseeing health actions, in accordance with Laws 8080/90 and 8142/90[30,31]. In this sense, Resolution 1/88 represents a paradigm change; however, even though the institutional configuration it has brought about has been essential in ensuring the independent and qualified nature of human research in the country, the standard has not been entirely capable of promoting and supporting the development of this type of research. Seven years after its approval, there was still low adherence[1]. Other problems included restrictions on medical research and the inappropriate expansion of activities into biosafety and health surveillance, for example[32].

CNS/MS Resolution 196/1996 created Conep/CNS/MS, the *locus* from which the CEP-Conep System was developed and structured[1,32]. During the 16 years it has been in force, the mechanisms for the creation, accreditation and operation of CEPs have been structured, developed, adapted and established, under the supervision of Conep. Despite the advances brought about by the Resolution, the growing number of submitted and processed research protocols has caused a mismatch with the advance of communication and information technologies. In addition, there was a need to expand the fields of research under ethical review[33].

This is how the foundations of the Plataforma Brasil (PB) were laid in 2008[34] as the exclusive means for submitting, processing, approving and monitoring research protocols. Resolution 466/12 adopted PB and foresaw the existence of complementary regulations[4]. The expression of regulation at this time proved to be essential to guide the dynamics of processes in the context of the pandemic scenario, although there were still regulatory gaps, such as the issue of research classification.

Until December 31, 2020 (the time limit for this study), the draft resolution on the classification of research and its design-dependent processing was in public consultation. However, even though it was approved on May 6, 2022, Resolution 674/2022 will only be operational after the restructuring of the PB (no date has been set yet)[35].

The evolution in the number of CEPs, users/researchers and protocols has shown growth over the years[1,36,37], although there was a decrease in 2020. However, it is necessary to elucidate the nature of the unusual structural pressure suffered by the System during the pandemic, which went far beyond what was expected from the programmatic quantities in Table 1. Other issues influence the outcome of this type of pressure, such as CEP performance, for example, an aspect that was not measured in this study, and based on specific indicators[5,38].

However, the application of these indicators is limited, since there is little identification of the need for new committees in different geographical areas, or in CEP specialties (biomedical and humanities), or even for procedures in health emergencies. On the other hand, after the Zika virus (ZIKV) emergency in 2015-2016, and in accordance with Res. 466/2012, Res. 580/18 was published, with some emphasis on the priority analysis of protocols of public health interest, defined by the Ministry of Health[39].

Furthermore, measuring the performance of existing CEPs in protocol analysis was impossible in the COVID-19 emergency, given the lack of

a historical indicator series, for example (i) the characteristics of approved protocols and (ii) the number of protocols analyzed per period and over time. The application of these indicators would have improved the management of the system during the pandemic[5,38,40].

The results of this study point to preventive action by Conep in the face of the outbreak of the pandemic. Since the structuring dimensions of the System were not capable of responding definitively and completely to the challenges posed by the need for fast and efficient ethical processing of an unforeseen number of research protocols involving human subjects, Conep took the necessary measures to overcome the limitations brought about by the normative and physical structure of the System, facing the complexity of the new reality.

When the WHO declared the COVID-19 health emergency, Conep immediately changed the process flow. The decision to centralize the flows for the protocols in which COVID-19 was involved was taken after a technical discussion with specialized institutions in January 2020 about the new disease and its possible consequences in terms of public health. There was initial uncertainty about the scale the pandemic would take, and recognition of its apparently erratic behavior at the time - to a greater or lesser extent over time[41].

By centralizing, Conep helped speed up and standardize the ethical examination of the protocols it received, as well as promoting agile adapting of processes as the pandemic spread across the country. On the other hand, potential vulnerabilities of ethical procedures within health services were being revealed as inpatients also became research participants[40]. But in fact, over time, decentralization began to take place. Three turning points contributed to the reversal of the centralization process: the better understanding of the disease, its sequelae and its causative agent, and the sequencing of viral lineages; the excessive workload on the members, which after a few months was too burdensome; and the gradual reorganization of the institutions that housed CEPs. The initial uncertainties were also reduced by the tests carried out with drugs and vaccines that showed the most promise[8,9]. This change also contributed to a better understanding of how protocols should be analyzed, bringing greater confidence to the decentralization process.

Among the health measures to possibly contain the pandemic was the requirement for social distancing, which led to the adoption of remote working by Conep[42,43]. In the traditional form of a face-to-face meeting, Conep itself establishes the limits of interaction between members during the evaluation and the flow of confidential information. Thus, adapting to virtual technical chambers was an ethical challenge, as it had to supplant the already consolidated managerial and logistical practices of the CEP-Conep System, which began to operate on an exceptional basis and in the absence of rules regulating the practice. The remote environment meant that there was need to be extra vigilant about ethical conduct, confidentiality and privacy of information, For this reason, when conducting the virtual examination, each rapporteur was instructed to take the necessary measures to protect the confidentiality of the information[20,23].

In order to function, and to adhere to their independent character, the CEP have members who receive initial and ongoing training for the intense work of reporting and for updating regulations. Maintaining a qualified and up-to-date team of reviewers is therefore no easy task[44]. During the pandemic, these difficulties grew significantly[41]. Conep found itself under intense pressure to analyze an increasing number of protocols in a timely manner, thus relying on the addition of *ad hoc reviewers.* However, even with the work of trained reviewers with experience in the system, Conep had to face difficulties in the availability of these same reviewers, especially when they came from private institutions, due to the need to justify the time dedicated to Conep. The final outcome in terms of speed and volume of analysis seems to have been positive[45], but nothing can be said about performance, for the reasons discussed above.

Bearing in mind the importance of internal educational processes, as necessary for members and *ad hoc*, during the pandemic the focus of Conep's actions was very much directed at the CEPs, a capillary network close to the interested parties, i.e. researchers and users of the System, who were also the target of educational actions.

In order to harmonize ethical analysis, in 2020, Conep team held virtual meetings with 357 CEPs, replacing *on-site* visits, totaling more than 3,900 viewers. Seven short distance learning courses were produced and made available, the target audience being volunteer members and administrative staff of CEPs, but open to other interested parties[27,28].

Normally, obtaining the Free and Informed Consent Form (FICF), submitting signed documents and processing amendments are, among

others, aspects of normative and procedural regulations in the CEP-Conep System that may generate pending issues. The pandemic required new procedures. Conep issued the document Guidelines for Conducting Research and CEP Activity During the Pandemic Caused by the Coronavirus Sars-CoV-2 (COVID-19), on May 9, 2020[23]. The intense work of the technical chambers, added to the normative changes in this document, innovated the practice and, in the end, accelerated the approval of protocols.

For the external public, Conep innovated by expanding the means of communication, by publishing, regularly and in aggregate form, public data from approved COVID-19 protocols and by making this data available on the internet, at the Observatory of Registered Scientific Research portal on the Brazil Platform (OPB). The series "*Boletim Ética em Pesquisa – Edição Especial COVID-19*" (Research Ethics Bulletin – COVID-19 Special Edition) was received by the scientific community and society as an excellent contribution [46], giving visibility to the research being processed at CONEP. The initiative was considered by the Pan American Health Organization (PAHO) as an example of strengthening transparent communication about ongoing research during the pandemic[47].

This study was based mainly on the minutes of the 2020 Conep, which are confidential, and, in addition, on other public documents issued by Conep. From the research universe viewpoint and also considering its *corpus,* analyzed documents are fully representative of the object of analysis. Conep is a body under the scrutiny of the researchers interested in its projects and the minutes are reviewed by all its members, so the text is highly reliable and standardized. These points add quality to the study materials. However, it is worth noting that the minutes were not generated for the purpose of providing answers to the research questions, which limits our results somewhat.

In addition, in order to reduce subjectivity, timeline figures were added to support the text with a description of the structuring dimensions and the changes in protocol processing. Whenever necessary and available, the information in the minutes was verified with other documents, although Conep does not analyze the characteristics of the protocols on a regular, systematic or public basis, which made it difficult to compare this timeframe with other periods.

Final considerations

This article examines Conep's trajectory during the first pandemic year. The analysis of the minutes was an innovative strategy that allowed understanding of the processes of change and adaptation caused by the COVID-19 pandemic and resulted in attaining research goals.. The fact that Conep is a Commission of the National Health Council (CNS) has given transparency, autonomy, plurality and independence to its work.

The structuring dimensions developed over time - regulations and physical structure - were not enough to deal with the needs and pressures arising from the pandemic. This required quick and effective changes so that the ethical procedures for research were not paralyzed. Conep responded quickly at the beginning of 2020, centralizing the analyses and making subsequent adaptations as the pandemic progressed and as knowledge about the disease and ongoing research was consolidated. In addition, there was intense mobilization of effective members for ethical examination and the addition of a contingent of *ad hoc* reviewers, forming a real task force for the full functioning of the System. Some educational and training strategies for society have been developed, especially the Report, which is recognized nationally and internationally, expressing the progress of research over time.

The various advances made during the health emergency give rise to the expectation that the lessons learned will be incorporated into flows in similar situations in the future. The analysis showed that the system adapted quickly to abrupt health demands and provided support and feedback to science. In addition, the vanguard of these changes during the pandemic within a system of ethical analysis as advanced as Brazil's was highlighted, which may inspire other countries. Undoubtedly, although the consolidated System needs to develop and implement performance indicators, this study shows that actual progress has been made.

Collaborations

I, CCF Vidotti, conceived the work, carried out the survey, extraction, organization of data and writing of the original version of the text; CGS Osorio-de-Castro approved the method and critically reviewed the text, approving the final version; A Esher, a research ethics specialist, approved the method and critically reviewed the text, approving the final version.

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