

Analysis of ethical regulations for healthcare research on SARS-CoV-2

Análisis de las normas éticas para la investigación sanitaria sobre el SARS-CoV-2

Análise das normativas éticas de pesquisas em saúde pelo SARS-CoV-2

**Alessandra Conceição Leite
Funchal Camacho¹**

ORCID: 0000-0001-6600-6630

Paola Paiva Monteiro^{1*}

ORCID: 0000-0002-3821-1693

Victor Hugo Gomes Ferraz¹

ORCID: 0000-0003-4784-449X

**Juliana de Oliveira Nunes da
Silva¹**

ORCID: 0000-0002-9111-3806

Suellen de Almeida Barroso¹

ORCID: 0000-0003-1947-8648

¹Universidade Federal
Fluminense. Rio de Janeiro,
Brazil.

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*Corresponding author:

paolapaivamonteiro@id.uff.br

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Abstract

The aim was to analyze the ethical regulations of health research on SARS-CoV-2. It is a proposal for reflective analysis, with a qualitative, descriptive approach with a view to dialogue focused on the regulations developed by the National Research Ethics Commission and the National Health Council with the purpose of giving visibility given its importance in the context of SARS-CoV-2. The article in question is based on the following discussions: ethics committees and their regulations and health research in the context of SARS-CoV-2. Understanding the pertinent subject in health, it is essential to highlight the challenges in analyzing these regulations for the enhancement of studies, but which also assist in an educational manner through ethics and research committees, the progress and ethical rigor in conducting research aimed at respect to human dignity. Therefore, it is relevant to carry out searches on this topic, contributing to the preparation, development and submission of health research projects on SARS-CoV-2.

Descriptors: Nursing; Pandemics; Coronavirus; Ethic; Health.

Resumen

El objetivo fue analizar las normas éticas de la investigación en salud sobre el SARS-CoV-2. Es una propuesta de análisis reflexivo, con un enfoque cualitativo, descriptivo con miras al diálogo centrado en la normativa desarrollada por la Comisión Nacional de Ética en Investigación y el Consejo Nacional de Salud con el propósito de dar visibilidad dada su importancia en el contexto del SARS-CoV-2. El artículo en cuestión se basa en las siguientes discusiones: comités de ética y sus regulaciones e investigaciones en salud en el contexto del SARS-CoV-2. Entendiendo el tema pertinente en el área de la salud, es fundamental resaltar los desafíos en el análisis de estas normas para el perfeccionamiento de los estudios, pero que también coadyuvan de manera educativa a través de los comités de ética y de investigación, el avance y el rigor ético en la realización. Investigación orientada al respeto a la dignidad humana. Por lo que resulta relevante realizar búsquedas sobre este tema, contribuyendo a la preparación, desarrollo y presentación de proyectos de investigación en salud sobre SARS-CoV-2.

Descriptores: Enfermería; Pandemias; Coronavirus; Ética; Salud.

Resumo

Objetivou-se analisar as normativas éticas de pesquisas em saúde pelo SARS-CoV-2. É uma proposta de análise reflexiva, com abordagem qualitativa do tipo descritiva com vistas ao diálogo voltado para as normativas desenvolvidas pela Comissão Nacional de Ética em Pesquisa e Conselho Nacional de Saúde com a finalidade de dar visibilidade dada a sua importância no contexto do SARS-CoV-2. O artigo em questão está pautado nas seguintes discussões: os comitês de ética e suas normativas e as pesquisas na saúde no contexto do SARS-CoV-2. Compreendendo o assunto pertinente na área da saúde, é imprescindível salientar os desafios na análise dessas normativas para o engrandecimento de estudos, mas que também auxiliam de maneira educativa através dos comitês de ética e pesquisa o andamento e rigor ético na condução das pesquisas visando o respeito à dignidade humana. Deste modo, é relevante a execução de buscas nesse tema colaborando para o preparo, desenvolvimento e submissão de projetos de pesquisa em saúde pelo SARS-CoV-2.

Descriptores: Enfermagem; Pandemias; Coronavirus; Ética; Saúde.



measures that must converge with the interests of the patient, their family and society⁵.

With this reality, challenges were articulated in the daily care of the healthcare team, faced with a new scenario and adaptations to new care routines, uncertainty regarding treatment⁶. The biggest concern is related to the problems of social vulnerability of the Brazilian population in accessing health services and which is even more worrying when we talk about patient care that requires immediate resolution, but in the previous situation the new coronavirus pandemic had already been critical⁴.

With this, observing the significant increase in projects for analysis, we relate this data to the pandemic period and increased concern of the scientific community in the face of an entire context, the Ethics and Research Committees have been fulfilling their responsibility as a local instance of ethical analysis of research protocols. Studies involving human beings in compliance with current ethical regulations and with the commitment required by the current situation¹.

Therefore, this article aimed to analyze the ethical regulations of health research on SARS-CoV-2.

Methodology

It is a documentary-type article with critical-reflective analysis on the ethical regulations of health research on SARS-CoV-2. It has its interaction guideline focused on dialogue that guides relevant discussions on ethical regulations during the pandemic caused by the new coronavirus translated into its principles: beneficence, autonomy and justice.

Given this critical-reflective analysis, this type of study can bring a wealth of knowledge and information to contribute to knowledge around knowledge in the area of Health Sciences, which includes Nursing with its particularities. Therefore, we are concerned with a qualitative approach based on content collected in the context of events with the purpose of describing certain particularities of interest⁷.

With the purpose of envisioning learning opportunities, relevant discussions and exchange of knowledge, there was an opportunity to expand discussions on the analysis of ethical regulations for health research by SARS-CoV-2 aimed at understanding its relevance in research as well as academic teaching.

This article provides an approximation of the ethical regulations that contextualize the actions of Ethics and Research Committees, however, without intending to exhaust the subject. It is important to give an overview of the discussions that have arisen today and have been the subject of questions and reflections on their fundamental principles that help in the analysis of research, especially in times of pandemic due to the new coronavirus.

It is noteworthy that the study preparation period took place from September 2022 to February 2023.

Results and Discussion

Based on the objective outlined, this topic is based on a narrative with discussion of the following relevant

Introduction

The analysis of regulations by Research Ethics Committees (CEPs) in Brazil became fundamental during the new coronavirus pandemic, as coping with it led to the sharing of ethics for the sake of research with the purpose of guaranteeing respect for the person. In this sense, the analysis focuses on people who may have some relationship with the research, be it the member of the study, the researcher, the worker in the areas where it is developed and, ultimately, society. The analysis of the study in health with human beings is mainly based on four fundamental points: the qualification of the research team and the project itself; in assessing the risk-benefit relationship; in informed consent and prior evaluation by an Ethics Committee¹.

In this perspective, Resolution of the National Health Council No. 466 of December 12, 2012, was highlighted, which approves the guidelines and regulatory standards for research involving human beings incorporating, from the perspective of the individual and communities, bioethics references, through of its reference principles, which are: autonomy, non-maleficence, beneficence, justice and equity, among others. From this angle, this regulation aims to guarantee the rights and duties that concern the components of observation, the scientific community and the State².

Given these considerations, with the emergence of the new coronavirus, the scientific community has mobilized to investigate this disease and its various aspects, directly and indirectly, as well as proposed treatment and cure. There are several research projects developed and submitted to CEPs for ethical analysis with the aim of ensuring the ethical principles of research, as well as the protection of research participants¹.

Due to this urgency that emerged, the National Research Ethics Commission (CONEP), in line with the World Health Organization (WHO), considering the relevance of the potential impact of SARS-CoV-2 for Brazilian society, research protocols on the virus were analyzed urgently and with special processing at CONEP through the recommendations of Circular Letter No. 4/2020-CONEP/SECNS/MS. Due to the increasing number of protocols sent for analysis, a collective effort was necessary so that studies related to SARS-CoV-2, sent for ethical analysis, were treated with the urgency that the situation required and, therefore, were prioritized³.

It is notable that, given the ethical issues in this reality, the analysis is focused on the epistemological field, bringing us relevant discussions in the social sphere linked to the rights of human beings with a view to their autonomy. In this sense, this situation has brought back all aspects related to human vulnerability, prioritizing the right to care for their needs and the availability of resources, giving the opportunity for inclusive actions and with important demands in times of SARS-CoV-2⁴.

In this sense, the challenges in the discussion about the pandemic caused by the new coronavirus have become relevant to list a visit to the individual's right to autonomy with a view to providing necessary social support, the analysis of vulnerability and the decision-making nature of



aspects: ethics committees: regulations and health research in the context of SARS-CoV-2.

The Ethics and Research Committees: the regulations

Due to the pandemic caused by the new coronavirus, the Ethics and Research Committees have received numerous studies to investigate SARS-CoV-2, imposing new challenges and debates in the ethical sphere. Although study initiatives of this nature are commendable during the pandemic, it was opportune to provide guidance to researchers through current regulations due to the new ethical challenges imposed by research protocols related to SARS-CoV-2⁸.

Ethics and Research Committees need sufficient human and material resources to handle complex challenges and, at the same time, value and account for the work of Committee members within the institutions. Reflection on urgent challenges that need to be faced to respect the dignity of human beings⁹.

A relevant issue was obtaining consent to participate in research, which is a mandatory procedure provided for in CNS Resolution No. 466 of 2012² and in several international reference documents on research ethics, except when the waiver of consent is previously authorized by the CEP/CONEP System upon justified request from the researcher.

Furthermore, CNS Resolution No. 510 of 2016¹⁰ which establishes the regulations applicable to studies in Human and Social Sciences whose methodological procedures involve the use of data directly obtained from participants or identifiable information or which may entail greater risks than those existing in everyday life, as defined in this Resolution as well were the focus of analysis in the pandemic caused by the new coronavirus.

In view of the health emergency situation declared in the country, and considering the potential benefit to research participants, it was considered permissible, in this particular situation, to proceed with alternative forms in the consent process for studies carried out on patients affected by SARS-CoV-2, unable to provide consent, where legal guardians are distant or in social isolation. The alternatives for the specific condition were forwarding of consent by digital means, with return of the duly signed document in digital copy; consent on an electronic platform; recorded consent (by phone or communication app). Alternative forms of consent must be described in the research project submitted to the CEP/CONEP System and regardless of the form of consent, it will be up to the researcher to maintain proof of consent in their records, whether digitally, electronically or recorded.

The procedures provided for in Resolution No. 510/2016 and No. 466/2012 are part of a set of social, political, economic and cultural norms within which ethics in research encompasses value and social function. of the study; the interests of society; the need for freedom to investigate; the focus on the person; the role and interests of managers of academic institutions; the principles and interests of scientific communities, in relations with students; the responsibility of funding agencies; the

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consequences of research results; and the popularization of science¹¹.

Given this reality, Circular Letter No. 1 of 2021 from CONEP/SECNS/MS established instructions for mechanisms in research with any phase in virtual space. These instructions, when used on study participants in vulnerable situations, must be in accordance with National Health Council Resolutions No. 466 of 2012 and No. 510 of 2016. In this circular letter as a guiding norm, there is clarification about cyberspace: that which covers the use of the internet (such as emails, electronic websites, forms made available by programs, among others), the telephone (voice call, video call, use of calling applications, among others), as well as other programs and applications who use these means. Establishes that the non-face-to-face mode: contact carried out through a virtual environment, including telephone devices, not involving the physical presence of the researcher and the study participant¹².

It is clear in this Circular Letter No. 1 of 2021 from CONEP/SECNS/MS that the guidelines on the study protocol that the observer must present in the methodology of the research project the clarification of all remote stages/phases of the study, sending, including, the model forms, terms and other documents that will be presented to the candidate research participant and research participants. Furthermore, the investigator must describe and justify the methodology to be adopted to obtain free and informed consent, as well as the form of recording or signing the form that will be used¹².

The Ethics and Research Committee of the National School of Public Health of the Oswaldo Cruz Foundation (ENSP/FIOCRUZ) highlights some relevant guidelines when choosing digital tools for interviews where: the researcher must master the functions they will use, minimizing problems and ensuring security and privacy; identifying the need to install the tool on the computer/tablet/cell phone to facilitate participant access and agreeing with the participant the procedures adopted in case of technical problems. Another aspect is that the more sensitive the topic of the interview, the safer the communication tool and the privacy of the environment must be, checking the possibilities of audio and/or video recording in the tool itself; safely identify the location where the audio and/or video file is saved (cloud, on the computer/ tablet/ cell phone). Furthermore, if the interview is recorded using the communication tool itself, it is saved on the researcher's computer and not in the platform's cloud, to ensure greater security; the tool's connection stability and sound and/or image quality must be assessed, and do not forget that video conferences must be held with passwords for access for greater security¹³.

With these considerations, it is essential to highlight CNS Resolution No. 580 of 2018 for strategic research of interest to the Unified Health System, procedures cannot interfere with the routine of health care services, unless the purpose of the study is justified, and is expressly authorized by the institution's director. Furthermore, research carried out in institutions that are part of the Unified Health System must comply with the ethical precepts and responsibility of



The CONEP recognizes ethics as “pluralistic”, which has a unifying “essence” that resides in the common interest in respecting the dignity of human beings participating in research. The question that arises here is not only who defines it, but also how human dignity is defined and its compatibility with specific scientific practices, seeking ways to respond to the desires of a diverse society¹⁶.

These prerogatives also considered the existence of situations in which research does not need to go through an ethics committee in Resolution No. 510/2016, which are: Public opinion research; Research that uses publicly accessible information, research that uses public domain information; census research; database research; review of scientific literature; reflective research; activity carried out with the aim of improving the educational process¹¹.

In these directives, some aspects did not generate controversies, such as: the definition and conception of research not restricted to obtaining generalizable knowledge, formulation of hypotheses and sample studies and the possibility of obtaining the Free and Informed Consent Form (TCLE). In addition, it presents standards relating to research in the areas of health sciences in specific items and sub-items and creation of a complementary resolution with guidelines and standards focused on the particularities of research in human and social sciences¹⁷.

With the visibility of the actions of CEPs and CONEP during the COVID-19 pandemic, the relevant regulations, the multidisciplinary composition and the exercise of social control over research ethics are important elements for this normative work. However, it is with the knowledge and approval of society and the partnership with the academic community that the work can be recognized in the political dimension. Because in their different instances they were created, based on the power of public authority, to achieve effective social and democratic participation¹⁷.

As CEP members have diverse world views, diverse knowledge and experiences, respect and plausible justifications enrich discussions and can help in the construction of protocols that meet the ethical and methodological aspects of research involving human beings. Thus, the assessment of the research protocol needs to consider the rights of the participant and resolve the dilemmas experienced to avoid violation of human rights¹⁸.

Within the scope of CEPs, collaborative and cooperative learning have been practiced through exchanging experiences with discussions during committee meetings and sharing of ideas and opinions. Thus, the continued training of participants in this study also occurs through these exchanges, which enable them to make decisions and resolve practical issues presented during the analysis of research protocols involving human beings¹⁸.

The ethical discussion has a high significance, considering its importance in the face of a reality where we observe techno-scientific development, with a diversity of current issues in the model of society in which we live, such as: emerging and persistent diseases; hunger; misery; violence; racism; social exclusion; disrespect for human

public service and social interest and should not be confused with health care activities. In other words, this resolution must be heeded by researchers since there is also compliance with research in units of the Unified Health System and the same applied in the conditions already mentioned in the COVID-19 pandemic¹⁴.

To this end, due to our current reality, members of ethics and research committees must be willing to carry out a continuous exercise of criticism and reflection, seeking to escape the accommodation of uniform, easy and ready-made responses in the norms. Research, in the most diverse areas of knowledge, raises different questions and challenges, which cannot be analyzed within a single perspective. An example is social research in the humanities, which cannot be evaluated under the same parameters used in the analysis of a clinical trial, and vice versa, each one will have its ethical specificities that must be evaluated, based on their characteristics⁹.

Health research in the context of SARS-CoV-2

During the new coronavirus pandemic, CONEP/CNS guided the adoption of guidelines from the Ministry of Health (MS), with the aim of minimizing potential risks to the health and integrity of research participants, researchers and members of CEPs⁸.

Therefore, it is worth highlighting that CEPs are collegiate bodies that act in a multi and transdisciplinary manner and are present in institutions that carry out studies involving human beings in Brazil, with the aim of protecting the interests, integrity and dignity of research participants. Its collegial structure is made up of researchers from the areas of health, exact, social and human sciences, evaluating the ethical aspects of study projects in their respective areas of knowledge. Consultative, deliberative, normative and educational in nature, CEPs must act independently, contributing to the quality of scientific work in the areas in which they apply, to ensure that researchers' procedures during their studies result in scientific recognition based on ethical principles¹⁵.

In this sense, guidelines were provided to researchers for conducting research protocols and it is advisable to adopt measures for the prevention and management of all research activities, ensuring actions that are essential to health, minimizing losses and potential risks, in addition to provide care and preserve the integrity and assistance of participants and the research team. Another relevant aspect was the importance of complying with operational difficulties arising from all measures imposed by SARS-CoV-2, making it necessary to ensure the best interests of the research participant, keeping them informed about modifications to the research protocol that could affect it, mainly with adjustments in the conduct of the study, schedule or work plan of the research protocol⁸.

Another important consideration is that some specific aspects of analysis to the detriment of Resolution No. 510/2016 in relation to No. 466/2012 are the definition of what does not need to be evaluated by the CEP/CONEP System; discernment between process and record of consent and free and informed assent; assessment of



beings and the environment, among many others that threaten life⁹.

These issues include CNS Resolution No. 304 of 2000 on research involving indigenous populations, which seeks to affirm the respect due to the rights of indigenous peoples about the theoretical and practical development of research on human beings that involves life, territories, cultures and natural resources of Brazil's indigenous peoples. This resolution also recognizes the right of indigenous people to participate in decisions that affect them¹⁹.

In the continuous exercise of an ethical and reflective analysis, we seek to move away from a status of accommodation of uniform, easy and ready-made responses to norms; since research, in the most diverse areas of knowledge, raises different questions and challenges, which cannot be analyzed within a single perspective. For example, social research in the humanities cannot be evaluated under the same parameters used in the analysis of a clinical trial, and vice versa; or even in the case of two clinical trials, each one will have ethical peculiarities that must be evaluated, based on their characteristics⁹.

It is from this perspective that many scientific journals are concerned with ethical regulations in the analysis of research articles, aiming to include best analysis practices based on diversity, equity and inclusion, observing the manuscript's implicit bias on race/ethnicity, politically appropriate language, representativeness social issues among other social issues ensuring diversity and equity in the editorial boards among the quality control guidelines of the content to be disseminated.

In this way, Circular Letter No. 166 of 2018 – CONEP/SECNS/MS is also an analysis parameter for reporting a clinical case or clinical experience in specific circumstances. The proposal must be analyzed and submitted via Plataforma Brasil and assessed by the CEP/CONEP system. In this aspect, it is pertinent to consider the TCLE as well as the Assent Form (when applicable) containing the reason for publishing the case report, the guarantees related to confidentiality, privacy²⁰.

Therefore, it is important to reflect on ethical and bioethical principles in the activities carried out by members of CEPs and to maintain a composition in accordance with the guidelines recommended by CONEP. On the other hand, generalizations should not be made, always checking the specificities of situations, and there is a need for studies on this topic to better understand reality²¹.

Therefore, an intensification of the debate in relation to the analysis of social research, with reviewers being more sensitive to other research techniques, considering vulnerability and informed consent, not exclusively based on guidance from the clinical research environment. Therefore, research is betting on changing this scenario based on the work of the Social and Human Sciences GT at CONEP²².

With this understanding, CEPs play an educational role, in the sense of promoting discussion and reflection on ethical aspects in science, focusing on studies that involve human beings, mainly through their interdisciplinary basis and the specific analysis that is their responsibility. Therefore, in a pluralistic culture like Brazil, the multidisciplinary composition of a committee is enriching and favorable. Arguments from professionals from different areas raise debates that clarify borderline situations, whether through the rigorous use of normative language or through the moral justification of decisions²³.

Conclusion

This article aimed to analyze the ethical regulations of health research on SARS-CoV-2 with a view to dialogue focused on the regulations developed by CONEP and the National Health Council, giving visibility in the context of the pandemic caused by the new coronavirus.

Understanding the pertinent subject in health, it is essential to highlight the challenges in analyzing these regulations for the enhancement of studies, but which also assist in an educational manner through ethics and research committees, the progress and ethical rigor in conducting research aimed at respect to human dignity. Therefore, it is relevant to carry out searches on this topic, contributing to the preparation, development and submission of health research projects for SARS-CoV-2.

Understanding the interdisciplinary character and diversity for the analysis of projects submitted for opinion in the CEPs, the importance of researching moral and/or ethical problems experienced by members of CEPs in their activities and knowing the strategies they use to solve them is evident. In this way, it will be possible to support public policies aimed at research involving human beings, stimulating educational practices for CEP members, academics and researchers, enabling responsible action when carrying out research.

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