



The experience of the ethics committee in research in human beings in times of pandemic COVID-19 (SARS-CoV-2)

Elisângela de Oliveira Cardozo^{1*}, Evaldo Dacheux de Macedo Filho²

¹ Program in Biomedical Engineering (PPGEB) UTFPR and IPO Hospital, Curitiba, Brazil.

² Program in Otorhinolaryngology, Hospital IPO, Curitiba, Brazil.

*Corresponding author: Elisângela de Oliveira Cardozo,
e-mail: elisakrill@hotmail.com.

DOI: <https://doi.org/10.54448/mdnt21634>

Received: 09-09-2021; Revised: 11-11-2021; Accepted: 12-09-2021; Published: 12-18-2021; MedNEXT-id: e21634

Introduction

In Brazil, research involving human beings is regulated by resolution 466/12 which replaced 196/96 and was published on June 13, 2013 in the Official Gazette of the Union [1]. Resolution 466/12 brings terms and conditions to be followed and deals with the CEP and / CONEP (National Commission for Research Ethics) System, which is a social control body linked to the Ministry of Health (MS) composing a system that uses the mechanisms, proper relationship tools and instruments aimed at protecting research participants [2].

However, since January 30, 2020 when the World Health Organization (WHO) declared the infection by the new Coronavirus also called (2019-nCoV and SARS-CoV-2) as a global public health emergency, some modifications and/or adaptations had to be implemented by CONEP due to the pandemic that was only officially declared as such on March 11, 2020 due to the rapid geographic spread that Covid-19 had been showing [3].

The aim of this article is to report the experience of the IPO Hospital during the covid19 pandemic period (SARS-CoV-2).

Methods

Descriptive and documentary study, which uses the case study as a reference. In this process, the totality of projects filed in the CEP of Hospital IPO in the period between March 2020 and September 2021 directly linked to covid19 was dimensioned. To identify the research protocols related to Covid19, the information contained in the mandatory fields of all the cover pages of the CEP research protocols in this period was analyzed.

Experience Report

Since the beginning of the pandemic in Brazil, CONEP has implemented several measures to control projects related to Covid19 and some of these measures had a direct impact on the work dynamics of ethics committees. The first measure was regarding the submission of all protocols related to the disease for evaluation by CONEP, which until then was not mandatory, except in specific cases in 466/12, as well as the processing of these criteria on an emergency basis, which selects to be recovered and sent to a CONEP within a maximum period of 7 days.

According to the new guidelines for conducting research and activities of CEPs during a pandemic caused by the coronavirus (Sars-Cov-2) edited by CONEP on April 1, 2020, the adopted ethics committees adopt new rules regarding the deadlines for analysis, virtual meetings, techniques to streamline the processing of projects and a series of other measures such as the acceptance of documents with digital signature, online TCLE or later, among others, which meant that CEP coordinators had to reorganize and monitor almost that daily information disclosed by CONEP.

The committee meetings that took place once a month in person are now held online through the zoom platform. To comply with the determination of the speed of the ethical evaluation, the CEP resorted to the technical chamber, where 4 of the members, including the coordinator and the vice, met on an emergency basis to validate the projects that were discussed with the other members at the next meeting. The CEP of the IPO Hospital erected between March 2020 and August 2020 39 projects related to covid 19, with 44% (n = 17) of research protocols where most of them were related to phase 2 and 3. The amendments corresponded to 28% (n = 11) the same percentage of notifications 28%

(n = 11).

The CEP of Hospital IPO is currently composed of 9 (nine) members representing 7 areas of knowledge, and this number of protocols gives an average of 4.3 projects for each member only related to COVID-19. The number of projects not related to covid19 prepared by CEP in this period was 153 which is the average of CEP in the last 5 years, the percentage of increase in reporting due to covid19 was around 24%.

Reflection on the experience

At the last CEP meeting held on August 24, 2021, the CEP members made an assessment of how the activity has been in times of pandemic. In the evaluation of the coordinator, the deputy coordinator and the majority of members as changes undertaken by CONEP due to the severity and proportion that a pandemic has brought to Brazil and to the world, despite being considered strictly necessary and comprehensive, since the rapid spread and severity of the disease that has already led to the death of more than 580 thousand Brazilians, according to data published by the Johns Hopkins University [4] brought some difficulties such as:

1. The mandatory evaluation of projects within seven days;
2. The reorganization of CEP procedures, as well as the adequacy of all members for virtual meetings;
3. The need for extraordinary meetings;
4. The number of projects with the participation of other institutions and the vast majority with financial support from international companies, which brings more complex characteristics to research protocols and even need more time and rigor in the evaluation;
5. The need for daily updating of the procedures edited by CONEP;

In addition to those that are specific and directly linked to the performance of members in CEP, we can also highlight that the practical home office activity little known in Brazil also brought other concerns, such as people's difficulty in separating work from home and family activities. It is important to remember that in the first year of the pandemic, where social distancing was practically mandatory, it was not only the parents who remained at home, but the whole family, so each member had to strive to keep the focus on professional responsibilities, as well as, take care of the routine at home and, in many cases, also take care of their children's schooling [3].

Also, the lack of social interaction, excessive working hours, concerns about health, loss of employment and income, and the fear of being infected by the disease, were also mentioned as negative experiences. Emotional aspects such as anxiety,

insomnia, irritability, among others, were also listed as negative points, especially after the loss of one of the oldest members of CEP who died in May this year. On the other hand, flexibility in time and not having to face the traffic while commuting are the positive points of the home office modality highlighted by the members [5,6].

Conclusions

The pandemic brought many lessons and in the field of education it was most of the time essential to maintain learning, but this type of online education brought to light or reaffirmed the great social inequalities that we live in the country. While a part of the population has adapted, despite some difficulty, to activities, some people have suffered and continue to suffer from the effects of this inequality. The technology, although it has grown a lot in recent years, according to experts, is still not accessible to all Brazilians. The internet, as well as other technologies necessary for technological education, is not universal in the country, which in practice contributes to a significant educational delay that should last for years in Brazil.

Keywords: Pandemic. Research Ethics. Public Health.

Acknowledgement

Nil.

Funding

Not applicable.

Data sharing statement

No additional data are available.

Conflict of interest

The authors declare no conflict of interest.

About the License

© The authors (s) 2021. The text of this article is open access and licensed under a Creative Commons Attribution 4.0 International License.

References

1. Ministry Of Health. National Health Council. Approves the guidelines and regulatory standards for research involving human beings. Brasília, Official Gazette of the Union, 16 Oct. 1996. Resolution n. 196, of October 10, 1996.
2. Ministry Of Health. National Health Council.

Approves guidelines and regulatory standards for research involving human beings. Brasília, Official Gazette of the Union, December 12th. 2012. Resolution no. 466 of December 12, 2012.

3. Bridi MA, Bohler FR, Zanoni A P. Technical-scientific research report: remote/home-office work in the context of the COVID-19 pandemic. Curitiba: UFPR, GETS, REMIR, 2020. [accessed on August 19, 2021]; 26(3). Available at: https://www.eco.unicamp.br/remir/images/Artigos_2020/ARTIGO_REMIR.pdf
4. Johns Hopkins University. Coronavirus COVID-19 Global Cases by Johns Hopkins CSSE [Internet]. Johns Hopkins University; 2020 [accessed 6 September 2021]. Available at: <https://gisanddata.maps.arcgis.com/apps/opsdashboard/index.html#/bda7594740fd40299423467b48e9ecf6>
5. Janete P, Jenerton AS, Leandro M. Educational challenges in times of pandemic - Cruz Alta: Illustration, 2020. 324 p.
6. De Negri F. Science and Technology in the face of the pandemic. Brasília, Center for Research in Science, Technology and Society, Ipea, (2020).