

**Ethics criteria for research in a virtual environment in Brazil****Critérios de ética para pesquisas em ambiente virtual no Brasil****Criterios éticos para investigaciones en el entorno virtual en Brasil**** Liriel Weinert Mezejewski<sup>1</sup>,  Beatriz Schmidt<sup>2</sup>,  Helen Bedinoto Durgante<sup>3</sup>****Received: 19/08/2021 Accepted: 15/05/2022 Published: 30/09/2022**

**Objective:** to present the new established and revised ethics criteria for conducting online research in Brazil. **Methods:** narrative review of the guidelines for internet use in Brazil, the regulations of the National Research Ethics Commission and the Scientific Electronic Library Online database, carried out from May to July 2021, considering the descriptors: 'pesquisa' (research), 'ética' (ethics), 'Brasil' (Brazil), 'on-line' OR 'virtual', including search terms and interterms, from 2011. **Results:** Six regulations from the National Research Ethics Commission and 233 studies were identified, 11 of which were selected for evaluation and greater detail regarding the criteria established for ethics in research in a virtual environment (online). The following criteria were established and/or adapted: data privacy; preservation of personal data/files; Free and Clear Commitment Term; disclosure; data collection and storage; research risks; limitations; and discard. **Conclusion:** potentialities and challenges of research in a virtual environment are presented with regard to ethical criteria.

**Descriptors:** Research; Ethics; Brazil; Information technology; Internet-based internet.

**Objetivo:** apresentar os novos critérios de ética estabelecidos e revisados para a condução de pesquisas *online* no Brasil. **Método:** revisão narrativa das diretrizes para uso de internet no Brasil, das normativas da Comissão Nacional de Ética em Pesquisa e do banco de dados da *Scientific Electronic Library Online*, realizada de maio a julho de 2021, considerando os descritores: 'pesquisa', 'ética', 'Brasil', 'on-line', OR 'virtual', incluindo termos e entretermos de busca, a partir de 2011. **Resultados:** Foram identificadas seis normativas da Comissão Nacional de Ética em Pesquisa e 233 estudos, sendo 11 selecionados para avaliação e maior detalhamento quanto aos critérios estabelecidos para ética em pesquisas em ambiente virtual (*online*). Os seguintes critérios foram estabelecidos e/ou adaptados: privacidade de dados; preservação de dados pessoais/prontuários; Termo de Compromisso Livre e Esclarecido; divulgação; coleta e armazenamento de dados; riscos da pesquisa; limitações; e descarte. **Conclusão:** apresentam-se potencialidades e desafios da pesquisa em ambiente virtual no que refere a critérios de ética.

**Descritores:** Pesquisa; Ética; Brasil; Tecnologia da informação; Intervenção baseada em internet.

**Objetivo:** presentar los nuevos criterios éticos establecidos y revisados para la realización de investigaciones en línea en Brasil. **Método:** Revisión narrativa de las directrices para el uso de Internet en Brasil, del reglamento de la Comisión Nacional de Ética en Investigación y de la base de datos *Scientific Electronic Library Online*, realizada de mayo a julio de 2021, considerando los descriptores: 'pesquisa' (investigación), 'ética', 'Brasil', 'online', OR 'virtual', incluyendo términos e intertérminos de búsqueda, desde 2011. **Resultados:** Se identificaron seis reglamentos del Comité Nacional de Ética de la Investigación y 233 estudios, de los cuales se seleccionaron 11 para su evaluación y posterior detalle en cuanto a los criterios establecidos para la ética en la investigación en un entorno virtual (*online*). Se han establecido y/o adaptado los siguientes criterios: privacidad de los datos; conservación de los datos personales/prontuarios; Término de Compromiso Libre e Informado; divulgación; recogida y almacenamiento de datos; riesgos de la investigación; limitaciones; y eliminación. **Conclusión:** se presentan las potencialidades y desafíos de la investigación en el entorno virtual en lo que se refiere a los criterios de ética.

**Descritores:** Investigación; Ética; Brasil; Tecnología de la información; Intervención basada en la internet.

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## INTRODUCTION

The COVID-19 pandemic mobilized researchers from all over the world, so that, in the years 2020 and 2021, science raced against time to understand the disease, the ways to fight it and the traces of physical and psychological damage that mark societies across the planet<sup>1-2</sup>. Studies on prevention measures, health protection factors against isolation and the production of vaccines took place in record time to combat this health emergency. The World Health Organization<sup>3</sup> has an open access database on the global literature produced on the pandemic. At the time of the present study, there were an impressive 331,370 studies produced and published on COVID-19.

In Brazil, until the emergence of this serious public health crisis, guidelines and norms of the Resolution of the National Health Council No. 466, of December 12, 2012<sup>4</sup> provided subsidies for the ethical regulation of research with human beings in person. However, new services offered in a virtual environment as a result of the COVID-19 pandemic need to meet criteria and rigor not only in terms of scientific basis, but fundamentally in methodological terms and in terms of ethical aspects of research in this modality.

Historically, the *Marco Civil da Internet*<sup>5</sup> established guidelines for the development of the internet based on civil rights. The use of the internet in Brazil must respect freedom of expression, human rights, personality and the exercise of citizenship<sup>6</sup>. In addition, the *Marco Civil da Internet* guarantees the privacy and protection of personal data. Thus, the user has the right to the inviolability of their privacy, the secrecy of the flow of communications over the internet and the secrecy of their private communications, except by court order.

Another important complement was the General Data Protection Law (LGPD)<sup>7</sup>, in force since September 2020. "*The law incorporates the principle of informative self-determination*"<sup>6:64</sup>; that is, it conditions the use of personal data to the citizen's written consent, or by another means that demonstrates the expression of their will. The use of personal data is now conditioned by the good faith of some principles, among them, having a legitimate purpose and explicitly informed to the data subject; not use the data for purposes other than those informed in the consent; ensure access to the form and duration of data processing and use of effective technical measures to ensure data security from unauthorized access. In addition, whenever possible, the anonymization of personal data is recommended.

Therefore, research and health services through teleservice, via devices or online platforms require special considerations. Ethical advances as a way of adapting research in the face of the pandemic become essential, and are not offered to make implementation difficult or exaggerate risks, but to help reflection on possible conflicts between professional-user, which

may arise as a result of this new model of intervention<sup>8</sup>. Therefore, in addition to adapting research protocols, it is also necessary to adapt criteria to ensure ethics, preservation of rights and safety of participants as subjects of online research. Thus, in view of the urgency of new health research services and protocols as a result of the COVID-19 pandemic, this study aims to present the new established and revised ethical criteria for conducting online research in Brazil.

## METHODS

This is a brief communication, with a narrative review of the scientific literature on established and/or adapted ethical criteria for conducting online research in Brazil. The databases used were SciELO and the national scientific portal for research ethics (National Research Ethics Commission - CONEP). The search was carried out from May to July 2021, containing the following descriptors: '*pesquisa*' (research), '*ética*' (ethics), '*Brasil*' (Brazil), 'on-line', OR 'virtual', including search terms and interterms from the last 10 years.

The data presented considered the period of research and writing of the study, which means that, in itself, works after this date are not covered.

## RESULTS

Six CONEP regulations<sup>4,9-13</sup> and 233 studies were identified, 11 of which were selected for evaluation and further detailing regarding the criteria established for ethics in research in a virtual environment (online)<sup>14-24</sup>.

The data obtained from the searches regarding the criteria established and/or adapted for ethics in research with human beings in a virtual nature, in relation to the criteria previously established for research in the face-to-face modality, are described in Table 1.

**Table 1.** Original criteria (face-to-face research) and established and/or adapted criteria for conducting virtual/online research in Brazil.

Criteria	Adaption to criteria (virtual)
Data privacy	Use of anonymous data system <sup>16</sup> ; Online questionnaires (such as SurveyMonkey and equestiona) with the function of directly sending the answers to the database, maintaining the participant's anonymity <sup>13,18</sup> ; Access to a restricted group of researchers, who have a registered user with a password and who use the data exclusively for the purpose of the research <sup>16</sup> .
Preservation of personal data/medical records	Any personal identifiers stored separately from the system <sup>16</sup> ; Database distributed on the internet or the email must be password protected <sup>16</sup> .
Free and Informed Consent (FIC)	Obtained in writing, sound or imagery <sup>13</sup> ; Copy of the document in the participant's personal file <sup>11,13</sup> ; Sending a copy signed by the researchers <sup>11,13</sup> ; Return of research questionnaire(s) by the participant is considered consent to participate in the research <sup>18</sup> .
Disclosure	Invitation to the entire available universe of the target audience <sup>8,16,18</sup> ; Use of the same platform for contact and data collection <sup>18</sup> .
Data collection and storage	Use of electronic devices with restricted access <sup>16</sup> .
Research risk	Guaranteed access to health services and long-term follow-up, even after completion of the research <sup>12,15</sup> .
Limitations	Inaccurate response rate calculation, due to sending to incorrect email addresses, concern about viruses, or user pattern of deleting unknown messages <sup>18</sup> ; Requirement of skills in the use of technology and appropriate access to the internet <sup>25-26</sup> .
Discard	The responsible researcher must keep the research data in a digital file, under their custody and responsibility, for five years <sup>4</sup> .

## DISCUSSION

Most of the selected works<sup>14,17,20-24</sup> discussed the CNS Resolution 4664, which deals with ethics in research with human beings. This is seen as a long and philosophical resolution, in consideration of bioethical references, namely: respect for dignity, freedom, autonomy, beneficence, non-maleficence, justice and equity to research participants<sup>22</sup>. On the other hand, although bioethics is consecrated in the context of research, there is a scarcity of materials that discuss how complex it is to carry out research encompassing inclusion criteria and methods that make anyone from the target audience eligible to participate<sup>23</sup>. Even if they are not studies on research in a virtual environment, it can be observed that the resolution is elementary to think about the implications that the researcher's choice of form of dissemination, contact and research collection have in the discussion of the results.

Data privacy is one of the biggest challenges faced in transitioning to the virtual environment. It is known that all research involving access and use of personal data must have professional human resources to guarantee its secrecy and confidentiality<sup>9</sup>. Restricted access only to responsible researchers, an anonymous data system whose information is treated

exclusively for research purposes and personal identifiers stored separately, both protected by a password, are conducts that seek to preserve confidentiality<sup>16</sup>.

This point, therefore, requires attention, as it concerns the perceived risks and benefits of participating in the online survey. Participants must be fully informed about the risks and benefits of the service in the online format as a result of their participation and the measures taken by the researcher(s) to minimize direct or indirect damages arising from the research<sup>12,15</sup>. New criteria provide for guaranteed access to health services and/or long-term follow-up to participants, even after completion of the research, if necessary.

The Free and Informed Consent Term (FICT) is the means by which the user demonstrates accepting the invitation to participate in a research. The FICT is an integral and unique document, and any changes in the research procedures require the generation of a new version of the FICT. This should include both unchanged information and information that has been replaced or changed. Once approved by the responsible Research Ethics Committee (REC), the informed consent must be presented again to the participant, with a view to obtaining consent<sup>10</sup>.

In the context of the COVID-19 pandemic, a Notice from SEI/MS<sup>13</sup> recalls that user consent for surveys in the virtual environment can be obtained in written, sound or image form (Google Forms, Redcap, SurveyMonkey, Zoom, Skype, and others.). Regarding research methodologies that provide for data collection in a virtual environment, questionnaires collected on the web must have the FIC on the first page, and the user can proceed to the response phase if they have agreed with the proposed terms. If the database receives the responses, the participant is considered to have given their consent<sup>18</sup>. Online questionnaires such as SurveyMonkey and equestiona are recommended, with the function of sending the answers to the database while maintaining the participant's anonymity<sup>13,18</sup>.

In a Communication<sup>13</sup> and Circular Letter<sup>11</sup>, CONEP emphasizes that the registration of consent must guide the participant to the importance of keeping a copy of the document in their files and/or guaranteeing that they will be sent a copy signed by the researchers. For invitations sent by email, it can have only one sender and one recipient, or be sent with a hidden list. Here, it is possible to observe the orientation to save virtual documents within the personal file, while it advises against, at any stage, the use of online clouds for the registration and/or sharing of files and suggests the download of the data. These must be stored in a digital file, under the custody and responsibility of the researcher, for five years<sup>4</sup>.

The dissemination, contact and collection platforms, as well as the source that sends this information, can also make a difference in research in a virtual environment<sup>16,18</sup>. In other

words, in addition to individual contact, broad dissemination of the invitation to research is recommended, either through printed materials or websites, aiming to generate a collective transmission of information about the investigation<sup>16</sup>.

It is also recommended that the contact and collection platform be the same; such as, if a potential participant has been contacted by email and has stated their consent, it is likely that they will want to respond to the questionnaire via email. Similarly, if a potential participant has been contacted via the web, it is likely that they will want to complete the questionnaire via the web<sup>18</sup>. Furthermore, it is mentioned that a greater number of questionnaires are answered if the source that sent them is an educational institution, which can be considered co-responsible for the research project by agreeing with its methodology and offering support to the researcher to carry out the study<sup>18-19</sup>.

Internet access can be an important virtual research bias<sup>25</sup>. When observing the data of clinical trial participants, most people from less privileged social classes and with restricted access to health actions and treatments are found<sup>15</sup>. That is, participants who, were it not for the research, could face greater obstacles to receive adequate care for their health demands. Thus, in the transition from any stage of research to the virtual environment, the population that is intended to be reached must be taken into account, seeking to avoid biases and compromise the representativeness of the findings for society in general<sup>18</sup>.

To reduce sampling error, the reviewed studies recommend inviting the entire available universe of the target audience, which may favor online surveys, given their greater potential for reach compared to face-to-face collection methods. Thus, it is understood that competence in the use of technologies can define the limits of sampling scope and data confidentiality, which must be addressed during the elaboration of the informed consent and, also, in the discussion of research results<sup>8</sup>.

Skills in the use of technology and appropriate access to the internet is an element to be considered. The possibility of having multiple identities online, the use of pseudonyms and the imprecision to confirm sociodemographic data also deserve attention<sup>26</sup>. In addition, the inaccuracy of the response rate (due to incorrect email addresses, multiple responses from the same participant, concern about viruses or the user's pattern of deleting unknown messages) constitute important challenges for research in a virtual environment<sup>18</sup>.

## CONCLUSION

The guidelines for the use of the internet and the rights of users are regulated in Brazil. Freedom of expression is emphasized, provided that the inviolability of privacy, the citizen's consent for the use of their personal data and the legitimate purpose of the researcher in the treatment of participant data are respected, always prioritizing data anonymization. This must be informed in the FICT, including the risks and benefits of participating in the research, as well as the measures taken to minimize possible damages. In case of direct or indirect damages resulting from participation, guarantees of access and/or follow-up of the participants are foreseen even after the conclusion of the study.

Consent can be obtained in writing, sound or images. In the case of online questionnaires, sites that keep the database anonymous are recommended. For invitations sent by e-mail, it must contain one sender and one recipient, or the use, by the researcher, of a hidden list. Cloud storage or file sharing is not recommended. It is recommended that the data be downloaded into the researcher's personal file, who will be responsible for the custody and security of the documents.

The support of the educational institution to the researcher is important for the transition from studies with online stages. The dissemination of research to the entire available universe of target audiences needs to be permanently improved, given the unequal access to the internet in the country. Strengthening competencies is also suggested to ensure the security of records and to reduce imprecision in data confirmation and in the response rate.

Despite the relatively small amount of recovered materials, which also reveals the scarcity of productions on this topic in the country, it was evidenced that the choice for research in a virtual environment offers new and old challenges, which need to be managed carefully by researchers, in order to preserve the rights and safety of participants.

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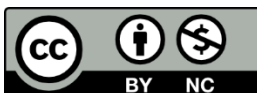
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