Ministry of Health
Executive Secretariat of the National Health Council
National Research Ethics Commission

Circular Letter No. 1/2021-CONEP/SECNS/MS

Brasília, March 3, 2021.

To the coordinators of Research Ethics Committees

Subject: Guidelines for research procedures at any stage in a virtual environment.

The National Research Ethics Commission (Conep) guides researchers and Research Ethics Committees regarding procedures that involve contact with participants and/or data collection at any stage of the research, in a virtual environment. Such measures aim to preserve the protection, safety and rights of research participants.

These guidelines, when applied to research participants in vulnerable situations, must be in accordance with the Resolutions of the National Health Council – CNS – nº 466 of 2012 and nº 510 of 2016.

It is understood by:

0.1. Virtual environment or environment: one that involves the use of the internet (such as emails, electronic websites, forms provided by programs, etc.), the telephone (audio and video calls, use of calling applications, etc.), as well as other programs and applications that use these means.

0.2. Non-face-to-face form: contact carried out through a virtual environment, including telephone, not involving the physical presence of the researcher and research participant.

Personal data: information related to the natural person 0.3. identified or identifiable (article 5 of the General Data Protection Law – LGPD – nº 13,709, of August 14, 2018), such as document numbers, medical records, etc.

of a Sensitive personal data - data on racial or ethnic origin, 0.4. religion, political opinion, membership trade union or organization of a religious, philosophical or political nature, data relating to health or sexual life, genetic or biometric data, when linked to a natural person (article 5 of LGPD nº 13,709, of 14 December August 2018).

In this sense, the following guidelines apply in research with human beings involving these tools:

1. IN RELATION TO SUBMISSION OF THE PROTOCOL TO THE SYSTEM CEP/CONEP:

1.1. The researcher must present the methodology of the research project research the explanation of all non-face-to-face stages/phases of the study, including sending templates for forms, terms and other documents which will be presented to the candidate research participant and the research participants.

1.2. The researcher must describe and justify the procedure to be adopted to obtain free and informed consent, as well as the registration or signature format of the term that will be used.

1.2.1. It will be up to the researcher to highlight, in addition to the risks and benefits related to participation in research, those risks characteristic of virtual environment, electronic media, or non-face-to-face activities, depending on the limitations of the technologies used. Additionally, they must be informed of the limitations of researchers to ensure full confidentiality and potential risk of its violation.

1.3. When Informed Consent Records/Terms of Free and Informed Consent are documentary, they must be presented, preferably, in the same format used for visualization of research participants.

2. IN RELATION TO PROCEDURES INVOLVING CONTACT THROUGH VIRTUAL MEANS OR TELEPHONE WITH THE POSSIBLE RESEARCH PARTICIPANTS:

2.1. The invitation to participate in the research should not be made with the use of lists that allow the identification of guests or the visualization of your contact details (email, telephone, etc.) by third parties.

2.1.1. Any individual invitation sent by email can only have one sender and a recipient, or be sent in the form of a hidden list.

2.1.2. Any individual invitation must clarify to the candidate the research participants, who before answering the researcher's questions made available in a non-face-to-face or virtual environment (questionnaire/form or interview), the Free and Informed Consent Form will be presented (or Assent Form, when applicable) for your consent.

2.2. When data collection occurs in a virtual environment (using programs for collecting or recording data, e-mail, among others), in modality of consent (Registration or ICF), the researcher must emphasize the importance of research participants keeping a copy in their files

of the electronic document.

2.2.1. Research participants must be guaranteed the right not to answer any question, without the need for explanation or justification To do so, you can also withdraw from the research at any time.

2.2.2. If there is a mandatory question, the right of the participant from not answering the question.

2.2.3. The research participant must be guaranteed the right to access the content of the instrument (topics that will be covered) before answer the questions for informed decision making.

2.2.4. The research participant will have access to the questions only after that you have given your consent.

2.3. When research in a virtual environment involves the participation of under 18 years of age, the first contact for consent must be with the parents and/or guardians, and based on their agreement, the consent of the minor.

2.4. It will be up to the responsible researcher to know the privacy of the tool used to collect personal information, even if through robots, and the risk of sharing these information with commercial partners to offer products and services way to ensure ethical aspects.

2.5. It must be made clear to the research participant, in the invitation, that the consent will be presented in advance and, if you agree to participate, consent will be considered when responding to the questionnaire/form or research interview.

2.5.1. The consent processes provided for in Art are excluded. 4th of CNS Resolution No. 510 of 2016.

2.6. It will be up to the researcher to explain how the costs will be assumed direct and indirect aspects of the research, when it takes place exclusively with the use of electronic tools at no cost for their use or already property of the same.

3. WITH REGARD TO SAFETY IN TRANSFER AND DATA STORAGE:

3.1. It is the researcher's responsibility to properly store of the data collected, as well as the procedures to ensure confidentiality and confidentiality of research participant information.

3.2. Once data collection is complete, the researcher is recommended responsible party to download *the* collected data to a device local electronic system, erasing any and all records from any platform virtual, shared environment or "cloud".

3.3. The same care must be followed for records of informed consent that are video or audio recordings. AND recommended to the responsible researcher to *download* the data, not its maintenance being recommended on any virtual platform, environment shared or "cloud".

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in In line with the provisions of CNS Resolution No. 510 of 2016, 3.4. article 9, item V), for participants research that use methodologies specific to the Human and Social Sciences, there must be an express expression of their agreement or not with the disclosure of their identity and other information collected.

4. REGARDING THE CONTENT OF THE DOCUMENTS PROCESSED:

Documents in electronic format related to obtaining the 4.1. consent must present all the information necessary for adequate clarification of the participant, with the guarantees and rights provided for in CNS Resolutions No. 466 of 2012 and 510 of 2016 and, in accordance with the particularities of the research.

The invitation to participate in the research must contain, 4.2. obligatorily, *a link* to an electronic address or text with the appropriate shipping instructions, which informs that it is possible, at any time and without any prejudice, to withdraw consent to use the research participant's data. In these situations, the responsible researcher is obliged to send the research participant the response stating that the research participant is interested in withdrawing their consent. In cases where it is not possible to identify the questionnaire 4.3. participant, the researcher must clarify the impossibility of excluding research data during the registration/consent process.

During the consent process, the researcher must 4.4. clarify to the participant in a clear and objective manner how their consent to participate in the research will be recorded.

with When research in the biomedical area necessarily requires 4.5. presence of the research participant the team, the ICF must be obtained in its physical form, in accordance with the provisions of CNS Resolution No. 466 of 2012, item IV.5.d. This consent must be obtained even if the research participant has already registered their consent electronically at a previous stage of the research. Cases not covered in this document, conflicting or not yet provided for in the available resolutions, will be evaluated by the CEP/Conep System panels.

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Document signed electronically by **Jorge Venâncio, Administrator,** on 03/09/2021, at 6:17 pm, according to official Brasília time, based on art. 6th, § 1st, of Decree No. 8,539, of October 8, 2015; and art. 8th, of Ordinance No. 900 of March 31, 2017.

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