Ministry of Health
Executive Secretary of the National Board of Health
Brazilian Independent Ethics Committee

CIRCULAR LETTER NO. 2/2021/CONEP/SECNS/MS

Brasília, February 24, 2021.

To Independent Ethics Committee coordinator,

Subject: Guidance for procedures in researches with any step in virtual environment.

I do hereby forward a document pursuant to guidance for procedures in researches with any step in virtual environment.

Regards,

CRISTIANE ALARCÃO FULGÊNCIO
Brazilian Independent Ethics Committee Executive Secretary

Reference: Proceeding no. 25000.026908/2021-15 SEI no. 0019229910

Brazilian Independent Ethics Committee - CONEP
SRTV 701, Via W 5 Norte, lote D Edifício PO 700, 3º andar - Bairro Asa Norte, Brasília/DF, CEP 70719-040
Site - saude.gov.br

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GUIDANCE FOR PROCEDURES IN RESEARCHES WITH ANY STEP IN

VIRTUAL ENVIRONMENT

Brasília, February 24, 2021.

The Brazilian Independent Ethics Committee (Conep) guides researches and the Independent Ethics Committees regarding procedures involving contact with subjects and/or data collection at any research step, in a virtual environment. Said measures aim at preserving subjects' protection, safety and rights.

These guidances, when applied to vulnerable subjects, should meet the National Board of Health Resolutions – CNS – no. 466 of 2012 and no. 510 of 2016.

The following are understood as:

0.1. Virtual means or environment: the one involving the use of internet (such as e-mails, websites, forms made available through programs, *etc*.), telephone (audio, video calls, use of call applications, etc.), as well as other programs and applications using these means.

0.2. Non personal type: contact made by virtual means or environment, including telephone, not involving the physical presence of the investigator and the subject.

0.3. Personal data: information related to the natural person identified or identifiable (article 5 of General Data Protection Act – LGPD – no. 13.709, dated August 14, 2018), such as document numbers, chart numbers, etc.

0.4. Sensitive personal data - data on race or ethnic origin, religion, politic opinion, participation in a union or religious, philosophic or political organization, data regarding health or sexual life, genetic or biometric data, when related to a natural person (article 5 of LGPD no. 13.709, dated August 14, 2018).

Thus, the following guidance applies in researches with humans involving these tools:

1. FOR PROTOCOL SUBMISSION TO IEC/CONEP SYSTEM:

1.1. The investigator should submit in research project methodology the explanation of all non-personal study steps/phases, including form templates, forms and other documents to be shown to the candidate subject and to subjects.

1.2. The investigator should describe and justify the procedure to be used to obtain the informed consent, as well as the record format or signature in the form to be used.

1.2.1. The investigator should point out, in addition to risks and benefits related to participation in the research, those risks characteristic to the virtual environment, electronic means or non-personal activities, due to limitations of technologies used. Moreover, the limitations of investigators to assure full confidentiality and potential risk of its violation should be informed.

1.3. When the Informed Consent Records/Informed Consent Forms are records, they should be submitted preferably in the same format used for subject view.

2. FOR PROCEDURES INVOLVING CONTACT THROUGH VIRTUAL ENVIRONMENT OR BY PHONE WITH POTENTIAL SUBJECTS:

2.1. The invitation to take part in the research should not be done using lists allowing the identification of guests or visualization of their contact data (e-mail, telephone, etc.) by third parties.

2.1.1. Any individual invitation sent by e-mail may only have one sender and one recipient, or may be sent as an occult list.

2.1.2. Any individual invitation should clarify to the candidate subject that, prior to answering the investigator's questions made available in a non-personal or virtual environment (questionnaire/interview form), the Informed Consent Form will be shown (or Assent Form, if applicable) for their consent.

2.2. When data collection takes place in a virtual environment (with use of programs for data collection, recording, e-mail, among others), in the consent type (Record or ICF), the investigator should stress the importance of the subject keeping a copy of the electronic document in their files.

2.2.1. The subject should be assured to right of not answering any question, without needing an explanation or rationale for this, and they may also withdraw from the research at any time.

2.2.2. If there is a mandatory question, the ICF should include the subject's right not to answer it.

2.2.3. The subject should be assured the right of access to the instrument contents (topics that will be addressed) prior to answering the questions, for an informed decision.

2.2.4. The subject will have access to questions only after providing their consent.

2.3. When research in virtual environment involves participation of minors, the first contact for consent should be with the parents and/or guardians, and from their agreement, the assent from the minor should be sought.

2.4. The investigator in charge is in charge of knowing the privacy policy of the tool used to collect personal information, even if through robots, and the risk of sharing this information with business partners for product and service offers, so as to guarantee ethical aspects.

2.5. In the invitation, it should be clear to the subject that the consent will be previously shown and, if they agree to take part, this will be deemed as a consent when answering to the research questionnaire/form or interview.

2.5.1. Consent processes foreseen in Art. 4 of CNS Resolution no. 510 of 2016 are excluded.

2.6. The investigator should explain how direct and indirect research costs will be covered, when it takes place solely by using electronic tools at no cost for use, since it is owned by them.

3. FOR SAFETY IN DATA TRANSFER AND STORAGE:

3.1. The investigator is in charge of properly storing data collected, as well as the procedures to assure secrecy and confidentiality of subject information.

3.2. Once data collection is completed, it is recommended that the investigator in charge downloads the data collected into a local electronic device, deleting all and every record from any virtual platform, shared environment or cloud.

3.3. The same care should be followed for informed consent records that are video or audio taped. It is recommended that the investigator in charge downloads data, and it is not indicated to keep them in any virtual platform, shared environment or cloud.

3.4. As provided for in CNS Resolution no. 510 of 2016, article 9, paragraph V), for subjects using own methodologies from Human and Social Sciences, there should be their express manifestation of agreement or not to disclose their identity and other information collected.

4. CONTENTS OF DOCUMENTS PROCESSED:

4.1. Electronic documents to obtain the consent should have all information required to properly clarify the subject, with the guarantees and rights foreseen in CNS Resolutions nos. 466 of 2012 and 510 of 2016 and as per the research particulars.

4.2. The invitation to take part in the research must contain a link to the electronic address or text with the due instructions for submission, informing that it is possible to withdraw the consent to use subject's data, anytime and without penalty. In these cases, the investigator must send the subject the reply to acknowledgment of subject's interest to withdraw their consent

4.3. When it is not possible to identify the subject questionnaire, the investigator should clarify the impossibility of excluding research data during the recording/consent process.

4.4. During the consent process, the investigator should clarify to the subject in a clear and objective fashion how their consent will be recorded to take part in the research.

4.5. When research in biomedical field requires the subject presence with the team, the ICF should be obtained physically, as foreseen in CNS Resolution no. 466 of 2012, item IV.5.d. This consent should be obtained even if the subject has recorded their consent electronically in a previous research step. Cases not contemplated herein, conflicting or not foreseen yet in resolutions available will be assessed by IEC/Conep System peers.

JORGE ALVES DE ALMEIDA VENANCIO
Brazilian Independent Ethics Committee Coordinator

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SRTV 701, Via W 5 Norte, lote D Edifício PO 700, 3º andar - Bairro Asa Norte, Brasília/DF, CEP 70719-040
Site - saude.gov.br