Ministry of Health
Executive Secretariat
Department of Interfederative and Participatory Management
Executive Secretariat of the National Health Council
Brazilian National Committee of Ethics in Research

CIRCULAR LETTER No. 23/2022/CONEP/SECNS/DGIP/SE/MS

Brasília, October 17, 2022.

To the Coordinators, members and administrative staff of Research Ethics Committees - RECs.

To Biobank Managers.

To the Investigators of the REC/Conep System.

Subject: Standardizing the use of electronic consent and assent for research and biobank subjects.

Dear all,

The Brazilian National Committee of Ethics in Research (Conep) guides investigators, biobank managers and Research Ethics Committees on procedures involving the electronic consent and assent of research and biobank subjects. Such measures aim to preserve subjects' protection, safety and rights, by incorporating the technological advances available, in order to guarantee their autonomy.

These guidelines must comply with the provisions of the current Resolutions of the National Health Council (CNS).

In this sense, the following guidelines apply to research with human beings that involve the formalization of electronic consent and assent.

1. TERMS AND DEFINITIONS.

1.1. For the purposes of this Official Letter, the following terms and definitions are adopted:

I - Electronic signature: final step of the electronic consent and assent processes, which demonstrates the subject's agreement to be part of a research or a biobank.

II - Remote activity: it is carried out remotely, without the need for the investigator and subjects to be in the same place and time.

III - In-person activity: it is the one carried out with the investigator and the subject in the same place and time.

IV - Electronic consent and consent: consist of formalizing consent and assent in an electronic system, platform or electronic tool that allows high levels of security for the consenting person's information, which can be carried out in person or remotely.

V - Personal identification data: information related to the identified or identifiable individual, which individually or jointly allows the person identification, including but not limited to: subject's name (or codename); postal information; phone numbers; electronic addresses (e-mail or website); individual record numbers; individual morphological characteristics.

VI - Sensitive personal data: personal data that, if known and processed, may be used in a discriminatory or malicious manner for the individual, family or social group, and even for the community, such as: data on racial or ethnic origin; socioeconomic status; religious convictions; political opinions; membership of unions or organizations of a religious, philosophical or political nature; data relating to health, sexual orientation and life; genetic and biometric data.

VII - Virtual environment: one that involves the use of the internet (such as emails, websites/electronic sites, forms made available by programs, etc.), the telephone (audio call, video call, use of call applications, etc.), as well as other programs and applications using these media.

VIII - Research subject: person who, in an informed and voluntary manner, or with the clarification and authorization of their legal guardian(s), agrees to be researched.

2. REGARDING CONSENT PROCESS TO PARTICIPATE IN RESEARCH.

2.1. Every research protocol that intends to use electronic consent and assent must base its choice on the potential benefits and risk minimization for the research subject, presenting the due justification to the REC/Conep System.

I - The investigator will be responsible for highlighting, in addition to the risks and benefits related to participation in the research, the risks characteristic of the virtual environment, electronic media, or non-face-to-face activities, due to the limitations of the technologies used. Additionally, the measures adopted must be informed, to ensure total secrecy and confidentiality of the subject's information.

2.2. - It is the investigator's responsibility to properly store the data collected, as well as the procedures to ensure the secrecy and confidentiality of the subject's information. The research protocol must detail the means of formalizing the consent and assent process.

I - It must include a consent document with language appropriate to the subjects' particularities.

II - It must describe how the research topic will be explained, considering the

subjects' characteristics, their particularities, the way in which access to technology will be given, how the interaction with the project team will be, as well as the place where the consent process will be carried out.

III - The investigator's responsibility cannot be delegated and cannot be declined and includes ethical and legal aspects, and is not transferable to the system/tool/platform due to possible failures in the consent and assent process and recording.

IV - The consent and assent process can take place in person or remotely, and the investigator must explain to the subject, in a simple and objective way, how to register their consent and assent to participate in the research. This information must be included in the research protocol and in the consent and assent forms.

V - The research team must offer the subject, before formalization of consent and assent, opportunities to discuss the study information, in real time.

VI - During the consent and assent process, times and ways to contact the investigator and his/her team must be made available, such as video conferences, telephone calls, electronic messages, e-mail, messaging applications, or online chat, giving opportunities for the subject to clear his/her doubts.

VII - Regardless of the means used for communication, the research team must explain to the subject about the importance of security in the place where the consent process will take place, so that the necessary secrecy and confidentiality are guaranteed.

VIII - The research protocol with electronic consent and assent and/or any part carried out remotely must follow the principles and standards set out in the Circular Letter no. 1/2021-CONEP/SECNS/MS, which provides guidelines for procedures in research with any stage in a virtual environment.

2.3. The formalization of electronic consent and assent can be used to complement this process and replace the paper record and/or form, when duly justified in the ethical assessment.

I - The subject must be guaranteed the possibility of having access to the forms in paper or in the format appropriate to their specificity, and these options must be identified in the protocol for ethical analysis.

2.4. Approved research that opts for the inclusion of an electronic consent and consent record, in addition to the forms already used, must submit such a procedural change for ethical analysis by means of an Amendment to the respective current research protocol.

3. REGARDING BIOBANK CONSENT PROCESS

3.1. The subject's consent and assent must be obtained prior to the incorporation of the biological sample into the biobank.

I - For biological samples collected exclusively for biobanks, the subject's consent and assent must be obtained prior to collection.

3.2. Any Biobank Development Protocol that intends to use electronic consent and consent must base its choice on the potential benefits and risk minimization to the research subject, presenting the due justification to the REC/Conep System.

3.3. It will be up to the person responsible for the biobank to highlight, in addition to the risks and benefits related to participation in the biobank, the risks characteristic of the virtual environment, electronic media, or non-face-to-face activities, due to the limitations of the technologies used. Additionally, the measures adopted to ensure secrecy and confidentiality of the subject's information must be informed.

3.4. The responsibility of the biobank manager cannot be delegated and cannot be declined and includes ethical and legal aspects, and is not transferable to the system/tool/platform due to any failures in the consent and assent process and registration.

3.5. The Biobank Development Protocol must detail the means of formalizing consent.

I - It must include a consent document with language appropriate to the subjects' particularities.

II - The document must describe the scope of the biobank, the subjects' characteristics, the form or place of obtaining consent and assent, how the subject will have access to the technology used and how the interaction with the biobank team will take place.

III - The consent and consent process can take place in person or remotely, and the person responsible for the biobank must explain to the subject, in a simple and objective way, how to register their consent to participate in the biobank. This information must be included in the Development Protocol and in the Informed Consent Form of the biobank.

IV - The biobank team should provide subjects, prior to formalization of consent and assent, with opportunities to discuss, in real time, information about the storage of biological samples.

V - During the consent and assent process, times and ways to contact the biobank must be made available, such as video conferences, telephone calls, electronic messages, emails, messaging applications, or online chats, providing opportunities for the subject to clear his/her doubts.

VI - Regardless of the means used for communication, the biobank team must explain to the subject the importance of security in the place where the consent and assent process will take place, so that the necessary secrecy and confidentiality are guaranteed.

VII - The biobank that opts to use electronic consent and/or any activity carried out remotely must follow the principles and rules set out in the Circular Letter no. 1/2021-CONEP/SECNS/MS, which provides for research in a virtual environment.

3.6. The formalization of electronic consent and assent can be used to complement this process and replace the paper form, when duly justified in the ethical assessment.

I - The subject must be guaranteed the possibility of having access to the forms in paper or in the format appropriate to their specificity, and these options must be identified in the biobank development protocol.

3.7. Approved biobanks that choose to include the consent and assent record in electronic media, in addition to the forms already used, must submit such procedural change for ethical analysis by means of an Amendment to the respective current development protocol.

4. REGARDING THE SYSTEM USED FOR ELECTRONIC CONSENT AND CONSENT

4.1. The electronic system used for the formalization of consent and assent must allow restricted access and must include methods that guarantee the confidentiality of the research or biobank subject's information. The system must encrypt the subject's information and, when this is not possible due to the study specificities, the investigator or the person responsible for the biobank must present an equivalent security measure and the proper justifications for its use.

4.2. The system must allow electronic consent and assent in audio, video or PDF document format, among others. When the consent and assent is documentary, it must be presented, preferably, in the same formats accessed by the research subjects.

4.3. Regarding the platform or system used for electronic consent and assent:

I - It must meet the criteria for Classification of Electronic Signatures, defined by article 4 of Law No. 14.063, of September 23, 2020.

II - I must meet all requirements of ethical standards in force.

III - It must allow for the individual submission of consent and assent, preventing subjects from being identified.

IV - It must ensure the integrity of the document.

V - It must guarantee the confidentiality of personal data and sensitive personal data of research and biobank subjects.

VI - It must allow for secure storage of electronic consent and assent

VII - It must allow sending to the subject the document signed by him/her and by the investigator or person delegated by him/her.

VIII - It must allow the preparation of a draft document for analysis of the consent and assent by the REC/Conep System and carrying out of the necessary adjustments before implementation and application of the consent and assent.

IX - It should preferably allow audits and monitoring.

5. REGARDING PROCESSED DOCUMENTS CONTENT:

5.1. Documents in electronic format related to obtaining consent and assent must have all the elements necessary to adequately inform the subject, with the guarantees and rights provided for in the current resolutions.

5.2. The invitation to participate in the research or biobank must contain a link to an electronic address or text with the appropriate instructions for sending.

5.3. The investigator or the person responsible for the biobank must submit the consent and assent record, Informed Consent Form (ICF) or Assent Form for ethical analysis, in a format that allows copying text, in addition to a link or form of access that will be made available to the subject.

5.4. The consent and assent record document must contain a link that allows the subject to withdraw consent and assent. The instrument that enables the withdrawal of these documents must have the same security and confidentiality criteria.

5.5. This Circular Letter revokes item 4.5 of Circular Letter n. 1/2021/CONEP/SECNS/MS and complements the provisions of letter d, of item IV.5, of CNS Resolution no. 466, of December 12, 2012 and paragraph 3, item X, art. 17, of CNS Resolution no. 510, of April 07, 2016.

Kind regards,

LAÍS ALVES DE SOUZA BONILHA
Coordinator of the Brazilian National Committee of Ethics in Research

Brazilian National Committee of Ethics in Research - CONEP
SRTV 701, Via W 5 Norte, lote D Edifício PO 700, 3º andar - Bairro Asa Norte, Brasília/DF, CEP (Zip code) 70719-040 Site - saude.gov.br