Ministry of Health
executive Secretary
Department of Interfederative and Participatory Management
Executive Secretariat of the National Health Council
National Research Ethics Commission

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 - CEPs.

To Biobank Managers.

To the Researchers of the CEP/Conep System.

Subject: Standardization of the use of electronic consent and assent for research and biobank participants.

Dear,

The National Research Ethics Commission (Conep) guides researchers, biobank managers and Research Ethics Committees in relation to procedures involving electronic consent and assent from research participants and biobanks. Such measures aim to preserve the protection, security and rights of participants, incorporating available technological advances, in order to guarantee their autonomy.

These guidelines must be in accordance with what is established in the current Resolutions of the National Health Council (CNS).

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

1. **TERMS AND DEFINITIONS.**

1.1. For the purposes of this Official Letter, terms and definitions are adopted as per he follows:

I - Electronic signature: final stage of the electronic consent and assent processes, which demonstrates the participant's agreement to

be part of research or a biobank.

II - Activity carried out remotely: it is one carried out remotely, without the need for the researcher and participants to be in the same place and time.

III - Activity carried out in person: carried out with the researcher and participant in the same place and time.

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

V - Personal identifying data: information related to the identified or identifiable natural person, which individually or jointly allows the identification of the person, such as: name of the participant (or codename); postal information; phone numbers; electronic addresses (email or website); individual record numbers; individual morphological characteristics; between others.

VI - Sensitive personal data: personal data that, if known and processed, could 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 condition; religious convictions; political opinions; membership of trade unions or organizations of a religious, philosophical or political nature; data relating to health, orientation and sexual life; genetic and biometric data.

VII - Virtual environment or environment: one that involves the use of the internet (such as emails, websites/electronic sites, 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.

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

ABOUT THE CONSENT PROCESS FOR PARTICIPATION 2. **UNDER RESEARCH.**

2.1. Any research protocol that intends to use electronic consent and assent must justify its choice based on the potential benefits and minimization of risks for the research participant, presenting the appropriate justification to the CEP/Conep System.

- It will be up to the researcher to highlight, in addition to the risks and benefits related to participation in the research, those 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 complete secrecy and confidentiality of the participant's information.

II - It is the researcher's responsibility to adequately store the collected data, as well as the procedures to ensure the secrecy and confidentiality of the research participant's information.

2.2. The research protocol must detail the means of formalizing the consent and assent process.

I - You must present a consent document with language appropriate to the particularities of the participants.

II - It must describe how the research topic will be explained, considering the characteristics of the participants, their particularities, the way in which access to technology will be given, what the interaction will be like with the project team, as well as the location in which the consent process will be carried out.

III - The responsibility of the researcher is non-delegable and non-delegable and includes ethical and legal aspects, and is not transferable to the system/tool/platform due to any flaws in the process and registration of consent and assent.

IV - The consent and assent process may take place in person or remotely, and the researcher must explain to the participant, in a simple and objective way, how their consent and assent to participate will be recorded of the research. This information must be included in the research protocol and in the terms of consent and assent.

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

VI - During the consent and assent process, times and forms of contact with the researcher and their team must be made available, such as video conferences, telephone calls, electronic messages, e-mail, messaging applications , or online *chat ,* providing opportunities for participants to ask questions.

VII - Regardless of the means used for communication, the research team must explain to the participant the importance of security in the location 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 Circular Letter No. 1/2021-CONEP/SECNS/MS, which presents guidelines for procedures in research at any stage in a virtual environment.

2.3. Formalizing consent and assent electronically it can be used to complement this process and replace the paper record and/or term, when duly justified in the ethical assessment.

I - The participant must be guaranteed the possibility of accessing the terms on paper or in the format appropriate to their specificity, and these options must be identified in the protocol for ethical assessment.

2.4. Already approved research that chooses to include registration. consent and assent in electronic form, in addition to the forms already used, must submit such procedural change to ethical assessment through an Amendment to the respective current research protocol.

3. ABOUT THE BIOBANK CONSENT PROCESS

3.1. The participant's consent and assent must be obtained before incorporating the biological sample into the biobank.

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

3.2. Every Biobank Development Protocol that intends to use electronic consent and assent must justify its choice based on the potential benefits and minimization of risks for the participant, presenting the appropriate justification to the CEP/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, those 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 participant's information must be informed.

3.4. The responsibility of the biobank manager is non-delegable and non-declinable and includes ethical and legal aspects, and is not transferable to the system/tool/platform due to any flaws in the process and recording of consent and assent.

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

I - You must present a consent document with language appropriate to the particularities of the participants.

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

III - The consent and assent process can take place in person or remotely, and the person responsible for the biobank must explain to the participant, in a simple and objective way, how their consent to participate in the biobank will be recorded. This information must be included in the Biobank's Development Protocol and Informed Consent Form.

IV - The biobank team must offer participants, before formalizing consent and assent, opportunities to discuss, in real time, information about the storage of biological samples.

V - During the consent and assent process, times and forms of contact with the biobank must be made available, such as video conferences, telephone calls, electronic messages, emails, messaging applications, or online *chats ,* providing opportunities so that the participant can clarify their doubts.

VI - Regardless of the means used for communication, the team

biobank must explain to the participant the importance of security in the location where the consent and assent process will take place, so that the necessary secrecy and confidentiality are guaranteed.

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

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

I - The participant must be guaranteed the possibility of accessing the terms on paper or in the format appropriate to their specificity, and these options must be identified in the biobank development protocol.

3.7. Already approved biobanks that choose to include registration of consent and assent in electronic form, in addition to the forms already used, must submit such procedural change to ethical assessment through an Amendment to the respective current development protocol.

4. ABOUT THE SYSTEM USED FOR CONSENT AND ELECTRONIC ASSENT

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

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

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

I - Must meet the Electronic Signatures Classification criteria, defined by article 4, of Law No. 14,063, of September 23, 2020.

II - Must meet all requirements of current ethical standards.

III - It must allow individual sending of consent and assent, preventing participants from being identified.

IV - It must guarantee the integrity of the document.

V - Must guarantee the confidentiality of personal data and sensitive personal data of research and biobank participants.

VI - It must allow secure storage of consent and assent

electronic.

VII - It must allow the participant to send the document signed by him/her and the researcher or person delegated by him/her.

VIII - It must allow the preparation of a non-definitive document for the assessment of consent and assent by the CEP/ Conep System and the making of necessary adjustments before the implementation and application of consent and assent.

IX - Preferably, allow audits and monitoring.

5. **REGARDING THE CONTENT OF THE DOCUMENTS PROCESSED:** Documents in electronic format related to obtaining the 5.1. consent and assent must present all the elements necessary to adequately inform the participant, with the guarantees and rights provided for in current resolutions.

or The invitation to participate in research or biobank must 5.2. must contain *a link* to an email address text with the appropriate shipping instructions.

The researcher or person responsible for the biobank must submit 5.3. for ethical assessment, the record of consent and assent, Free and Informed Consent Form (TCLE) or Assent Form in a format that allows copying the text of the document and also a *link* or form of access that will be made available to the participant.

5.4. The consent and assent registration document must contain a *link* that allows the participant to withdraw consent and assent. The instrument that enables the removal of these documents must meet the same security and confidentiality criteria.

This Circular Letter revokes item 4.5 of Circular Letter 5.5. nº 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 in § 3, of item X, art. 17, of CNS Resolution No. 510, of April 7, 2016.

Yours sincerely,

LAÍS ALVES DE SOUZA BONILHA

Coordinator of the National Research Ethics Commission

Document signed electronically by **Laís Alves de Souza Bonilha, Coordinator of the National Research Ethics Commission,** on 10/17/2022, at 6:00 pm, according to official Brasília time, based on § 3 of art. 4th, of Decree No. 10,543, of November 13, 2020; and art. 8th, of Ordinance No. 900 of March 31, 2017.

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National Research Ethics Commission - CONEP SRTV
701, Via W 5 Norte, lot D Edifício PO 700, 3rd floor - Bairro Asa Norte, Brasília/DF, CEP 70719-040 Website - saude.gov.br