



Ministry of Health
Executive Secretary

Department of Interfederative and Participatory Management
Executive Secretary of the National Health Council
National Research Ethics Committee

CIRCULAR LETTER No. 11/2023/CONEP/SECNS/DGIP/SE/MS

Brasilia, July 26, 2023.

To coordinators, members, administrative staff of Research Ethics Committees and researchers.

SUBJECT: Guidelines related to the process of obtaining the consent of research participants under 18 years of age and people with "absence of autonomy", permanent or temporary, to consent.

1. The National Research Ethics Commission (Conep), in recognition of the respect and dignity of research participants under 18 years of age and people with "absence of autonomy", permanent or temporary, to consent, establishes, for researchers and analysis of the CEP/Conep system, the following guidelines on the processes and registration of assent, when writing the detailed project and the assent term.

The guidelines contained in this document are based on the definitions for the 2nd free and informed assent and the term of assent, provided for in items II.2 and II.24, of CNS Resolution No. 466/2012, as well as on the definitions for the free and informed consent and the process of consent and assent, provided for in items I and XX, of art. 2nd CNS Resolution No. 510/2016.

The process of consent to participate in the research is essential and begins with the 3. preparation of the invitation addressed to those who exercise parenthood (father or mother) or guardianship (legal representative), without prejudice to listening to the participant under 18 years of age. age or the person with "absence of autonomy", permanent or temporary, to consent.

It must be ensured that the assent is made in the form of an invitation without any degree of 4. induction or coercion, written in understandable and easy-to-understand language for adequate elucidation about the research.

5. The assent process must consider the capacity of understanding of the participant under 18 years of age and the judgment of the person with "absence of autonomy", permanent or temporary, to consent.

6. The integral protection of children and adolescents is the duty of all people, public authorities and society in general (Statute of Children and Adolescents, article 4). Based on this principle, the minimum age is set at seven years for the obligation to obtain the term or record of assent.

For researchers and for analysis by the CEP/Conep System, it is recommended an assessment of the 7. needs of each research participant, their capabilities and emotional maturity, for the presentation of different terms or assent records, according to age group (from childhood and adolescence) and the complexity of the research.

For surveys in which CNS Resolution No. 510/2016 applies, the record of assent 8. can be obtained in written form or in other forms, whether: sound, imagery, or others that meet the characteristics of the survey and participants.

It is warned that the aforementioned resolution, in its article 16, establishes that "the researcher must 9. justify the most appropriate means of recording, considering, for this, the degree of risk involved, the characteristics of the research process and the participant" .

10. In the preparation of the term or record of assent, simple and understandable language should be adopted for the level of understanding of the research participant, without constituting a reproduction of information written in the term/ record of free and informed consent intended for those who exercise the parenthood (father or mother) or guardianship (legal representative).

11. In the research participant assent process, the following are recommended: items in the assent term or record:

- a) Introduction - introduce yourself as a researcher to (a) the potential research participant; explaining who they are, what they do, what they are researching and why they are being invited to participate in the research. Then, invite him or her to be a research participant. Also clarify that those responsible will be consulted and will allow him/her to participate in the research. Explain that if he or she doesn't want to, their decision will be respected (whenever possible). Also, say that she can talk to someone before agreeing or not to participate. For people with "absence of autonomy", permanent or temporary, to consent, explain according to the degree of understanding of the person.
- b) Objectives – explain the research purposes in language understandable to the participant.
- c) Voluntary participation – explain in friendly and understandable language that he or she is the one who decides whether or not to participate in the research. If you decide not to participate, say that nothing will change in your treatment or in your relationship with the professionals responsible for the care. And yet, even if you initially agreed to participate, it is possible to change your mind and withdraw, without any problem.
- d) Information about the investigational product – if the research involves drugs or immunobiologicals, explain which product is being researched, which will be administered, by which route of administration, what it is used for and what is being tested.
- e) Procedures – explain in simple language which procedures are used, seeking to meet the participant's expectations. For example: that your participation in the research will imply attendance "x" times at the study site, that blood (or other biological material) will be collected "x" times, without associating the volume to objects used in your daily life to eating (for example: soup spoon, dessert spoon), how long the procedures are expected to take, and what other procedures may be necessary.
- f) Risks – explain all the risks in language understandable to the participants, as well as the actions taken to minimize or correct them.
- g) Discomfort – simply explain any physical and/or emotional discomfort, restrictions on daily activities, pain or illness.
- h) Benefits – describe all the benefits that will be generated with the research, even if they are not direct benefits.
- i) Induction to participation – based on CNS Resolution No. 466/2012, it is forbidden to offer financial incentives, gifts, or others that may interfere with the full freedom to participate in the research.

j) Right to reimbursement - ensure that the reimbursement of expenses with treatment, travel and food, as well as other expenses, and that their parents or guardians will not bear any cost of the research.

k) Confidentiality – inform that other people may know about the participation in the research, making it clear that the information about the participants is confidential and nobody, except people directly related to the research, can have access to them.

l) Dissemination of results - clarify that after the research is over, the results will be communicated to the participant and may also be published in a magazine, or book, or conference, etc.

m) Right to refuse or withdraw informed consent - reinforce to the participant that participation is voluntary.

n) Contact with the researcher – list the name of the researcher or people with whom the participant can easily get in touch, in case he wants to talk about the research. In the case of participants under 18 years old, explain that they may even be your teachers, friends, relatives. o) Contact with the Research Ethics Committee (CEP) - make a brief

explanation of what a CEP is and inform the telephone contact and/or e-mail.

p) Contact with Conep (when applicable) - make a brief explanation of what Conep is and inform the telephone contact and/or e-mail.

12. The implementation of these guidelines is effective from this date.

Cordially,

LAIS ALVES DE SOUZA BONILHA

Coordinator of the National Research Ethics Commission



Document electronically signed by **Laís Alves de Souza Bonilha, Coordinator of the National Research Ethics Committee**, on 07/27/2023, at 7:07 pm, according to official Brasília time, based on § 3 of art. 4, of [Decree No. 10,543, of November 13, 2020](#); and art. 8, of [Ordinance No. 900 of March 31, 2017](#).



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