PENDING ISSUE DATABASE

SUGGESTIONS FOR STANDARDIZATION

VERSION 1

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LIST OF ABBREVIATIONS AND ACRONYMOUS

IRB/IEC	Institutional Review Board/Independent Ethics Committee
CNPq	National Council for Scientific and Technological Development
CONEP	Brazilian National Research Ethics Committee
FAPs	Research Support Backgrounds
Finep	Funder of Studies and Projects
AF	Assent Form
ICF	Informed Consent Form
US-NIH	United States – National Institutes of Health

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INTRODUCTION

During the pre-accreditation process, CONEP Acredita team identified the opportunity to prepare and make available to the Institutional Review Boards/Independent Ethics Committees (IRBs/IECs) documents to assist in the improvement and harmonization of the ethical analysis of research protocols, as well as in the preparation of unified opinions. One of these documents is the Pending Issue Database, which was prepared during the pre-accreditation process of IRBs/IECs candidates for Public Call Notice No. 001/2020, based on the study of current Brazilian ethical standards.

This Pending Issue Database has systematized information and suggestions for building pending issues on various ethical topics related to the analysis of research protocols. As a document with pending issue suggestions, the texts presented here are pending issue samples that can be used in their entirety or adapted to the reality of each analysis and in compliance with possible updates of current ethical rules.

Good reading.

SCHEDULE

Lack of Schedule

According to CNS Operational Standard No. 001, of September 30th, 2013, item 3.4.1.9, all research protocols must contain: Schedule: informing the total duration of the study in Brazil and, eventually, in the world and the different stages of the research, in number of months. In the project, the performance schedule must indicate the beginning of the study on a date compatible with the protocol process in the IRB/IEC/CONEP System. An explicit commitment to start the study must be submitted only after the IRB/IEC/CONEP System final approval. Adequacy is requested.

Outdated Schedule

- The study schedule is not adequate, as it informs that it would have already started. Therefore, clarifications are requested and, if necessary, the adequacy of the schedule in relation to the start date of the study since it has been analyzed in the IRB/IEC/CONEP System until this date. It is also worth mentioning the need to adapt the schedule in order to describe the duration of the different stages of the research, with the researcher's explicit commitment that the study will only start after approval by the IRB/IEC/CONEP System (CNS Operational Standard No. 001, of 2013, item 3.3.f).

- It is noteworthy that the conduct of the IRB/IEC/CONEP System has been not to issue an opinion on completed or ongoing research. This decision is based on the fact that the ethical opinion is not merely bureaucratic, but a contribution to the adequacy of the research project to the current ethical standards, thus protecting the interests of the participants and, consequently, of all those involved in the process: researcher, institution, IRB/IEC, and the IRB/IEC/CONEP System itself. Clarifications are requested and, if necessary, adjustment of the schedule in relation to the study start date (CNS Resolution No. 466, of 2012, item XI.2.a).

STATEMENTS

Patenting and Commercial Use - Foreign Institution

It is requested that the commitment of the recipient institution abroad is included in Plataforma Brasil regarding the prohibition of patenting and commercial use of human biological material stored in a biorepository (CNS Resolution No. 441, of 2011, Item 16; Ordinance MS No. 2201, 2011, Article 12; CNS Operational Standard No. 001, 2013, Item 3, Annex II).

Registration Status of the New Medical Equipment or Device in the Country

- On page X, of document YY, it was reported that the new medical equipment/device used in this research is approved by the FDA (Food and Drug Administration). In this sense, clarification is requested on the status of registration of new medical equipment/device in the country.

COVER PAGE

Thematic Area

- Did not select CONEP thematic area of responsibility:

Field 3 of the Cover Letter ("Thematic Area") must be completed with the correct corresponding area of the study. This field is directly related to the items that are marked at Plataforma Brasil, in the "Thematic Area" field (second page of the Platform, "Study Area" tab), and the researcher is responsible for the correct selection of the relevant items (CNS Operational Standard n. 001, of 2012, item 3.3.a). It should also be clarified that the researcher can select more than one thematic area option. Adequacy is requested.

- Study does not fall into CONEP thematic area of responsibility:

In order to prevent this research protocol and future amendments or notifications from being automatically forwarded to CONEP, it is requested to remove the indication that it is research in the thematic area "INSERT THE NAME OF THE THEMATIC AREA", in the registration of the research protocol at Plataforma Brasil, since the study does not meet the definitions indicated in both CNS Resolution No. 466, of 2012, item IX.4 and Circular Letter No. 172/2017/CONEP/CNS/MS.

Signatures

The identification of signatures in the fields must clearly contain the full name and function of the person signing, preferably indicated by stamp (CNS Operational Standard No. 001 of 2013, item 3.3.a). Adequacy is requested.

Fields to be completed

All fields on the Cover Letter must be completed, dated, signed, and with the identification of the signatories. The identification of signatures must clearly contain the full name and function of the person signing, preferably indicated by a stamp. It should be noted that, during the pandemic, it will not be necessary to include the signature in the Proposing Institution and Main Sponsor fields, just completing the information correctly. Adequacy is requested (CNS Operational Standard No. 001, of 2012, item 3.3.a).

Conflict of interest

In some cases, the researcher is also the institutional responsible, which would make them sign simultaneously the fields of the Proposing Institution and those intended for the researcher. This situation is clearly conflicting and can, in certain circumstances, compromise the safety of subjects. In order to reduce potential conflicts of interest, in this situation, the

IRB/IEC requests that another institutional responsible, without conflicts of interest, sign the Cover Letter (CNS Operational Standard No. 001, 2013, Annex II, Mandatory Items for Research Protocols, sub-item 3). Adequacy is requested.

Main Sponsor

CNS Resolution No. 466, of 2012, item II.11, establishes a sponsor as “an individual or legal entity, public or private, that supports research, through financing, infrastructure, human resources or institutional support” (CNS, 2012). The definition of the study sponsor is shown on the Cover Letter, in the “Primary Sponsor” field. The researcher must indicate, in this field, the institution, body, agency or company that will provide the financial resources for the research (CNS Operational Standard No. 001, of 2012, item 3.3.a). In the specific case of national (for example, CNPq, Finep, FAPs, etc.) and international (for example, US-NIH) funding agencies, it is accepted that the fields title/function, registered with Individual Taxpayer's Roll (CPF), signature and date are blank in the part reserved for the sponsor, provided that the funding body is expressly identified on the Cover Letter and that a document proving the funding is submitted. Adequacy is requested.

Basic Research Information

Benefits

The "Benefits" field at Plataforma Brasil is intended to inform any possibility of direct or indirect, immediate, or subsequent benefit, EARNED BY THE PARTICIPANT and/or their community, as a result of their participation in the research, in the performance of the study. In view of the above, it is requested to adapt the information about the benefit to the study participant, in the "Benefits" field, in Tab 4 - Study Details, at Plataforma Brasil (CNS Resolution No. 466, of 2012, item II.4).

Risks

The "Risk" field at Plataforma Brasil is intended to inform any possibility of damage to the physical, psychic, moral, intellectual, social, cultural or spiritual dimension of the human being, in any research and resulting from it, that is, any direct/indirect damage, as well as late/immediate, TO THE SUBJECT, and not to the study performance. In view of the above, it is requested to adapt the information regarding the risk to the study participant, in "Risk" field, in Tab 4 - Study Details, at Plataforma Brasil (CNS Resolution No. 466, of 2012, item II.22).

Budget

Lack of Budget

According to CNS Operational Standard No. 001, of 2013, item 3.3.e, all research protocols must contain a budget that details the resources, sources, and destination, as well as presenting an estimate of reimbursement of the participant and their companion expenses, when necessary. Therefore, it is requested that a detailed financial budget is submitted, specifying ALL resources, sources, and destination.

Contradictory information

The budgets presented in documents X and Y (LIST THE NAME OF THE DOCUMENTS) are discrepant. It is up to the responsible researcher to present a detailed financial budget, which specifies all the resources, sources, and destination. In this sense, clarifications and adaptation of documents are requested, if necessary (CNS Operational Standard No. 001, of 2013, item 3.3.e).

Zero cost

For the IRB/IEC/CONEP System, there are no "zero cost" research. Even if the researcher understands that it will not be necessary to obtain or make resources available to carry out the study, they will need to inform the amount necessary for each procedure and stage of the study (even if, in fact, the researcher does not pay for such expenses), for example , expenses with professionals in the area, exams, office supplies, forecast of reimbursement of subjects, but not limited to. Therefore, it is requested that a detailed financial budget is presented, specifying ALL resources, sources, and destination. (CNS Operating Standard No. 001 of 2013, item 3.3.e).

DETAILED PROJECT

Inclusion and exclusion criteria

It is requested to insert, in the detailed project, the inclusion and exclusion criteria of the subjects, which must be presented according to the requirements of the methodology to be used (CNS Operational Standard No. 001, of 2013, item 3.4.1.11).

Schedule

It is requested to insert, in the detailed project, the total duration and different stages of the research, with an explicit commitment from the researcher that the research will only be started after approval by the IRB/IEC/CONEP System (CNS Operational Standard No. 001, of 2013, item 3.4.1.9).

Location of the research performance

All research protocols must contain the locations where the research stages will take place. It is requested to insert, in the detailed project, information about the place(s) of the research performance (CNS Operational Standard No. 001, of 2013, item 3.4.1.5).

Methodology

- It is requested to insert, in the detailed project, the detailed description of the research methods and procedures, based on the scientific backgrounds (CNS Operational Standard No. 001, of 2013, item 3.4.1.8).
- It is requested to insert, in the detailed project, a description of the approach or plan for the recruitment of potential subjects (CNS Operational Standard No. 001, of 2013, item 3.4.1.8).

Objectives

All research protocols must contain research objectives showing its purpose. It is requested to insert, in the detailed project, the research objectives (CNS Operational Standard No. 001, of 2013, item 3.4.1.4).

Budget

It is requested to insert, in the detailed project, the research budget, detailing the resources, sources and destination of the funding (CNS Operational Standard No. 001, of 2013, item 3.4.1.10).

Placebo

It is understood that the use of placebo must be fully justified, in terms of non-maleficence and methodological need, and the benefits, risks, difficulties and effectiveness of a new therapeutic method must be compared to the best prophylactic, diagnostic methods, and current therapies. Therefore, the use of the so-called placebo arm is not appropriate, as it does not offer patients the best available treatment and puts them at unjustified risk, from an ethical and methodological point of view. Clarifications and adequacy are requested, if necessary (CNS Resolution No. 466, of 2012, item III.3.b).

Population to be studied

All research protocols must contain a description of the population to be studied, for example, size, age group, sex, etc. In the absence of the delimitation of the population, rationale must be submitted for not presenting the description of the population and the reasons for the use of vulnerable groups, when applicable. It is requested to insert, in the detailed project, information about the study population (CNS Operational Standard No. 001, of 2013, item 3.4.1.6).

Research Result

It is requested to insert, in the detailed project, the guarantee of the researcher that the results of the study will be disclosed to the subjects and to the institutions where the data were obtained (CNS Operational Standard No. 001, of 2013, item 3.4.1.14).

Washout

To better clarify to the subject, it is requested to insert, in the Informed Consent Form (ICF), more information about the washout period that will be carried out in the research protocol and its associated risks (CNS Resolution No. 466, 2012, item IV.3.a).

Biological and genetic material

Samples from pathology laboratories

It is requested that, in case of use of biological material collected and stored for diagnostic purposes, a statement is included in Plataforma Brasil assuring that only the surplus of biological material will be used for research, and that the remaining sample will be returned to the institution, as soon as its manipulation is completed (MS Ordinance No. 2.201, of 2011, Article 14, Paragraph 3.°).

Constitution or participation in a biorepository: more than one institution

The study involves more than one institution; therefore, it is requested to submit an agreement signed between the participating institutions. This agreement should contemplate ways of operationalizing, sharing, and using human biological material stored in a biorepository, including the possibility of future dissolution of the partnership and the consequent sharing and destination of data and stored materials, as provided for in the ICF. It is noteworthy that it is necessary to explain the type and quantity of shared materials, informing their destination after use (CNS Resolution No. 441, of 2011, items 13 and 13.I).

Central laboratory

Clarifications are requested on the location of the central laboratory where the biological material will be sent, as well as the destination of the samples, their storage and disposal. It should be noted that, if storage in a biorepository is foreseen, the protocol must comply with CNS Resolution No. 441, of 2011, and MS Ordinance No. 2,201, of 2011, and the required documentation must be submitted (see pages 48 and 49 of the document “Frequent Pending Issue in Clinical Research Protocols”, available at Plataforma Brasil, “Manuais da Plataforma Brasil” icon).

Storage rationale for future use

Whenever it is anticipated the storage of human biological material in the country or abroad, aiming at the possibility of use in future investigations, rationale must be presented regarding the need and opportunity for future use. In view of the above, it is requested to submit this rationale (CNS Resolution No. 441, of 2011, item 2.I).

Patenting and commercial use - foreign institution

It is requested that the commitment of the recipient institution abroad be included in Plataforma Brasil regarding the prohibition of patenting and commercial use of human biological material stored in a biorepository (CNS Resolution No. 441, of 2011, item 16;

Standard CNS Operational No. 001, 2013, Annex II, Documents required for the storage of human biological material in a biorepository - linked to a specific research project, - item 3).

Storage period

The storage period for human biological material in a biorepository must be in accordance with the corresponding research schedule and may be authorized for up to ten (10) years. Renewals of the storage authorization are allowed upon request of the responsible researcher to the IRB/IEC, accompanied by a rationale and report of the research activities carried out with the material during the period. Clarifications are requested about the storage time of biological samples and, if necessary, adequacy of the study documents (CNS Resolution No. 441, of 2011, item 12).

Genetic data storage

It is unclear which institution/researcher will be responsible for storing the genetic data obtained in the study, and who will have access to them. Considering the need to observe the protection of human rights, fundamental freedoms, and respect for human dignity in the collection, processing, use and storage of human genetic data, clarification is requested about the location and the person responsible for storing the genetic data obtained in the study (CNS Resolution No. 340, 2004, Recitals).

Family investigations - genetic studies

For studies in which family investigations are expected to be carried out, the ICF of each individual studied must be obtained. Adequacy is requested (CNS Resolution No. 340 of 2004, item V.1.h).

Research in a virtual environment

Protocol submission

- It is requested that the Detailed Project methodology includes an explanation of all non-contact stages/phases of the study, sending, including via Plataforma Brasil, the models of forms, terms, and other documents that will be presented to the candidate to participate in research and subjects (Circular Letter No. 1/2021-CONEP/SECNS/MS, item 1.1)
- It is requested that the Detailed Project contains the description and rationale of the procedure to be adopted to obtain the Informed consent, as well as the format of registration or signature of the form that will be used (Circular Letter No. 1/2021-CONEP/SECNS/MS, item 1.2).
- When the Informed Consent/ICF Registration are documentary, they must be submitted, preferably, in the same format used for viewing the subjects. Adequacy is requested (Circular Letter No. 1/2021-CONEP/SECNS/MS, item 1.3)

Procedures that involve virtual or telephone contact with potential subjects

- The invitation to participate in the research must not be made using lists that allow the identification of guests or the visualization of their contact data (email, telephone, etc.) by third parties. Thus, clarifications are requested on how to send the invitation and, if necessary, adequacy (Circular Letter No. 1/2021-CONEP/SECNS/MS, item 2.1).
- Any individual invitation, sent by email, can only have a single sender and recipient, or be sent in the form of a hidden list. Thus, clarifications are requested regarding the personal invitation and, if necessary, adequacy (Circular Letter No. 1/2021-CONEP/SECNS/MS, item 2.1.1).
- When research in a virtual environment involves the participation of persons under 18 years old, the first contact for consent must be with the parents and/or guardians, and after agreement, the consent of the minor must be sought. Thus, clarifications are requested regarding the personal invitation and, if necessary, adequacy (Circular Letter No. 1/2021-CONEP/SECNS/MS, item 2.3).
- It is up to the responsible researcher to know the privacy policy of the tool used regarding the collection of personal information, even through robots, and the risk of sharing this information with commercial partners to offer products and services, in order to ensure ethical aspects. In this sense, clarifications are requested regarding the privacy policy of the platform to be used and, if necessary, adequacy (Circular Letter No. 1/2021-CONEP/SECNS/MS, item 2.4).

Security in data transfer and storage

- It is the researcher's responsibility to properly store the collected data, as well as the procedures to ensure the secrecy and confidentiality of the subject's information. Therefore, clarifications are requested about the storage of data collected in the study, as well as what procedures will be adopted to protect the secrecy and confidentiality of the subject's information (Circular Letter No. 1/2021-CONEP/SECNS/MS, item 3.1).

- Once the consent registration (e.g., video or audio recorded) and data collection are completed, the responsible researcher is recommended to download the collected data to a local electronic device, erasing any and all records from any virtual platform , shared environment or "cloud". Therefore, clarifications are requested regarding the storage of data and documents of the study, after the end of the collection (Circular Letter No. 1/2021-CONEP/SECNS/MS, items 3.2 and 3.3).

- For research in a virtual environment that uses methodologies specific to the Human and Social Sciences, there must be an express statement from the subject as to whether or not they agree with the disclosure of their identity and other information collected, in accordance with the provisions of CNS Resolution No. 510, of 2016, article 9, item V). Clarifications are requested and, if necessary, adequacy of the consent record (Circular Letter No. 1/2021-CONEP/SECNS/MS, item 3.4).

Content of processed documents

- It is requested that the documents in electronic format related to obtaining consent contain all the information necessary for the adequate clarification of the participant, with the guarantees and rights provided for in CNS Resolutions No. 466, of 2012, and No. 510, 2016, and according to the particularities of the research (Circular Letter No. 1/2021-CONEP/SECNS/MS, item 4.1).

- It is requested that the consent process include that the researcher must explain to the participant, in a clear and objective manner, how to register their consent to participate in the research (Circular Letter No. 1/2021- CONEP/SECNS /MS, item 4.4).

- For research in the biomedical area that necessarily requires the presence of the subject with the team, the informed consent 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 subject has already registered their consent electronically in a previous stage of the research. Clarifications and, if necessary, adaptation are requested (Circular Letter No. 1/2021- CONEP/SECNS/MS, item 4.4).

Assent Form

AF for subjects under the age of 18

- If participants under 18 years old are included in the study, they are requested to submit an Assent Form (AF), which must be prepared by the researcher, in a language accessible to the understanding of subjects IN THEIR DIFFERENT AGE GROUPS, and it is not appropriate to prepare only one document for all participants under the age of 18. Therefore, we request the submission of AF prepared in a language accessible to the understanding of the different age groups of the individuals to be recruited for the research (CNS Resolution No. 466, of 2012, item II.2).

- Unlike an informed consent for an adult, the AF should not overly address procedures that may generate anxiety, fear, or fantasies, negatively interfering with the perception of reality. In this sense, the aforementioned form must be presented "in accessible language for minors or the legally incapable, through which, after the subjects are duly informed, they will explain their consent to participate in the research, without prejudice to the consent of their legal guardians" (CNS Resolution No. 466/2012, item II.24). Graphic arguments such as drawings, characters, illustrative stories can be used, so that the child understands, in appropriate language, the importance, procedures and objectives of the research.

Form of invitation

The AF is the document in which the researcher communicates to the potential participant what the research to which they are being invited will be, providing them with the necessary clarification to freely decide whether to participate or not. In view of the above, it is requested that the AF be written in the form of an invitation (CNS Resolution No. 466, of 2012, items II.24 and IV).

Consent and Assent Registration - CHS

Consent process

The process of informed consent and assent involves the establishment of a relationship of trust between researcher and participant. This process needs to be continually open to dialogue and questioning, which can be carried out through oral, written, sign language or other appropriate manners, considering the individual, social, economic, and cultural characteristics of the person or group of people participating in the research, as well as the methodological approaches applied. In this sense, it is requested that the process of consenting subjects be incorporated into the research protocol (CNS Resolution No. 510, of 2016, Articles 4 and 5).

Access to results and feedback to the community

- It is requested to include, in the Informed Consent Registration and/or the Informed Assent, the guarantee of access to the research results by the participants (CNS Resolution No. 510, of 2016, Article 17, Item VI).
- It is requested to include, in the Process and Registration of Informed Consent and/or Informed Assent, the researcher's commitment to disseminate the research results, in a format accessible to the group or population that was researched (CNS Resolution No. 510, of 2016, Article 3, Item IV; Article 17, Item VI).

Assistance

The Informed Consent and/or Informed Assent Registration must ensure, in a clear and affirmative manner, information on the form of follow-up and assistance to which subjects will be entitled, including considering benefits, if any, if relevant in the research project under analysis (CNS Resolution No. 510, of 2016, Article 17, Item V). It is noteworthy that the type of assistance should not be specified or limited. Adequacy is requested.

Benefits

A research benefit is defined as the “current or potential contributions of research to human beings, to the community in which they are inserted and to society, enabling the promotion of a decent quality of life, based on respect for civil, social and social rights”, cultural and ecologically balanced environment” (CNS Resolution No. 510, of 2016, Article 2, Item III; Article 17, Item V), without including benefits to the researcher. Thus, it is requested to clearly inform, in the Informed Consent Registration and/or the Informed Assent, what will be the benefits, directly related to the research, for the subject, for the community in which they are inserted and for the society.

Signature and initials fields

If the researcher chooses for the Informed Consent Registration and/or the Informed Assent in writing, the signature and initials fields must be identified according to the terminology provided for in CNS Resolution No. 510, of 2016, Article 2, Items XIII and XVII, that is, using the terms "responsible researcher" and "subject/legal responsible". Signature fields must not be separate from the rest of the document (except when, for page setup reasons, this is not possible) and must not contain additional fields other than name and date. Adequacy is requested.

Indemnity

It is requested to inform, in the Informed Consent and/or Informed Assent Registration, that the participant is guaranteed the right to request compensation through legal means (Civil Code, Law 10.406 of 2002, Articles 927 to 954 and CNS Resolution No. 510, of 2016, Article 9, Item VI).

Rationale and objective

It is requested to include, in the Informed Consent and/or Informed Assent Registration, the rationale and objectives of the research, in a clear and accessible language to the subjects, respecting the nature of the research (CNS Resolution No. 510, of 2016, Article 17, Item I).

Freedom of refusal and withdrawal

The Informed Consent and/or Informed Assent Registration shall guarantee the full freedom of the subject to decide on their participation, being able to withdraw their consent at any time during the research, without prejudice (CNS Resolution No. 510, of 2016, Article 9, Item II; Article 17, Item III). Adequacy is requested.

Language

- The Informed Consent and/or Informed Assent Registration is the means by which the Informed consent of the participant or their legal representative is made explicit, in written, sound, image form, or in other forms that meet the characteristics of the research and of those invited to participate in it and must contain information in a CLEAR AND EASY TO UNDERSTAND LANGUAGE for sufficient clarification about the research (CNS Resolution No. 510, of 2016, Article 15). Adequacy is requested.

- The Informed Assent Registration must be prepared by the researcher in a language accessible to the understanding of the subjects, IN THEIR DIFFERENT AGE GROUPS. It should be clarified that it is not appropriate to submit only a single form of Assent Registration for all participants under 18 years old. It is understood that it is necessary to consider the different age groups of participants under 18 years old, building a record that best corresponds to their understanding. Adequacy is requested.

Means of contact with the IRB/IEC and CONEP

The Informed Consent and/or Informed Assent Registration must inform the means of contact with the IRB/IEC (such as the address, e-mail, and national telephone number), as well as the opening hours for the public. It is also necessary to submit, in a simple language, a brief explanation of what the IRB/IEC is. If the study involves an ethical review by CONEP, the contacts of this Commission must also be included (CNS Resolution No. 510, of 2016, Article 17, Item IX). Adequacy is requested.

Means of contact with the researcher

The Informed Consent and/or Informed Assent Registration must explicitly provide the means of contact with the responsible researcher (such as address, e-mail and national telephone number). If there is no written Record of this Process, the researcher must submit this information in writing (CNS Resolution No. 510, of 2016, Article 17, Items VIII). Adequacy is requested.

Research procedures

It is requested to include, in the Informed Consent and/or Informed Assent Registration, the procedures that will be used in the research, with information on the methods to be used, in a clear and accessible language to the subjects, respecting the nature of the research (CNS Resolution No. 510, of 2016, Article 17, Item I).

Refund

The Informed Consent and/or Informed Assent Registration must ensure, in a clear and affirmative manner, the guarantee of reimbursement to the subject, as well as the description of the ways of covering the expenses incurred by the participant arising from the research, when applicable (CNS Resolution No. 510 of 2016, Article 17, Item VII). Adequacy is requested.

Risks

- Research risk is defined as "the possibility of damage to the physical, psychic, moral, intellectual, social, cultural dimension of the human being, at any stage of the research and resulting from it" (CNS Resolution No. 510, of 2016, Article 2, Item XXV; Article 17, Item II). By underestimating the risks involved in a study, the researcher does not communicate the information necessary for the individual to make an autonomous decision about their participation in the research. Thus, it is requested that the research risks are clearly expressed in the Informed Consent Registration and other documents, as well as the presentation of the measures and precautions to be used to avoid and/or reduce effects and conditions that may come to cause any harm to the subject.

- It is requested that the possible damages resulting from participation in the research be explained, in addition to the presentation of the measures and precautions to be used to avoid situations that may cause damage, considering the subject characteristics (CNS Resolution No. 510, of 2016, Article 17, Item II).

Secrecy and confidentiality

- In the Informed Consent and/or Informed Assent Process and Registration, the guarantee that the participant will decide whether or not their identity will be disclosed, as well as what will be, among the information provided, which may be treated publicly, or whether they will choose secrecy and confidentiality of their identity. If the participant chooses to remain anonymous, it is up to the researcher to describe the procedures that ensure confidentiality and privacy, data protection and non-stigmatization of subjects. In this sense, it is important to note that the data can only be passed on to third parties after being anonymized (CNS Resolution No. 510, of 2016, Article 17, Item IV). Adequacy is requested.

- It must be entered, in the Informed Consent and/or Informed Assent Registration, that the researcher and the sponsor will respect the participant's option regarding the maintenance of their confidentiality and privacy or for the disclosure of their identity and which, among the information provided, are those that can be treated publicly, during all its phases, even after the end of the research (CNS Resolution No. 510, of 2016, Article 9, Item V; Article 17, Item IV). Adequacy is requested.

Use of image and/or voice

Regarding the participants' rights, set out in CNS Resolution No. 510, of 2016, in its Article 9, to have their privacy respected; to have guaranteed the confidentiality of personal information; and to decide, among the information they provided, which can be treated publicly, it is requested to insert options that exclude each other ("yes, I authorize the disclosure of my image and/or voice" and "no, I do not authorize the disclosure of the my image and/or voice") in the Informed Consent Registration, so that participants can exercise such rights.

An original copy of consent/assent registration

- If the researcher chooses the Informed Consent and/or Informed Assent Registration in writing, this document must ensure, in a clear and affirmative manner, that the subject will receive an original copy (and not a copy) of the document, signed by the subject (or their legal representative) and by the researcher, and initialed on all pages by both (CNS Resolution No. 510, of 2016, Article 17, Item X).

- For cases in which the informed consent or assent is not registered in writing, it is requested that it be made explicit that the participant may have access to the consent or assent registry, whenever requested (CNS Resolution No. 510, of 2016, Article 17, Item X, §2).

ICF - Research in a virtual environment

IMPORTANT - Other rights of the subject

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

Thus, Circular Letter No. 1/2021-CONEP/SECNS/MS will be applied in a complementary manner to the other ethical standards in force.

Form of consent

It is requested that it be made clear, in the invitation to the subject, that consent will be previously presented and, if they agree to participate, consent will be considered when the questionnaire/form or research interview is answered. (Circular Letter No. 1/2021-CONEP/SECNS/MS, item 2.5).

Consent required

It is requested that the consent (Registration or ICF) include that any individual invitation must clarify to the candidate to subjects that, before answering the researcher's questions made available in a non-face-to-face or virtual environment (questionnaire/form or interview), the Informed Consent Registration/Form (or Assent Form/Registration, when applicable) will be presented for their consent (Circular Letter No. 1/2021-CONEP/SECNS/MS, item 1.2.1).

Save electronic consent document - by the subject

It is requested that the ICF contains that when data collection takes place in a virtual environment (using programs to collect or record data, e-mail, but not limited to), in the form of consent (Registration or ICF), the researcher must emphasize the importance of the subject keeping a copy of the electronic consent document in their files (Circular Letter No. 1/2021-CONEP/SECNS/MS, item 2.2).

Access to the topic of the instrument to be used in the research

It is requested that the consent (Registration or ICF) states that the subject has the right to access the content of the instrument (topics that will be addressed), before answering the questions, for an informed decision-making (Circular Letter No. 1/2021- CONEP/SECNS/MS, item 2.2.3).

Risk

It is requested that the consent (registration or ICF) includes the risks related to participation in the research, as well as those risks characteristic of a virtual environment, electronic media, or non-face-to-face activities, due to the limitations of the technologies used. Additionally, the limitations of the researchers to ensure total confidentiality and potential risk of its violation must be informed (Circular Letter No. 1/2021-CONEP/SECNS/MS, item 1.2.1).

Benefit

It is requested that the benefits related to participation in the research be included in the consent (registration or ICF) (Circular Letter No. 1/2021-CONEP/SECNS/MS, item 1.2.1).

Freedom to answer questions

- It is requested that the consent (Registration or ICF) states that the subject has the right not to answer any question, without the need for explanation or rationale for this, and may also withdraw from the research at any time (Circular Letter n. 1/2021-CONEP/SECNS/MS, item 2.2.1).
- If the questionnaires applied have any mandatory question, it is requested that the participant's right not to answer the question be included in the consent (Registration or ICF) (Circular Letter No. 1/2021-CONEP/SECNS/MS, item 2.2.2).

How to access the research questions

It is requested to include in the consent (Registration or ICF) that the subject will have access to the questions only after they have given their consent (Circular Letter No. 1/2021-CONEP/SECNS/MS, item 2.2.4).

Research costs

It is requested that it be included in the consent (Registration or ICF) that will be up to the researcher to explain how the direct and indirect costs of the research will be assumed, when this is exclusively with the use of electronic tools at no cost for its use by the subject or already owned (Circular Letter No. 1/2021-CONEP/SECNS/MS, item 2.6).

Disclosure of the subject's identity

It is requested that the consent (Registration or ICF) contains an express expression of agreement or not, by subjects who use methodologies specific to the Human and Social Sciences, regarding the disclosure of their identity and other information collected (CNS Resolution No. 510 of 2016, Article 9, item V; Circular Letter No. 1/2021-CONEP/SECNS/MS, item 3.4).

Withdrawal of Consent

It is requested that the invitation to participate in the research contains a link to an electronic address or text with the appropriate sending instructions, which informs that it is possible to withdraw consent to use the subject's data at any time and without no harm. In these situations, the responsible researcher is obliged to send, to the subject, the response of the subject's interest in withdrawing their consent (Circular Letter No. 1/2021-CONEP/SECNS/MS, item 4.2).

Research where there is no identification of the subject

It is requested that the consent (Registration or ICF) contains that, in cases where it is not possible to identify the participant through the questionnaire, the researcher must clarify the impossibility of deleting research data during the registration/consent process (Circular Letter No. 1/2021-CONEP/SECNS/MS, item 4.3).

ICF - Biomedical Research

General

Contraception

- It is requested that subjects be assured, in the ICF, that, in cases where the use of contraceptives is necessary, they will be provided by the responsible researcher/sponsor free of charge, for as long as necessary for the study, that is, during treatment and for the safety period after the end of treatment (CNS Resolution No. 466 of 2012, items III.2.o).

- It is understood that the choice of the best contraceptive method to be used is a decision shared between the doctor and the subject. Thus, it is requested to include, additionally, in the informed consent, that the choice of contraceptive method will be a joint decision between the study doctor and the subject (Code of Medical Ethics, Chapter 5, Article 42).

- Given the existence of participants who do not engage in sexual intercourse (abstinent) or who engage in sex without reproductive risk (as in homosexual relationships, for example), it would not be appropriate to require the unnecessary use of contraceptive methods, which are not free from adverse events. Thus, it is requested that the ICF text is revised and adapted, opening a space conducive to the autonomy of the participant and their sexual life, that is, guaranteeing them the right to participate in the research without the mandatory use of contraceptive methods (Resolution CNS No. 466, of 2012, item III.2.t).

Form of invitation

The ICF is the document in which the researcher communicates to the potential participant or responsible, what the research to which they are being invited will be, providing all the necessary clarifications for them to freely decide whether to participate or not. In view of the above, it is requested that the ICF is written in the form of an invitation, since the Informed Consent process is understood to be all the steps to be necessarily observed so that the person invited to participate in research can express himself/herself, in an autonomous, conscious, Informed manner (CNS Resolution No. 466, of 2012, item IV).

Form of declaration

The ICF is written in the form of a declaration. This document must follow the terminology of CNS Resolution No. 466, of 2012, item IV, and be presented to the subject in the form of an invitation. Expressions such as "I understand that I am being invited..."; "I understand that the refusal..."; "... I understand that I should do..."; "I went..."; "I read and understood...", but not limited to, may compromise the autonomy of the potential subject.

It is understood that the signature of the subject, by itself, is enough to seal their consent, and it is up to the researcher to inform all the study procedures and the guarantees to the subject to, at the end of the document, request their consent. If the researcher wants to insert a final declarative sentence of the subject, it must have a simple wording, such as "I have read and I agree to participate". Adequacy is requested (Circular Letter No. 051, of 2017, item 3).

Post-study supply

- Access to study medication

It is requested to be informed, in the ICF, in a clear and affirmative manner, that the subject will have free access, and for as long as necessary, to the study drug, if it proves to be beneficial, provided by the sponsor, as soon as their participation in the study is completed (after your participation in the study has ended, as well as at the end of the entire study). It is also worth remembering that, in order to avoid any conflict of interest, in addition to the study doctor, if the participant is accompanied by a doctor not linked to the research, the latter may also prescribe the medication (CNS Resolution No. 466, of 2012, items III .3.de III.3.d.1).

- Post-study supply linked to an extension study

This study links guaranteeing post-study access to mandatory participation in an extension study, which is not ethically appropriate. In case of individual benefit, the sponsor must ensure the supply of the investigational product, even if the participant does not want to participate in the extension study. In view of the above, it is requested that the informed consent is clearly and affirmatively stated that the subject will have free access to the study drug for as long as necessary, if it proves to be beneficial, as soon as their participation in the study is completed – after the end of their participation in the study, as well as at the end of the entire study (CNS Resolution No. 466, of 2012, items III.3.d and III.3.d.1).

Indemnity

The ICF must not contain a reservation that denies the responsibility of the researcher or that implies that the subject waives their rights, including the right to seek compensation for eventual damages. In view of the above, it is requested to insert, in the ICF, the explanation about the right to seek compensation in the face of possible damages resulting from the research (CNS Resolution No. 466, of 2012, item IV.3.h).

Language

- The Consent Form is the document in which the Informed consent of the participant and/or their legal representative is explained, in writing, and must contain all the necessary information, in a clear and objective language, easy to understand, for the most complete clarification of the research. It is requested that a revision of the ICF be carried out, according to the grammatical rules of Portuguese, thus, making it clearer, more objective, and understandable. (CNS Resolution No. 466, of 2012, items II.23 and IV.1.b).

- The ICF must be concise and easily understood by the public in general, and the use of complex grammatical constructions is not desirable. In view of the above, it is requested that the ICF is revised, using a CLEAR AND ACCESSIBLE language. It should be noted that it is necessary to replace the technical terms with words that are easy to understand or add a brief explanation of the term used in the text (CNS Resolution No. 466 of 2012, items II.23 and IV.1.b).

Alternative methods

It is requested that the text of the ICF includes that the participant must receive information about the existence or not of alternative treatment methods – clinical trials (CNS Resolution No. 466, of 2012, item IV.4.a).

Means of contact with the IRB/IEC and CONEP

1. IRB/IEC:

   - It is requested that the text of the ICF includes that the participant must have access to the means of contact with the IRB/IEC, as well as name, address, telephone contact, and public working hours (CNS Resolution No. 466, of 2012, item IV.5.d).

   - In order to better inform the subject, it is requested that a brief description of what the IRB/IEC is, what its role in the study is, in a language suitable for the subject.

2. CONEP - study falls into one of the special thematic areas:

   - It is requested that the ICF text includes that the participant must have access to the means of contact with CONEP, as well as the name, address, telephone contact and the Commission working hours (CNS Resolution No. 466, of 2012, item IV.5.d).

Page numbering

In order to guarantee its integrity, the document must have the numbering of the pages, and it is also recommended that this be inserted in a way that also indicates the total number of pages, for example: 1 of 2, 2 of 2. Adequacy is requested.

Charge of other health services

It is requested that it be clearly and objectively expressed, in the ICF, that the researcher and the sponsor will not charge the health plans, the SUS, or the subject himself/herself, being responsible for all expenses related to health care. routine (exams and procedures) necessary after signing the informed consent (Resolution No. 466, of 2012, item III.2.o).

Participants over 18 years old

A single informed consent was submitted to ethical analysis, intended both for subjects over 18 years old and for the parents/legal representative of a participant under 18 years old, alternating the use of the terms “you” and “your”, referring to the participant and the child/guardian, respectively. In order to facilitate the language of the ICF, it is requested that two ICF be submitted to ethical analysis at Plataforma Brasil, one for parents and/or guardians and the other for subjects over 18 years old.

Placebo

- It is requested to clarify, in the ICF, about the possibility of including the participant in a control or placebo group, clearly explaining the meaning of this possibility (CNS Resolution No. 466, of 2012, items IV.3.a and IV.4.B).

- To better clarify to the subject, it is requested to inform, in the ICF, that the placebo group will also receive the standard treatment.

Gifts to subjects

Based on items II.10 and II.12 of CNS Resolution No. 466, of 2012, the text referring to the provision of gifts or presents must be excluded from the ICF. What is offered to the subject should always be reimbursement of expenses or whatever may be necessary to participate in the study, and not an incentive to participate. Adequacy is requested.

Research procedures

- It is requested to describe, in the ICF, in a clear and objective manner, all the procedures involved in the research, with the details of the methods to be used, presenting the procedures that will be carried out, from the participant's entry into the study until its completion (CNS Resolution No. 466, of 2012, item IV.3.a).

- It was noted that the ICF does not present enough information about the procedures to be carried out in the research. Thus, it is requested to describe, in the ICF, which procedures will be used in the research, with details, in simple language and accessible to lay people, of the methods to be used, that is, to explain to the subject what exactly the procedures will be performed directly with them, their data, biological samples, but not limited to (CNS Resolution No. 466, of 2012, item IV.3.a).

Risks

- It is noteworthy that all research with human beings involves risks in different types and degrees. In item II.22, of CNS Resolution No. 466, of 2012, research risk is defined as the possibility of damage to the physical, psychic, moral, intellectual, social, cultural or spiritual dimension of the human being, in any research and resulting from it. In view of the above, it is requested that the ICF includes the potential risks and discomforts that the study may cause to the subject (CNS Resolution No. 466, of 2012, item IV.3.b).

- For the IRB/IEC/CONEP System, there is no risk-free research. It is necessary to observe that risk is any possibility of damage to the physical, psychic, moral, intellectual, social, cultural, or spiritual dimension of the human being, in and resulting from any research. Thus, it is requested that the possible discomforts and risks arising from participation in the research be described, including the risks inherent in maintaining secrecy and confidentiality during data collection and use (CNS Resolution No. 466, of 2012, items II.22 and IV.3.b).

Refund

- The ICF must ensure, in a clear and affirmative manner, the reimbursement of all expenses that the participant and their companion(s) will have as a result of the research. Thus, it is requested that the ICF be guaranteed, in a clear and affirmative manner, the reimbursement of expenses incurred by the subject and their companion as a result of their participation in the research, being able to mention, as an example, transportation and meals, but not limited to (CNS Resolution No. 466, 2012, items II.21 and IV.3.g).
- To better clarify the subject, it is requested that they are informed, in the ICF, that all expenses incurred with the research will be the responsibility of the responsible researcher/sponsor, that is, the subject and their companion will not bear any costs. referring to the study procedures and/or exams (CNS Resolution No. 466, of 2012, items II.11 and IV.3.g).
- In line with items II.5, II.10, II.11 and IV.3.g of CNS Resolution No. 466, of 2012, it is understood that the reimbursement of expenses must be provided to the subject or whatever is necessary for participation in the study, and not an incentive to participate. In this sense, clarifications and adaptation of the document are requested, if necessary.

Safe

- It is requested that the information about the insurance is removed from the ICF, as the insurance only represents a financial instrument to minimize possible economic losses of the sponsor, and under no circumstances will the insurance value limit the expenses incurred with immediate and integral follow-up and assistance due to direct/indirect and immediate/late damages.

- In order to better clarify to the potential candidate for subject, it is requested to include, in the ICF, that the study has the necessary human and material resources that will guarantee, without restriction, the well-being of the subject. Monitoring conditions, treatment, comprehensive assistance, and guidance, as appropriate, as necessary, free of charge, must also be guaranteed in cases of damage resulting from their participation in the study. It should be noted that the insurance represents only a financial instrument to minimize possible economic losses of the sponsor, and under no circumstances will the value of the insurance limit the expenses incurred with follow-up and immediate and comprehensive assistance due to direct or indirect, immediate or late damages (Resolution CNS No. 466, of 2012, items III.2.h. and III.2.o).

Secrecy and confidentiality

- Confidentiality and secrecy are the rights of the subject and, in order to maintain research ethics, procedures must be provided to ensure data confidentiality and privacy, image protection and non-stigmatization of subjects, ensuring that use of information to the detriment of individuals and/or communities. Thus, it is requested to guarantee the participant that the research data will be used exclusively for the purposes of this study, as well as to ensure anonymity when transferring the data. (CNS Resolution No. 466 of 2012, items III.2.i and IV.3.e).

- Considering that the subject has the right to privacy, secrecy and confidentiality, and the medical team has the duty to guarantee them, we ask for the adequacy of the excerpt mentioned, describing in a clear and affirmative manner that the confidentiality of the data will be ensured. personal data of subjects, that is, it must be ensured that data and documents are anonymized before being forwarded by the medical team responsible for the care of the study participant to any other instance, either to the sponsor or to other researchers (CNS Resolution n. 466, of 2012, items III.2.i and IV.3.e).

Terms "patient", "subject", but not limited to

It is understood that the terminology adopted by CNS Resolution No. 466, of 2012, item II.10 - subject, must be used in all documents of the research protocol, including the ICF, in place of volunteer, patient, etc. . Adequacy is requested.

Original Copy

- It is requested that the ICF contains the information that this document will be prepared in two ORIGINAL COPIES, which must be signed, at the end, by the person invited to participate in the research, or by their legal representative, as well as by the responsible researcher, or by the person(s) delegated by them. It should be noted that the signature fields of both must be on the same page (sheet). (CNS Resolution No. 466, of 2012, item IV.5.d).

- The ICF must ensure, in a clear and affirmative manner, that the subject will receive an original copy (AND NOT a COPY) of the document, signed by them (or their legal representative) and by the researcher (or by the person delegated by them). Adequacy is requested (CNS Resolution No. 466, of 2012, item IV.5.d).

Biological sample

Storage of samples in a foreign institution

In the case of research involving more than one institution (one of which is foreign) and if the biological samples are stored outside the country, it is requested to present a document guaranteeing, to the Brazilian researcher and institution, the right to access and use the biological material stored abroad, (and not just the samples deposited by the researcher (CNS Resolution No. 441, of 2011, item 14; Ordinance MS No. 2,201, of 2011, Article 11).

Authorization for use of biological sample

It is requested to include, in the ICF, the request for authorization for the collection, deposit, storage and use of human biological material in the country and abroad, if applicable (CNS Resolution No. 441, of 2011, item 2.II). To better clarify the subject, it is requested to inform, in the ICF, the name and country of the central laboratories, in which the biological samples collected in the study will be processed and stored.

Exploratory biopsy

From an ethical point of view and taking into account the participant's autonomy, the collection of biological material only for research purposes (exploratory purpose) should be an optional procedure for the subject, and this information must be clearly highlighted in the informed consent. In view of the above, it is requested that the information about the optional biopsy be inserted in a highlighted box of the text and with capital letters, also informing that not performing the optional biopsy will not harm participation in the research. It is also requested to insert a field where the participant can express whether or not they want to undergo such a procedure (it may be written in the form of mutually exclusive alternatives) (CNS Resolution No. 466, of 2012, items III.2.h. and III.2.o).

Description of procedures

Research, in any area of knowledge, involving human beings, must observe the following requirements: use the biological material and data obtained in the research exclusively for the purpose provided for in its protocol, or in accordance with the participant's consent; it is not appropriate to carry out additional tests on biological samples without the subject's consent. Thus, it is requested to inform that only the tests on biological samples that are described in the ICF will be carried out (CNS Resolution No. 466, of 2012, item IV.3.a; CNS Resolution No. 441, of 2011, item 6).

Sample loss or destruction

The subject must be informed about the loss or destruction of their biological samples, as well as about the closure of the biorepository, when applicable. It is requested that this information be included in the ICF (CNS Resolution No. 441, of 2011, item 8).

Future research

The stored biological samples can be used in future research, as long as they are previously approved by the IRB/IEC/CONEP System. Thus, it is requested to describe, in this item of the ICF, that each new research carried out by the sponsor or by independent researchers is conditioned to: (a) submission of a new research project to be analyzed and approved by the IRB/IEC/CONEP System; (b) rationale of the need for future use of the stored sample; and (c) new consent of the subject through a specific ICF referring to the new research project (or, when duly justified, obtaining approval for the waiver of the Form by the Committee). It should also be noted that if there is an intention of future research with biological material, this information must be clearly included in the ICF (CNS Operational Standard No. 001, of 2013, Annex II, item "Documents necessary for the storage of human biological material in a biorepository (linked to a specific research project, aiming at the possibility of use in future investigations).

Withdrawal of Consent

- It is requested to be informed, in the ICF, that the withdrawal of consent for the storage of human biological samples stored in a bank must be carried out in writing and signed, and may be given at any time, without prejudice to the subject, with validity to from the date of communication of the decision (CNS Resolution No. 441, of 2011, items 10 and 10.I).

- It is not appropriate to inform that, even after withdrawal of consent, in writing and signed, the biological samples collected, not analyzed, will be processed. After this withdrawal, no new data can be collected, requiring the return/destruction of ALL biological samples collected during the study. Adequacy is requested (CNS Resolution No. 441, of 2011, items 10 and 10.I).

- It is inappropriate to inform that, even after withdrawal of consent, biological samples collected in the study will be destroyed ONLY AFTER THEY ARE NO LONGER NEEDED FOR THE RESEARCH. Thus, it is requested that a statement from the sponsor be inserted in Plataforma Brasil guaranteeing that, in cases of withdrawal of consent for the use of samples, ALL biological samples collected during the study will be returned and/or destroyed, as required by the subject (CNS Resolution No. 441, of 2011, items 10 and 10.I)

Genetics

Access to exam results

It is requested that the type and degree of access to the results by the subject be included in the ICF, with the option of knowing or not knowing this information (CNS Resolution No. 340, of 2004, item V.1. d).

Genetic counseling

NOTE: pending only for studies in which it is possible to perform genetic counseling.

It is requested that the genetic counseling and clinical follow-up plan be included in the ICF, with the indication of those responsible, at no cost to subjects (CNS Resolution No. 340, of 2004, item V.1.c).

Stigmatization

It is requested that the ICF contains the measures that will be taken to protect against any type of discrimination or stigmatization, individual or collective (CNS Resolution No. 340, of 2004, item V.1.g).

Genetic data storage

It is up to the subject to authorize or not the storage of genetic data and materials collected within the scope of the research. In this sense, it is necessary to request the authorization of the subject, in the ICF, to store the genetic data of the study, informing the location (name of the institution and country) where the data will be stored. Adequacy is requested (CNS Resolution No. 340, of 2004, item III.6).

Withdrawal of Consent

- It is requested that, in the ICF, it is informed that the withdrawal of consent to keep the human genetic data stored in banks must be carried out in writing and signed, and may be given at any time, without prejudice to the subject, with validity to from the date of communication of the decision, also clarifying that the subject has the right to withdraw their genetic data from the banks where they are stored (CNS Resolution No. 340 of 2004, items III.6 and III.7; CNS Resolution No. 441, of 2011, items 10 and 10.I).

- It is requested that the ICF contains that the withdrawal of consent for the storage of human biological samples and associated genetic data must be carried out in writing and signed, and may take place at any time, without prejudice to the subject, valid

from the date of communication of the decision, requiring the return/destruction of ALL biological samples collected during the study (CNS Resolution No. 340, of 2004, item III.7; CNS Resolution No. 441, of 2011, items 10 and 10.I).

Genetic Tests

It is requested to describe, in the ICF, which FAMILIES of genes/DNA and/or RNA segments will be analyzed in the biological samples collected for the study. The researcher will be able to describe the genes studied in a grouped way, according to functionality or effect (example: genes related to the appearance of cancer, inflammation, cell death, response to treatment, etc.), it is not necessary to list them individually, respecting the subject's ability to understand (Circular Letter No. 041/2015/CONEP/CNS/MS, items 2.a and 2.b).

Covid-19

Forms of consent during the pandemic

Consent to participate in research is a mandatory procedure, provided not only in CNS Resolution No. 466, of 2012, but also in several other international reference documents in research ethics, except when the waiver of consent is previously authorized by the IRB/IEC upon justified request of the researcher.
In case of critically ill patients admitted to Intensive Care Units (ICU), every effort should be made to obtain the consent of legal guardians, when the participant cannot do so.
In the setting of clinical trials, *a posteriori* consent is not desirable, given that it is no longer possible to reverse the experimental intervention already performed on the subject. This form of consent, in clinical research, is authorized in very exceptional cases, with a reasoned rationale from the researcher.
Faced with the health emergency resulting from Covid-19, which requires the adoption of lasting measures of confinement and social distancing during a pandemic, and considering the potential benefit to subjects, it is plausible, at this particular moment, to proceed with ways alternatives in the consent process of subjects or their legal guardians, namely:

1. Forwarding of the consent form, by digital means, to research participants or legal representatives, with return of the duly signed document, in digital copy.
2. Electronic Consent Registration.
3. Record of Consent recorded by voice/video call, provided that previously informed and authorized by the caller.

Regardless of the form of consent, it will be up to the researcher to keep proof of consent in their files, either digitally, electronically, or recorded.

As soon as possible, the research team must ALSO obtain the consent of those legal representatives in a physical environment (Guidelines for Conducting Research and IRB/IEC Activity During the Pandemic Caused by Coronavirus SARS-CoV-2 (COVID-19) of 2020, item 6).

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