



**MINISTRY OF HEALTH
NATIONAL HEALTH COUNCIL**

OPERATIONAL STANDARD Nº 001/2013

1. GENERAL PROVISIONS:

This Operational Standard provides for the organization and functioning of the System CEP/CONEP, and on the procedures for submission, evaluation and monitoring of research and development involving human beings in Brazil, under item 5, Chapter XIII, of CNS Resolution No. 466 of December 12, 2012.

Research and development proposals, as well as their implementation and dissemination of opinions from the Research Ethics Committees (CEP) and the National Research Ethics Commission (CONEP) must occur through the Brazil Platform.

Registration on the Plataforma Brasil is essential to present the research to assessment of the CEP/CONEP System and for its respective ethical evaluation, of all researchers, CEPs and institutions involved in the research.

2. ADMINISTRATIVE PROCEDURES OF THE CEP/CONEP SYSTEM

2.1. COMMON ASPECTS

A) Conflict of interest: CEP and CONEP members must act voluntarily, autonomously and independently in the exercise of their functions, which are of high public interest. Both members and alternates are prohibited from engaging in activities in which private interests may compromise the public interest and their impartiality in the exercise of their activities in the CEP/CONEP system. Financial relationships lead to the most easily recognized conflicts and include employment relationships, consultancy, ownership of shares or options, fees and patents with research funding institutions or organizations. Conflicts of interest may also arise characterized by the exercise of power within the institution that maintains the CEP. Members of the system

CEP/CONEP must present a written declaration proving their autonomy and independence in exercising their role as member, at the time of their application or acceptance of indication.

B) Operation: the operation of the CEP/CONEP System will be governed by internal regulations, approved by its plenary, with a minimum quorum of two-thirds of the members. The regulations must address, among others, the following aspects: number of meetings; maximum number of absences/year of its members; attendance control; quorum and *modus operandi* of deliberative meetings; operating hours; location and

opening hours for the general public and researchers; duration of the term of office and form of renewal of its members; provisions on secrecy and confidentiality; training of its members and promotion of education in research ethics involving human beings.

C) Confidentiality: the content treated throughout the analysis procedure protocols processed in the CEP/CONEP System are strictly confidential; their meetings will always be closed to the public. Members of the CEP and CONEP and all employees who will have access to documents, including virtual ones, and meetings, must maintain confidentiality by committing themselves, in a written statement, under penalty of liability.

D) Meeting records: minutes will be drawn up during meetings and made available to all CEP/CONEP members within 30 (thirty) days. The minutes must include: the plenary session's deliberations; the date and time of the beginning and end of the meeting; meeting; the nominal record of those present and the justifications for absences.

E) Opinion: the opinion must be prepared in a clear, objective, detailed manner and be sufficiently motivated to support the decision of the collegiate body, with emphasis on the following points: ethical analysis of the protocol; risk-benefit of the research and its relevance. social; process of recruitment, inclusion and exclusion of research participants; process of obtaining the TCLE; justification for exemption from the TCLE, if applicable; procedures suitable for ensuring secrecy and confidentiality; protection of research participants who are in vulnerable situations, when applicable; budget for conducting the research; execution schedule. The opinion

will be validated on the Brazil Platform preferably during the meeting work.

F) Ethical analysis: the CEP/CONEP System is responsible for the ethical analysis of research protocols involving human beings, presented in accordance with item three (3) of this Standard (Research Protocol).

G) Ethical deliberation: the analysis of the research protocol will culminate in its classification as one of the following categories, as applicable:

1) Approved: when the protocol is fully suitable for execution.

2) Pending: when the decision is for the need for correction, hypothesis in which changes or additions to the research protocol will be requested. No matter how simple the requirement, the protocol remains "pending" until it is completely met.

3) Not Approved: when the decision considers that the ethical obstacles of the protocol are of such gravity that they cannot be overcome by processing in "pending".

4) Archived: when the researcher fails to meet the deadline for submitting the responses to the issues highlighted or to appeal.

5) Suspended: when the approved research, already in progress, must be interrupted for security reasons, especially regarding the research participant.

6) Withdrawn: when the CEP/CONEP System accepts the researcher's request responsible by providing justification for withdrawing the protocol, prior to its ethical evaluation. In this case, the protocol is considered closed.

H) Processing of amendments and extensions:

1. An amendment is any proposal for modification to the original project, presented with the justification that motivated it. Amendments must be presented to the CEP in a clear and succinct manner, identifying the part of the protocol to be modified and its justifications. The amendment will be analyzed by the bodies responsible for its final approval (CEP and/or CONEP).

2. Extension is the proposal to extend or continue the research with the same recruited participants, without essential changes to the objectives and methodology of the original project. If there are important changes to the objectives and methods, another research protocol must be presented.

I) From the file: the CEP/CONEP System must keep, under its care and responsibility, research protocols and other documents, including digitized documents, for a minimum period of five (5) years from the end of the protocol. After this period, the CEP must evaluate the documents with a view to their final destination, in accordance with current legislation.

1. Protocols prior to the implementation of the Brazil Platform may be digitized for archiving.

J) Serious Adverse Events (SAE) processing: SAE is any unfavorable medical occurrence that results in: 1) Death; 2) Threat or risk to life; 3) Hospitalization or extension of a preexisting hospitalization, except for elective surgeries and hospitalizations provided for in the protocol; 4) Persistent or significant disability; 5) Congenital anomaly or birth defect and 6) Significant medical occurrence that, based on appropriate medical judgment, may harm the patient and/or require medical or surgical intervention to prevent any of the others

abovementioned occurrences. Research reports must be sent every six months, informing the CEP of the occurrence of expected or unexpected adverse events. The CEP will assume, with the researcher, joint responsibility for the preservation of conduct ethically correct in the design and development of the research, and is also responsible for reporting the occurrence of serious adverse events to CONEP and Anvisa. The notification form is http://conselho.saude.gov.br/web_comissoes/conep/index.html is found available, to filling, in:

K) Reports and situations of ethical infractions: upon receiving reports or perceive situations of ethical infractions, especially those that imply risks to research participants, the facts must be communicated to the competent authorities for investigation and, when applicable, to the Public Prosecutor's Office.

2.2. OPERATIONAL ASPECTS OF CEP

A) CEP accreditation/re-accreditation: the process of accreditation and renewal of a CEP is regulated by a specific CNS Resolution.

1. The registration, accreditation or renewal of registration and accreditation of the CEP will be carried out upon request made by the person responsible for the institution accompanied by the internal regulations and a document committing to ensure the minimum operating conditions of the CEP, among other documents required in a specific resolution.

2. The operationalization of the CEP includes, among others, the mandatory initial and ongoing training of its members, and proof of such training must be sent to CONEP.

B) Composition: the CEP shall be composed of at least seven (7) members, including at least one user representative, respecting the proportionality of the number of members. At least 50% of the members must demonstrate research experience. Its composition may vary according to the specificities of the institution and the research topics to be analyzed. It shall always be multidisciplinary in nature, with no more than half of its members belonging to the same professional category, and may include people of both sexes. It may also include consultants.

“ad hoc”, whether or not belonging to the institution, with the purpose of providing subsidies technicians.

1. Indication of the user member: the indication of the representation of The selection of users is preferably made by the Municipal or State Health Councils, and it is up to the CNS, through CONEP, to contribute to the process of strengthening the participation of user representatives. The user may also be nominated by social movements, entities representing users and forwarded for analysis and approval by CONEP.

2. Replacement of members: the CEP is responsible for communicating situations of vacancy or removal of members and forward the replacements made to CONEP, justifying them.

C) Vacancy, removal and absences: it is up to the CEP, in the event of vacancy, removal or unjustified absences on the part of its members, to adopt replacement measures, communicating the fact to CONEP.

D) Deadlines: The deadline for issuing the initial opinion by the CEP is thirty (30) days from the full acceptance of the protocol documents, whose documentary check must be carried out within 10 days after submission.

E) If the opinion is pending, the researcher will have thirty (30) days, counting from the date of its issuance on the Plataforma Brasil, to respond to it. After this period, the CEP will have thirty (30) days to issue the final opinion, approving or rejecting the protocol.

F) Any merely documentary issues will be previously assessed by the technical-administrative staff and/or the CEP coordination, and communicated directly to the researcher.

G) Compliance with CONEP recommendations: the CEP is responsible for verifying, together with the researcher, compliance with the recommendations made in CONEP reports, before to authorize the start of the research. Upon verifying non-compliance with these recommendations, the CEP is responsible for keeping the protocol "pending" or, in justifiable cases, not approving it, complying with the deadline established for processing responses to pending issues.

H) Appeals: an appeal for reconsideration may be filed against CEP's decisions, own CEP, within thirty (30) days.

I) If the CEP denies the appeal for reconsideration, the researcher may file a appeal to CONEP, as a last resort, within thirty (30) days.

J) Educational and training role: aims to strengthen their decisions, as well as the full protection of research participants. To this end, the CEP must approve, in the first two months of each year, a permanent training plan for its members, and may work with other Committees to implement this plan.

K) Reports to CONEP: CEP activity reports must indicate, qualitatively, how the dynamics of the Committee's activities occurred among its members, as well as with researchers, research participants and the supporting institution. They must be sent to CONEP in the first two months of each semester, indicating the qualitative data of the activities of the last 6 months, according to the guidelines on the website.

from CONEP (Annex I).

L) CEP articulations: CEPs must articulate among themselves, as well as seek to establish articulations outside the CEP-CONEP System to fulfill their mission of protecting research participants. The following stand out from their network of articulations: social movements, educational institutions, and entities representing research participants.

users and health workers, Social Control bodies such as Councils and Conferences, and media outlets.

2.3. OPERATIONAL ASPECTS OF CONEP

A) Characterization and linkage: the National Research Ethics Committee (CONEP/CNS/MS) is a collegiate body, of a consultative, deliberative nature, normative, educational, independent, linked to the National Health Council, whose electoral process, organization and competencies will be carried out in accordance with the rules of the CNS.

B) From the Executive Secretariat: the Secretariat of Science, Technology and Inputs Strategic Planning of the Ministry of Health (SCTIE/MS) acts as Executive Secretary

of CONEP/CNS, being responsible for its organizational management and for promoting the articulation of the CEP-CONEP System with the National Policy for Science, Technology and Innovation in Health (PNCTIS), respecting the higher responsibilities of the Commission and the CNS. It is also the responsibility of the secretary of SCTIE/MS to indicate an executive secretary, an assistant coordinator and two members representing SCTIE/MS to compose the CONEP/CNS, under the terms of CNS Resolution 446/2011.

C) Composition: CONEP/CNS/MS will have a multidisciplinary composition, with equitable gender participation and will be composed of 30 (thirty) full members and 5 (five) alternate members, who will take over in the event of vacancies or inability of the full members, and among the full members, 8 (eight) will represent the segments of the National Health Council, on an equal basis (According to Art. 2 of Resolution 446/2011 of the CNS).

D) Ethical deliberation: CONEP's ethical deliberation will observe, in addition to the categories listed in item 2.1.H above, the following:

1. **Approved with recommendations to the CEP:** when CONEP considers that the protocol corrections can only be verified within the CEP.

2. **Returned:** when there is an error submitting the research protocol part of the CEP, to CONEP.

E) Vacancy, removal and absences: it is up to CONEP to communicate to the CNS the situations of vacancy, removal or unjustified absences on the part of its members, to provide replacement measures.

F) Ethical analysis: The deadline for issuing the initial opinion, by CONEP, is sixty (60) days from the acceptance of the documentation.

CONEP will have up to 15 days to carry out the document review, starting from the date of the submission of the protocol by the researcher.

In the event of a pending opinion, the researcher will have a period of thirty (30) days, counted from its issuance on the Brazil Platform, to attend to it. After receiving the response to the pending issue from the researcher, CONEP will have a maximum period of forty-five (45) days to issue a final opinion, approving or rejecting the protocol.

Any merely documentary issues will be previously assessed by the technical-administrative body and/or by the CONEP coordination and communicated directly to the researcher, who must observe the documentary list required for the specificities of his/her protocol, in Annex II.

G) Regarding the appeal: CONEP will decide:

1) The appeal for reconsideration filed against decisions made in protocols that fall under the original jurisdiction of CONEP. The researcher will have thirty (30) days to file an appeal, presenting new facts that justify the reanalysis, and CONEP will issue its final opinion within forty-five (45) days;

2) Appeal filed by the researcher as described in item 2.2.F. due to the denial of a previous appeal for reconsideration. The CEP's decisions may be appealed to CONEP within thirty (30) days.

CONEP will analyze the appeal forwarded by CEP, issuing a decision in the sense of:

- i. Approved;
- ii. Approved with recommendations to the CEP;
- iii. With pending issues;
- iv. Not approved: if the appeal is not approved, the processing of the appeal is terminated.

protocol, which will be archived.

H) Hearings: CONEP grants hearings upon requests from researchers and interested parties, when, during the analysis process, the CONEP plenary consider it important for the researcher to present his/her arguments verbally or in other situations that may be pertinent, always at the discretion of the plenary session. Hearings must be requested by email at conep.audiencia@saude.gov.br.

I) Educational and training role: among the various attributions of CONEP, there is its educational role, aiming at strengthening its internal decisions, as well as the final protection of research participants. To this end, CONEP promotes and participates in educational events. CONEP's participation agenda is the responsibility of its plenary, based on demands presented to its Executive Secretariat by email conep.eventos@saude.gov.br.

J) Activity report: CONEP must prepare and forward its annual activity report for analysis and approval by the CNS in the first two months of each year, based on an analysis of the execution of its budget planning.

K) Work plan: CONEP must prepare and forward for analysis and approval by the CNS, in the first quarter of each year, of its work plan, in line with the CNS three-year plan and the annual budget forecast.

L) CEP accreditation/re-accreditation: the process of accreditation and renewal of a CEP is regulated by a specific CNS Resolution. CONEP is responsible for accrediting, re-accrediting or de-accrediting CEPs.

M) About the CEP monitoring process: the CEPs will be monitored by CONEP through:

1. CEP analysis on the Brazil Platform;
2. Analysis of the CEP's half-yearly report;
3. Inspection Visits, decided by the CONEP Coordination, carried out by members of CONEP

and CNS, which may occur at any time, with or without notice. prior to the CEP;

4. Complaints from researchers, research participants, members of CEP and CONEP and others.

N) CONEP's articulations: CONEP must articulate internally and externally with the CEP-CONEP System to fulfill its mission of protecting research participants. Its network of articulations includes: Anvisa, the Science Secretariat, Technology and Strategic Inputs – SCTIE, the bodies of the Legislative Branch, the bodies of the Judiciary Branch, the Public Prosecutor's Office, social movements, educational institutions, scientific entities, entities representing users, workers, the productive sector and health service providers and other instances of Social Control such as Councils and Conferences and communication bodies.

3 – RESEARCH PROTOCOL

3.1) **Research protocol:** is the set of documents, which may vary depending on the theme, including the project, and which presents the proposal for a research project to be analyzed by the CEP-CONEP System (see Annex II of this Operational Standard).

3.2) **Requirements for submitting a protocol:** In order to be submitted for ethical review, the protocol must have its responsible researcher registered on the Plataforma Brasil at the following electronic address: <http://www.saude.gov.br/plataformabrasil> and follow the guidelines for registration. Only research protocols launched on the Plataforma Brasil will be considered. and that they present all the requested documentation, in Portuguese, accompanied by the originals in a foreign language, when applicable.

3.3) **All research protocols must contain:**

a) Cover page: all fields must be completed, dated and signed, with identification of the signatories. The information provided must be compatible with that in the protocol. The identification of the signatures must clearly contain the full name and function of the signer, preferably indicated by a stamp. The title of the research must be presented in Portuguese and will be identical to that of the research project;

b) Relevant declarations, as per the checklist presented in Annex II of the this standard, duly signed;

c) Declaration of commitment by the responsible researcher, duly signed, to attach the research results to the Brazil Platform, ensuring confidentiality regarding intellectual property and industrial patents;

d) Guarantee that the benefits resulting from the project return to the research participants, whether in terms of social return, access to research procedures, products or agents;

e) Financial budget: detail the resources, sources and destination; form and value of the researcher's remuneration; present in national currency or, when in foreign currency, with the official exchange rate in Reais, obtained during the period of the research proposal; present a forecast for reimbursement of expenses of the participant and their partners.

companions, when necessary, such as transportation and food and material compensation in the cases excepted in item II.10 of CNS Resolution 466/12;

f) Schedule describing the total duration and different stages of the research, with an explicit commitment from the researcher that the research will only begin after approval by the CEP-CONEP System;

g) Free and Informed Consent Form (TCLE) is a public document specific to each research, including information about the circumstances under which consent will be obtained, about the person responsible for obtaining it and the nature of the information to be provided to the research participants, or the exemption from the TCLE must be justifiably requested by the responsible researcher to the CEP/CONEP System, for assessment;

h) Proof of the existence of the necessary and suitable infrastructure for the development of the research and to address any problems resulting from it, with a document that express the agreement of the institution and/or organization through its competent senior officer;

i) Other documents that may be necessary, according to the specificity of the search;

j) Original research project in full.

3.4) **Research project:** the research project is the fundamental document for the CEP-CONEP System to be able to carry out the ethical analysis of the proposal, and must be formulated by the researcher and, in the case of international multicenter projects, reviewed, interpreted and correctly translated into Portuguese. Project items vary according to their nature and methodological procedures used.

3.4.1) All research protocols must contain:

1 – **Theme:** contained in the title;

2 – **Research object:** what is intended to be researched;

3 – **Social relevance:** importance of research in its field of activity, presented by the researcher;

4 – **Objectives:** research purposes;

5 – **Location of the research:** with details of the facilities, services, centers, communities and institutions in which the various stages of the research will be carried out. In the case of multicenter national or international studies, a list of participating Brazilian centers must be presented, including the name of the researcher in charge, the institution, the Federative Unit (UF) to which the institution belongs and the CEP responsible for monitoring the study in each of the centers. In the case of studies in the Social Sciences and Humanities, the researcher, when applicable, must describe the field of research, characterizing it geographically, socially and/or culturally, as appropriate;

6 – **Population to be studied:** expected characteristics of the population, such as: size, age range, sex, color/race (IBGE classification) and ethnicity, sexual orientation and

gender identity, classes and social groups, and others that are relevant to the description of the population and that may, in fact, be significant for the ethical analysis of the research; in the absence of delimitation of the population, justification must be presented for not presenting the description of the population, and the reasons for the use of vulnerable groups, when applicable;

6.1 – The ethical specificities of research with indigenous populations, given their particularities, are covered in a Complementary Resolution of the Council National Health/CNS.

7 – **Ethical guarantees for research participants:** measures that guarantee freedom of participation, the integrity of the research participant and the preservation of data that may identify him/her, ensuring, especially, privacy, secrecy and confidentiality and the method of implementation. Specific protocols in the area of human sciences that, in their nature, allow the disclosure of the identity of their research participants, may be exempt from the obligation to guarantee secrecy and confidentiality, provided that the participant is duly informed and gives his/her consent;

8 – **Method to be used:** detailed description of the methods and procedures justified on the basis of scientific foundations; description of the approach or recruitment plan for potential participants, methods that directly or indirectly affect research participants, and that may, in fact, be significant for ethical analysis;

9 – **Schedule:** informing the total duration and the different stages of the research, in number of months, with an explicit commitment from the researcher that the research will only begin after approval by the CEP-CONEP System;

10 – **Budget:** Presented in accordance with item 3.3.e;

11 – **Inclusion and exclusion criteria for research participants:** must be presented in accordance with the requirements of the methodology to be used;

12 – **Risks and benefits involved in carrying out the research:** the risk, assessing its gradation, and describing the measures for its minimization and protection of the participant. research; measures to ensure the necessary care in the event of harm to individuals; the possible benefits, direct or indirect, for the population studied and the society;

13 – **Criteria for closing or suspending research:** must be explained, when applicable;

14 – **Study results:** researcher's assurance that the study results will be disclosed to research participants and institutions where the data were obtained.

15 – **Disclosure of results:** guarantee by the researcher to forward the results research results for publication, with due credit to the authors;

15.1 - In cases involving patenting, possible postponements of disclosure of results must be notified and authorized by the CEP-CONEP System;

16 – Declarations of responsibility, duly signed, by the researcher, by responsible person with the highest competence of the institution, the promoter and the sponsor, according to Annex II, observing the Thematic Area;

17 – Declaration signed by the institutional manager, providing the existence of the infrastructure necessary for the development of the research and to meet any potential needs. problems resulting from it.

3.4.2) Specific requirements for research protocols:

a) If the purpose is to test a new health product or device, Brazil, whether of foreign origin or not, the current registration status with the regulatory agencies of the country of origin must be indicated, if any;

b) Identify the research material sources, such as specimens, records, data, to be obtained from human beings, indicating whether such material will be obtained specifically for the purposes of the research or whether it will also be used for other purposes;

c) List of participating institutions, depending on the protocol proposed:

i. Multicenter protocols in Brazil: list the coordinating center, centers participants (indicating the researcher responsible for the research at the center and the CEP that will monitor the progress of the study);

ii. Protocols with co-participating centers: list, in addition to the center proponent of the study, the co-participating centers.

d) Research with coordination and/or sponsorship originating outside Brazil with co-sponsorship from the Brazilian Government must make this explicit through official approval issued by the federal manager of Science, Technology and Strategic Health Inputs.

Standard prepared and approved by the Plenary of the National Health Council, on September 11 and 12, 2013.

Date of Issue: 09/30/2013
Effective Date: Immediate

Annex I – Guidelines for preparing the CEP's half-yearly report:

The report must inform:

1. Meetings:

- Frequency of meetings;
- Description of the dynamics of the meetings;
- Percentage of member attendance;
- Project Demand; average time spent on project analysis;
- Average time for project processing on the platform

2. Structure and operation: (inform whether the minimum operating conditions informed at the time of registration of the CEP persist or whether there have been changes)

- Adequate collegiate composition (multi and transdisciplinary), representative of users, etc.
- Designated administrative employee (exclusive to the CEP or not)
- Set opening hours for the secretariat, contact telephone number, exclusive room, file etc.)

- Project Demand;

3. Monitoring the development of research projects: (inform the measures that were taken)

- Researcher reports; (periodicity)
- Reporting of adverse events
- Opening of investigations in case of allegations of irregularities

4. Advisory and Educational Role of the CEP: (list the events)

- Guidance provided and advisory material made available to researchers
- Internal educational activities for CEP members and the scientific community (from from the previously presented schedule, relate the events)
- Educational activities for research participants and the community in general.
- Meetings with other CEPs;
- Participation of members in events, forums, seminars, round tables.

The Report on the demand for Projects analyzed by the CEP will be consulted on the Platform Brazil.

Annex II – Document checklist for research protocols involving or not the storage of biological material (biorepository) and biobank development protocols:



**NATIONAL HEALTH COUNCIL
NATIONAL COMMISSION ON RESEARCH ETHICS**

CHECKLIST FOR RESEARCH PROTOCOLS
<u>MANDATORY ITEMS FOR RESEARCH PROTOCOLS</u>
01. All documents attached by the researcher must enable the use of the resources “Copy” and “Paste” any word or section of text.
02. Research Protocol: Attach the full Research Project file. As per item 1 of this checklist, this document must allow the use of “Copy” and “Paste” features.
03. Present a “Cover Sheet” with the terms of commitment duly dated and signed. The terms of commitment must be signed by the Institution’s highest official. If the researcher is the person most responsible for the Institution, his/her substitute must sign the document.
04. Present the Free and Informed Consent Form – TCLE. In the absence of the TCLE, provide justification.
<u>DOCUMENTS REQUIRED FOR STORAGE OF HUMAN BIOLOGICAL MATERIAL IN</u>
<u>BIOREPOSITORY (LINKED TO A SPECIFIC RESEARCH PROJECT) – According to the</u>
<u>CNS Resolution 441/2011 and MS Ordinance 2.201/11</u>
<u>NOTE: The biorepository's term of validity is the term of the project to which it is linked.</u>
01. Regarding the participant's consent: The TCLE presented must contain authorization consent for the collection, deposit, storage and use of human biological material linked to the specific research project (CNS Resolution 441/11, items 2.II and 6; MS Ordinance 2.201/11, Chapter II, Articles 5 and Chapter III, Article 8).
02. Research involving more than one institution: Present an agreement between the institutions participants contemplating operationalization, sharing, use of biological material human stored in a Biorepository, including the possibility of future dissolution of the partnership and the consequent sharing and destination of the stored data and materials. (CNS Resolution 441/2011, item 13; Ordinance MS 2,201/11, Chapter IV, section II, article 19).
03. Establishment or participation in a biorepository abroad: Present a document guaranteeing the Brazilian researcher and institution the right to access and use the biological material human stored abroad (and not just samples deposited by the researcher). It must proportionality in participation must be guaranteed, at the very least, and the recipient institution abroad must present a commitment to prohibiting the patenting and commercial use of human biological material, in accordance with Brazilian regulations, in particular item 14 of CNS Resolution 441/2011 and MS Ordinance 2,201/11, chapter IV, section I, articles 11 and

12.
DOCUMENTS REQUIRED FOR STORAGE OF HUMAN BIOLOGICAL MATERIAL IN BIOREPOSITORY (LINKED TO A SPECIFIC RESEARCH PROJECT, AIMED AT POSSIBILITY OF USE IN FUTURE RESEARCH) – According to Resolution CNS 441/2011 and Ordinance MS 2.201/11
<u>NOTE: The biorepository's term of validity may be authorized for up to 10 years, with the possibility of renewals (CNS Resolution 441/11, article 12, item I).</u>
01. Regarding the justification of the need for future use of stored samples. Present a document containing justification for the future use of human biological samples collected and stored during the research (CNS Resolution 441/11, items 2.I and 12).
02. Regarding the participant's consent: The TCLE presented must contain authorization consent for the collection, deposit, storage and use of human biological material. linked to the specific research project (CNS Resolution 441/11, items 2.II and 6; MS Ordinance 2.201/11, Chapter II, Articles 5 and Chapter III, Article 8). The same TCLE must also inform the participant of the possibility of future use of the stored sample. It is emphasized that the use of the same will be conditioned to: (a) presentation of a new research project to be analyzed and approved by the CEP/CONEP System and (b) obligatorily, the participant's consent to research through a specific TCLE regarding the new research project (CNS Resolution 441/11, item 6 and Ordinance MS 2,201/11, chapter II, article 5 and chapter IV, section II, articles 17, 18 and 22).
03. Regarding the Declaration of submission to the CEP/CONEP System in case of new studies: Present a document, duly signed by the researcher, attesting to the commitment that Any new research to be carried out with the stored material will be submitted for approval by the Institutional CEP and, when applicable, CONEP (CNS Resolution 441/11, item 2.III). A new TCLE will be required for each new project.
04. Research involving more than one institution: Present an agreement between the institutions participants contemplating the operationalization, sharing and use of human biological material stored in the Biorepository, including the possibility of future dissolution of the partnership and the consequent sharing and destination of stored data and materials. (CNS Resolution 441/2011, item 13; Ordinance MS 2.201/11, Chapter IV, section II, article 19).
05. Establishment or participation in a biorepository abroad: Present a document guaranteeing to the Brazilian researcher and institution the right to access and use biological material human samples stored abroad (and not only samples deposited by the researcher). At the very least, proportionality in participation must be guaranteed and the recipient institution abroad must present a commitment to prohibit patenting and commercial use of human biological material, in compliance with Brazilian regulations in particular, to item 14 of Resolution CNS 441/2011 and Ordinance MS 2.201/11, chapter IV, section I, articles 11 and 12.
<u>DOCUMENTS REQUIRED FOR USE OF HUMAN BIOLOGICAL MATERIAL STORED IN BIOBANK</u>
01. Regarding the justification for the need for use: Present justification for the use of human biological samples stored in a Biobank (CNS Resolution 441/11, item 15.II.a).

<p>02. Regarding the participant's consent: Present the approved TCLE model when authorization for storage of human biological material in a Biobank. In the case of the intention to use samples stored in a Biobank in which the participant opted for the new consent for each research, it is necessary to present a specific TCLE model and relating to the research in question or the request for its exemption (CNS Resolution 441/11, items 15.II.b and 15.II.c; Ordinance MS 2.201/11, Chapter II, article 4, paragraphs 1 to 4 and chapter III, article 8).</p>
<p>03. Regarding the Operating Regulations: Present a document proving approval of the establishment and operation of the institutional Biobank in which the samples are stored.</p>
<p>DOCUMENTS REQUIRED ONLY FOR APPLICATION OF CONSTITUTION OR _____ REGULARIZATION OF INSTITUTIONAL BIOBANK OPERATION (PROTOCOL OF _____ DEVELOPMENT) _____ NOTE: This function is not yet implemented in the Plataforma Brasil System and, therefore, _____ documentation must be sent by mail (printed copies and on CD) to CONEP _____</p>
<p>01. Regarding the referral letter: Present the document signed by the coordinator of the POCKET.</p>
<p>02. Present the Regulation (Development Protocol) in accordance with items 1.V and 3 of the CNS Resolution 441/2011 and section III, article 23 of Ordinance MS 2.201/11, containing:</p>
<p>a. Identification of those responsible for the Biobank (Management Declaration and Institutional Responsibility Term; Ordinance MS 2,201/11, Chapter I, Article 3, item XVII and Chapter IV, Section III, Article 23).</p>
<p>b. TCLE model to be used (CNS Resolution 441/2011, item 5; MS Ordinance 2.201/11, Chapter II, Article 4 and Chapter IV, Section III, Article 24) duly approved by the CEP: The TCLE must contain the following alternatives, which are mutually exclusive: (I) need for new consent for each survey and (II) exemption from new consent for each survey.</p>
<p>c. Information to be recorded regarding the participant and samples.</p>
<p>d. Operational procedures relating to the collection, processing, storage, distribution and disposal of samples (Ordinance MS 2,201/11, Chapter IV, Section III, Article 23).</p>
<p>e. Internal Regulations of the Biobank (Ordinance MS 2.201/11, Chapter I, Article 3, item XIV and Chapter IV, Section III, Article 23).</p>
<p>03. Declaration of commitment to submit an Activity Report (CNS Resolution 441/2011, item 11.I; Ordinance MS 2.201/11, Chapter IV, Section III, Article 35).</p>
<p>04. Establishment or participation in a biobank abroad: Present a document guaranteeing the Brazilian researcher and institution the right to access and use human biological material stored abroad (and not only the samples deposited by the researcher). It must be guaranteed, at least, proportionality in participation and a commitment must be presented of the recipient institution abroad regarding the prohibition of patenting and commercial use of human biological material, in compliance with Brazilian regulations, in particular, item 14 of CNS Resolution 441/2011 and Ordinance MS 2,201/11, chapter IV, section I, articles 11 and 12.</p>
<p>05. Storage and sharing of samples between institutional Biobanks: Present</p>

agreement between the participating institutions covering operationalization, sharing, use of human biological material stored in the Biobank, including the possibility of future dissolution of the partnership and the consequent sharing and destination of data and materials stored (CNS Resolution 441/2011, item 13; MS Ordinance 2,201/11, Chapter IV, Section III, Article 31).

If there are original documents in a foreign language, in addition to the version translated into Portuguese the original versions must be presented.