



**MINISTRY OF HEALTH
NATIONAL COUNCIL OF HEALTH**

OPERATIONAL STANDARD Nº 001/2013

1. GENERAL PROVISIONS:

This Operational Standard states about the organization and functioning of the CEP/CONEP System, and the procedures for submission, evaluation and research's follow up and development involving human beings in Brazil, according to item 5, chapter XIII, Resolution CNS nº 466 of December 12th, 2012.

The development and submission of the research, as well as its implementation and disclosure of opinions from the Committees of Ethics in Research (CEP) and from the National Commission of Ethics in Research (CONEP), shall occur through *Plataforma Brasil*.

The registry on *Plataforma Brasil* is essential for presenting the study to the CEP/CONEP System's appreciation and for its ethical evaluation, from all investigators, CEPs and all institutions involved in researches.

2. ADMINISTRATIVE PROCEDURES OF CEP/CONEP SYSTEM

2.1. COMMON ASPECTS

A) Conflict of interests: CEP and CONEP members shall work voluntarily, autonomously and independently when performing their functions, which is of a high public interest. It is forbidden to members as well as to alternates, to practice activities with private interests that could compromise public interests and its impartiality when performing activities in the CEP/CONEP system. Financial relations bring to the most easily recognized conflicts, including employment relationship, consulting, shares or options holdings, fees and patents with institutions or financial research organizations. Conflict of interests characterized by the exercise of power inside CEP's supporting institution may occur. Members of CEP/CONEP system shall submit a written statement, proving their autonomy and independence for the function as a member, at the moment of their application or assent to the nomination.

B) Functioning: The functioning of CEP/CONEP System will be disciplined by internal rules, approved by its plenary, with a minimum quorum of two thirds of the members. The plenary must approach, among others, the following aspects: number of meetings; maximum number of absences/year of its members; attendance recording; quorum and *modus operandi* deliberative meetings; office hours; premises and business hours for customer and researcher service; term of office and form of replacing its members; provisions regarding secrecy and confidentiality; training of its members and promotion of education on ethics in research involving human beings.

C) Confidentiality: the content treated throughout the procedure of analyzing the protocols processed in the CEP/CONEP System is strictly confidential; its meetings shall always be closed to the public. CEP and CONEP members and all employees with access to documents, including virtual documents, and meetings, shall maintain secrecy by committing themselves, through a written statement, under penalty of responsibility.

D) Records of meetings: minutes shall be drawn during the meetings and shall be made available to all CEP/CONEP members, within the period of 30 (thirty) days. The minutes shall state: plenary resolution; meeting date and opening/closing time; nominal registry of attendants and absence justifications.

E) Report: the report must be written in a clear, objective and detailed manner and be sufficiently motivated to help the collegiate make a decision, with emphasis on the following points: protocol ethical analysis; risk-benefit of research and its social concerns; recruitment process, inclusion and exclusion of research participants; process for obtaining the Informed Consent Form (ICF); justification for the dismissal of the ICF, when appropriate; eligible procedures that guarantees privacy and confidentiality; protection to investigation subjects found in a vulnerable situation, when appropriate; budget to perform the research; execution schedule. The report will be validated on *Plataforma Brasil* and preferably during the meetings.

F) Ethical analysis: It is CEP/CONEP responsibility to do an ethical analysis of the research protocols involving human beings, as presented on item three (3) in this Standard (Research Protocol).

G) Ethical resolution: the research protocol analysis will culminate with its classification as one of the following categories, according to:

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

2) **Pending:** when the decision is for the need of correction; a situation to request changes or amendments in the research protocol. No matter how simple the demand is, the protocol will remain as "pending", until said demand is fully satisfied.

3) **Not Approved:** when the decision considers the ethical obstacles of the protocol of such gravity that they cannot overcome the process of "pending".

4) **Filed:** When the researcher disrespects the deadline to appeal or to send the answers for said pending.

5) **Suspended:** when the approved research, already in progress, must be discontinued for safety reasons, especially when related to the investigation subject.

6) **Withdrawn:** when the CEP/CONEP System agrees with the demand of the head investigator to withdraw the protocol through justification, before its ethical evaluation. In this case, the protocol shall be considered as closed.

H) Amendments and extensions in course:

1. Amendments refer to any proposal to modify the original project, and are presented with a motivated reason. The amendments shall be presented to CEP in a clear and summarized form, identifying the part of the protocol said to be modified and the reasons to do so. The amendments will be analyzed by the instances of its final approval (CEP and/or CONEP).

2. Extension refers to the proposal for extending or continuing the research with the same recruited participants, without essential changes in the objectives and methodology of the original project. In case of any important change in the objectives and methods, another

research protocol shall be submitted.

I) Records: The CEP/CONEP System shall maintain, under its custody and responsibility, the research protocols and other documents, including scanned documents, with a minimum period of five (5) years as from the protocol closure. After this period, CEP shall evaluate all documents focusing on its final destination, according to the legislation in force.

1. The previous protocols before the implementation on *Plataforma Brasil* shall be scanned for filing.

J) Serious Adverse Events (SAE): it refers to any unfavorable medical problem that may result in: 1) Death; 2) Risk or life-threatening; 3) Hospitalization, initial or extended, not including elective surgeries and admissions foreseen in the protocol; 4) Persistent or significant disability; 5) Congenital anomaly or birth-defect and 6) Important medical problem that, based upon medical judgment, it may affect the patient and/or require medical or surgical intervention to prevent any of the above occurrences. The research reports shall be sent every six months, reporting to CEP the existence of expected or non expected adverse events. CEP will take over, along with the researcher, the co-responsibility for preserving the ethical conduct behavior in the project and research development, as well as, reporting to CONEP and Anvisa the existence of serious adverse events. The report form will be available for filling out at: http://conselho.saude.gov.br/web_comissoes/conep/index.html.

K) Complaints and situations on ethical violation: once receiving complaints or noticing situations of ethical violation, especially those that put in risk the research participants, the facts shall be reported to the competent authorities to be examined and, when applicable, be reported to the Public Ministry.

2.2. CEP OPERATIONAL ASPECTS

A) CEP accreditation/re-accreditation: The process for a CEP accreditation and renovation is settled by a specific Resolution of CNS.

1. The registration, accreditation or registry renovation and CEP accreditation will be validated through a request from the responsible for the institution followed by internal regulations and a commitment document assuring the minimal conditions for the operation of CEP, among other documents required in specific resolution.

2. For a CEP to be established, the initial and permanent training of all members is mandatory, and said training, among others, shall be proved and forwarded to CONEP.

B) Composition: CEP is composed by a minimum number of seven (7) members, among them, at least one user representative, respecting the proportionality number of members. At least 50% of the members shall prove an expertise on researches. Its composition may vary according to the institution's peculiarities and the research topics to be analyzed. It shall always have a multi-disciplinary character, not exceeding more than half of its members belonging to the same professional category and participants may be from both genders. It could also count on with the support of "ad hoc" consultants, belonging, or not, to the institution, with the purpose of providing technical support.

1. **User member nomination:** the nomination of the user representative is made, preferably, by the Health State or Municipal Councils, being up to CNS, through CONEP, to contribute in the process of strengthening the participation of the users' representatives. The user nomination could also be made by social movements and user representative entities, and sent to CONEP

for analysis and approval.

2. **Replacement of members:** CEP is responsible for communicating vacancy or member's resignation and forward to CONEP the replacements made, justifying them.

C) Vacancy, resignation and absences: CEP is responsible for assuming the replacements when existing vacancy, resignation or absence from its members, and shall report the facts to CONEP.

D) Deadline: The deadline for issuing the initial report by CEP is of thirty (30) days as from the date the protocol documents were fully accepted and the checking of the documents shall be accomplished in up to 10 days after its submission.

E) If it is a pending report, the researcher will have a period of thirty (30) days to submit it, counting from the date it was issued on *Plataforma Brasil*. After this date, CEP will have thirty (30) days to issue the final report, approving or failing the protocol.

F) The pending generally based on the paperwork only, shall be previously considered by the technical-administrative body and/or by the CEP coordination, and directly notified to the researcher.

G) Accomplishment of CONEP's recommendations: CEP is responsible for verifying, along with the researcher, and before authorizing the start-up of the research, the accomplishment of all recommendations stated in CONEP's report. When those recommendations are not fulfilled, CEP shall be responsible for maintaining the protocol as "pending" or, in justified cases, not approving it, respecting the deadline for submitting the answers to pending processes.

H) Appeal: CEP shall be responsible for reconsidering the petition within a period of thirty (30) days.

I) If CEP rejects the petition for reconsideration, as a last instance, the researcher may file an appeal to CONEP within a period of thirty (30) days.

J) Training and Educational role: it aims in strengthening its decisions, as well as in protecting the investigation subjects. And to accomplish this, CEP shall approve in the first two months of each year, a permanent training plan for its members, having the possibility of joining other Committees in order to execute such plan.

K) Reports to CONEP: CEP activities report shall indicate, qualitatively, how the engagement between its members and the committee occurred, as well as with researchers, investigation subjects and supporting institution. It shall be sent to CONEP in the first two months of each semester, indicating the qualitative data of all activities for the last six months, as per instructions on CONEP's web page (Annex 1).

L) CEP Strategic meetings: Strategic meetings shall happen between CEPs, as well as establishing connections outside CEP-CONEP System to accomplish its missions of protecting research participants. It stands out from its network: social movements, educational institutions, entities that represent users and health workers, Social Control entities such as Boards and Conferences, and communication institutions.

2.3. CONEP OPERATIONAL ASPECTS

A) Characterization and linking: The National Committee of Ethics in Research (CONEP/CNS/MS) is a collegiate entity of advisory, deliberative, normative, educational and independent nature, linked to the National Council of Health, which electoral process, organization and duties are in accordance to the CNS standards.

B) Executive board: The Secretariat of Science, Technology and Strategic Inputs from the Ministry of Health (SCTIE/MS) exerts the function of CONEP/CNS Executive Secretariat, being responsible for its organizational management and for promoting the CEP-CONEP System movement with the National Science Politics, Health Technology and Innovation (PNCTIS), respecting the superior attributions of the Committee and CNS. The Secretariat SCTIE/MS is also responsible for nominating an executive-secretary, a Deputy Coordinator and two SCTIE/MS representative members to compose CONEP/CNS, under the terms of Resolution CNS 446/2011.

C) Layout: CONEP/CNS/MS shall have a multidisciplinary composition, with a fair level of gender participation. It shall be appointed thirty (30) members and five (5) substitute members, that will assume in the event of vacancies or absences, having among the holders eight (8) members that will equally represent the segments of the National Council of Health (according to Section. 2 of Resolution 446/2011 from the CNS).

D) Ethical resolution: Besides the listed categories on item 2.1.H above, CONEP's Ethical resolution shall comply with the following:

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

2. **Returned:** When occurs an error on a research protocol submission from CEP to CONEP.

E) Vacancy, resignation or absences: shall be CONEP's responsibility to communicate situations of vacancy, resignation or unjustified absences from its members to the CNS to provide proper replacements.

F) Ethical analysis: CONEP shall have a deadline of sixty (60) days, as from the date the documents were accepted, to issue the initial report.

CONEP shall have fifteen (15) days to review the documents, as from the date the researcher submitted the protocol.

In response to pending reports, the researcher shall have thirty (30) days, as from the date it was issued on *Plataforma Brasil*, to submit it. Once the researcher receives the answer for the pending report, CONEP shall have a maximum of forty-five (45) days to issue a final report, approving or not the protocol.

The pending generally based on the paperwork only, shall be previously considered by the technical-administrative body and/or by the CEP coordination, and directly notified to the researcher, who shall observe the document relation needed to comply with the specificities of such protocol, as stated in Annex II.

G) Appealing: CONEP shall decide about:

1) The appeal placed against the decisions made in protocols which are originally CONEP's duties. The researcher shall have thirty (30) days to place an appeal, submitting new facts that supports the reevaluation, giving the responsibility to CONEP to issue the final report in forty-five (45) days;

2) Appeal placed by the researcher as described on item 2.2.F. due to a refusal from a previous appeal. From CEP's resolutions, CONEP shall appeal within thirty (30) days.

CONEP shall analyze the referred appeal from CEP, pronouncing the decision as:

i. Approved;

ii. Approved with recommendations to CEP;

iii. Pending;

iv. Not approved: in case the appeal is denied, the protocol shall be considered as closed and may be filed.

H) Hearings: CONEP allows hearings upon researchers' requests, interested when, during the process of analysis, CONEP's plenary may consider important that the researcher presents verbal arguments, or in other situations that may be appropriate, and always with due regard for the convenience and opportunity of said plenary. The hearings shall be requested by e-mail at conep.audiencia@saude.gov.br.

I) Training and educational role: Among the diverse attributions of CONEP, lies its educational role, aiming in strengthening its internal decisions, as well as in providing a final protection to its investigation subjects. Therefore, CONEP promotes and participates in educational events. The participation agenda of CONEP goes according to its plenary, through requests made to its Executive Board by the e-mail at conep.eventos@saude.gov.br.

J) Activities report: CONEP shall elaborate its annual activity report in the first two months of each year and forward it to the CNS for analysis and approval, upon analysis of its budget planning execution.

K) Work plan: CONEP shall elaborate its work plan in the first quarter of each year and forward it to the CNS for analysis and approval, in accordance with the CNS three-year plan and with the annual budget forecast.

L) CEP accreditation/re-accreditation: The process for a CEP accreditation and renovation is settled by a specific CNS Resolution. CONEP is responsible for the accreditation, re-accreditation or disqualification of CEPs.

M) CEP monitoring process: CEPs shall be monitored by CONEP through:

1. CEP's analysis via *Plataforma Brasil*;
2. CEP's biannual analysis report;
3. Inspection visits performed by CONEP and CNS members, and settled by CONEP's coordination, that may happen at any moment, with or without prior notice to CEP;
4. Any charge derived from the researchers, research participants, CEP and CONEP members and others.

N) CONEP linkages: CONEP shall work internally and externally with the CEP-CONEP System in order to accomplish its mission of protecting research participants. From its network of relations, the following are highlighted: Anvisa, Secretariat of Science, Technology and Strategic Inputs - SCTIE, Legislative and Judiciary institutions, Public Ministry, social movements, educational institutions, scientific and user's representative entities, workers, industrial sector and healthcare providers and other Social Control instances such as communication Boards, Conferences and institutions.

3 – RESEARCH PROTOCOL

3.1) **Research protocol:** It is a set of documents that may vary depending on the subject, including the project, presenting a research proposal to be analyzed by the CEP-CONEP System. (See Annex II of this Operational Standard).

3.2) **Requirements for submission of a protocol:** In order to be submitted for an ethical revision the protocol shall have its leading researcher registered on *Plataforma Brasil* at <http://www.saude.gov.br/plataformabrasil>, by following the instructions thereof. Only research protocols posted on *Plataforma Brasil* and presenting all required documents will be accepted,

in Portuguese, and when applicable, accompanied by the originals in foreign language.

3.3) Every research protocol shall include:

a) Cover page: All fields shall be completed, dated and signed, with the signatories' identification. The information provided must be compatible with those stated in the protocol. The signature's identification must clearly contain the signer's full name and function, and preferably identified with stamps. The research title is presented in Portuguese and it shall be identical of that stated in the research project;

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

c) Statement of commitment from the leading researcher, duly signed, to attach the results of the research on *Plataforma Brasil*, ensuring confidential treatment to intellectual properties and industrial patents;

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

e) Financial budget: detail the resources, sources and destination; form and amount of researcher's compensation; submit it in national currency or, when in foreign currency, with the Real official exchange rate, obtained within the period of proposing the research; submit an estimated reimbursement of expenses for the participant and his/her companions, when necessary, such as transportation and meal and material compensation in cases pointed out in item II.10 of Resolution CNS 466/12;

f) A schedule describing the total length and the different stages of the research, with an explicit commitment from the researcher stating that the research will only be initiated upon CEP-CONEP System's approval;

g) Informed Consent Form (TCLE) is a specific public document for each research, including information about the circumstances of which the consent shall be obtained, about the person responsible for obtaining it and the nature of the information to be provided to the research participants, or the TCLE dismissal shall be rightly requested by the leading researcher to the CEP/CONEP System, for appreciation;

h) Data proving the existence of the infrastructure needed for developing the research and attending eventual problems that may result from it, and with a document expressing the institution and/or organization agreement from its responsible with a higher position.

i) Other documents that may be necessary, in accordance with the research specificity;

j) Original research project in full.

3.4) Research project: The research project is the fundamental document for the CEP-CONEP System to proceed with the proposal's ethical analysis and it shall be developed by the researcher and, in case of international multicentre projects, it shall be revised, interpreted and correctly translated into Portuguese. The items of the project vary according to its nature and methodological procedures used.

3.4.1) All research protocols must include:

1 – **Topic:** in the title;

2 – **Object of research:** that intended to be investigated;

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

4 – **Objectives:** research purposes;

5 – **Places for conducting the research**: details of premises, services, centers, communities and institutions in which all stages of the research will be conducted. In the case of national or international multicentre studies, a list of all Brazilian Centers participating in such research must be submitted, including the name of the leading researcher, institution and the Federative Unit (UF) to which the institution belongs to, and the CEP responsible for monitoring the study in every center. In case of Social and Human Science studies, the researcher shall describe, when applicable, the research field as geographical, social and/or cultural, according to the case;

6 – **Population to be studied**: expected population characteristics, such as: height, age-group, gender, color/race (IBGE rating) and ethnicity, sexual orientation and gender identity, classes and social groups, and others that may be relevant to describe the population and that may be, in fact, significant for the ethical analysis of the research; when not possible to delimit the population, a justification must be submitted for not presenting such description and, when appropriate, the reasons for using vulnerable groups;

6.1 – The ethical specificities of the research with indigenous population, due to their particularities, are described in Complementary Resolution of the National Council of Health/CNS.

7 – **Ethical agreement for the research participants**: measures to ensure the research participant's freedom of engagement, integrity and preservation of his/her identification data, guaranteeing, in particular, the privacy, discretion and confidentiality and the way it was registered. Specific protocols in the Human Science field that, by its nature, allow the identity of the research participant to be exposed, may be exempt from the guarantee of discretion and confidentiality, as long as the participant is duly informed and gives his/her consent;

8 – **Methods to be used**: detailed description of methods and justified procedures based on scientific justification; the description of form of approach or a recruitment plan for possible individual participants, the methods that affect directly or indirectly the research participants, and that may be, in fact, significant for the ethical analysis;

9 – **Schedule**: it shall inform the total length and different stages of the research, in number of months, with an explicit commitment from the researcher stating that the research will only be initiated following CEP-CONEP System's approval;

10 – **Budget**: Submitted as per item 3.3.e;

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

12 – **Risks and benefits involved in the research's execution**: Grading the risks and describing the measures taken to minimize them and protecting the research participant; the measures to ensure the necessary care, in case of any damage to individuals; possible benefits, directly or indirectly, for the studied population and society;

13 – **Closing or interruption criteria of researches**: shall be explained, when appropriate;

14 – **Study results**: guarantee from the researcher that the study results will be revealed to the research participants and institutions where the data has been derived from.

15 – **Publishing results**: guarantee from the researcher to forward the research results for publication, ensuring due credits to the authors;

15.1 - In cases involving copyright, possible delays for publishing the results shall be notified

and authorized by the CEP-CONEP System;

16 – Researcher responsibility statement, duly signed by a higher responsible person with competence in the institution, by the promoter and sponsor, as per Annex II, following the Subject Area.

17 – Statement signed by the responsible for the institution, providing the necessary infrastructure for developing the research and for solving possible problems that may result from it.

3.4.2) Specific requirements from research protocols:

a) If the purpose is testing a product or health device, new in Brazil, from foreign countries or not, the actual registry situation shall be indicated to the regulatory agencies from its country of origin, if applicable;

b) Identify the research material sources, such as specimens, records and data to be obtained from human beings, indicating if such material will be used specifically for research purposes or if as well as for any other purposes;

c) List of participant institutions, according to the proposed protocol:

i. Multicentre protocols in Brazil: list the clearinghouse, participant centers (indicating the researcher responsible for the research in such center and the CEP that will monitor the study's progress);

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

d) Researches with coordination and/or sponsorship originated outside Brazil and co-sponsored by the Brazilian Government shall state it through official agreement issued by the Federal manager of Science, Technology and Strategic Input Board in Health.

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

Date of the dispatch: 2013/09/30

Date to come into effect: Immediately

Annex I – Script for Developing CEP's Biannual Reports

The report shall include:

1. Meetings:

- Frequency of meetings;
- Description of the dynamic of meetings;
- Percentage of member's attendance;
- Projects demands; average time devoted to the analysis of projects;
- Average time for processing projects on *Plataforma Brasil*.

2. Structure and functioning: (communicate if there were any changes made to the minimal conditions of functioning, or if they persist, that were mentioned at the moment CEP was registered)

- Composition of an appropriate board (multi and transdisciplinary), user representative, etc
- Designated administrative employee (exclusive for CEP or not)
- Office hours planned for the secretariat, contact phone number, exclusive office, filing cabinet, etc.)
- Project demands;

3. Follow-up of research projects development: (inform the measures taken)

- Researcher's report; (periodicity)
- Notifications of adverse events

- Prosecution inquiry in case of complaints of irregularities
- 4. CEP's Educational and Advisory Role:** (relate the events)
- Provide guidance and advisory material available to researchers
 - Internal educational activities to CEP members and scientific community (as per schedule previously presented, relate the events)
 - Educational activities to all research participants and wider community.
 - Meetings with other CEPs;
 - Members' participation in events, forums, seminars, round tables.

The Report for the Project's demand analyzed by CEP shall be accessed on *Plataforma Brasil*.

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

NATIONAL COUNCIL OF HEALTH
NATIONAL COMMITTEE OF ETHICS IN RESEARCH



CHECKLIST FOR RESEARCH PROTOCOLS
MANDATORY ITEMS FOR RESEARCH PROTOCOLS

- 01. All documents attached by the researcher shall allow the use of "Copy" and "Paste" in any word or excerpt of the text.**
- 02. Research protocol: Attach the complete file of the research project.** According to item 1 of this checking list, this document shall allow the use of "Copy" and "Paste".
- 03. Submit a "Cover Page" with the terms of commitment duly dated and signed.** The terms of commitment shall be signed by the responsible with the higher position in the Institution. Should the researcher be the one with the higher position, his/her substitute shall sign the document.
- 04. Submit the Informed Consent Form - ICF.** In the absence of the ICF, a justification shall be submitted.

REQUIRED DOCUMENTS FOR STORAGE OF HUMAN BIOLOGICAL MATERIAL IN BIOREPOSITORIES
(RELATED TO A SPECIFIC RESEARCH PROJECT) - According to Resolution CNS 441/2011 and Ordinance

MS 2.201/11

NOTE: The period of validity for the biorepository is the same as the period of validity of the project to which it is linked to.

01. **Participant consent:** The submitted ICF shall include authorization consent for collection, storage and usage of the human biological material linked to the specific research project (Resolution CNS 411/11, Items 2.II and 6; Ordinance MS 2.201/11, Chapter II, Article 5th and Chapter III, Article 8th).
02. **Researches involving more than one institution:** Submit an agreement among participating institutions envisaging functionality, sharing, and the usage of human biological material stored in Biorepository, including a possible partnership break down and the consequent sharing and destination of data and stored materials. (Resolution CNS 441/2011, Item 13; Ordinance MS 2.201/11, Chapter IV, Section II, Article 19).
03. **Constitution or participation in biorepository overseas:** Submit document ensuring the researcher and Brazilian institutions the right to access and to use the human biological material stored overseas (and not only the samples provided by the researcher). It shall be guaranteed, at least, the proportionality of participation and the receiving institution's commitment shall be presented overseas in regards to the prohibition of copyrighting and the commercial usage of human biological material, considering, in particular, the Brazilian standard, item 14 of Resolution CNS 441/2011 and Ordinance MS 2.201/11, Chapter IV, Section I, Articles 11 and 12.

REQUIRED DOCUMENTS FOR STORAGE OF HUMAN BIOLOGICAL MATERIAL IN BIOREPOSITORIES (RELATED TO A SPECIFIC RESEARCH PROJECT, AIMING AT THE POSSIBILITY OF ITS USAGE IN FUTURE INVESTIGATIONS) - According to Resolution CNS 441/2011 and Ordinance 2.201/11

NOTE: The period of validity for the biorepository shall be authorized for up to 10 years, with possible renewals (Resolution CNS 441/11, Article 12, Item I).

01. In relation to justifications needed for future usage of stored samples.

Submit document during the research with a justification related to the future usage of collected and stored human biological samples (Resolution CNS 441/11, Items 2.1 and 12).

02. In relation to the participant's consent: The ICF submitted shall include an authorized consent for collection, processing, storage and usage of the human biological material linked to the specific research project (Resolution CNS 441/11, Items 2.II and 6; Ordinance MS 2.201/11, Chapter II, Articles 5° and Chapter III, Article 8). The same ICF shall also communicate the participant about possible future usage of stored sample. It shall be remembered that the usage of such samples are conditioned to: (a) submission of a new research project to be analyzed and approved by the CEP/CONEP System and (b) regarding the new research project, it is a must that the research participant gives a re-consent through a specific ICF (Resolution CNS 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. In relation to the Statement of Submission to the CEP/CONEP System in case of new studies:

Submit a document, duly signed by the researcher, certifying the commitment that all new researches to be carried out with the stored material, shall be submitted for approval from the institutional CEP and, when applicable, from CONEP (Resolution CNS 441/11, Item 2.III). For every new project a new ICF shall be necessary.

04. Researches involving more than one institution: Submit an agreement among participating institutions envisaging functionality, sharing, and the usage of human biological material stored in Biorepository, including a possible partnership break down and the consequent sharing and destination of data and stored materials.

(Resolution CNS 441/2011, Item 13; Ordinance MS 2.201/11, Chapter IV, section II, Article 19).

05. Constitution or participation on biorepository overseas: Submit document ensuring the researcher and Brazilian institutions the right to access and to use the human biological material stored overseas (and not only the samples provided by the researcher). It shall be guaranteed, at least, the proportionality of participation and the receiving institution's commitment shall be presented overseas in regards to the prohibition of copyrighting and the commercial usage of human biological material, considering, in particular, the Brazilian standard, item 14 of Resolution CNS 441/2011 and Ordinance MS 2.201/11, Chapter IV, Section I, Articles 11 and 12.

**REQUIRED DOCUMENTS FOR THE USAGE OF HUMAN BIOLOGICAL MATERIAL
STORED IN BIOBANKS**

01. In relation to the usage justification when needed: Submit a justification for the usage of human biological samples stored in Biobanks (Resolution CNS 441/11, Item 15.II.a).

02. In relation to the participant's consent: Forward the approved ICF at the time of the authorization of the storage of human biological samples in Biobanks. In case of intending to use samples stored in Biobanks in which the participant has opted for the new consent in every research, it shall be necessary the submission of a specific ICF referring to the research in question or to the request for dismissal. (Resolution CNS 441/11, Items 15.II.b and 15.II.c; Ordinance MS 2.201/11, Chapter II, Article 4th, paragraphs 1st to 4th and chapter III, article 8th).

03. In relation to the Operating Regulation: Submit a proof of the approval document of the constitution and functioning of the institutional Biobank in which the samples are stored.

**REQUIRED DOCUMENTS FOR REQUESTING THE CONSTITUTION OR REGULARIZATION OF THE
FUNCTIONING OF THE INSTITUTIONAL BIOBANK ONLY (DEVELOPMENT PROTOCOL)**

NOTE: This function is not yet implemented in the System of *Plataforma Brasil* and, therefore, the documentation shall be mailed to CONEP. (Printed copies and CD)

01. In relation to the Official Letter: Submit the document signed by the CEP coordinator.

02. Submit the Regulation (Development Protocol) in accordance with Items 1.V and 3 from Resolution CNS 441/2011 and section III, article 23 of Ordinance MS 2.201/11, including:

a. Identification of the persons in charge for the Biobank (Statement of management and Term of Institutional Responsibility; Ordinance MS 2.201/11, Chapter I, Article 3rd, item XVII and Chapter IV, Section III, Article 23).

b. ICF to be used (Resolution CNS 441/2011, item 5; Ordinance MS 2.201/11, Chapter II, Article 4th and Chapter IV, Section III, Article 24) duly approved by CEP: The ICF must include the following alternatives, excluding each other: (I) the need for a new consent in every research and (II) the dismissal of a new consent in every research.

c. Information related to the participants and samples to be registered.

d. Operational procedures related to the stages of collection, processing, storage, distribution and disposal of samples (Ordinance MS 2.201/11, Chapter IV, Section III, Article 23).

e. Biobank Internal Rules (Ordinance MS 2.201/11, Chapter I, Article 3rd, item XIV and Chapter IV, Section III, Article 23).

03. Statement of commitment to send the activities Report (Resolution CNS 441/2011, Item 11.I; Ordinance MS 2.201/11, Chapter IV, Section III, Article 35).

04. Constitution or participation in Biobanks overseas: Submit document ensuring the researcher and Brazilian institutions the right to access and to use the human biological material stored overseas (and not only the samples provided by the researcher). It shall be guaranteed, at least, the proportionality of participation and the receiving institution's commitment shall be presented overseas in regards to the prohibition of copyrighting and the commercial usage of human biological material, considering, in particular, the Brazilian standard, item 14 of Resolution CNS 441/2011 and Ordinance MS 2.201/11, Chapter IV, Section I, articles 11 and 12.

05. Sample storage and sharing among institutional Biobanks: Submit an agreement among participating institutions envisaging functionality, sharing, and the usage of human biological material stored in Biobanks, including a possible partnership break down and the consequent sharing and destination of data and stored materials. (Resolution CNS 441/2011, Item 13; Ordinance MS 2.201/11, Chapter IV, section III, Article 31).

If the original documents are in a foreign language, besides the translated version into Portuguese, the original versions shall be submitted.