CNS RESOLUTION No. 441, OF MAY 12, 2011.

The Plenary of the National Health Council, at its Two Hundred and Twenty-First Ordinary Meeting, held on May 11 and 12, 2011, in the use of its regulatory powers and attributions conferred by Law No. 8.080, of September 19, 1990, by Law No. 8,142, of December 28, 1990, and by Decree No. 5,839, of July 11, 2006, and

Considering the need to update the supplementary regulation of the CNS Resolution No. 196/96 regarding the storage and use of human biological material for research purposes;

Considering the importance of using human biological material for the development of health sciences;

Considering the subsidies coming from the EP/CONEP System and the accumulated experience in the analysis of research projects involving human biological material;

Considering the need to observe the protection of Human Rights, fundamental freedoms and respect for human dignity in the collection, deposit, storage, use and disposal of human biological material, resolves to:

Art. 1st Approve the following guidelines for the ethical analysis of research projects involving the storage of human biological material or use of material stored in previous research:

1. For the purposes of this Resolution, it is considered: I - Biobank: organized collection of human biological material and associated information, collected and stored for research purposes, according to regulations or pre-defined technical, ethical and operational standards, under the responsibility and institutional management, non-commercial purposes;

II - Biorepository: collection of human biological material, collected and stored throughout the execution of a specific research project, according to regulation or pre-defined technical, ethical and operational standards, under institutional responsibility and under the management of the researcher, without commercial purposes;

III - Human Biological Material: specimens, samples and aliquots of original material and its fractional components;

IV - Research Project: document in which the research is described in its fundamental aspects, including information related to the subject of the research, details regarding the methods that will be used for the collection and treatment of biological samples, qualification of researchers and responsible bodies;

V - Development Protocol: document in which the constitution of a Biobanco, its responsible and its fundamental aspects, such as the Term of Free Consent and Clarified (TCLE) to be used; information concerning the subject and the samples; and the stages of collection, processing, storage, distribution and disposal of human biological material; It is

VI - Research subject: the person who, in an informed, free and autonomous manner, consents to participate in research, current or potential, associated with the storage of human biological material in a Biorepository or Biobank.

2. Whenever there is a forecast for storing human biological material, in the country or abroad, with a view to the possibility of its use in future investigations, in addition to complying with the requirements of CNS Resolution No. 196/96 and complementary ones, the following must be presented: I - justification as to the need and opportunity for future use; II - consent of the research subject, authorizing the collection, deposit, storage and use of human biological material; III - statement that all new research to be carried out with the stored material will be submitted for approval by the institutional Research Ethics Committee (CEP) and, when applicable, by the National Research Ethics Committee (CONEP); It is

IV - regulation approved by the depositary institution for the constitution and operation of the bank of human biological material.

3. In the case of a

Biobank: I - the Regulation corresponds to its Development Protocol, which must first be analyzed by the institutional CEP or by CEP indicated by CONEP and, when approved, necessarily be evaluated and receive a final opinion from CONEP; II - the Development Protocol

is necessary for the accreditation of the Biobank, and must be presented at the time of its proposal and evaluated in accordance with the processing deadlines established in the CEP/CONEP System; It is

III - the Biobank must have a secure identification system that guarantees secrecy, respect for confidentiality and recovery of research subjects' data, to provide information of interest to them or to obtain specific consent for use in new research ; IV - when there is a change in the ownership of responsibility by the Biobank, this

fact must be promptly communicated to the CEP/CONEP System; and V - Biobanks are subject to health inspection by the competent bodies.

4. In the case of a Biorepository, the conditions associated with the storage of human biological material must be explained in the respective Research Project, and its Regulation must be assessed by the institutional CEP or by CEP indicated by CONEP and, when applicable, by CONEP, according to attributions defined in CNS Resolution 196/96 and complementary. –

5. The free and informed consent regarding the collection, deposit, storage and use of human biological material in Biobank is formalized through TCLE, through which the subject of the research must expressly express himself regarding the following alternatives, excluding each other:

I - need for a new consent for each survey; and II - new

consent waiver for each survey. a) The TCLE must

contain reference to the types of information that may be obtained in future research, from the use of stored human biological material, for the purposes of knowledge and autonomous decision of the subject. b) The TCLE must contain the express

guarantee of the possibility of access by the subject of the research, including the form(s) of contact for such, the knowledge of the results obtained with the use of his biological material and the guidelines regarding its implications, including genetic counseling where applicable, at any time.

c) The TCLE may contain an express manifestation of the research subject's will regarding the assignment of rights over the stored material to successors or others indicated by him, in case of death or disabling condition. d) The TCLE

must inform the subject that the data provided, collected and obtained from surveys may be used in future surveys. e) The TCLE may contain a reference to

the disposal authorization of the stored material and the situations in which it is possible.

6. Free and informed consent regarding the collection, deposit, storage, use and disposal of human biological material in a Biorepository is formalized through a specific TCLE for each research, as recommended in the resolutions of the National Health Council (CNS).

7. The transfer of human biological material stored between Biobanks or Biorepositories, from the institution itself or from another institution, must be communicated to the research subject, whenever possible or, failing that, justification must be presented to the CEP/CONEP System.

8. The research subject must be informed about the loss or destruction of their samples biological resources, as well as the closure of the Biobank or the Biorepository, when applicable.

9. The human biological material stored in a Biobank or Biorepository belongs to the research subject, remaining under institutional responsibility.

- The management of human biological material stored in a Biobank is the responsibility of the institution and, in the case of a Biorepository, the responsible researcher.

10. The research subject, or his legal representative, at any time and without any burden or damages, may withdraw the consent to keep and use the biological material stored in the Biobank or Biorepository, with withdrawal valid from the date of formalization of this.

I - The withdrawal of consent will be formalized by manifestation, in writing and signed, by the subject of the research or his legal representative, being responsible for returning the existing samples.

11. The term for storing human biological material in a Biobank is indefinite, maintenance of its accreditation being subject to compliance with current regulations.

I - Every five years, counted from its constitution, or at any time, upon request by CONEP, the institution responsible for the Biobank must submit a report of activities for the period to the CEP/CONEP System, including, obligatorily, the number of subjects included in the period and the list of studies that used stored samples.

II - The disposal of human biological material stored in the Biobank can occur: a) by the express will of the subject of the research; b) due to the inadequacy of the sample by quality criteria; c) on the initiative of the institution; and d) for the dissolution of Biobanco.

III - In the hypotheses provided for in items “c” and “d”, the following are mandatory: a) the formal offer of the stored material to at least two research institutions that have a Biobank and the proof of refusal; and b) the submission of the institutional decision and the destination of the biological material to the CEP, which will forward them for evaluation by CONEP.

12. The period for storing human biological material in a Biorepository must be according to the corresponding research schedule and may be authorized for up to ten years.

I - Storage authorization renewals are permitted upon request by the responsible researcher, to the CEP, accompanied by justification and report of research activities carried out with the material during the period.

II - At the end of the research period, the human biological material stored in Biorepository you can:

a) remain stored, if in accordance with the relevant CNS standards; b) be formally transferred to another Biorepository or Biobank, upon approval by the CEP and the institutions involved; and c) be discarded, in accordance with current regulations of competent technical bodies, and in accordance with with the TCLE, respecting the confidentiality and autonomy of the research subject.

13. In the case of research involving more than one institution, there must be an agreement signed between the participating institutions, contemplating ways of operationalizing, sharing and using human biological material stored in a Biobank or Biorepository, including the possibility of future dissolution of the partnership and the consequent sharing and destination of stored data and materials, as provided for in the TCLE.

I - It is necessary to explain the type and quantity of shared materials, informing their destination after use.

14. In case of setting up or participating in a bank of human biological material abroad, the national and international standards for sending material must be obeyed and the regulation of the receiving institution must be presented for analysis by the CEP/CONEP System regarding compliance with the requirements of this Resolution.

I - The Brazilian researcher and institution must have the right to access and use, in future research, human biological material stored abroad, not necessarily the samples deposited by the researcher, guaranteeing, at least, the proportionality of participation.

II - The right of access and use includes the samples, associated information and results incorporated into the bank, obtained in surveys approved by the CEP/CONEP System.

III - rights relating to human biological material stored abroad cannot be considered exclusive to the State or institution.

IV - The use of samples from Brazilians stored abroad can only be carried out if art. 5 of this Resolution and with the participation of a Brazilian researcher and/or institution.

V - The recipient institution abroad must undertake to respect Brazilian legislation, in particular the prohibition of patenting and commercial use of human biological material.

15. Regarding the use of samples of stored human biological material: I - the stored samples can be used in new research approved by CEP and, when applicable, by CONEP; II - research projects that intend to use stored samples must include: a) justification for using the material; b) copy of the TCLE used when collecting the material, containing storage authorization and possible future use in research, if the storage occurred after the approval of CNS Resolution 196/96 ; It is

c) Specific TCLE for new research or the request for its waiver, as provided in art. 5 of this Resolution.

III - when based on the impossibility of obtaining specific consent for the new research, upon the subject's option to be consulted in each research, it is up to the CEP to authorize, or not, the use of human biological material stored in a Biobank or Biorepository.

16. Brazilian legislation prohibits the patenting and commercial use of human biological material stored in Biobanks and Biorepositories.

17. The Biobanks constituted from the ratification of this Resolution must adapt to it and those constituted previously will have a period of one year for their regularization, counted from the date of ratification.

I - the regularization provided for in art. 17 will be analyzed and approved by the CEP/CONEP System.

18. CNS Resolution No. 347, of January 13, 2005, published in the Diário Federal Official No. 47, of March 10, 2005.

ALEXANDRE ROCHA SANTOS PADILHA
President of the National Health Council

I ratify CNS Resolution No. 441, of May 12, 2011, pursuant to Decree No. 5.839, of July 11, 2006.

ALEXANDRE ROCHA SANTOS PADILHA
Minister of State for Health