

NATIONAL HEALTH COUNCIL

RESOLUTION N° 347 OF 13th JANUARY 2005

National Health Council Plenary Assembly in its One Hundredth Fiftieth Ordinary Meeting, held on January the 11th, 12th and 13th 2005, in the use of its regimental competencies and granted attributions by Law n° 8.080 from 19th September 1990 and by the Law n° 8.142, from 28th December 1990, and considering the need of regulating the storage and utilization of human biological material obtained in research projects

DECIDES:

To approve the following guidelines for ethical analyzing of research projects that involve material storage or utilization of stored materials in prior researches:

1. Beyond the points foreseen in Resolution NHC n° 196/96, research projects involving human biological materials storage for further investigations shall present:

1.1. Justification on the need and opportunity for possible future use;

1.2. Consent from research subjects, donors of the biological material, authorizing the storage;

1.3. Declaration expressing that all new research to be performed with the material is going to be submitted to the approbation by the CEP of the institution and, if necessary, by the National Committee for Ethics in Research – CONEP;

1.4. Rule or regulation elaborated by the depositary institution for the storage of human biological materials.

2. The biological material shall be stored under the responsibility of the depositary institution, which must have rules or regulation approved by the institutional CEP, including:

2.1. Definition of people in charge of the storage and for authorizing the future use;

2.2. Mechanisms that guarantee secret and maintenance of confidentiality (codification);

2.3. Mechanisms that assure contact with donors for providing of information on their interest (for example, exam results which have clinical relevance or genetic advice) or for obtaining specific permission for use of the stored material in a new research project.

3. The storage shall be authorized for a period of 5 years long, since the project has been approved by the CEP and, if necessary, by CONEP, such period may be renovated by solicitation of the depositary institution containing a justification and a report of the research activities developed with the material.

4. In case of research developed by more than one institution, there shall be an agreement among the participating institutions, contemplating how the stored material may be used.

5. In case of storage and/or creation of biological material bank in foreign country, sending of the material shall obey the legislation in progress and regulation shall be presented for analyze by the CEP concerning the requests of the item II.

5.1. Brazilian institutions and researchers shall be considered contributors of the bank, with the right of access for future researches. This way, the stored material shall not be considered an exclusive property of the country or depositary institution.

6. About the use of stored samples:

6.1. Storage samples may be used in the development of new researches approved by the CEP and, if necessary, by CONEP;

6.2. Research protocols that may use the stored material shall include:

- a) Justification for use of the material;
- b) Description of the collecting and storage methodology, with start data or period defined;
- c) Copy of the Freely Given and Informed Consent Form-ICF obtained for the research in which the material was harvested for, including authorization for storage and possible future use, if the storage was performed for research approved after the Resolution n° 196/96; and
- d) Specific ICF for new research: in case of impossibility of specific consent obtention for new research (died donor, anterior attempts of contact without success or other), justifications shall be presented as part of the protocol for appreciation by the CEP, which may dispense or not the individual consent.

6.3. In case of storage of biological material to which ANVISA rules are applicable, these rules shall also be observed.

HUMBERTO COSTA
President of the National Health Council

I ratify the Resolution HNC n° 347, of 13th January 2005, in the terms of the Competency Delegation Decree of 12th November 1991.

HUMBERTO COSTA
Minister of Health