

NATIONAL HEALTH COUNCIL

RESOLUTION N° 340, 8TH JULY 2004

The National Health Council Plenary Assembly, in its 144th Ordinary Meeting, held from the 7th to the 8th July 2004, in the use of its regimental competencies and granted attributions by the Law n° 8.080 of 19th September 1990 and by the Law n° 8.142, of 28th December 1990, and

Considering the recent technical-scientific advance and its applications on human genetic research, requiring positioning of institutions, researchers and the Committees for Ethics in Research (CEP) on a national basis, thus requiring complementary regulation on Resolution (NHC) CNS N° 196/96 (Guidelines and Regulating Rules for Research Involving Human Beings) attribution of the National Commission for Ethics on Research (CONEP), in accordance with item VIII.4 of such Resolution;

Considering the subsidies received from the CEPs-CONEP system and the cumulated experience on research project analysis on this area up to the present moment; and

Considering the need to observe the potential risks for health and the protection of human rights, fundamental freedom and the respect for human dignity upon collection, processing, usage and storage of data and human genetic materials,

DE C I D E S:

To approve the following Guidelines for the Ethical Analysis and the Evaluation of the Research Project on Human Genetic Special Thematic Area:

I – Preamble

The present Resolution incorporates all clauses stated in Resolution CNS N° 196/96 of the National Health Council, concerning Directives and Adjustment Rules on Research Involving Human Beings, of which it is a complementary part of the specific thematic area, and includes also, whichever applies, if necessary, the dispositions of Resolutions CNS N° 251/97, 292/99, 303/2000 e 304/2000.

II - Terms and Definitions

II.1 – The human genetic research involves the production of genetic or proteomic data of human beings and may consist of different types:

a) research on basic genetic mechanisms: studies on localization, structure, function and expression of human genes and chromosome organization;

b) research on clinical genetics: research that consists of the descriptive study on subjects individually and/or on their families, aiming at elucidating conditions of probable genetic etiology which may involve clinical information analysis and genetic material tests;

c) research on populational genetics: studies on normal or pathological genetic variability on groups of individuals, and the relationship among these groups and a particular condition;

d) human molecular researches: researches that involve molecular assays whether or not associated to diseases; genetic or epigenetic studies on nucleic acids (DNA and RNA) or proteins aiming for novel treatments or the prevention of genetic disorders other pathologies or the identification of molecular variability;

e) researches on gene and cellular therapy: introduction of recombinant DNA or RNA molecules in human somatic cells *in vivo* (gene therapy *in vivo*) or human somatic cells *in vitro*

and transferring of these cells to an organism (gene therapy *ex vivo*) and researches with human stem cells with genetic modifications; e

f) research on behavioral genetics: study aiming at establishing possible relationships between genetic characteristics and human behavior.

II.2 – All procedures related to human genetics that have not been fully accepted in the scientific literature will be considered as research and, therefore, must comply with the guidelines set forth in this Resolution. It includes genetic procedures on assisted reproduction not yet regulated by the Federal Medicine Council.

III – Ethical Aspects

The main purpose of researches on genetics shall be related to scientific knowledge accumulation that promotes suffering relief and improves the health of individuals and humanity.

III.1 – The genetic research produces a special data category by containing medical, scientific and personal information and thus, the knowledge impact shall be evaluated on the individual, family and the group to which he belongs.

III.2 – Data protection means shall be anticipated in order to avoid the stigmatization and discrimination of individuals, families or groups’.

III.3 – Researches involving predictive tests must be preceded by clarification, before material collecting, with respect to the meaning and possible usage of expected results.

III.4 – It shall be offered to research subjects the option to choose whether or not they want to be informed of the results of their medical exams.

III.5 – Research projects must contain a proposal for genetic advice, whenever the case.

III.6 – It is the research subjects’ liability to authorize or not data storage and collection of materials within the scope of the research, after being informed about the procedures defined in the Resolution concerning storage of biological materials.

III.7 – Every individual has access to his/her genetic data, as well as the right to retrieve them from banks where they are stored.

III.8 – In order to have individual genetic data irreversibly dissociated from any identifiable individual, justification must be provided for such procedure so as to be evaluated by CEP and CONEP.

III.9 - In the event of genetic data dissociation approval by CEP and CONEP, the research subject must be informed of advantages and disadvantages of such dissociation and a specific Term of Consent for this finality signed.

III.10 –The item V.7 of Resolution CNS N°196/96 must be observed including a possible patent registration.

III.11 – The resulting genetic data of a research associated to an identifiable individual shall not be divulged nor become accessible to a third party, particularly to employers, insurance companies and educational institutions. In addition to that, such resulting data shall not be provided for crossing with other stored data for judicial purposes or other finality, unless otherwise duly authorized by the research subject.

III.12 – Human genetic data collected on researches with a predefined purpose shall only be used for a different purpose if duly authorized by the donor or his/her legal representative. It is also required a new research protocol duly approved by the Committee for Ethics in Research and, if necessary, by CONEP. In the event of not obtaining the TCLE, a formal justification shall be presented to CEP evaluation.

III.13 – In the case of human genetic data exchange among institutions, there shall be an agreement among themselves towards mutual cooperation and equal data access.

III.14 – Human genetic data shall not be stored by individuals, requiring the participation of a responsible institution that ensures adequate protection.

III.15 – The benefits of human genetic data utilization collected within the research scope, including populational genetic studies, shall be shared among the involved communities, on an international or national basis.

III.16 – Researches for genome modification shall only be carried out with somatic cells.

IV- Research Protocol:

IV.1 – Researches on the area of human genetics shall be submitted to CEP evaluation as complete protocols and, if necessary, submitted also to CONEP, in accordance with chapter VI of Resolution CNS Nº 196/96, not being accepted as amendments, addends or sub-study of another area's protocol. It shall also include:

- a) research justification;
- b) how genes, DNA and RNA segments or gene products in study are correlated with a possible condition of the research subject;
- c) clear explanation of exams and tests that will be carried out and the indication of genes, DNA and RNA segments or gene products that will be studied;
- d) justification for choice and size of the sample, particularly when it regards a vulnerable population or group and distinct cultures (for example, indigenous group);
- e) recruitment means of both the research subjects and controls, when necessary;
- f) careful analysis of potential and current risks and benefits for the individual, the group and future generations, when necessary;
- g) information regarding the use, storage or other destinations of biological material;
- h) measures and cares for assuring the privacy and avoiding stigmatization and discrimination of the research subject, the family and the group in any way;
- i) explanation of preexistent agreement related to the property of generated information as well as the industrial property, when necessary;
- j) description of the genetic advice planning and clinical surveillance, when indicated, including the names and contacts of the responsible professionals, approach type according to expected situations, consequences to subjects and foreseen conducts. The responsible professionals for the genetic advices and clinical surveillance must comply with the professional formation and certificates required by the professional councils and specialty societies;
- l) a justification for the transport of biological material and/or data to other institutions, national or foreign, with clear indication of material and/or data types as well as the

listing of exams and tests to be carried out. It is also required to clarify the reasons why the exams or tests can not be performed in Brazil, if this is the case; and

m) in international cooperation projects the opportunities for technology transfer should be described.

V - Freely Given and Informed Consent Term – TCLE

V.1 – The TCLE must be elaborated according to the rule in chapter IV of Resolution CNS N° 196/96, with special emphasis on the following items:

a) clear explanation of exams and tests that will be performed, the indication of genes, DNA and RNA segments or gene product that will be studied and their correlation with a possible condition of the research subject;

b) guarantee of secrecy, privacy and, when necessary, anonymity;

c) the genetic advice planning and clinical surveillance, with the indication of the responsible people, without cost to the research subjects;

d) kind and degree of access to results by the subject, with the option to acknowledge or not this information;

e) in the case of material storage, the information should be included in the TCLE, explaining the possibility of utilization in a new research project. It must state that the subject will be contacted for further authorization for the use of the material in future projects and, when impossible to do so, the fact shall be justified to the CEP. In addition to that, it is also required to explain that the material will only be used upon approval of a new project by CEP and CONEP (when necessary);

f) information on protection measures of individual data, exam and test results as well as the clinical report will only be accessed by the involved researchers and not by third parties (insurance companies, employers, hierarchical supervisors, etc);

g) information on protection measures against any kind of individual or collective discrimination and/or stigmatization; and

h) in investigations of families, it is required to obtain the Freely Given and Informed Consent Term of each individual of the study.

VI – Operational:

VI.1. It is CEP's duty, based on chapter VII of the resolution CNS N° 196/96, to analyze research projects, assuming co-responsibility as far as ethical aspects are concerned.

VI.2. It is CEP's duty to promptly return to the researcher a protocol that does not contain all the relevant information (chapter VI – Resolution CNS N° 196/96, as well as chapters III and IV of the present Resolution).

VI.3. It is CONEP's duty the final approval on human genetic researches that include:

a) the dispatch abroad of genetic material or any human biological material aiming at obtaining genetic material;

b) the storage of biological material or human genetic data, abroad or in this country, when in partnership with foreign or commercial institutions;

c) alterations of the genetic structure of human cells for *in vivo* utilization;

- d) researches on the area of human-reproduction genetics (repro-genetics);
- e) researches on behavioral genetics; and
- f) researches that anticipate irreversible dissociation of research subject and data.

VI.4 – In the cases mentioned in VI.3 above, CEP must examine protocol, elaborate the fundamented report and send both to CONEP with the complete documentation according to Resolution CNS N° 196/96, items VII.13.a and b and VIII.4.c.1. The researcher shall be informed that he must await the report issued by CONEP so as to start up the project execution.

VI.5 – It is delegated to CEP the final approval of human genetic projects that are not included in item VI.3 above. In this case, CEP must send to CONEP the front page and the fundamented report, whether it has been approved or not.

VI.6 – Dispatch of material abroad must obey the normative and legal rules of the country.

HUMBERTO COSTA
President of the National Health Council

I ratify the Resolution CNS n° 340, of 8th July 2004, in the terms of the Competency Delegation Decree of 12th November 1991.

HUMBERTO COSTA
Minister of Health