

NATIONAL HEALTH COUNCIL

RESOLUTION N#304, 9TH AUGUST 2000

The Plenary Assembly of the National Health Council , in its 100th Ordinary Meeting, occurred on 9-10 August 2002, in the use of its regimental competencies and granted attributions by the Law n# 8.080, of 19 November 1990 and by the Law n# 8.142, of 28 December 1990, **considering:**

- The need of a complementar regulation of Resolution CNS n# 196/96 (Guidelines and Regulating Norms of Research Involving Human Beings), attributions of the CONEP accordingly to item VIII.4.d of the same Resolution, regarding the special thematic area “indigenous populations” (item VIII.4.c.6).

Decides:

- To approve the following Rules to Researches Involving Human Beings – Area of Indigenous Peoples.

I – Introduction

This resolution attempts to assert the just respect rights of the indigenous peoples, concerning the practical and theoretical development of research in human beings that involves life, territory, culture and natural resources of the indigenous peoples from Brazil. It also recognizes the rights of the indigenous to participate in the decisions that affect them.

These rules incorporate the guidelines foreseen in Resolution 196/96 of the National Health Council , and based on the principal internacional documents on UN’s human rights, particularly the Convention 169 on Indigenous and Tribal Peoples in Independent Countries and Resolution on Action of ILO – International Labour Organization, concerning the Indigenous and Tribal Peoples, of 1989, of the Constitution of the Federal Republic of Brazil (Title VIII, Article VIII of Indigenous peoples) and of all national legislation of support and respect to the rights of Indigenous Peoples while individual and collective subjects of research.

Researches involving indigenous communities or individuals correspond to and consider the ethical and cientific requirements indicated in Resolution CNS 196/96 that contains the guidelines and regulating Norms of research involving human beings and its complementary rules. Particular attention should be also given to Resolution CNS 292/99 on research with foreign cooperation, besides other CNS resolutions on ethics in research, Decrees 86715 of 10/12/81 and 96830, of 15/01/90 that regulate the temporary visa to foreigners.

II – Expressions and Definitions

This resolution adopts in its scope the following definitions:

1 – Indigenous Peoples – peoples with proper organizations and identities, owing to the awareness of their historic continuity as pre-colombian societies.

2 – Indigenous – one who considers him/herself as part of an indigenous community and is recognized as a member by this community.

3 – Isolated Indigenous – Individuals or groups who avoid or are not in contact with the involving society.

III – Ethical aspects of research involving indigenous peoples.

Researches involving indigenous peoples should also obey the bioethics referencial, considering the peculiarities of each people and/or community.

1 – The benefits and advantages resulting from the development of research should consider the need of targeted individuals and groups of the study, or similar societies and/or national societies, taking into account the promotion and maintenance of welfare, preservation and protection of biological and cultural diversity, collective and individual health and the contribution to the development of knowledge and own technology.

2 – Any research involving the indigenous or his/her community should:

2.1 – Respect view of the world, the costumes, esthetic attitudes, religious beliefs, social organization, peculiar philosophies, linguistics differences and political structure;

2.2 – Not allow physical, mental, psychological or intellectual and social exploration of the indigenous;

2.3 – Not allow situations that can put at risk the integrity and the physical, mental and social welfare of the indigenous;

2.4 – Have the agreement of the targeted community which can be obtained through the respective indigenous organizations or local councils, respecting the individual consent, which in common agreement with the referred communities will designate the mediator to the contact between the researcher and the community.

2.5 – Guarantee equality of consideration of the involved interests, taking into account the vulnerability of the group in question.

3 – It is recommended, preferentially, not to do researches in isolated indigenous communities. In special cases, there should be presented detailed justification.

4 – It will be considered ethically unacceptable to patent, by somebody else, chemical products and biological material of any kind, obtained from researches with indigenous peoples.

5 – The formation of DNA banks, of cell lineage or any other biological material related to indigenous peoples, is not admitted without the explicit agreement of the involved community, without the presentation of a detailed proposal in the research protocol to be submitted to the Committee for Ethics in Research – CEP (in Portuguese) and to the National Committee for Ethics in Research – CONEP (in Portuguese), and the formal approval of these Committees.

6 – The non-observance of any of those items above should be communicated to the institutional CEP and to the CONEP of the National Health Council, to take appropriated steps.

IV – The Research Protocol

The protocol to be submitted to ethical evaluation should consider item VI of Resolution 196/96, adding:

1 - The commitment of obtaining the approval of the involved communities as foreseen in item III Article 2 of this rule, describing the procedures to obtain the approval.

2 – Description of the process to obtain and register the Freely given and Informed Consent Term – TCLE (in Portuguese), assuring the adjustment to cultural and linguistic peculiarities of the involved ones.

V – Protection

1 – The research can be interrupted at any time, obeying the rule in item III.3.z of Resolution 196/96, since:

1.1 – The indigenous community that is being studied asks for it;

- 1.2 – the research that is being developed generates conflicts and/or any kind of uneasiness inside the community;
- 1.3 - there is violation of the organization and survival form of the indigenous community, especially the one related to subjects' lives, to human resources, phylogenetics resources, to knowledge of properties of the soil, subsoil, fauna and flora, to oral traditions and all artistic expressions of that community.

VI – Attributions of CONEP

- 1 – Within the foreseen attributions in item VIII.4.c.6 of Resolution CNS 196/96, CONEP is in the charge of, after the institutional approval of CEP, evaluating the researches fitted in this thematic area, even when they are fitted in another one.
- 2 – A report of the Intersectorial Committee for Indigenous Health (CISI), (in Portuguese), when consultancy is needed, can be requested by CONEP. – National Commission for Ethics in Research.

JOSÉ SERRA

President of the Nacional Health Council

I ratify the Resolution CNS n# 304, of 10 August 2000, in the terms of the Competency Delegation Decree of 12 November 1991

JOSÉ SERRA

Minister of Health