

NATIONAL HEALTH COUNCIL

RESOLUTION N° 346 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 accumulated experience in the National Committee for Ethics in Research – CONEP in the appreciation of multicentric research projects and aiming at simplifying the formalization, establishes the following regulation for multicentric research projects formalization in the Committees for Ethics in Research -CEPs- CONEP system.

DECIDES:

I- Term definition:

Multicentric project – research project to be led according to unique protocol in several research centers and, therefore, to be carried out by a responsible researcher in each center, who may follow the same procedures.

II- Formalization of multicentric research protocols:

The multicentric research protocols that must receive report from CONEP, through Resolution HNC n° 196/96 and its complementary resolutions shall be formalized according to the following procedure:

1. CONEP shall analyze only the first protocol, sent by one of the centers, along with a list of the implicated centers and the fundamented report from CEP. CONEP, after eventual rearrangements have been made, shall send the final report to such CEP and the other centers implicated;

a) In case of there be a national coordinator of the research, the CEP that shall receive the protocol and send it to CONEP may be the CEP of the institution to which the coordinator belongs or a CEP indicated by CONEP according to Resolution CNS n° 196/96 item VII.2;

2. Research protocol disapproved by CONEP for the first center shall not be carried out in any center.

3. Research protocol approved by CONEP shall be presented by the respective researchers to the CEPs of their centers, which may require the researcher to attach declaration of identical protocol to the one presented by the first center.

a) Eventual modifications or additional material referring to responses to the requests of CONEP report shall be presented separately, well identified, added to the protocol after the documents above.

4. CONEP shall delegate to the other CEPs the final approbation of the projects cited in the item 3 above, maintained the prerogative of the CEP to approve or not the protocol in its institution, having always:

a) to verify the suitability of the protocol with the institutional conditions and with the competence of the responsible researcher in the institution;

b) to require the accomplishment of eventual modifications approved by the CONEP and the requests of the CEP; and

c) to send the fundamented report to CONEP, in case of non final approbation by the CEP.

5. Only the CEP of the first center may be in charge of sending the notifications to CONEP in case of serious adverse events occurring in foreign centers, interruption of the researches or relevant modifications, being necessary that each researcher send the notifications to the local CEP.

a) In case of adverse event occurring in the country, the responsible researcher of the center where it occurred, after analyzing it, must notify the CEP and this, in case of serious adverse event, to the CONEP.

6. The regulation of 8th August 2002 of Resolution HNC n° 292/99 remains revoked, upon delegation for researches with foreign cooperation, keeping the Resolution HNC n° 292/99 of the 8th July 1999 in its integrality.

HUMBERTO COSTA
President of the National Health Council

I ratify the Resolution CNS n° 346, of 13th January 2005, in the terms of the Competency Delegation Decree of 12th November 1991.

HUMBERTO COSTA
Minister of Health