NATIONAL HEALTH COUNCIL

RESOLUTION No – , 346, OF JANUARY 13, 2005

The Plenary of the National Health Council at its 150th Ordinary Meeting, held on January 11, 12 and 13, 2005, in the use of its regimental powers and attributions conferred by Law No. 8,080, of September 19, 1990, and by Law nº 8.142, of December 28, 1990, and considering the experience accumulated in the National Commission of Ethics in Research-CONEP in the appreciation of multicenter research projects and aiming at a simplified procedure, establishes the following regulation for processing multicenter research projects in the system of Research Ethics Committees-CEPs – CONEP.

RESOLVES:

I- Definition of the term:

Multicenter projects – research project to be conducted according to a single protocol in several research centers and, therefore, to be carried out by a responsible researcher at each center, who will follow the same procedures.

II- Processing of multicenter research protocols:

The multicenter research protocols that must receive an opinion from CONEP, under CNS Resolution nº 196/96 and its complementary ones, will have the following procedure: 1. Only the first protocol, sent by one of the centers, will be analyzed by CONEP. The list of centers involved must accompany the protocol and the CEP's substantiated opinion. CONEP, after any pending issues have been resolved, will send the final opinion to this CEP and to the other centers involved;

a) In case there is a national research coordinator, the CEP to initially receive the protocol and send it to CONEP must be the CEP of the institution to which it belongs or, according to CNS Resolution nº 196/96 item VII.2, the CEP appointed by CONEP;

2. The research protocol not approved by CONEP for the first center cannot be carried out in any center.

3. The research protocol approved by CONEP must be presented by the respective researchers to the CEPs of the other centers, which must require the researcher to attach a declaration that the protocol is identical to that presented to the first center.

a) Any changes or additions referring to responses to the requirements of CONEP's opinion must be presented separately, in a well-identified manner, attached to the protocol after the documents above.

4. CONEP will delegate to the other CEPs the final approval of the projects mentioned in item 3 above, The prerogative of these CEPs to approve or not the protocol in their institution is maintained, and it is always up to them to:

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

b) require compliance with any modifications approved by CONEP and requirements of the

ZIP CODE; and

c) send the substantiated opinion to CONEP, in case of non-approval by the CEP.

5. Only the CEP of the first center will be in charge of notifications to CONEP in case of serious adverse events occurring in foreign centers, interruptions of research or relevant changes, keeping the necessary notifications from each researcher to the local CEP.

a) in the event of an adverse event occurring in the country, the researcher responsible for the center where it occurred, after analysis, it must notify the CEP and the latter, in the event of a serious adverse event, to CONEP.

6. The regulation of 08/08/02 of CNS Resolution No. 292/99, on delegation to research with foreign cooperation, maintaining CNS Resolution nº 292/99 of 07/08/99 in full.

HUMBERTO COSTA
President of the National Health Council

I ratify CNS Resolution No. 346, of January 13, 2005, pursuant to the Delegation of Competence Decree of November 12, 1991.

HUMBERTO COSTA
Minister of State for Health