

**National Health Council
National Committee for Ethics in Research – CONEP/CNS/MS**

**Regulation of Resolution CNS 292/99 on researches with foreign
cooperation (approved in CNS on 8 August 2002)**

Brasília, 7 August 2002

Resolution CNS 292/99 defines the specific thematic area of research with foreign cooperation. According to item VIII of that Resolution, projects included in this area, as defined, should have both the CONEP and CEP approval.

CONEP, in its six years of experience, judges necessary to propose a competency delegation to the Committee for Ethics in Research – CEP, to final analysis of part of the projects of this thematic area.

According to this and the features and complexities involved in this matter, CONEP established that:

- 1 – Projects with foreign cooperation will continue to depend on the approval of CONEP as they involve:
 - a) phases I (one) and II (two);
 - b) comparative groups of research subjects kept, during any time, in a schedule of exclusive use of placebo and/or even without a specific treatment, including periods of wash-out;
 - c) storage or development of biological material banks;
 - d) medicine to HIV/AIDS.

- 2 – The final approval of other projects of this thematic area can be delegated to CEP, since:
 - a) CEP expresses this option, requesting officially to CONEP the cession of competency to the final approval of the projects;
 - b) CEP is evaluated in the Evaluation Program proposed by CONEP, being necessary, at least, the accomplishment of the first phase of the program that includes:
 - Analysis of the questionnaires received about the organization and functioning of CEP;
 - Analysis of attendance data of CEP available at CONEP, including reports and project profiles received in the previous year with an consistency index between the opinion of CEP and CONEP;

- c) CEP claims the presentation of the complete protocol, according to specific items of Resolution 196/96 and its complementaries to effective evaluation.
- 3 – CONEP can request CEP, at any time and accordingly to its own criteria, the complete project to be analysed.
- 4 - This delegation has an experimental feature and can be reviewed by CONEP.

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