NATIONAL HEALTH COUNCIL

RESOLUTION Nº 292, DATED 8 JULY 1999

The Plenary of the National Health Council, in its 88th Regular Meeting, held on July 7 and 8, 1999, in the exercise of its competencies, as set forth in its by-laws, and the attributions in Law 8.080 and Law 8.142, respectively dated 19 September 1990 and 28 December 1990, and **CONSIDERING** the need for complementary regulation of CNS Resolution Nº 196/96 (Guidelines and Norms Regulating Research Involving Human Beings), a competency of CONEP as stated in item VIII.4.d of that Resolution, as regards the special thematic area "*research coordinated abroad or with foreign participation and research that involves sending abroad biological material*" (item VIII.4.c.8), **RESOLVES** to approve the following norm:

I – Definition: Research coordinated abroad or with foreign participation is any research involving the promotion and/or execution of:

- **a)** collaboration with foreign, individuals or companies, whether public or private;
- **b)** sending and/or receiving biological material from a human being;
- **c)** sending and/or receiving data and information collected for inclusion in research findings; and
- **d)** international multiple-center studies.

I.1 – Due compliance being given to the conditions above, the following [research] is not included in this thematic area:

- **a)** research entirely carried out in this country by foreign researchers who belong to the technical staff of a national entity; and
- **b)** research carried out by multinational corporations with headquarters in this country.

II – In all research, it is mandatory:

II.1 – to prove the Brazilian participation and to identify the co-responsible national researchers and institutions; and

II.2 – to set forth the responsibilities, rights and obligations through an agreement of the parts involved [in the research].

III – This Resolution incorporates all provisions contained in Resolution Nº 196/96 of the National Health Council on Guidelines and Norms Regulating Research Involving Human Beings, whose specific thematic area is hereby complemented.

III.1 – CNS Resolutions referring to other thematic areas simultaneously contemplated in the research should complied with.

IV – The burden and benefits arising from the investigation and the research results must be distributed fairly among the parts involved and should be clearly set forth in the protocol.

V – The national researcher and institution should be well aware of the legal norms and regulations on sending material abroad and those that protect industrial property and/or technology transfers (Law Nº 9.279, dated 14 May 1996, which regulates the rights and duties associated with industrial property; Decree Nº 2.553/98, which regulates Law Nº 9.610/98 on copyright), expounding, as the case may be, the agreements established, as well as the legal norms on sending biological material abroad.

VI – During the research, the sponsors and researchers should communicate to the Committees on Research Ethics (CEP) any relevant information of public interest, in addition to the regular reports required by law.

VII – In preparing the [research] protocol, special attention must be given to the presentation of the following items:

VII.1 – Approval document issued by the Committee on Research Ethics or equivalent institution in the country of origin that will promote or also execute the project.

VII.2 – When the project is not to be developed in the country of origin, a justification should be attached to the protocol, for consideration by the Committee on Research Ethics of the Brazilian institution.

VII.3 –Detailed exposition of the financial resources involved: sources (whether international and foreign and whether there is a national/institutional counterpart); manner and value of the remuneration of the researcher and other human resources; expenditures with infrastructure; and impact on the routine of the health services [rendered by] the institution [where the project will be implemented]. To the extent possible, the financial input should not create situations where health professionals and/or users are discriminated, since these resources could lead to extraordinary benefits for the participants and research subjects.

VII.4 – Statement of the research promoter or sponsor, as the case may be, that the terms of the resolutions on ethics in research involving human beings issued by the National Health Council will be complied with.

VII.5 – Statement on how the biological material and the information and data gathered exclusively for the purpose foreseen in the protocol will be used by all individuals manipulating the material.

VII.6 – Statement of the researcher on the protocol, in the event the researcher was unable to participate in the design of the project.

VIII – According to the attributions set forth in item VIII.4.c.8 of Resolution Nº 196/96, CONEP, after approval by the Committee on Research Ethics of the institution, must appreciate all research included in this thematic area, even when other thematic areas are also included.

VIII.1 – Any case referring to the ethical aspects of research not contemplated in this resolution shall be resolved by the National Committee on Research Ethics.

JOSÉ SERRA
President of the National Health Council

I hereby ratify CNS Resolution Nº 292, dated 8 July 1999, in the terms of the Decree on the Delegation of Competency dated 12 November 1991.

JOSÉ SERRA
Minister of Health of Brazil