

Fifteenth Section of the International Bioethics Committee (IBC) of Unesco

Human Cloning and International Governance
Public Hearings

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BRAZILIAN RESEARCH ETHICS STRUCTURE

Brazilian Research Ethics Commission (CONEP)

CONEP is an independent collegiate body, accountable to the National Health Council and with powers to provide consultancy and to deliberate, regulate, and inform.

- **VIII.1 Membership:** Thirteen regular members, and respective alternate members.
- It has a multi- and transdisciplinary representation including both male and female members.
- Five of the members must be well-known individuals in the field of ethics in research and health
- and eight, personalities with noteworthy contributions to theology, law and other fields of knowledge, one of whom must always come from the health management area.
- CONEP has also representatives of the users.

VIII. 4 - Duties of CONEP

CONEP is responsible for reviewing all ethical aspects of research involving human subjects, as well as adapting and updating pertinent guidelines and norms.

• Its duties include:

a) To foster the creation of institutional and other Research Ethics Committees (REC);

b) to register institutional and other RECs;

c) to approve, within 60 days, and monitor the protocols of research in special areas, such as:

1 - human genetics;

2 - human reproduction;

3 - pharmaceutical products, medical drugs, vaccines, and diagnostic tests, either new (phases I, II and III) or without registration in the country (even in phase IV), or when the research is related to the use of products that have modes, indications, doses, or ways of administration different from those previously established, including their combined use;

•4 - health equipment, inputs and devices, either new or without registration in the country;

5 - new procedures not yet established in the literature;

6 - Indigenous populations;

7 - projects involving biosafety;

8 - research coordinated from abroad or with the participation of foreigners, and research involving the sending of biological material to foreign countries; and

9 - research projects which a ERC considers worthy of analysis by CONEP;

VIII. 4 - Duties of CONEP

d) to promote specific ethical standards for research, including research in special areas, as well as recommendations for their application;

e) to act as final appellate body, *ex-officio* or on the basis of regularly supplied information, claims, or requests made by interested parties, and to decide the matter at issue within than sixty (60) days;

f) to review responsibilities, forbid or interrupt research, on a temporary or permanent basis, and to request protocols of research for ethical review, including protocols already approved by a ERC

g) to set up an information system to monitor the ethical aspects of research involving human subjects in the country, and to keep the databases updated; **SISNEP and the expanded PLATAFORMA BRASIL**

h) to provide input and advice to the Ministry of Health, the National Health Council and other agencies of the Unified Health System, as well as to the government and society at large, on ethical issues pertaining to research on human subjects;

i) to disseminate information about this and other norms related to ethics in research involving human subjects;

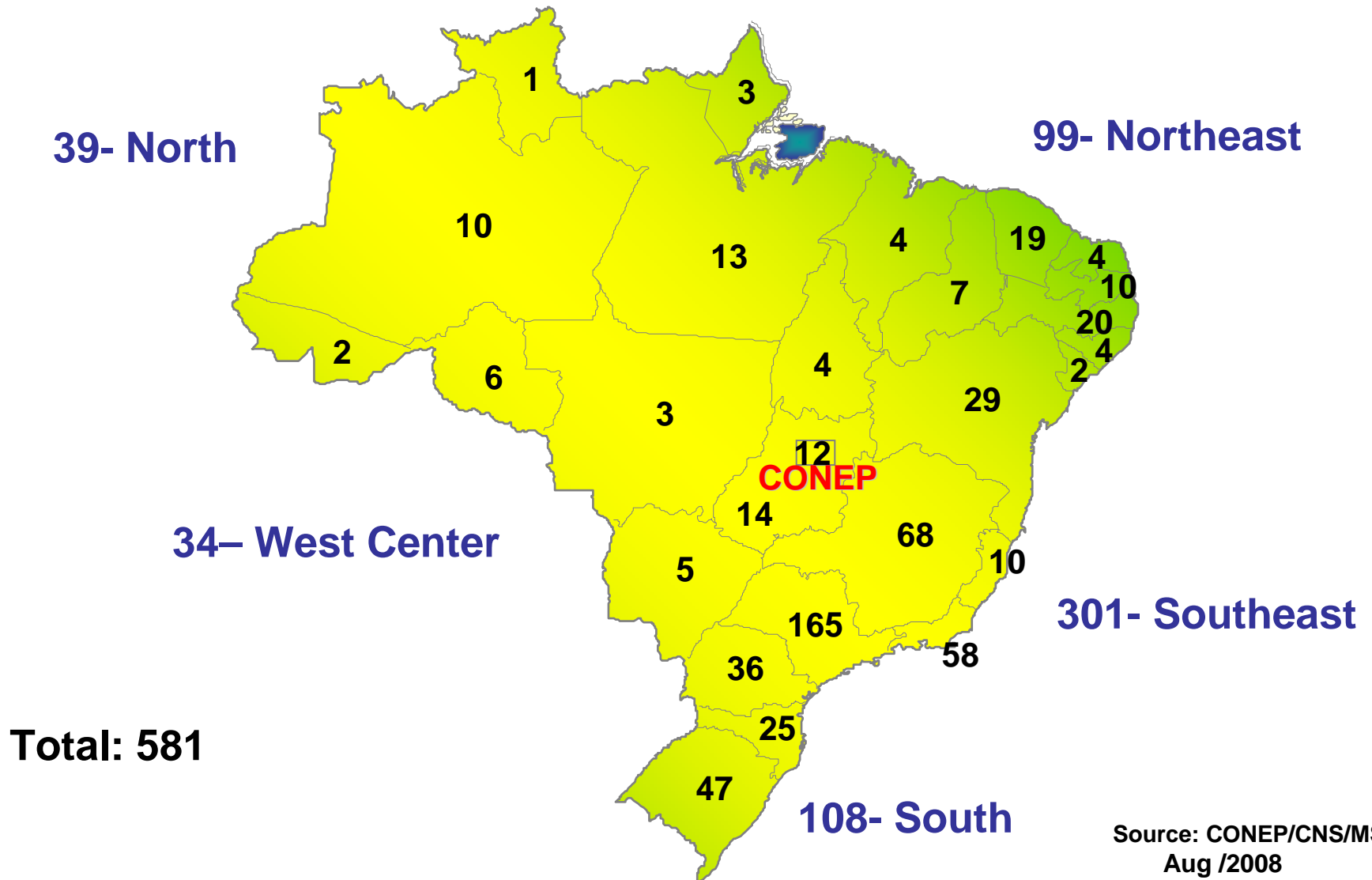
Brazilian Health Council

Resolution 340/2004–Special area: Genetic Research

- **II.1 – Research on human genetics are those producing genetic or proteomic data from human beings, including:
e) Research on cellular or genic therapies: introduction of recombinant DNA or RNA molecules in somatic human cells in vivo or in vitro and posterior transference of these cells to the organism (ex vivo genic therapy) and research with genetically modified human stem cells;**
- **II.2 Any procedure related to human genetics that has not been fully accepted in the scientific literature, will be considered research and, therefore, must comply with the guidelines set forth in this Resolution.**

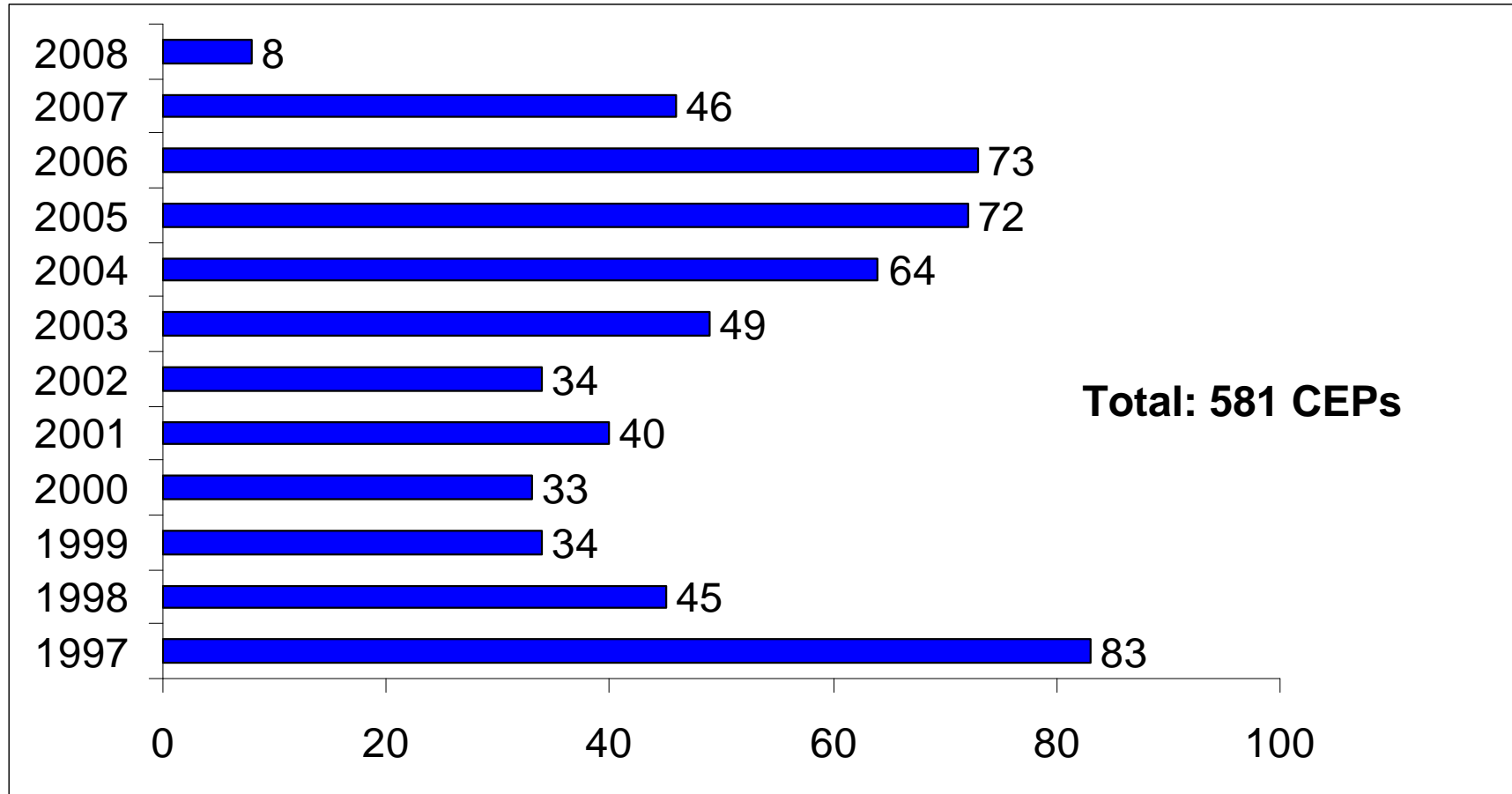


Brazil - Institutional Research Ethics Committees registered at CONEP - 2008





BRAZIL - No. of registered Ethics Research Committees (CEP) per year (1997-2008)



CONEP Brasil

Number of research protocols evaluated per year

Year	Number of evaluated protocols
1999	667
2000	963
2001	1318
2002	1576
2003	1540
2004	1792
2005	1255
2006	1065
2007	840
2008	335
TOTAL	11351

**110 Stem cell research projects
evaluated by CONEP
(2000-2007)**

**Brazilian laws and regulations
Human cloning and stem cell research**

Brazilian Law no. 11.105/2005

Establishes norms and mechanisms to oversee activities related to genetically modified organisms and their derivatives, to reorganize the National Biosafety Council (CNBS), to restructure the National Biosafety Technical Commission (CNTBio) among others.

Article 5 - it is permitted, for research and therapeutic purposes, the use of embryonic stem cells obtained from human embryos produced by **in vitro fertilization** and not utilized for this procedure, adding the following conditions: **I - This embryos are not viable;**

II - They have been frozen for three or more years on the date of the enactment of this law

&1 - In any case parental consent is mandatory

Chapter VIII- Crime and punishment

Art. 24. Use of the human embryo in discordance with article 5:

Penalty: imprisonment for one to three years and fine

Brazilian Law no. 11.105/2005

&2 Research institutions and health services performing research or treatment involving human embryonic stem cells **have to submit their projects to evaluation and approval by the Research Ethics Committee**

&3 It is forbidden the commercial use of any biological material referred to on this article and its practice is considered a crime ([Law 9.434/1997, article 15](#)).

Brazilian Law no. 11.105/2005

Article 6 - It is forbidden

II. Genetic engineering of living organisms or in vitro manipulation of natural or recombinant RNA/DNA performed not in strict accordance to the norms established by this law;

III. Genetic engineering of human germinal cells, human zygotes and human embryos;

IV. Human cloning

Chapter VIII- Crime and punishment

Art. 25. Genetic engineering of human germinal cell, human zygotes or human embryo:
Penalty: imprisonment for one to four years and fine

Art. 26. Perform human cloning:
Penalty: imprisonment for two to five years and fine.

Brazilian current position

- **Human cloning is strictly forbidden**
- **Stem cell use for research and therapeutic purposes is allowed – specific law.**
- **All projects must be submitted to an ERC and to the Brazilian Research Ethics Commission (CONEP)**

Ban reproductive research, allow research cloning for 10 years

Suggestions for plenary discussion

As a preamble: Guidelines from a representative organism leading to an international law - avoid duplication of guidelines/laws

Elaborate on:

- Prudence
- Social Justice
- Demystification (clearly informed data)
- Visibility/clarity: including but not limited to an international database of norms (not only a few selected from wide spoken languages);
- an international database of research proposals and up-to-date results open to all
- Civil society participation

CONEP - BRASIL

**[http://conselho.saude.gov.br/comissao/
conep/resolucao.html](http://conselho.saude.gov.br/comissao/conep/resolucao.html)**

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