

Experience of the Brazilian Research Ethics Commission (CONEP) to facilitate Ethical Research

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Coordinator National Research Ethics Commission (Conep)
Member National Health Council (CNS)
2024

No conflicts of interest

Health professional

Public university professor

Health counselor – National Health Council

Conep coordinator

Potential research participant

Brazilian citizen



Conep/CEP System

National Health Council (CNS)



Guaranteed by the 1988 Brazilian Federal Constitution

The CNS created the National Research Ethics Commission (CONEP) by Resolution 196/1996, succeeded by Resolutions 466/2012, which established regional research ethics committees (CEPs). This CEP/CONEP System is responsible for the ethical supervision of all research projects involving human subjects in Brazil

CNS Commissions

1. Health Care for People with Pathologies
2. Primary Health Care
3. Health Care in Life Cycles - Child, Adolescent, Adult and Elderly
4. Attention to the Health of People with Disabilities
5. Food and Nutrition Science
6. Technology and Pharmaceutical Assistance
- 7. National Research Ethics Commission (Conep)**
8. Permanent Education for SUS Societal Control
9. Budget and Financing Equity Promotion Policies
10. Promotion, Protection, Integrative and Complementary Practices in Health
11. Human Resources and Labor Relations
12. Indigenous people's Health
13. Women's Health
14. Mental Health
15. Worker's Health
16. Supplementary Health in the SUS
17. Health Surveillance
18. Oral Health



The CNS composition

- 48 members, and their respective first and second alternates
- National bodies of health professionals/health sector scientific community
- National entities of health service providers
- National entities with activities in the area of health
- Federal government representatives
- Entities and Social Movements using the Unified Health System (SUS)

In order to maintain the balance of interests of the entities involved, the composition of the CNS is made up of:

- 50% of users of the Unified Health System(SUS)
- 25% of workers
- 25% of service providers and managers

Monthly plenary session



CEP/Conep System

NATIONAL RESEARCH ETHICS COMMISSION (CONEP) (established by Resolution CNS 196/1996)

Collegiate body, normative, deliberative, regulatory, advisory, educational and formulator of guidelines for ethics in research with human beings

Analyzes the ethical aspects of research with human beings, its adequacy and regulatory updating, monitoring and monitoring of compliance

Managed by the National Health Council/CNS/MS and the Secretariat of Science and Technology, Innovation and Health Complex – SECTICS of the Ministry of Health

(Res CNS 446/2012)

Approves the existence and supervises 898 research ethics committees

CONEP Composition

1 COORDINATOR
3 DEPUTY
COORDINATORS

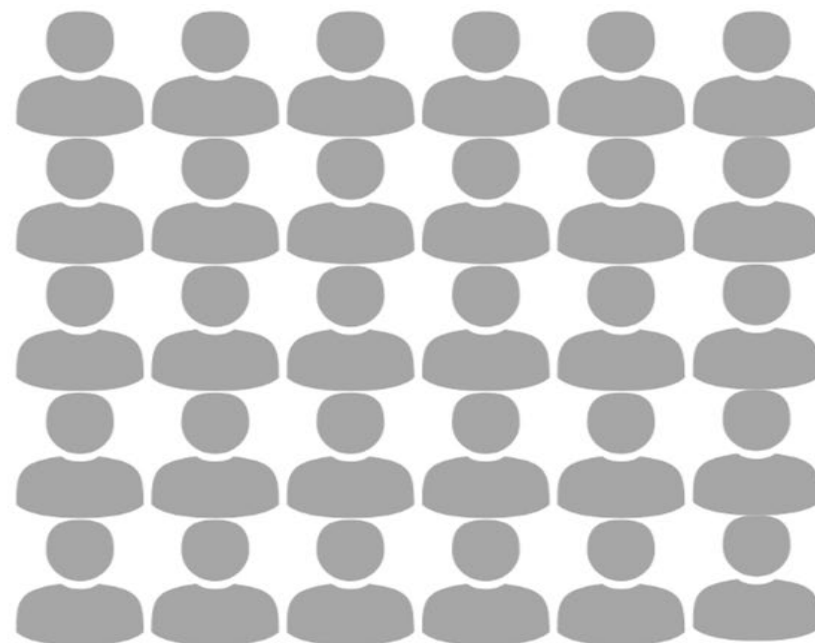
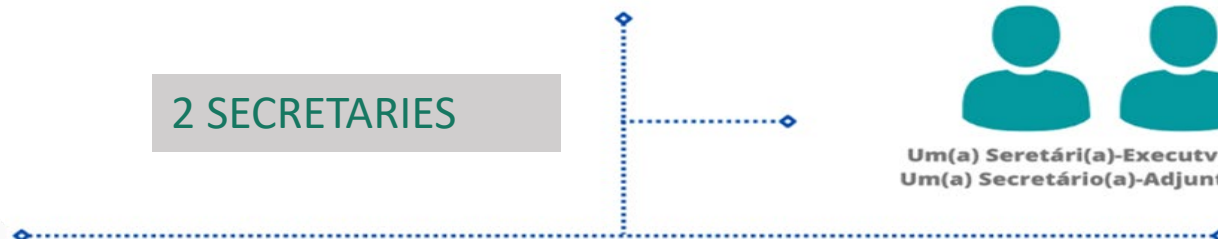


Um(a) Coordenador(a) e três Coordenadores Adjuntos

2 SECRETARIES



Um(a) Secretário(a)-Executivo(a) - MS
Um(a) Secretário(a)-Adjunto(a) - CNS



Trinta membros titulares



Cinco membros suplentes

30 FULL MEMBERS

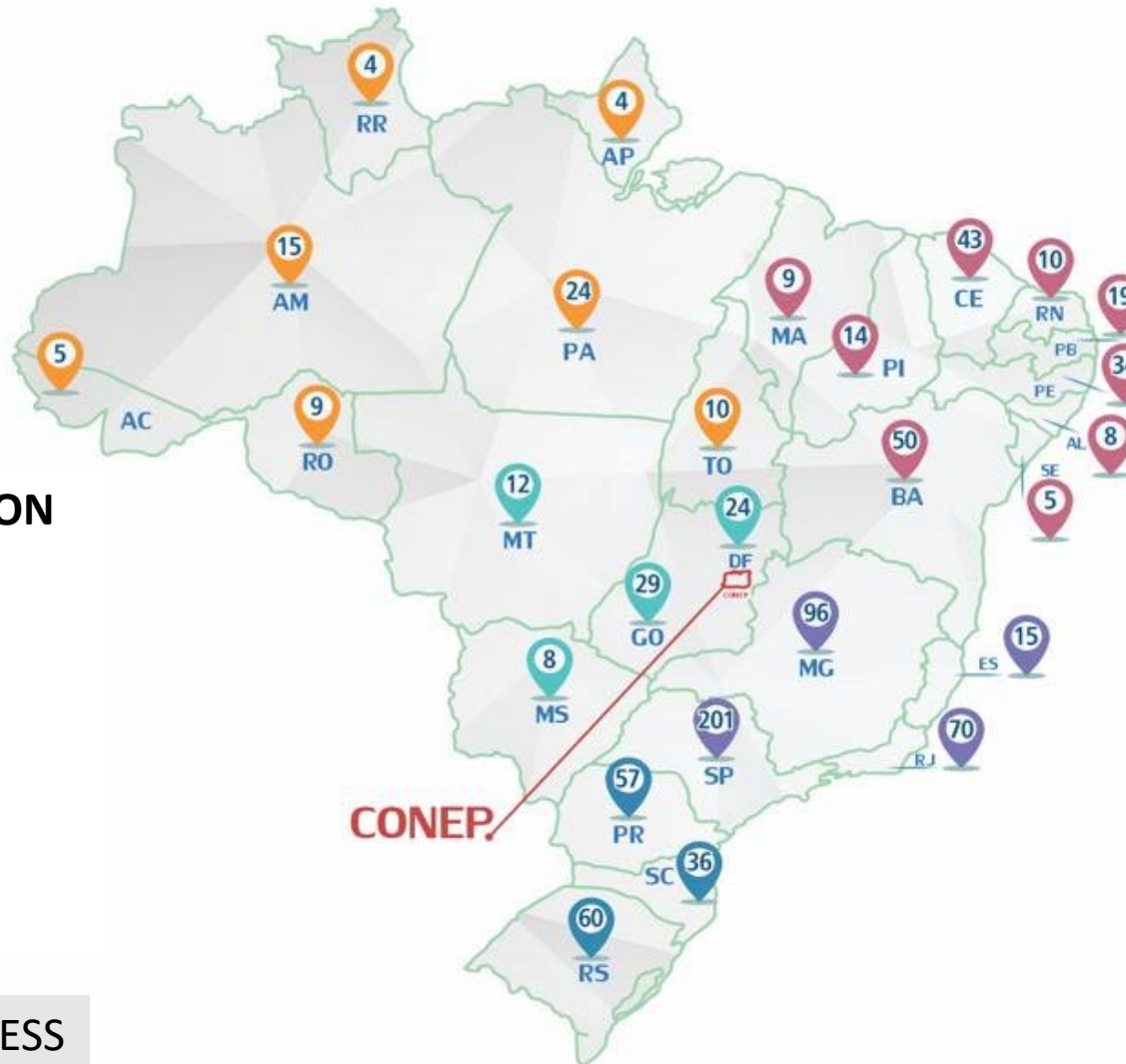
5 SUBSTITUTE MEMBERS



Consultores e membros *ad hoc*

17 AD HOC

National Research Ethics Commission (Conep) and Research Ethics Committees (CEP)



NUMBER of CEPs BY REGION

NORTH : 72

NORTHEAST: 199

WEST-CENTRAL: 74

SOUTHWEST: 399

SOUTH: 154

TOTAL: 898

08 ACCREDITED COMMITTEES

PEOPLE WHO PARTICIPATE IN CEPs

COORDINATORS: 1,813

REPORTING MEMBERS:
13,272

USER'S REPRESENTATIVES:
953

SECRETARIES/OTHER: 966

TOTAL: 17,064



National meeting of research ethics committees
2024

CEP/Conep System



898 Research Ethics Committees



1.137.275 registered users on System (the Brazil Platform)



946.166 research projects registered on the Brazil Platform (since 2011)



32.249 institutions registered on the Brazil Platform
33.641 Brazilian; 1.856 foreign



89 approved biobanks

Current Role of Conep



Images: Pixabay

Analysis of
research protocols
Social value
VVV

Normative update
CEPs Management

Follow-up and
monitoring

Protection of the rights of **research participants**

Current characteristics
Multi-professional
composition and various
áreas of knowledge

Restricted use of placebo,
strictly when there is no
effective and safe
treatment

Post-study access for an
indefinite period and
under the responsibility of
the sponsor

Limits for sending
biological material abroad

Modifications included in the new research ethics law approved in May 28, 2024



Analysis of research protocols

Research ethics committees (CEP)

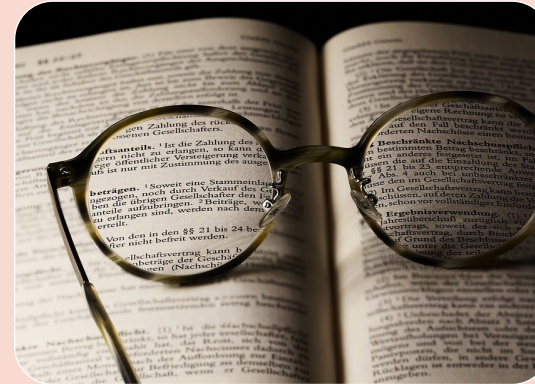
Low and medium risk

Accredited committees

High risk



Normative update
CEPs Management



Images: Pixabay

Follow-up and monitoring
Resource Analysis

Role of CONEP

Other risk of the law:

- CONEP to be established outside of social control, with increased risks of conflicts of interests
- Limitations on the right to post-study access to medication/treatment
- More flexible standards for sending biological material outside the country

Thank You!

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