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# Novas diretrizes éticas para estudos epidemiológicos: visão de um CEP

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# Comitês de Ética em Pesquisa

## Declaração de Helsinki II (Tóquio, 1975)

### I - PRINCÍPIOS BÁSICOS

2 - O projeto e a execução de cada procedimento experimental envolvendo seres humanos devem ser claramente formulados em um protocolo experimental que deverá ser transmitido a uma **comissão independente especialmente nomeada, para consideração, comentário e orientação.**

# Comitês de Ética em Pesquisa

## Resolução CNS 01/88

### CAPÍTULO II

#### ASPECTOS ÉTICOS DA PESQUISA EM SERES HUMANOS

Art. 5 — A pesquisa que se realiza em seres humanos deverá desenvolver-se conforme as seguintes bases:

VII. **Contar com o parecer favorável do Comitê de Ética** e de Segurança Biológica, quando for o caso;

### CAPÍTULO XIII

#### DOS COMITÊS INTERNOS NAS INSTITUIÇÕES DE SAÚDE

Art. 83— Em **toda instituição de saúde** credenciada pelo Conselho Nacional de Saúde na qual se realize pesquisa deverá existir:

1. **COMITÊ DE ÉTICA** caso se realize pesquisas em seres humanos;

# Comitês de Ética em Pesquisa

## Resolução CNS 196/96

### II - TERMOS E DEFINIÇÕES.

A presente Resolução, adota no seu âmbito as seguintes definições:

II.14 - **Comitês de Ética em Pesquisa - CEP** - colegiados interdisciplinares e independentes, com “munus público”, de caráter consultivo, deliberativo e educativo, criados para defender os interesses dos sujeitos da pesquisa em sua integridade e dignidade e para contribuir no desenvolvimento da pesquisa dentro de padrões éticos.

### VII - COMITÊ DE ÉTICA EM PESQUISA - CEP

**Toda pesquisa envolvendo seres humanos deverá ser submetida à apreciação de um Comitê de Ética em Pesquisa.**

### VIII - COMISSÃO NACIONAL DE ÉTICA EM PESQUISA (CONEP/MS)

A **Comissão Nacional de Ética em Pesquisa - CONEP/MS** é uma instância colegiada, de natureza consultiva, deliberativa, normativa, independente, vinculada ao Conselho Nacional de Saúde.



**Council for  
International  
Organizations of  
Medical  
Sciences**

**1991 International Guidelines for Ethical Review  
of Epidemiological Studies**

**2008 International Ethical Guidelines  
for Epidemiological Studies**

**1991**

**53 Diretrizes**

**22 relacionadas a avaliação ética**

# **ETHICAL REVIEW PROCEDURES**

- **Requirement of ethical review (32-33)**
- **Ethical review committees (34-36)**
- **Ethical conduct of members of review committees (37)**
- **Representation of the community (38)**
- **Balancing personal and social perspectives (39)**
- **Assuring scientific soundness (40)**
- **Assessment of safety and quality (41)**
- **Equity in the selection of subjects (42)**
- **Vulnerable and dependent groups (43)**
- **Control groups (44)**
- **Randomization (45)**
- **Provision for multi-centre studies (46)**
- **Compensation for accidental injury (47)**
- **Externally sponsored studies (48-51)**
- **Distinguishing between research and programme evaluation (52)**
- **Information to be provided by investigators (53)**

**2008**

**24 Diretrizes**

**com comentários**

**Guideline 2**

**Ethical review committees**

**Guideline 3**

**Ethical review of  
externally sponsored research**

**Council for International Organizations of Medical Sciences (CIOMS).  
International Ethical Guidelines for Epidemiological Studies.  
Geneva: CIOMS, February 2008:7.**

## **Guideline 2**

### **Ethical review committees**

**All proposals to conduct epidemiological research involving human subjects must be submitted for review of their scientific merit and ethical acceptability to one or more scientific review and ethical review committees. The review committees must be independent of the research team, and any direct financial or other material benefit they may derive from the research should not be contingent on the outcome of their review. The investigator must obtain their approval or clearance before undertaking the research. The ethical review committee should conduct further reviews as necessary in the course of the research, including monitoring the progress of the study.**

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# **Guideline 2**

## **Ethical review committees**

### **Commentary on Guideline 2**

- **Inclusion in, or exemption from, review**
- **General observations**
- **Scientific review**
- **Ethical review**
- **National (centralized) or local review**
- **Committee membership**
- **Multi-centre research**
- **Research in emergency situations**
- **Sanctions**
- **Potential conflicts of interest**

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## **Guideline 3**

### **Ethical review of externally sponsored research**

**An external sponsoring organization and individual investigators should submit the research protocol for ethical and scientific review in the country of the sponsoring organization, and the ethical standards applied should be no less stringent than they would be for research carried out in that country. The health authorities of the host country, as well as a national or local ethical review committee, should ensure that the proposed research is responsive to the health needs and priorities of the host country and meets the requisite ethical standards.**

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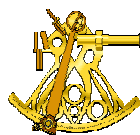
### **Commentary on Guideline 3**

- **Ethical and scientific review**
- **Industry-sponsored research**

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# **Pontos Importantes sobre Avaliação Ética de Projetos em Epidemiologia**

- **Comitê qualificado, multiprofissional e independente**
- **Avaliação ética e metodológica de todos os projetos**
- **Aprovação prévia a execução do projeto**
- **Processo de monitorização e avaliação da execução do projeto**
- **Avaliação no país de origem do projeto**
- **Projeto de interesse para o país sede da execução**
- **Impedir duplo-standard**
- **Políticas para lidar com potenciais conflitos de interesse**
- **Sanções para inadequações na submissão ou execução de projetos ou para fraudes**



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