RESEARCH ETHICS COMMITTEES IN ROMANIA

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Legal framework

**International**
- Helsinki Declaration
- Oviedo Convention
- EU directives

**National**
- Law 206/2004 on good conduct in scientific research, technological development and innovation
- Law 677/2001 on protection of personal data
- Guidelines for Good Practice in Research
- Code of Deontology of the Romanian College of Physicians
- Codes of ethics for various research fields
National Ethics Commission for Drug Studies

- Independent body

- Affiliated to the Ministry of Health

- Health care professionals & members who are not physicians- 6 physicians, 3 pharmacists, 1 priest, 1 jurist, 1 representative of the patients

Mission → to protect the rights, safety and comfort of the participants in clinical trials

- Analysis of the study protocol, investigators’ abilities and the suitability of the research facilities

- Analysis of the methods and documents which are used to inform the study participants in order to obtain their informed consent
Institutional Ethics Commissions

- Independent bodies

- Main task → to safeguard the rights, safety and comfort of the participants in the clinical trials

- Membership → an adequate number of members who have the necessary qualification and experience for evaluating the scientific, medical and ethical aspects of the studies

Recommendations:
- At least 5 members
- At least one of the members without scientific background
- At least one independent member

- Only the members who are independent from the investigator or sponsor may vote
Procedure

- Phase I-III clinical trials → local EC and the National Ethics Committee (NEC) → 30-40 days.

- Phase IV clinical trials → approved by the local Institutional Ethics Commission & notification to the NDA

- The clinical trials can be conducted only in the institutions authorized by the Ministry of Health
  - Authorization has to be renewed every 2 years
  - Institutional ethics commission is mandatory
Procedure

- The sponsor must provide to the ECs and NDA:
  - informed consent form & information to be provided to the participants - written in Romanian or bilingual;
  - conventions regarding the compensation of the subjects if they will suffer damages because of the study;

Specialists from other fields of science can be invited to the meetings of the EC according to the studies under evaluation

On-going evaluation of the approved studies according to the risks to the participants - at least once a year.

The relevant written documents must be stored for 3 years after the closure of the study.
National Ethics Council for Scientific Research, Technological Development and Innovation - National Ethics Council

- Consultative body
- Affiliated to the Ministry of Education and Research
- 11 members – a 4 years mandate
  - persons with a prestigious scientific activity, specialists in the juridical field and specialists in research ethics.
  - from Romania or abroad
- Mission → coordination and monitoring the application of the norms of moral and professional conduct in research and development activities.
National Ethics Council

- Elaboration of the Codes of Ethics for various research fields
- Monitoring the application of the requirements of the Codes of Ethics
- Evaluation of the research-development projects, research centers, researchers
- Opinions about the ethical issues raised by the evolution of science
- Analyzing the violation of the norms of good conduct in research → sanctions
- Possible → temporary or permanent working groups
Ethics Commissions

- Set up in the institutions in which research activity is performed
- Affiliated to the scientific council or administrative council of the institution
- Membership – proposed by the scientific/administrative councils- approved by the manager of the institution
- Tasks
  → To monitor the application of the code of ethics requirements
  → To investigate cases of violation of the ethical rules
Stem cells research/therapy

- 2007- controversial, not usual therapies
- High risk for violation of the ethical rules in research
- The approval should be obtained from
  - The Ministry of Health
  - The Bioethics Commission of the Ministry of Health
  - National Transplant Agency
  - The Bioethics Commission of the Romanian College of Physicians- multi-centric studies (non-clinical)
Critical issues

- No figures about the number, structure and activity of the Institutional Ethics Commissions

- No central system to reporting misconduct in research

- Lack of training in research ethics for the members of the RECs → members of the ethics commissions- personalities in their activity fields

- Lack of the networking- networking understood as control