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

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- 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 of 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

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- High risk for violation of the ethical rules in research

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- 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