

NATIONAL NETWORK OF RESEARCH ETHIC'S COMMITTEES IN BULGARIA

LEGAL BASIS

Drug law

Ethics Committees

Art. 103. (1) **Ethics Committee for multicentre clinical trials** is established to the **Minister of Health**. Its the composition is determined by an order of the Minister=

(2) **Ethics committees** are established to the **hospitals** where clinical trials are to be conducted. Their composition is determined by an order of the manager of the hospital.

(3) The Bulgarian Drug Agency (BDA) keeps a register of the ethics committees.

(4) The register of the hospital ethics committees have been published on the internet site of the BDA.

Art. 104. (1) The committees according to Art. 103 para 1 and 2 are composed of 7 to 12 persons with qualification and experience to review and assess the scientific, medical, and ethic aspects of the proposed clinical test.

(2) The committees according to para 1 include at least two persons of non-medical education, representatives of both genders, who are financially and administratively independent of the healthcare establishment where the clinical test is to be conducted.

(3) The committees according to para 1 can involve external specialists for the needs of their work.

(4) In clinical trials in minor or underage persons the respective ethics committee at the healthcare establishment can involve external experts in order to facilitate its work.

Art. 105. (1) The mandate of the ethics committee members has duration of 4 years.

(2) One half of the composition of the ethics committees determined by lot is to be renewed every 2 years.

(3) A member of an ethics committee cannot be appointed in the same committee for more than two consecutive mandates.

Art. 106. (1) The ethics committees according to Art. 103, para 1 and 2, draw written standard operating procedures according to the rules for Good Clinical Practice and thus determine the conditions and order for their work.

(2) The standard operating procedures of the ethics committees are approved by the executive director of the BDA.

(3) The sessions of the ethics committees are not open to public. In case of necessity, the chairman of the ethics committee can invite the contractor or the principal researcher to participate.

(4) Only members of ethics committees who do not participate in a particular clinical trial and are administratively and financially independent of the contracting authority and the principal researcher can vote and participate in the discussion.

(5) To certify the circumstances according to para 4, the members of the ethics committees are signing declaration for conflict of interests.

The ethics commission for multi-central trials gives opinion on drug trials with people and clinical trials with medical devices according the standard operating procedures. The activity of the commission is directed to protect the rights, safety and welfare of all participants in the clinical trials. Special attention is paid to the vulnerable groups of patients, participating in the trials.

Art. 107. (1) **Central Ethics Committee** is established to the **Council of Ministers**.

(2) The Central Ethics Committee consists of 9 members, representatives of both genders and shall obligatorily include medical doctors, doctors of dental medicine, a psychologist, a theologian, and a lawyer.

(3) The composition of the committee is determined by a decision of the Council of Ministers according to a proposal of the Minister of Health for a period of 4 years.

(4) The Central Ethics Committee provides opinions on deontological and ethics issues in the field of clinical trials where it is approached by the ethics committees according to Art. 103, para 1 and 2, the BDA, or by contracting authorities.

(5) The Central Ethics Committee carries out the methodical guidance in respect to the ethics committees according to Art. 103, para 1 and 2.

(6) The sessions of the Central Ethics Committee are not open to public. In case of necessity, the chairman of the Central Ethics Committee can invite the contractor or the principal researcher to participate.

(7) The conditions and order for the work of the Central Ethics Committee are determined by a regulation of the Council of Ministers, according to a proposal of the Minister of Health

Art. 108. (1) A member of the Central Ethics Committee cannot be appointed in the same committee for more than two consecutive mandates. The duration of a mandate is 4 years.

(2) Half of the composition of the Central Ethics Committee is to be renewed every 2 years.

Law on medical devices.

Section II.

Clinical Trial Authorizations

Art. 45. (1) Clinical trials of implantable medical devices and invasive medical devices for long-term use medical devices which take place on the territory of the Republic of Bulgaria can start upon receiving a positive stand of the Multi-centre Research Ethics Committee or the ethics committee at the respective medical establishment, and an authorization by the Executive Director of the Bulgarian Drug Agency (BDA).

(2) Clinical trials of other medical devices which take place on the territory of the Republic of Bulgaria can start upon notification to the Executive Director of BDA, if the relevant ethics committee under para 1 has given a favourable opinion.

(3) The provisions of para 1 and para 2 shall also apply to medical devices with applied "CE" marking in case the clinical trials are conducted with the purpose of change in their intended purpose.

Art. 46. The contractor or the principal/coordinating investigator can submit an application form for notification or authorization for conducting a clinical trial to the relevant ethics committee and to BDA simultaneously or consequently.

Art. 47. (1) In the case of multi-centre clinical trial on the territory of the Republic of Bulgaria persons as per Art. 46 submit an application form to the Multi-centre Research Ethics Committee.

(2) In the case of one-site clinical trial on the territory of the Republic of Bulgaria persons referred to in Art. 46 submit an application form to the Multi-centre Research Ethics Committee or to the ethics committee at the respective medical establishment.

Art. 48. (1) In order to obtain a stand by the relevant ethics committee, the principal, respectively the coordinating investigator or the assigner, shall provide:

1. administrative documentation;
2. information about the subject;
3. documents related to the study plan;
4. documentation on the medical device being investigated;
5. documents related to the technical specifications of the medical establishment and qualifications of the personnel;
6. information about the financing source and trial administrative organization.

(2) The contents of documentation under para 1 is determined in an ordinance of the Minister of Health.

(3) Where the ethics committee establishes that documentation under para 1 is incomplete it shall notify the applicant within 14 days and shall fix a deadline for completing the documentation.

(4) Within 30 days after submission of the valid documentation the ethics committee passes a stand which shall be presented to the applicant and BDA.

Art. 49. (1) If the opinion of the ethics committee as per Art. 48 is negative, the applicant can appeal before the Central Ethics Committee established under the Law on Medicinal Products in Human Medicine (Drug law) within 14 days from the date of notification.

(2) The Central Ethics Committee passes a stand within 14 days from the receipt date of the written request by the applicant.

(3) The decision of the Central Ethics Committee is final and binding on the respective ethics committee.

Central Ethics Committee to the Council of Ministers.

Provides opinions on deontological and ethics issues in the field of clinical trials where it is approached by the ethics committees.

Ethics Committee for multicentre clinical trials to the Minister of Health.

Provides opinions on clinical trials.

5 RECs at the Medical Universities

Prior evaluation on medical research projects

20 RECs at the University Hospitals

Prior evaluation on medical research projects

27 RECs at the Regional Hospitals

Prior evaluation on medical research projects

NETWORKING BETWEEN RECs

Training of the members

Basic training for the members of the Ethics commission for multi-centre trials is held on the **legal instruments**: The Drag law – chapter IV Clinical trials; The law on medical devices; Regulations on the good clinical practice; The Hesinki Declaration; The EU Directives 2001/20/ and 2005/28/ on the good clinical practice; The leading principles of the European community on drugs;

Continuing training: Annual training course is organized by BDA for the members of RECs .

Seminars and local meetings are organized on relevant subjects and practical issues.