



Developing the System of Ethical Review of Biomedical Research in Lithuania

dr. Asta Čekanauskaitė
Lithuanian Bioethics Committee /
Vilnius University Medical Faculty

Content of the presentation

- Emergence of the system of ethical review
- Legal framework
- Institutions
 - Lithuanian Bioethics Committee
 - Regional biomedical research ethics committees

Steps of developing ethical review of biomedical research

- **Late 80s/early 90s:** started from two IRBs at two largest medical schools
- The main impetus – international collaboration of researchers / funding
- 1994: The Law on Health Care System
 - LBC - the only institution authorized to issue approval
- 2001: The Law on Ethics of Biomedical Research
 - two tier review system: national+regional RECs

The Law on Ethics of Biomedical Research: Scope

„Biomedical research means verification of hypotheses of biomedical sciences by means of methods of scientific research pursuing the aim of developing scientific knowledge about human health, diseases, diagnosis, medical treatment or prevention thereof“

- **Biomedical research may be undertaken on**
- living or deceased human subjects or their groups
- a human biological sample / health information
- a human embryo, a human fetus

The Law on Ethics of Biomedical Research: Content

The law covers:

- Ethical requirements for biomedical research
- Vulnerable subjects and protection of their interests
- Informed consent
- Confidentiality
- Compensation for Costs (for research participants)
- Requirements for the investigator
- Civil liability and insurance
- Authorisation and monitoring of the conduct of biomedical research
- Procedure for Examining Complaints
- Terms of biobanking activity

Amendments to the Law on Ethics of Biomedical Research (2004; 2007; 2011; 2016; 2017; 2019)

2004: implementation of the Directive on Clinical Trials

- changes in the procedure of issuing approval for CDT (approval by SMCA, favourable opinion of LBC)
- harmonization of standards across the EU

2016: new version of the Law on Ethics of Biomedical Research

- biobanks
- research with persons unable to consent (finally permitted!)
- emergency research

2017 implementation of the EU regulations (CDT; Medical Devices)

- changes in the procedure of issuing approvals
- centralized assessment procedure; harmonization of standards across the EU

A number of by-laws and soft law



The screenshot shows the website of the Lithuanian Bioethics Committee (Lietuvos bioetikos komitetas). The header includes the committee's name and logo. A navigation menu on the left lists categories such as 'ABOUT US', 'LEGAL DOCUMENTS', 'BIOMEDICAL RESEARCH', 'PROJECTS AND NETWORKING', 'EVENTS', 'ETHICAL ISSUES', 'PUBLICATIONS', 'NEWS', and 'LINKS'. The main content area is titled 'REGULATIONS ON BIOMEDICAL RESEARCH' and lists several international documents and legal acts applicable to biomedical research. The list includes:

- International documents legally binding in Lithuania
 - Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use
 - Commission Directive 2005/28/EC of 8 April 2005 laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorisation of the manufacturing or importation of such products
 - Convention of the Council of Europe for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine
- Legal acts applicable to all types of biomedical research
 - a) Laws
 - Law on Ethics of Biomedical Research (2008, last amended in 2016) (available in English)
 - Law on Legal Protection of Personal Data (1996, last amended in 2017) (available only in Lithuanian)
 - b) Decrees of the Ministry of Health (MCH)
 - Decree on the Composition of the Group of Biomedical Research Experts of the Lithuanian Bioethics, No. V-1483 (2014) (available only in Lithuanian)
 - Decree on the Detailed Requirements for the Content of a Person's Consent to Participate in Biomedical Research and for the Information about the Biomedical Research as well as a Procedure for Giving and Withdrawing the Consent, No. V-28 (2016) (available only in Lithuanian)
 - Decree on the List of Interventional Methods of Biomedical Research Causing a Slightly Detrimental and Temporary Impact on the Subjects Health, No. V-1480 (2014) (available only in Lithuanian)
 - Decree on the Rules of Compulsory Civil Liability Insurance for the Principal Investigator and the Sponsor No. 745 (2000, last amended in 2016) (available only in Lithuanian)
 - Decree on the Procedure for Calculating and Paying Compensation for the Expenses Incurred Due to Participation in Biomedical Research and the Time Spent, No. V-15 (2016) (available only in Lithuanian)
 - Decree of Ministry of Health and Ministry of Social Affairs on the Procedure for a Minor's Participation in Biomedical Research, No. V-233/A1-83 (2010) (available only in Lithuanian)
 - Decree on the Procedure for Keeping a Record of Biomedical Research, Collecting, Storage and Providing Information on Biomedical Research, No. V-405 (2010) (available only in Lithuanian)
 - Decree on the Territories Assigned to the Jurisdiction of the Regional Biomedical Research Ethics Committees, No. V-1076 (2007) (available only in Lithuanian)

- Decrees of the Ministry of Health
- Orders of the Lithuanian Bioethics Committee
- Guidelines and recommendations of the Lithuanian Bioethics Committee

Lithuanian Bioethics Committee

A governmental institution
accountable to the MoH

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- Mission:

To issue approvals and monitoring the ongoing research

- To discuss, consult and inform about the broad scope of bioethical issues
- Our target audience - biomedical community, general public, government, politicians, media

The main functions of the Lithuanian Bioethics Committee



Ethical review of biomedical research



Coordination of the activities of regional RECs



Consultation on bioethical issues (incl. drafting guidelines, recommendations)

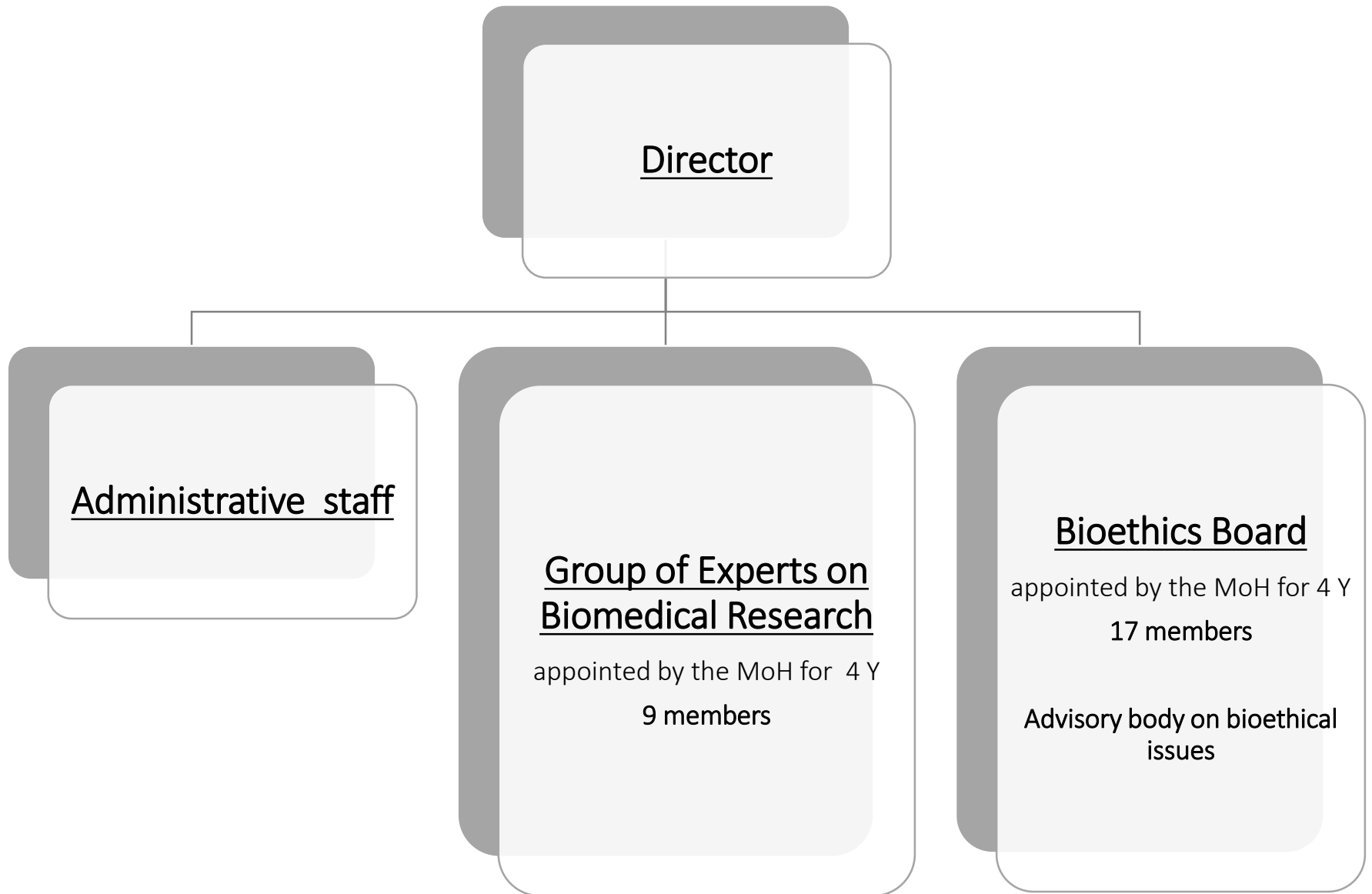


Assistance for Hospital Ethics Commissions



Representation at international organisations

The structure of LBC



Regional biomedical research ethics committees

- Two regional committees:
 - Vilnius university (2008)
 - Lithuanian University of Health Sciences (2001)
- Regional biomedical research ethics committees shall be established under universities offering three-cycle medical studies (Art 22)
- Funded from the state budget

Other functions of RECs

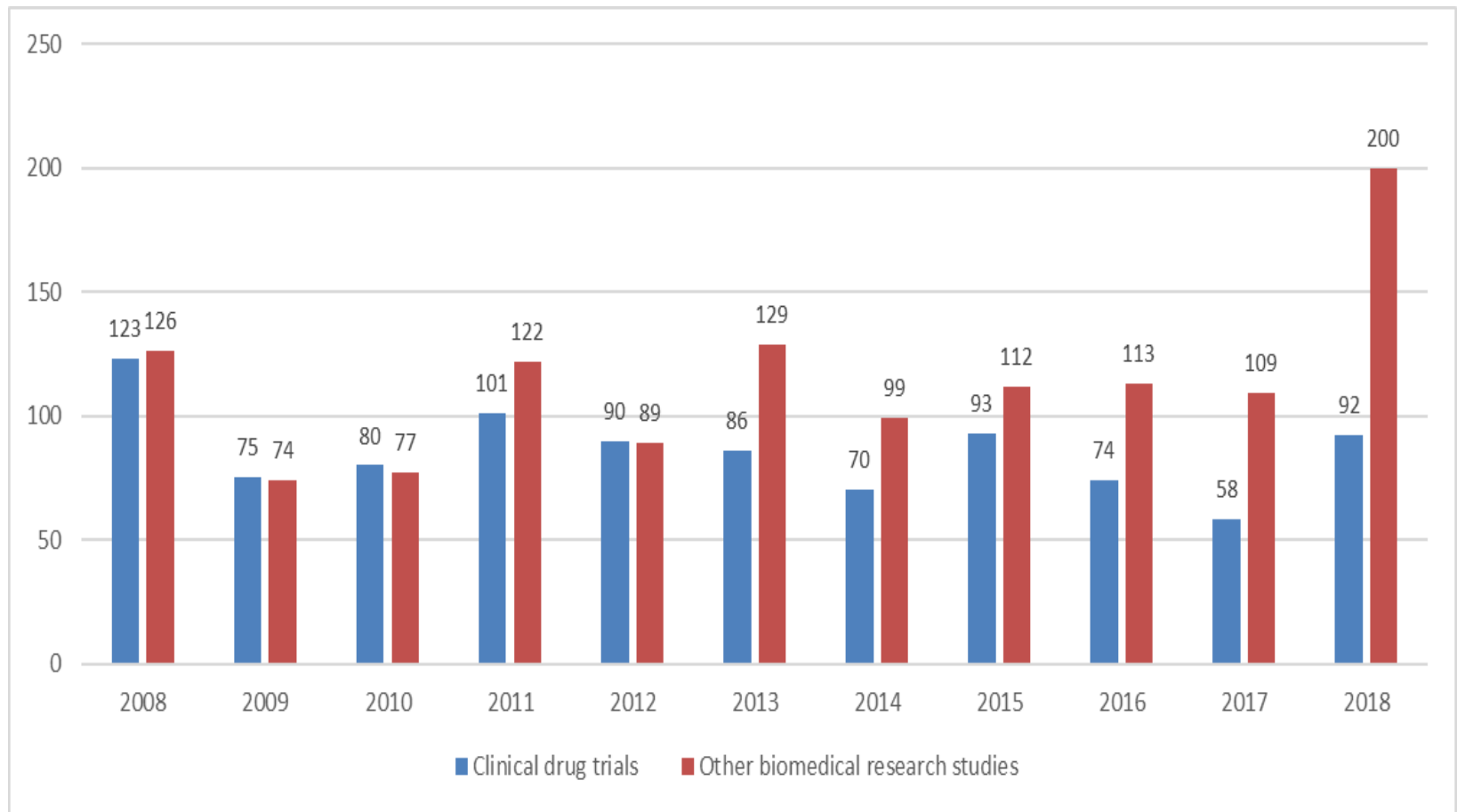
Monitoring of ongoing research studies

- Review of the amendments
- Review of safety information
- Planned/unplanned inspections

Consultation service for researchers / sponsors

Training for researchers

Number of CDTs and other biomedical research studies (2008-2018)



Addressing the need for ethical reflection in other fields of research

- Biomedical research is the only field of research legally regulated and required to undergo ethical assessment
- Only very general guidelines for other fields of research (e.g., codes of academic ethics)
- Guidelines usually do not address ethical issues specifically related to participation of human subjects
- LBC Draft Guidelines „Ethical principles in non-biomedical research“
 - Urges to assess the need for ethical review
 - Explains why ethical reflection is relevant also in non-biomedical research
 - Provides with the principles to be followed



The screenshot shows the website for the Lithuanian Bioethics Committee. At the top left is the Lithuanian coat of arms, followed by the text "Lietuvos bioetikos komitetas" and "Lithuanian Bioethics Committee". At the top right is the LBK logo, which features a chalice with a cross and the letters "LBK" on a banner. Below the header is a navigation menu with links for "Home", "Site map", and "Lietuviškai". A sidebar on the left contains a list of menu items: "ABOUT US", "LEGAL DOCUMENTS", "BIOMEDICAL RESEARCH", "PROJECTS AND NETWORKING", "EVENTS", "ETHICAL ISSUES", "PUBLICATIONS", "NEWS", and "LINKS". Below the sidebar is a search box with the text "Search in Site:" and a "Search" button. There is also a "Subscribe news" section with a text input field for "Your email address" and a submit button. The main content area on the right is titled "About Us" and contains several paragraphs of text describing the committee's mission, activities, and structure. The text is partially cut off at the bottom.

Home » Site map » Lietuviškai »

- » ABOUT US
- » LEGAL DOCUMENTS
- » BIOMEDICAL RESEARCH
- » PROJECTS AND NETWORKING
- » EVENTS
- » ETHICAL ISSUES
- » PUBLICATIONS
- » NEWS
- » LINKS

Search in Site:

Word input

» **Subscribe news**

Your email address

About Us

Lithuanian Bioethics Committee is a governmental institution, which aims to promote and protect human rights and dignity in the field of healthcare. The Committee was established in 1995 following the provisions of the Law on Health Care System. It has been founded and its Statute approved by the Ministry of Health.

Taking into account limited resources available to deal with bioethical issues in the country, the Lithuanian Bioethics Committee takes responsibility for the two broad areas of activities:

- To inform biomedical community and general public on ethical issues and moral dilemmas arising in the context of modern health care.
- To facilitate the protection of patients' rights in the field of biomedical research and to coordinate the ethical review of biomedical research projects in Lithuania.

The Lithuanian Bioethics Committee provides methodological support for the regional research ethics committees as well as for the hospital ethics committees. The Committee is also involved in organizing workshops and conferences as well as translating, publishing and disseminating materials on biomedical ethics within the biomedical community and the broader society.

The institution consists of the administrative staff and two boards of experts, namely, the Group of Experts of Biomedical Research and the Bioethics Board. The Committee is managed by the [Director](#).

The mandate of the Group of Experts on Biomedical Research is to conduct a multidisciplinary review and to issue approvals for biomedical research projects, including clinical drug trials. The Group consists of 9 members (5 professionals of biomedical sciences, 4 professionals holding a degree in the area of social sciences or humanities) appointed by the Minister of Health for four years time period for the term from 2014 to 2018. It should, however, be noted that the approvals to conduct biomedical research