Developing the System of Ethical Review of Biomedical Research in Lithuania

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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

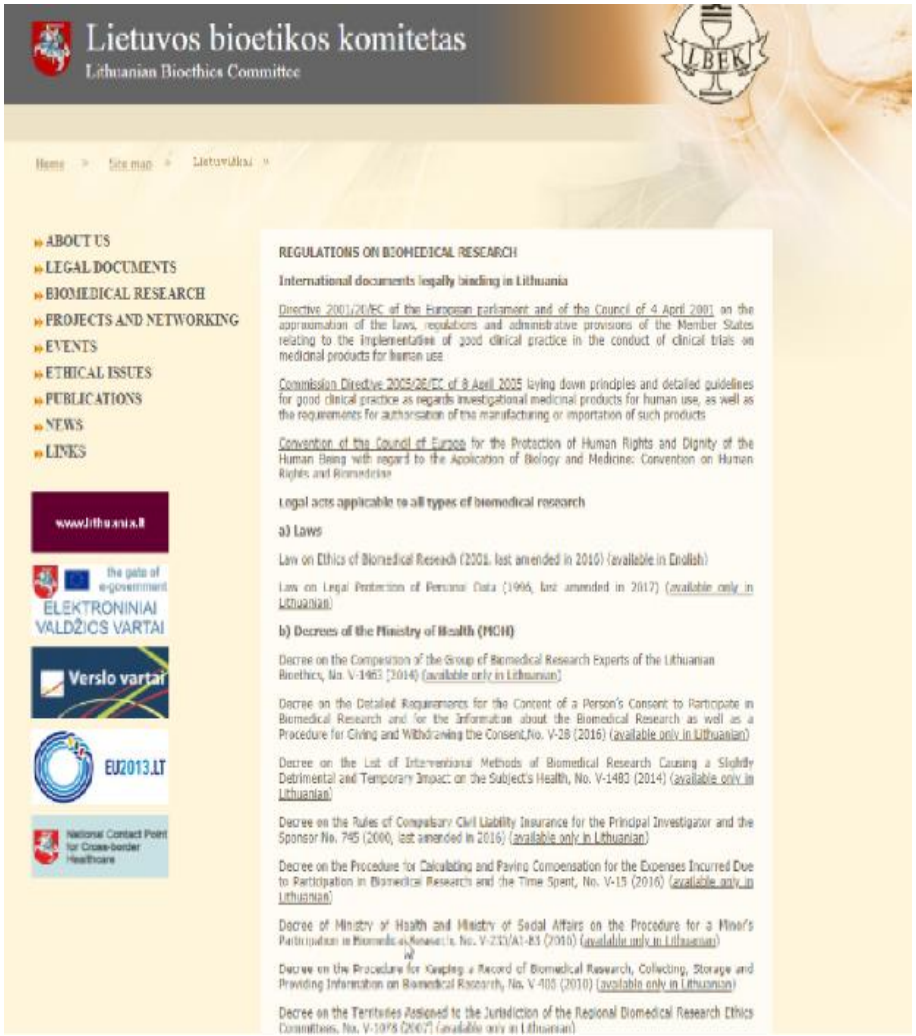
The law covers:

- 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



- 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

- Mission:

To issue approvals and monitoring the ongoing research

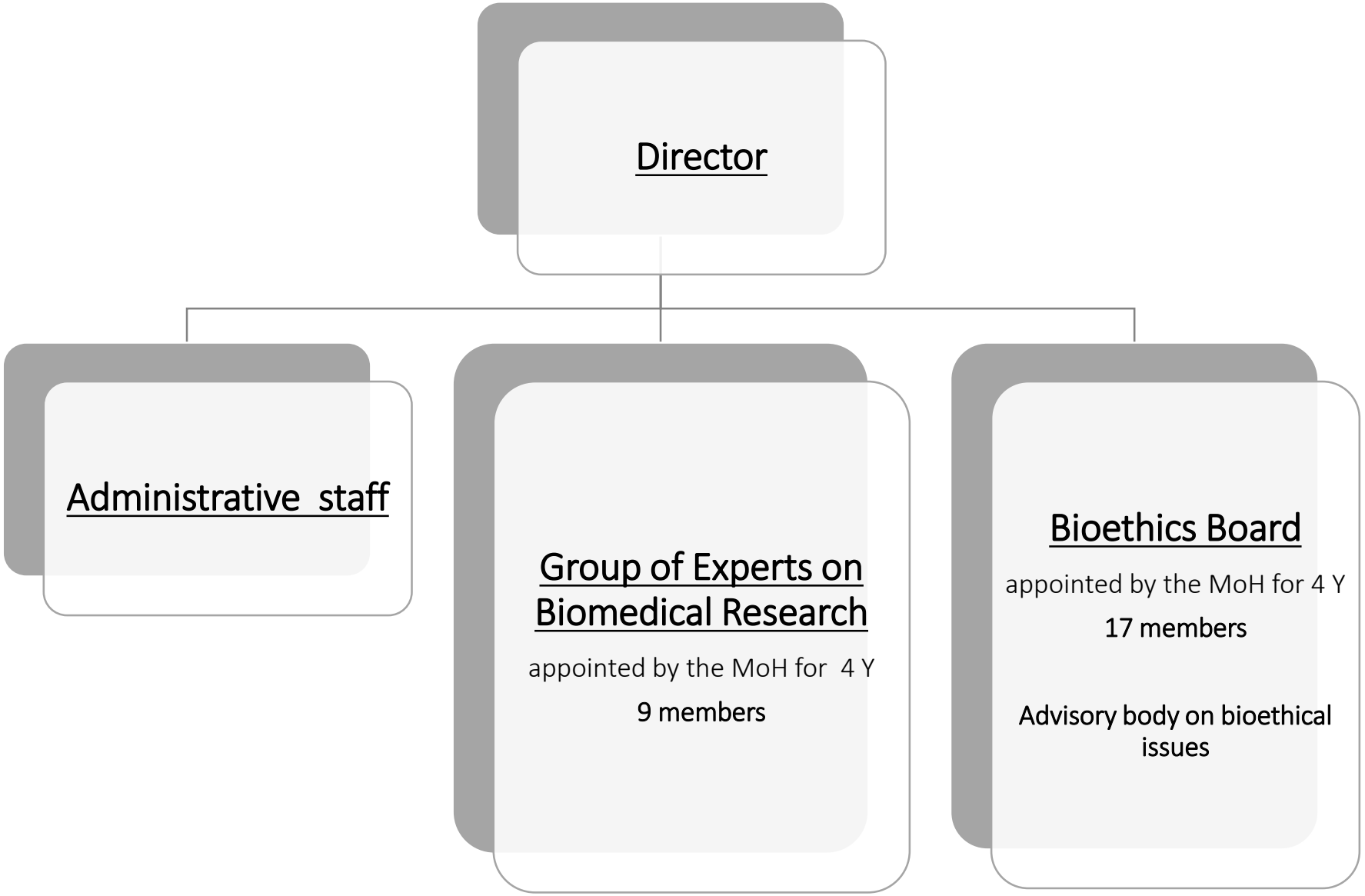
- To discuss, consult and inform about the broad scope of bioethical issues

- 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

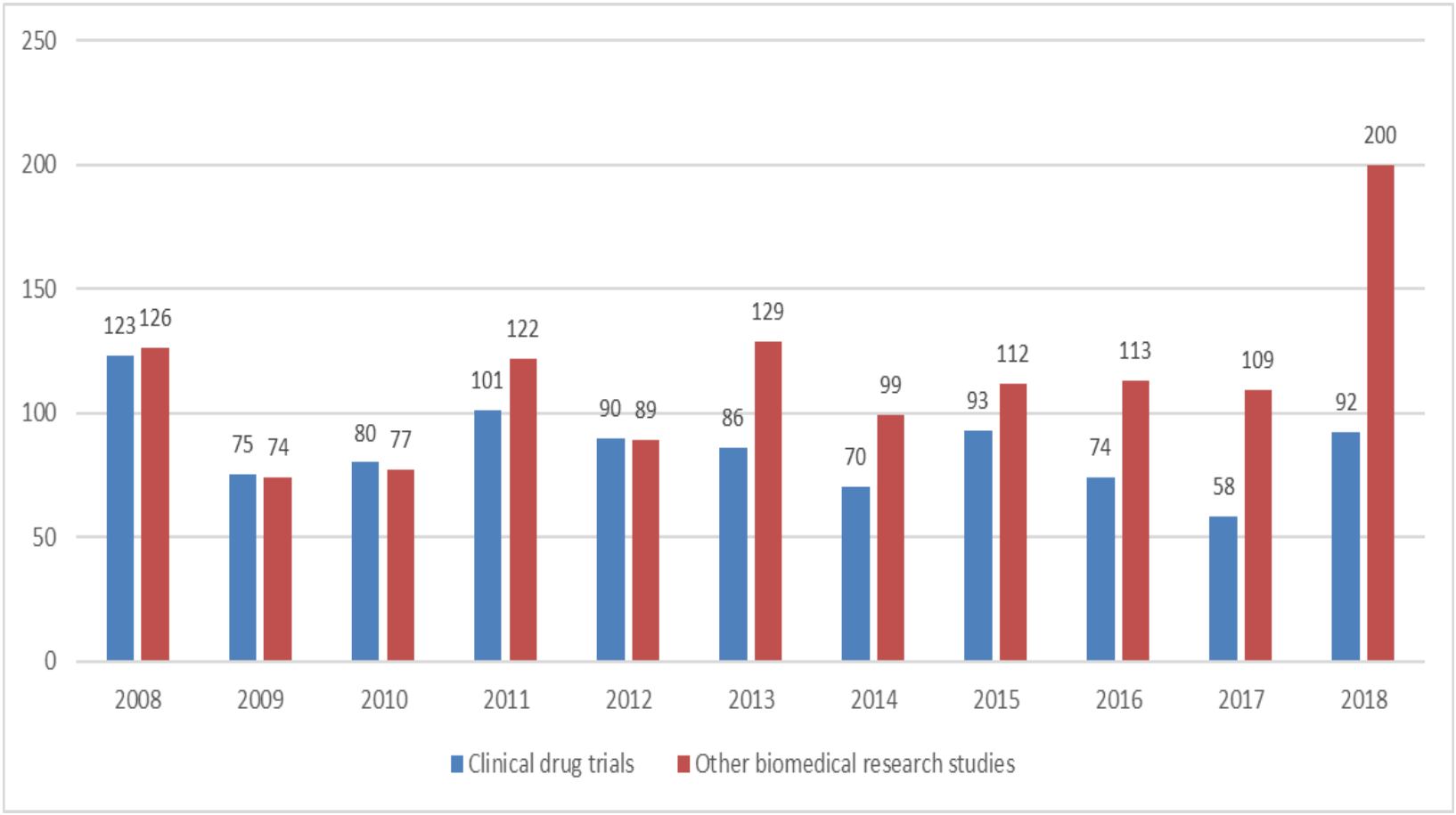
Monitoring of ongoing research studies

- 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

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