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

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

<table>
<thead>
<tr>
<th>Function</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethical review of biomedical research</td>
</tr>
<tr>
<td>Coordination of the activities of regional RECs</td>
</tr>
<tr>
<td>Consultation on bioethical issues (incl. drafting guidelines, recommendations)</td>
</tr>
<tr>
<td>Assistance for Hospital Ethics Commissions</td>
</tr>
<tr>
<td>Representation at international organisations</td>
</tr>
</tbody>
</table>
The structure of LBC

Director

Administrative staff

Group of Experts on Biomedical Research
appointed by the MoH for 4 Y
9 members

Bioethics Board
appointed by the MoH for 4 Y
17 members
Advisory body on bioethical issues
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)
• 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
Lietuvos bioetikos komitetas
Lithuanian Bioethics Committee

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 1993 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 approval to conduct biomedical research.

asta.cekanauskaite@bioetika.sam.lt

dr. Asta Čekanauskaitė, 2019-06-26