Ethical review of biomedical research in the Baltic States

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Structure of the presentation

- Historical notes and overview of the Baltic RECs
- Areas of concern in the emerging systems of ethical review
- Concluding remarks: networking of RECs

Diversity of RECs' systems in the Baltic states

- The first RECs have been relatively recently established in CEE:
  - Nordic countries: 1970s
  - Baltic states: late 1980s
- Lithuania – 2-tier system of ethical review of multicenter protocols: 1 National Committee plus two regional RECs
- Latvia - 7 RECs; the National Committee only takes specific projects
- Estonia – 2 RECs based at the universities, National Committee is not involved in ethical review

Estonian RECs

- Membership and composition defined in the Statute of the University (two RECs – in Tallinn and Tartu)
- Statute of the Tartu University REC:
  - at least 13 members
  - "the Committee shall consist of persons representing **various different fields** of life with the preparation in the specialties of biomedicine as well as in other specialties. Each member of the Committee shall be a **recognized specialist in his or her field with the necessary expertise** to perform the duties of a member of the committee and shall have an impeccable reputation"
- Fee of 383 Euro
- Tartu and Tallinn RECs exchange information about the applications submitted – RECs "shopping" avoided
- Source of information:
  http://www.eurecnet.org/information/estonia.html

Latvian RECs

- Central Medical Ethics Committee reviews only some types of research (e.g., related to National Genome studies)
- At least 7 RECs (all in the capital city Riga) have been identified:
  - 3 RECs for clinical drug trials,
  - 4 RECs for other types of biomedical research,
  - 1 REC – both types

- Geographical regions are not defined – RECs "shopping" not excluded
- Some of the RECs take fees
- It is not clear if all the RECs have statutes

- Source of information:
  - http://www.eurecnet.org/information/latvia.html
  - http://bioethics.lv/en/
  - Dranseika et al, 2010

Lithuanian RECs I

- Lithuanian Bioethics Committee - Group of Experts of Biomedical Research:
  - issues approvals for "multi-regional" biomedical research projects.
  - a favorable/ "single opinion" for all clinical drug trials conducted in the country.
- Specific legislation on RECs and ethical review
- LBC also acts as an appeal body for regional RECs
- State tax (not a fee paid to the REC's insttution) for the ethical review
- Source of information:
  - http://www.eurecnet.org/information/lithuania.html
  - http://bioetika.sam.lt/

Lithuanian RECs II

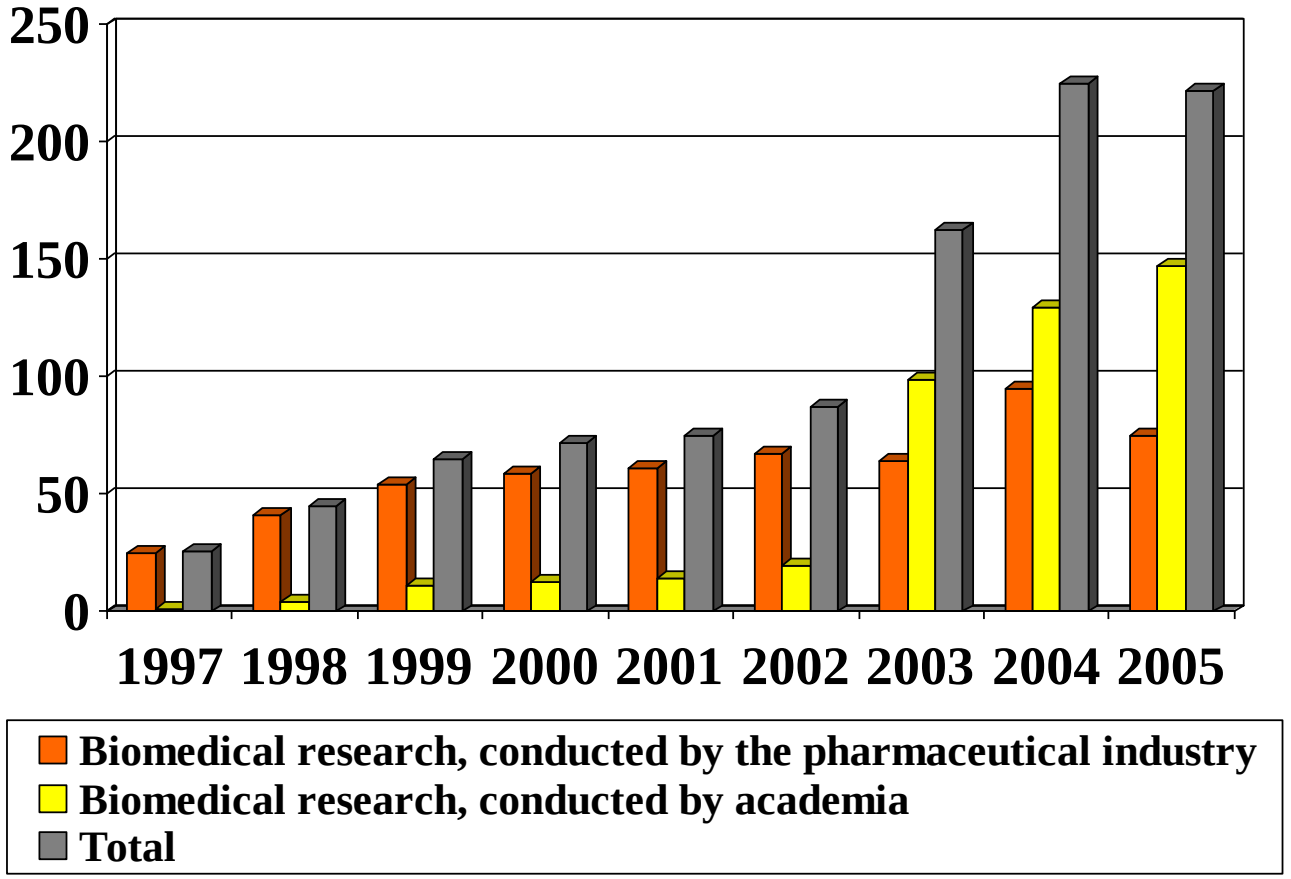
- 2 regional RECs (in Vilnius and Kaunas) are based at the Universities with the tertiary medical education level
- 2 Regions cover the whole country
  - opinions on clinical drug trials
  - ethical review of all other biomedical research carried on in the region
- Composition defined in the Law:
  - 9 members:
    - 1 member representing patients' organization
    - 4 degree-holding representatives of the respective university (2MDs, 2 Social sciences/humanities),
    - 4 members nominated by the Ministry of Health (3MDs, 1 social sciences/humanities) and.

Steps of developming RECs system in Lithuania (population 3,2 mln)

- **Late eighties/early nineties**: "***Pre-legal state***" - Started from two IRBs at two largest medical schools;
- **1997**: a special *Decree of the MoH on the ethical expertise of biomedical research* - LBEC is the only institution authorized to issue ***approvals upon the recommendation of the SDCA***)
- **2001**: The Law on Ethics of Biomedical Research - ***two tier system*** (national+regional RECs);
- **2004**: Amendments of the Law EBR (***changes of the procedure - approval by SDCA, favourable opinion of REC***)
- **2007**: Amendments of the Law on EBR (***changes of the regulation of regional RECs***)

Dynamics of commercial/non-commercial research reviewed by RECs in Lithuania (1997-2005)

http://archive.eurecnet.org/information/lithuania.html



Areas of concern

- Difficulties to collect information about
  - RECs functioning
  - Number of protocols reviewed/rejected
  - Fees taken, remuneration of the members, etc.

- RECs
  - Institutional vs regional RECs
  - Problematic process of ethical review (emphasis on IC, monitoring of AE, etc.)
- Structural
  - Non-equivalence of ethical review

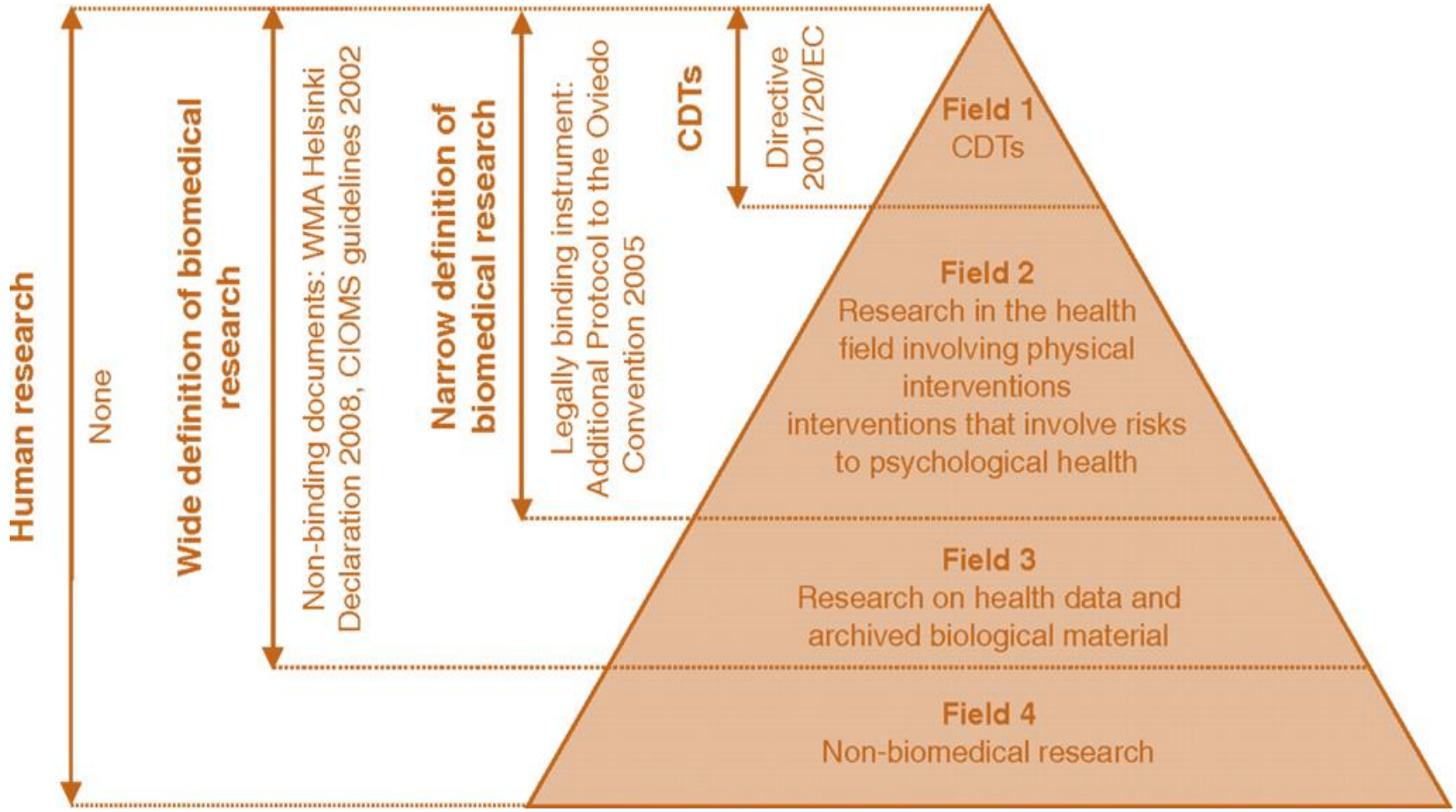
Availability of information

- Baltic states
  - Overview of the Baltic RECs (Dranseika et al., 2010):
    - Very few websites
    - information on statutes, procedures, composition, protocols reviewed not publicly available
    - Sometimes information is not even given if the institution is contacted directly
  - However, few recent improvements:
    - Tartu University REC website (in both Estonian and English)
    - Lithuanian Bioethics Committee

RECs: Problematic points

- "Regional" or institutional?
  - How to establish de facto independent system of ethical review?
  - Is the regional model feasable in the context of weak municipal health services?
- Procedure of ethical review
  - emphasis on "procedure rather than ethics" (N.Goodman, Chair of Southmead LREC, UK, 2004)
  - Emphasis on IC, methodology of biomedical research/clinical trials is not always critically evaluated
  - How efficient is monitoring of ongoing research: safety information collected (e.g., piles of adverse events reports…)?
  - Clinical drug trials: how to achieve an efficient collaboration between RECs and competent authorities?

Types of human research and international regulatory framework.



Gefenas E et al. J Med Ethics 2010;36:435-439

Non-equivalence or "Asymmetry" of ethical review in CEE

- Discrepancies between different regimes of ethical review applied to different types of human research
- Stringency of regulations decreases as we go from:
  - *Field I: clinical drug trials:* double control, legally binding provisions of ethical review;
  - to *Field II: other types of biomedical research* (e.g., as defined by theAP to the Oviedo Convention): usually only regulated by the statutes of RECs, IRBs
  - to *Field III:* research on personal data (medical files), biological materials: very diverse regulations
  - to *Field IV: non-biomedical human research - no binding instruments: very often out of the scope of ethical review*

Networking as the way forward: Eurecnet

http://www.eurecnet.org/index.html

- fostering a sustainable infrastructure for European RECs
  - **gathering information on RECs** in Europe to build a basis for mutual exchange
  - collecting and evaluating **training materials** for REC members
  - conducting capacity building to facilitate the development of **national REC networks**
  - identifying **emerging ethical issues** to develop common solutions for challenges posed by new technologies and scientific methodologies.