Ethical review of biomedical research in the Baltic States

E. Gefenas, MD, PhD, Chair of the CDBI
Vilnius University, Lithuanian Bioethics Committee
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
  – 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 institution) 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 developing 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

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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 feasible 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.

Field 1
CDTs

Field 2
Research in the health field involving physical interventions interventions that involve risks to psychological health

Field 3
Research on health data and archived biological material

Field 4
Non-biomedical research


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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 the AP 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.