Newsletter 2011/1
http://www.eurecnet.org/newsletter

Content

Editorial

The EUREC secretariat is located at the German Reference Centre for Ethics in the Life Sciences (DRZE), which is a central institution of the University of Bonn. The secretariat acts as the responsible coordinator for the EURECNET project which started in March 2011. It is based on the results of a previous project EUREC (2006 – 2010) coordinated by the University of Lyon and will continue its networking process.

Apart from coordinating the overall project and managing the communication of the project partners with the European Commission it is responsible for providing the project's interim and final results to the public, e.g. by circulating an Electronic Newsletter

Article

EUREC
A European Representation of National Networks of Research Ethics Committees

by Elmar Doppelfeld

Just like other kinds of research, medical research is increasingly often carried out in transnational settings today. As part of this process the aims and methods of medical research became widely standardized, especially during the last decade. This applies not least to clinical trials aiming at the development of new drugs and medicinal products. Nowadays, the various players on international research are represented by various interests groups which act on the national, European and international level.

There is broad national as well as international consent that certain fundamental ethical principles must be observed in the conduct of medical research. These include the respect for self-determination, protection against harm as well as of discrimination and other forms of unfair treatment. The principles are implemented both into national laws and into non-binding provisions, so called 'soft laws'.

National authorities and in particular research ethics committees (RECs) are responsible for the adherence to these principles by a given research project. Their ability to fulfil this task can be challenged by difficulties linked to different religious and cultural traditions and the national legal system as well as prominent moral attitudes within the state or region where the research shall be conducted.

In order to harmonize clinical drug trials at least on a European level, the European Union has issued the Directive 2001/20/EC binding its 27 Member States. The Directive requires the establishment of national research ethics committees. Details of their functioning, their competences, their administrative position and regulation are left to the Member States and only a small number of common principles have been made compulsory. One such principle is that any kind of clinical drug trial needs the approval by the responsible research ethics committee. In addition the Directive enumerates the international broadly accepted ethical principles, such as the principles

mentioned above, as a fundamental requirement for any such approval.

The terms on which research ethics committees work on a national level differ considerably, for instance in terms of their responsibilities and institutional shape and affiliation. In some Member States research ethics committees are responsible for the assessment of the overall project, whereas in others they are only responsible for the assessment of specific parts of a project. In some Member States RECs are only entitled to assess specific areas of medical research, such as clinical drug trials or basic research, whereas in other Member States they are responsible for the assessment of all kinds of medical research.

There is even more variety in terms of their institutional shape and affiliations:

RECs may be linked to administrative bodies, to public health institutions, to faculties of medicine, to research institutions, to hospitals or, although rare, to medical associations.

In spite of this diversity there is considerable interest in the establishment of networks of research ethics committees – on a national as well as on an international, at least a European, level – as this may allow RECs to find common solutions for common problems and to enlarge their competence as dialogue partners in contact with the above mentioned organizations and institutions.

In some States networks already exist on a national level. A European network of research ethics committees, however, is still lacking. In order to fill this lacuna, the European Commission granted a three-year-project to build up such a network called EUREC, organized within the EC funded project EURECNET. Its central objective is the harmonization - not equalization – of REC's work and the formation and/or continued education of persons who are becoming or already are members of a REC.

EUREC brings together national REC associations, networks or comparable initiatives, the Forum of National Ethics Committees (NEC Forum), and other bodies relevant in this field and the European Commission's ethical review system. By doing so it helps forming the necessary but currently missing infrastructural basis to promote awareness of specific working practices of RECs across Europe, to enhance the shared knowledge base of European RECs, to support coherent reviews and the development of opinions, and to meet new challenges and emerging ethical issues. For further information click on: http://www.eurecnet.org

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EUREC – Project News

On 1 March 2011 the Kick-Off Meeting of the EURECNET project has taken place at the conference centre of the Rheinisches Landesmuseum in Bonn. The main objective of the meeting was to bring together all project partners in order to provide them with information about the details of the several working packages the project comprises and to discuss the further proceeding and strategic considerations necessary in order to set up EURECNET as a permanent platform for the networking of Research Ethics Committees (RECs) in Europe.

After a welcome note and a general introduction to the Kick-Off-Meeting by the coordinator of the EUREC Project, Dr. Dirk Lanzerath (DRZE), Dr. Lino Paula (Scientific Officer, European Commission, Directorate General for Research and Innovation) gave an overview on the project's concept, its history and aims. In this context he touched upon the historical milestones of research ethics committees (RECs), the need for European exchange, and hence for EUREC.

Dr. Lanzerath's and Dr. Paula's presentations were followed by presentations by Professor Dr. Elmar Doppelfeld (Permanent Working Party of Research Ethics Committees in Germany, Cologne), Professor David Townend (Care and Public Health Research Institute, Maastricht), Professor Dr. Dominique Sprumont (Université Neuchâtel - Institut de droit de la santé, Neuchâtel), Dr. Michael Bone (The Association of Research Ethics Committees Sunderland, Newcastle), Professor Dr. Eugenijus Gefenas (The Lithuanian Bioethics Committee, Vilnius) and Professor Dr. Knut Ruyter (National Committee for Medical and Health Care Research Ethics, Oslo) who are the leaders of the five main working packages of the EUREC Project.

Recent REC-related Publications by EUREC-Members

Doppelfeld, Elmar: Ethics committees for clinical research : the West-European paradigm, 2010. In: Ethics in psychiatry : European contributions / Hanfried Helmchen ; Norman Sartorius, eds. - Dordrecht [u.a.] : Springer, (2010). - (International library of ethics, law, and the new medicine ; 45). - ISBN 978-90-481-8720-1. - S. 97-107

Hinweise und Regeln der Max-Planck-Gesellschaft zum verantwortlichen Umgang mit Forschungsfreiheit und Forschungsrisiken, 2010. In: Jahrbuch für Wissenschaft und Ethik ; 15 / hrsg. von L. Honnefelder und D. Sturma. [Red.: Dietmar Hübner ; Michael Fuchs ; Luise Scholand]. - Berlin : de Gruyter, (2010). - ISBN 978-3-11-022289-0. - S. 347-356

Recent Publications of the Ethics Committee of the Medical University of Vienna:
http://ethikkommission.meduniwien.ac.at/ethik-kommission/wissenschaft-und-forschung/publikationen/

Upcoming Conferences

09/21/2011 **Forum Bioethik: Arzneimittelforschung mit Kindern - Ethisch geboten oder bedenklich?**
Forum, Berlin, Germany

09/30/2011 **Synthesis — Interdisciplinary Interconnections in Synthetic Biology**
Conference, Bielefeld, Germany

10/10/2011 **Does size matter? Ethical, societal, legal and biological aspects of large animals as biomedical models**
Freising/München, Germany

10/21/2011 **Transforming Human Nature**
Conference, Dublin, Ireland

10/27/2011 **SAKK Symposium State of the Art in Oncology Research - Ethical Considerations in Clinical Research**
Bern, Switzerland

10/28/2011 **Bucharest Conference in Applied Ethics - Ethical Aspects in Emerging Technologies**
Conference, Bukarest, Romania

11/23/2011 **Werkstatt Leben. Bedeutung der Synthetischen Biologie für Wissenschaft und Gesellschaft**
Conference, Mannheim, Germany

11/29/2011 **Ethical considerations for paediatric trials - how can Ethics Committees (ECs) in the European Member States and the Paediatric Committee (PDCO) at the European Medicines Agency work together?**
Workshop, London, United Kingdom

Your help is appreciated: to make sure that your events on research ethics in Europe appear early in our calendar please send your announcements to calendar@eurecnet.org

Acquisitions

Elger, Bernice S.: Research on prisoners: a comparison between the iom committee recommendations (2006) and european regulations. - Malden, MA: Blackwell Publishing, 2010. In: Bioethics (24)1, 1-13

Haynes, Richard: Animals in research, 10. In: Life science ethics / Gary L. Comstock, ed. - 2. ed. - Dordrecht [u.a.]: Springer, (2010). - ISBN 978-90-481-8791-1 - ISBN 978-90-481-8792-8., 267-285

Hossne, William Saad: Ethics of research involving human subjects: the Brazilian experience, 2010. In: Ibero-American bioethics : history and perspectives / Leo Pessini; Christian de Paul de Barchifontaine

Fernando Lolas Stepke, eds. - Dordrecht [u.a.]: Springer, (2010). - (Philosophy and Medicine; 106). Einheitssacht.: Bioética na Ibero-América: história e perspectivas . - ISBN 978-1-402-09349-4., 333-341

Kodama, Satoshi: Neither a "person" nor a "thing": the controversy concerning the moral and legal status of human embryos in Japan, 2010.In: Contested cells : global perspectives on the stem cell debate / eds. Benjamin J. Capps ; Alastair V. Campbell. - London [u.a.]: Imperial College Press, (2010). - ISBN 978-1-84816-437-6 - ISBN 1-84816-437-8. , 421-439

Silverstein, Jeffrey H.: Ethical function of human subjects review boards: a US perspective, 2011. In: Clinical ethics in anesthesiology: a case-based textbook / ed. by Gail A. Van Norman. Co-eds. Stephen Jackson

European Textbook on Ethics in Research. - Luxembourg: Publications Office of the European Union, 2010. - 203 S. - (Studies and reports)

National bioethics committees in action. - Paris: UNESCO, 2010, 115

Reviewing clinical trials: a guide for the ethics committee. - Hong Kong: Clinical Trials Centre, 2010, 153

(For further information please go to: http://www.drze.de/belit-1/search-2?set_language=en)