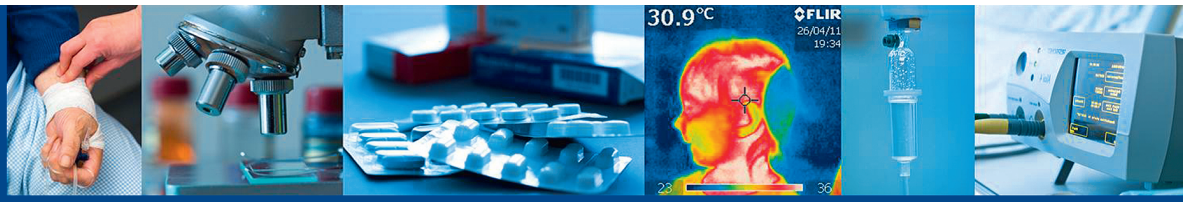

European Network of Research Ethics Committees

Capacity Building
Report on the Participation of New Partners of EUREC

One of the main objectives of the EURECNET project's Work-package 4 (WP4) was to promote capacity building in order to facilitate the development of national Research Ethics Committee (REC) networks. With regard to this objective, WP4 planned to identify the countries in which no network of RECs has been established. To achieve this, WP4 made the analysis of the European Union countries as well as two other countries represented in the EURECNET project (Norway and Switzerland) on what kind of well-functioning national REC network models already exist and where there is a lack of reliable information if the networking is functioning in practice and (or) the model of REC networking is unclear. As a result, 14 countries have been identified in the WP4 deliverables where national committees responsible for coordinating local (regional) RECs are established, but there is no reliable data if REC network is practically functioning and (or) REC networking model is unclear. That is Belgium, Bulgaria, Czech Republic, Estonia, Greece, Hungary, Italy, Latvia, Poland, Portugal, Romania, Slovakia, Slovenia, and Spain. After such countries were identified, WP4 contacted possible representatives from the mentioned countries and invited them to four EUREC conferences and meetings organized by the EURECNET project in Bratislava (12-13 April 2012), Oslo (6-7 September 2012), Lisbon (19-21 June 2013), Brussels (16 September 2013). One of the purposes of the mentioned meetings (conferences) was to establish closer relations with these countries and discuss the existing or planned networking activities (if any) between RECs in their countries. During these meetings (conferences) 8 out of 14 countries - Latvia, Slovakia, Bulgaria, Rumania, Czech Republic, Italy, Spain, Greece, and Hungary - presented their REC systems and their potential or existing network among themselves. As the next step, WP4 identified three countries – Slovakia, Czech Republic and Spain – which have functioning national REC networks. Countries like Latvia, Bulgaria, Romania, Greece and Hungary still are trying to clarify their national situation. Italy is invited to give a presentation in the closing meeting of EURECNET project that is held on August 25, 2014 in Berlin.

Discussion about the existing (or planned) networking activities and the identified problems (obstacles) in establishing and (or) promoting them led to the preparation of a Road-map for establishing national networks of RECs. The Road-map has specifically focused on the introduction to possible models of REC networking acquaintance with a good networking practice as well as some guidance how to develop the most suitable model of REC networking. Analysis of the situation in the 15 European countries with functioning REC networking allowed us to distinguish three types of national REC networks:

1. network with a central (national) ethics committee (vertical (top-down) structure);
2. network in a form of a national association of RECs, working group of RECs, forum of RECs or as an informal agreement among RECs (horizontal (bottom-up) structure);
3. 'mixed' network combining types 1) and 2) of national REC networks.

The Roadmap provides recommendations for the countries which intend to establish national REC networks. In particular, it suggests which networking model to select considering the existing REC system, the size of population and the advantages and disadvantages of each type of networking. The Road-map also emphasizes the importance to define minimal criteria of the REC networking. These criteria would provide content for the definition of the network in the EUREC statute („In order to become a Full Member, a network must evidence to the Board its claim to national representation"(para. 4). It seems that regardless of which REC network is chosen in the country, the representative of a national REC network could be a national organization that addresses questions of coordination and harmonization among RECs. Specifically the following functions assigned to the representative of national REC network are important:

- training of REC members (and secretariats)
- decision making policy (guidelines, SOP etc)
- quality assurance system for controlling the quality of REC decisions
- dealing with appeals of REC decisions.

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Finally, it is important to explicit about the procedure of application to become a member of EUREC. A potential representative of a national REC network should submit a written declaration obtained from RECs as the evidence of a REC network to the Board of EUREC. The potential representative should be active in participating at the international fora (conferences, workshops, statements, other activities). However, it should also be noted that it may be difficult to decide who should make this assessment especially when more than one institution would like to become a national representative of EUREC.

Eugenijus Gefenas and Jurate Serepkaite

Developing New Discussion Fora on Legal Issues for RECs

Understanding law requires the study of law in operation: legal context (the constitutional Law, for example), and its social and cultural context. EURECNET has provided a place to share the context within which the Law on paper finds its meaning and expression in REC's practice in Europe. With the end of current funding, we need to find new ways to maintain EUREC debates on capacity building, encouragement, and even harmonisation of operations and procedures.

EUREC wishes to contribute to this challenge with two new, linked initiatives: blogs and webinars. Both of these vehicles will enable us to share our ideas about the operation of the Law (and to develop position papers that EUREC are prepared to publish and contribute to the public debate), and to continue all very fruitful discussions without traditional face-to-face meetings.

Blogs.
The Maastricht partner has been working throughout the time of EURECNET on position papers on key issues in Research Ethics Committee (REC) work. We have separated these into two areas: procedural and substantive issues. In relation to procedural issues, we have focussed on two main questions: what is the purpose of an REC? and what are the necessary elements that natural justice and procedural justice bring to REC work? When thinking about the purpose of an REC, we have considered the question about where the responsibility for ensuring ethical conduct in a research project lies. RECs are traditionally seen as functioning to safeguard participants' rights. However, this does not remove the researchers' primary responsibility for ethical conduct. Indeed, there is an argument that the presence of an REC could give researchers the impression that ethics are not their concern - that the REC deals with the ethics, and if the paperwork passes the REC's requirements, then ethics is dealt with. Responsible research requires that ethical conduct is included in research methodology and practice by design. This can be discussed by questioning whether RECs have a 'tribunal' or 'permission' function in the process, or a supporting, expert 'sounding board' function. The latter has been developed by thinking about and applying the work of Habermas and of Widdershoven.
For the second procedural question, we have considered the 'natural justice' and 'procedural justice' issues that REC constitutions should include: these are primarily issues about, for example, identifying and addressing conflicts of interest; giving reasons for decisions (both generally about how decisions will be made and about specific reasons for decisions in particular cases); the skills required on a committee and how representatives should be chosen; the fair and proper resourcing of committees; and about how appeals from REC decisions should be handled.
The list of substantive issues includes, for example, how RECs should respond to the broad human rights agenda that underpins Law; how 'privacy' is defined in relation to medical research; the extent that individuals can claim autonomy, particularly in the face of a claim of solidarity in the public interest; how the European Regulations and Directives should be interpreted in relation to local sensitivities, for example, the data protection Directive (and the discussion about the forthcoming data protection Regulation), about the clinical trials Regulation, and about the Directive on the use of animals in medical research; about handling incidental findings in research; about the ethical use of property that emerges from research, or that is used in research; about therapeutic misconception, particularly expressed by participants in jurisdictions that are less economically developed than the EU, or are least economically developed countries, and how EU RECs should respond to research proposed in such countries.

The format of the blog is one 'page' for each issue. Each page has first a definition of the problem, second a discussion of the problem, and third literature to help the discussion. Thereafter, there is the traditional opportunity for individuals to contribute their comments and experiences, and to develop written discussion with members of EURECNET. This part will be on the closed section of the site.

Webinars.
Building on the papers and comments from these 'blog' pages, we will use on-line 'webinar' technology to maintain (albeit virtually) our face-to-face discussions following the end of our current funding. This format is straight forward. EURECNET members are invited to participate in the discussions at the published times. Thereafter, Maastricht University participants will write up the discussion and place it on the blog, as a consolidating exercise, which is then, of course, open to further blog-based, written comments. When we have a paper that we are happy reflects our collective position, we will publish the views as 'position papers' on the public part of the website. By hosting the webinars on a regular basis (every two months - five sessions per year), it is hoped that the consortium will remain active in discussion. The first year will look in detail at procedural issues - particularly ideas about how far RECs in the EU can or should be harmonised. We will also discuss the data protection Regulation, which, it is hoped, will be settled and being prepared for implementation by mid-2015.

David Townend

Date	Topic	Questions
Monday 29/09/2014 1400-1600	The Function of RECs	How far is the REC a sounding board for researchers who have ethical responsibility for their own conduct, or a body that permits research? Is this a democratic issue? Does the clinical trials Regulation, or international Law, help to clarify the required function? Could a more 'dialogue' based approach improve the safeguards for participants? What would such an approach look like in RECs?
Tuesday 25/11/2014 1400-1600	How far should RECs be harmonised in EU?	What is the competence that the EU has (or has assumed) in the area of Medical Research? What is the reality and importance of regional sensitivity in REC work? Are REC members representative of local views, and how do they know those views? Are there universal principles that transcend local views? Are these European or international values? What would harmonisation look like? How could it be achieved? Could the Brussels Convention (international organisation of applicable law and courts) be a template for RECs?
Wednesday 21/01/2015 1400-1600	Natural and Procedural Justice issues for RECs	Are there administrative principles that we must follow in RECs? Who should sit on RECs? Are there particular skill sets that must be included? How should RECs identify and address conflicts of interest? Is the 'ethics' in RECs more than a checklist? Should there be substantive ethics discussions about projects? And how do we manage competing ethical perspectives? Should these ethical substantive issues be published as part of the 'goalposts' for researchers? What should the appeal structure for RECs look like?
Thursday 26/03/2015 1400-1600	What do we mean by the right to a private life?	How do different disciplines define and explain 'privacy'? Are typographies like that of Professor Anita Allen ('Informational','Decisional', 'Physical' and 'Proprietary' privacies) useful? Do we make such distinctions in our REC work? Is 'privacy' an objective concept, or is it really subjective? If so, is 'the public interest' a more useful concept for RECs?
Friday 22/05/2015	Data Protection in the EU	What will the Data Protection Regulation (DPR) mean for RECs? What are the principles of the DPR? How far do they differ from those in the Directive (95/46/EC)? What guidance do we already have? What discretion do we have for Member State interpretation of elements in the Regulation? Are there areas that we would wish to develop as 'good practice' for medical research uses of personal data? Does the DPR assist in addressing issues of 'Big Data' and 'Cloud' technologies in medical research?

General Information on EURECNET

Today, the ethical review of research projects which involve human participants has become a mandatory standard that is reflected in national laws as well as in supranational and international documents. Not only those people who are willing to participate as subjects in research projects, but also both, researchers undertaking projects and the general public, have come to expect that an independent review process is in place which ensures the highest degree of protection possible and, more generally, that research is carried out in an ethically acceptable manner. In the early second half of the 20th century review bodies started to emerge, mainly as a form of self-regulation of the medical profession and often in an ad-hoc form responding to concrete problems. However, in the past decades Research Ethics Committees (RECs) have, in most European countries and worldwide, been established as permanent and independent bodies. As such they build, at least in Europe and other western countries, the core of a robust infrastructure which monitors and reviews research projects.

EURECNET is a network that brings together national Research Ethics Committees (REC) associations, networks or comparable initiatives on the European level. The network interlinks European RECs with other bodies relevant in the field of research involving human participants like National Ethics Councils and the European Commission's ethical review system. Such a network forms the 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 opinions and to meet new challenges and emerging ethical issues. The central objective of EUREC as a Coordinating Action is to foster the already existing network of European REC networks.

In particular, the contribution of EURECNET aims at five different levels:

- fostering a sustainable infrastructure for European RECs to promote exchange and cooperation and to allow for international cooperation
- gathering information on RECs in Europe to build a basis for mutual exchange
- collecting and evaluating training materials for REC members to enhance the quality of review
- 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.

Since September 2012 EUREC is listed as association in the register of associations. The EUREC Secretariat is located in Bonn. Full Membership is open to one national network per member country or the national research ethics committee where only one exists. Nominated networks must be independent having no commercial or other conflicts of interest. The Board of EUREC is responsible for the daily work of the Association, prepares and chairs the General Assemblies, takes care of the information, and informs the Members about its work.

EUREC is connected with the EURECNET Project. The project is a consortium of twenty European research facilities, which has been established in March 2011 and is being funded by the European Commission under Framework Program 7 (FP7). It is coordinated by the German Reference Centre for Ethics in the Life Sciences (DRZE). Following already existing efforts, especially efforts within a previous project, one of its primary objectives is to foster a sustainable infrastructure for European RECs. In order to achieve this aim in 2011 a EURECNET secretariat has been set up which, aside from managing and coordinating the project as a whole, is responsible for managing the communication of the project partners with the European Commission and for making available the project's interim and final results to the public.

This newsletter is published by
EUREC Secretariat
Bonner Talweg 57
D – 53113 Bonn

Telephone +49 228 33641930
Fax +49 228 33641940

Head of Secretariat PD Dr. Dirk Lanzerath
Scientific Adviser PD Dr. Bert Heinrichs
Editor Dorothee Güth
EUROPEAN NETWORK OF RESEARCH ETHICS COMMITTEES (EUREC)
http://www.eurecnet.org