ADOPT BBMRI-ERIC GA676550

Report:
Ethics Review of European Biobank Research: Towards Mutual RECognition?

Organised and hosted by BBMRI ERIC Common Services ELSI
in joint collaboration with BBMRI Large Prospective Cohorts and B3Africa
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Summary:

Currently, there are no standards for European or worldwide ethics review of data/sample access requests for cross border research projects. In fact, it transpires that even within countries the rules by which RECs operate can vary widely – more according to the emphasis of the institutes they represent than ethical considerations (after all, what are ethics?). And even then, there can be or is inconsistency between rulings by one and the same REC, depending on factors like: who chairs the REC meeting? Since most REC rulings are either not made public at all, or made public without divulging details such as grounds for approval or disapproval, and often without an opportunity for appeal, reaching a pan-European standard seems lightyears away.

This meeting identified the issues mentioned above, and tried to come up with solutions (or rather, initial steps needed to be able to come to solutions). The need for solutions is evident, since nobody benefits from a system of RECs operating by non-transparent, inconsistent methods.

And as a first step, the meeting was certainly useful. It introduced people from RECs across Europe to each other and got them thinking and talking about existing practices and the need for change.

Presentations: Anne Cambon-Thomsen

BBMRI-ERIC CS ELSI director Anne Cambon-Thomsen gave a short introduction of the work that is being done by BBMRI-ERIC's Common Services ELSI team to come to standardized and harmonized work practices across the BBMRI-ERIC member states biomedical institutions, ranging from legal, ethical to societal impact projects.

Presentations: Elmar Doppelfeld

In the presentations, EUREC chair Elmar Doppelfeld highlighted the challenges that face any initiative trying to standardize protocols for RECs across Europe. Responding to his presentation, Mats Hansson pointed out that the implementation of the GDPR may present an opportunity to work towards a mutual methodology for RECs.

Jane Reichel put the question that has to be answered before a consensus can be reached: what is ethics, and how do you define 'mutual recognition', if not in the strict legal sense? Should RECs strive for a legal consensus, or work towards a consensus of persuasion, where reciprocity and cross-fertilization enable all RECs to learn from each other, gain trust, and grow?

Anne Cambon-Thomsen responded to this, saying that in her experience, the best way to go about finding a solution is not to be too philosophical, but to look for practical, hands-on best practices already in place here and there, and see if they can work across the board.

An interesting perspective was also provided by B3 Africa representative Dr. Erisa Mwaka, who recognized the problems presented, and pointed out the solutions already in place in his homeland

of Uganda: when a decision on a data/sample request for a research project has to be made by several RECs, one REC is chosen as the leading decision-maker, while the other RECs can appeal the decision. It is a matter of trust.

Presentations: Irene Schlünder and Roland Jahns

Thankfully, Irene Schlünder and Roland Jahns were able to present a more hopeful picture: in Germany, a federal state made up out of 53 counties, a system is being implemented that removes much of the red tape associated with lengthy REC assessment processes. It relies on written guidelines, but also on a consensus of trust, the idea being that one REC can make an informed decision for all RECs involved in a request procedure.

This prompted Gertjan van Ommen to remark that, in his experience, although RECs are there to protect patients and participants and uphold legal and ethical standards of the country, there is a fourth party, whose interests appear to be a higher priority than those of the other three: i.e., the institutions involved.

Presentations: Edward Dove and Chiara Garattini

Gertjan's remark was promptly echoed in the next, interactive presentation, given by Edward Dove and Chiara Garattini. They got the attendees thinking about the problems, challenges and solutions facing scientists involved in cross-border (or even cross-institute) research in an interactive session, asking them to respond to statements made by researchers across the world. Sure enough, one of the cards identifying problems stated that RECs are overly concerned with the reputations of the institute they represent; in effect, the assessment they make is not so much ethical as a risk assessment.

Jasper Bovenberg remarked that this presents an opportunity: risk assessment can be made tangible, with clearly defined parameters. But Sara Casati remarked that it also calls for a better definition of ethics and an evaluation of ethical / legal standards.

Defining the REC's work as risk assessment takes away an important part of what the REC is there for: protection of patients and participants, Michaela Mayrhofer stressed.

Anne Cambon-Thomsen added that it also begs the question: what is the liability of an REC? How can it be held accountable, especially if their decisions are not made public, or in a way that is incomprehensible to lay persons?

Berge Solberg, Sara Casati, and Jane Kaye made the point that a REC should be able to reach a rational decision, based on clearly defined ethical considerations. Implementing a broad consent procedure that clearly states its parameters could help define these considerations and their consequences.

Elmar Doppelfeld remarked that in order to do this, there first has to be a consensus on the question 'what are good ethics'? This could prove difficult, as the answer might differ from country to country. To reach a solution, there would have to be a consensus on which ethical arguments would be admissible when building a legal framework.

Presentations: Gertjan van Ommen

Gertjan van Ommen, speaking from his personal experience as PI for an ongoing LPC-project, stressed that the obstacles to be overcome are mostly man-made and could be dealt with in a far earlier stage than the REC assessment process.

His presentation provided food for thought, as it confronted the attendees with the daily practice of a cross-border project.

Break-out session

It was then the turn of the attendees to go to work themselves: in a breakout session, five groups tried to come up with answers to a shortlist of questions prepared by Jasper Bovenberg (link to presentation). The responses were diverse, but most groups seemed to be in agreement that RECs should aim for mutual recognition of ethics review for European cross-border research projects.

Group 1 came to the conclusion that the best approach towards mutual recognition would be a 'soft' model, so a basis of reciprocity and mutual respect.

Group 2 stated that red tape is what causes delays in research projects, not (so much) RECs. A system to perform a unified risk evaluation at the start of every cross-border research project would save time; BBMRI could play a major role in devising such a system.

Group 3 opts for a coalition of the willing, where representatives from different countries get together and identify the issues to overcome to get to mutual recognition. There has to be clarity on the scope of the RECs, what is their remit: legal questions have to be addressed separately, and global issues should be separated from local ones.

Group 4 also stressed that red tape is causing a lot of the problems discussed. A way around this would be to establish one REC per country for cross-border research projects. But in a practical sense, developing standardized forms for MTA's and DTA's would already save much time. A common portal where research projects could be submitted might also prove a more collaborative approach than trying to gain approval from specific institutions.

Group 5 urged harmonization of any processes that can be standardized, helped by patient organizations. BBMRI can collect usecases and solutions to help RECs and researchers; the only workable model for working towards mutual recognition would be reciprocity. A patient ombudsman should be installed, to give patients a voice in the decision-making process. More meetings like this one are necessary to think about practical solutions.

Conclusion and next steps:

RECs across Europe are perceived to be solitarily-operating bodies, and their tasks, responsibilities, liabilities, and procedures often appear based on a generic, non-specific definition of the term 'ethics'. This leads to great differences in the way RECs work – not only different from each other, but also from case to case, as personal interpretations of ethical terms can hold too much sway over the decision-making. The fear of putting the institute that has installed the REC at risk may make for decisions in which the patient/participant/scientific perspective is deemed less relevant. To what extent this is so cannot be checked, however, as many RECs do not make public their assessments and rulings.

To come to a system of mutual recognition, first of all the definition of what a REC is, i.e. exactly what it does and by which guidelines and standards it is ruled, has to be clearly defined. To make sure that bureaucracy does not hamper scientific projects, there has to be a consensus on how multi-institute, cross-border projects are assessed: in practice, this will probably mean that the RECs involved will have to concede authority to one of their number. The best basis on which to do this would be, in the minds of the people present today, one of reciprocity. Trust is key in this matter: RECs and their governing institutions have to recognize that they have the same interests at heart and will not run unnecessary risks when assessing research projects.

To further avoid unnecessary red tape, the concept of broad consent would have to be worked out more and become a standard by which assessments can be made more quickly. Pan-European guidelines, such as the GDPR, could also be used as input for standards by which RECs work.

An important final note is that, in protecting the patients' and participants' interests, RECs should involve these stakeholders in their decision-making; at least publish their rulings, and perhaps involve them in the decision-making.

A shortlist of next steps could be:

- For now, legal basis far away, so not top priority
- Practical approach, bottom-up
- Evaluate case by case, project by project and biobank by biobank
- Align with EUREC, if possible; find common ground:
    - joint access procedure
    - common minimum standards
        - specific topics?
            - Data protection?
            - Opportunity offered by GDPR EU Code of Conduct?
    - Common conditions for release of data
- BBMRI-ERIC: REC portal;
- Next meeting; Stockholm 2017

Appendix 1: Attendees, speakers and chair

Present:

Country / Institute	**BBMRI-ERIC ELSI team representative**	**REC representative**
Austria	Johannes Starkbaum	
Belgium	Isabelle Huys	Léon Luyten (member of the Ethics Comité of the University Hospitals of Antwerp (UZA/UA) and Head of Medical Information)
Estonia	Liis Leitsalu	
Finland	Tom Southerington	Kaisa Silander (Research coordinator, THL Biobank)
France	Gauthier Chassang	Georges Dagher (BBMRI, INSERM)
Germany	Irene Schlünder	Roland Jahns (vice chair of the Ethics Committee of the Medical Faculty, Würzburg University & Repr. Of the WP-MEC Working group 'Biobanking')
Greece	Olga Tzortzatou	
Italy	Sara Casati	
Malta	Gillian Martin	Bridget Ellul (member of Maltese national Bioethics Consultative Committee and the national Health Ethics Committee)
Netherlands	Martin Boeckhout	Gerhard Zielhuis (BBMRI-NL, Radboud Biobank)
Norway	Berge Solberg	Lars Ursin (a.o. CS ELSI Biobank Norway)
Poland	Jakub Pawlikowski	Marek Czarkowski (Chairman of the Center of Bioethics of the Medical Supreme Council – Polish Chamber of Physicians & Dentists)
Sweden	Jane Reichel	Deborah Mascalzoni (Centre for Research Ethics & Bioethics, Uppsala)
UK	Jane Kaye	Nalin Thakkar (UK Health Research Authority)
IARC / Uganda	Eduardo Seleiro	Mwaka Erisa Sabakaki (Chair SBS Higher Degree Research Ethics Committee, Makerere School of Biomedical Sciences – Kampala)
BBMRI-ERIC CS ELSI Board	Marialuisa Lavitrano, Mats Hansson, Anne Cambon-Thomsen, Jasper Bovenberg	
BBMRI-LPC	Gertjan van Ommen	

Intel Life and Health Sciences	Chiara Garattini
University of Edinburgh	Edward Dove
EUREC	Elmar Doppelfeld
BBMRI-ERIC	Meghan McCarroll, Michaela Mayrhofer
Heesakker C&C	Margot Heesakker

Chair/organiser

Jasper Bovenberg (Co-Director BBMRI ERIC Common Services ELSI)

Speakers

Anne Cambon-Thomsen (Director BBMRI ERIC CS ELSI)

Elmar Doppelfeld (Chair, European Network of Research Ethics Committees (EUREC))

Irene Schlünder (BBMRI-ERIC CS ELSI Germany)

Roland Jahns (Working Party of the German Medical Ethics Committees (WP-MEC))

Edward Dove (School of Law, UoEdinburgh) & Chiara Garattini (Intel Health and Life Sciences)

Gertjan van Ommen (Co-director, BBMRI-LPC, founder BBMRI-NL)

Appendix 2: Programme

9.00-9.15	Registration and coffee
9.15-9.30	Welcome and introduction, by Jasper Bovenberg, Co-Director BBMRI ERIC Common Services ELSI
9.30-9.45	Tour de Table REC Members
09.45-10.15	Presentation BBMRI ERIC CS ELSI Team – Anne Cambon Thomsen, Director BBMRI ERIC CS ELSI
10.15-10.30	*The problem:* *Ethics Review for International Data Intensive research - Jasper Bovenberg*
10.30-10.45	*Solutions: existing Models at EU level:* Ethics Review of European Clinical Trials - the European Network of Research Ethics Committees (EUREC) – Professor Elmar Doppelfeld (EUREC Chair)
10.45-11.00	*Existing Tools:* "Infrastructures for Medical Research" (TMF): freely available ELSI tools & generic concepts for researchers - Irene Schlünder (BBMRI-ERIC CS ELSI Germany); "Role and tools provided by the Working Party of the German Medical Ethics Committees (WP-MEC)" - Roland Jahns (WP-MEC working group 'Biobanking')
11.00-11.15	Coffee break
11.15-12.15	*Expert Perspectives:* Developing Ethics Review Mutual Recognition in International Data-Intensive Research: Expert Perspectives - Mr. Edward Dove (School of Law, UoEdinburgh) and Chiara Garattini (Intel Health and Life Sciences):
12.15-13.15	Lunch
13.15-13.45	*Case study* Data Going Cross Border? Professor Gertjan van Ommen (co-director, BBMRI-LPC)
13.45-15.00	*Break-out Session:* Ethics Review of European Biobank research: towards Mutual Recognition? - all
15.00-15.30	Tea break
15.30-16.30	Presentations of Break-out Sessions: Ethics Review of European Biobank research: towards Mutual Recognition? - all
16.30-17.00	Wrap up and next steps
17.00 -	Drinks and Bites