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ANNUAL WORKSHOP REPORTS

Executive Summary

BBMRI-ERIC and its ELSI team have organized and held several (virtual and physical) Common Service ELSI team meetings and task force working meetings as well as workshops on “Ethics Review of European Biobank Research: Towards Mutual RECOgnition?” Workshop (2016), the “Sharing and access to data and human biospecimens for the benefit of patients - Towards a BBMRI-ERIC Policy” Workshop (2015) and the “Workshop Ethical and Legal Issues” (2017).

With ADOPT resources, the workshops resulted, to date, in three public reports, FAQs on the GDPR (Version 2.0) and a survey on the practices of informed consent attached in the Annex.



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Document log

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1. Background

1.1 First year

The Common Service ELSI has set as 1st year priorities the following and the necessary tools and procedures: Ethics check of projects proposing to use BBMRI-ERIC resources and organisation of the corresponding expert network, advice function and helpdesk, with criteria, procedures and report devices to be used; a procedure to follow public consultations and policy documents related to legal, regulatory, ethics framework evolution at European/international level, an annual workshop on a relevant topic, a minimum tool for dissemination of relevant ELSI information and two practical tools for legal information that are being improved as a priority (Wiki legal platform¹ and hSERN² (human samples exchanges regulation navigator)).

1.2 Second year

The Common Service ELSI has set as 2nd year priorities the following: continue in a more efficient manner the work started in year 1, especially by establishing the position of an ELSI Helpdesk Coordinator.

2. Approaches (Methods)

The task was to organise meetings and workshops on relevant topics and use the findings for BBMRI-ERIC's Common Service ELSI. To achieve this in an efficient and coordinated manner, the approx 30 experts of the Common Service ELSI (comprising of at least 1 expert per member state) are organised in the following thematic Task Forces:

- **International Organisations' Policy Assessment and Monitoring**

Monitors and comments on relevant recommendations during public consultation phase and promoted published recommendations such as the WMA Declaration of Taipei on Ethical Considerations regarding Health Databases and Biobanks. Its key focus is on public consultations of the Commission, most recent the one on the Digital Single Market.

- **GDPR**

Produced FAQs on the GDPR (currently version 2.0). A version 3.0 is in the making in collaboration with other research infrastructures in the context of CORBEL. It also follows and reports on the national implementations of the GDPR and informs the Code of Conduct initiative with its expert knowledge.

- **Rule Making US**

Presented its findings in the context of the CS ELSI team meeting in Stockholm concluding lessons-learned in relation to US rule making.

- **Sharing and Access to Data and Human Biospecimens**

¹ http://www.bbmri-wp4.eu/wiki/index.php/Main_Page

² <http://www.hsern.eu/>



Organised a workshop on the topic and provided input on the access policy of BBMRI-ERIC (developed by WP4). The task force is completed.

- **Societal Issues**

Executes a user-perspective survey on IC (in collaboration with other projects and initiatives). Details see Annex (poster). In the long run, this task force will produce how to guides and conceptualise education & training activities with the focus on societal dialogue.

- **ELSI Helpdesk and Knowledge Base**

This Task Force sets up the custom-based Helpdesk (supported by its electronic request tracking system) and the online Knowledge Base. This task force combines the previously distinct task forces on ELSI Helpdesk and ELSI tools. It is led by the ELSI Helpdesk Coordinator.

The task forces meet on a regular basis, typically in tele conferences, wherever needed in face-to-phase working sessions. Twice a year, the status on task force achievements is reported to the whole Common Service ELSI team (last meeting: 2017-09-12 in Stockholm).

3. Results

3.1 Annual Workshops

2015 09 08-09: Access and Sharing Meeting (meeting organized prior to ADOPT BBMRI-ERIC but report completed in the context of the project)

The workshop and this report have highlighted the importance of the sharing of, and access to biomaterials and data. They have also addressed the barriers to more wide-spread, efficient and ethically acceptable sharing (e.g. adequate recognition, issues with (broad) consent) as well as aspects that are particularly salient to the activities and context of sharing in biobanking research (e.g. the trust of participants, intellectual property, and the EU legal context). Addressing the issues of sharing and access to biomaterials and data is an important activity for the BBMRI ELSI group. Future steps could include the consideration of reviewing and mapping out existing current documents that address these issues (e.g. from OECD 2009 guidelines on Human Biobanks and Genetic Research Databanks, Global Alliance 2014 Framework for Responsible Sharing, International Cancer Genome Consortium (ICGC) Goals, Structure, Policies and Guidelines, Consortium Policies and Guidelines, International Charter of principles for sharing bio-specimens and data (RD Connect)). Should these documents still have gaps and/or do not address fully areas important to BBMRI, a following step could then be to develop a set of recommendations on biomaterial and data sharing and access.

- ***The findings of the workshop and input from individual experts informed D4.2 and ultimately the Access Policy & Procedure of BBMRI-ERIC***
- ***Report publicly available at <http://www.bbmri-eric.eu/publications/>***

2016 09 12: Ethics Review of European Biobank Research: Towards Mutual RECOgnition? (supported by BBMRI-ERIC, ADOPT BBMRI-ERIC, BBMRI-LPC, B3Africa)



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The workshop brought together research ethics committee representatives and stakeholders to discuss standards for a European-wide ethics review of data/sample access requests for cross border research projects (Vienna, September). The workshop was jointly organised with the BBMRI-LPC and B3Africa projects and concluded that BBMRI-ERIC could provide a platform for a necessary joint dialogue. The meeting concluded that 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. 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. 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. A follow up meeting was envisioned for 2017. Systematic change requires long time involvement and commitment. BBMRI-ERIC could provide such a platform.

- ***The findings of the workshop inform D5.3.***
- ***Report publicly available <http://www.bbmri-eric.eu/publications/>***

2017 06 20: Workshop Ethical and Legal Issues, Athens (supported by BBMRI-ERIC, ADOPT BBMRI-ERIC and BRAFFA)

The workshop aimed to increase awareness on ethical & legal issues that immerge within the context of biomedical research. Experts representing key institutions across Europe & Greece analysed the changes that the new General Data Protection Regulation (GDPR) will bring to biomedical research. Key insights concerning the various ways that certain EU countries plan to implement the GDPR in their respective legislations were explored. The workshop was open to all. Researchers, bioethicists, lawyers, students, as well as members of the general public who wished to get informed on ethical & legal issues concerning biobanking attended.

- ***The findings of the workshop inform D5.3.***
- ***Report publicly available <http://www.bbmri-eric.eu/publications/>***

3.2 Physical Working Meetings of the BBMRI-ERIC Common Service ELSI task forces (selection):

- 2015 11 12: Integrating ELSI tools Workshop (legal WIKI, hSERN; organized together with BioMedBridges)
- 2016 05 31 - 06 01 GDPR Task Force assessing impact on biobanks, Leiden
- 2016 07 27 ELSI tools + Help Desk Workshop, Graz (in conjunction with CORBEL ELSI tool meeting)
- 2016 11 14-15 TF Societal, Vienna (supported by BBMRI-ERIC, ADOPT BBMRI-ERIC)
- 2017 01 27: Joint Common Service ELSI & IT Meeting, Berlin (supported by BBMRI-ERIC, ADOPT BBMRI-ERIC)



- 2017 04 27: Common Service ELSI Team Meeting, Paris (supported by BBMRI-ERIC, ADOPT BBMRI-ERIC)
- 2017 07 26-27: Code of Conduct Writing Group Meeting (supported by BBMRI-ERIC, ADOPT BBMRI-ERIC)
- 2017 09 12: Common Service ELSI Team Meeting, Stockholm (supported by BBMRI-ERIC, ADOPT BBMRI-ERIC)

3.3 Virtual meetings of the BBMRI-ERIC Common Service ELSI (selection):

- 2016 02 19 Teleconference ELSI playground (6 attendees, integrating tools)
- 2016 02 18 - WEBINAR Introducing the Ethics Check (27 attendees)
- Approximately bimonthly virtual working meetings between November 2015 and September 2017

The deliverable is on time. The deliverable report was slightly delayed due to a sick leave of the WP lead.

4. Discussion and Conclusions

The following section elaborates on **lessons learned** and issues encountered based on the results and considerations behind the outcomes and decisions of the workshops, reports and consensus statements. They are divided in short-, mid- and long-term. The findings refer to BBMRI-ERIC, National Nodes and Common Service ELSI experts.

Short-term:

The Common Service ELSI comprises 30 ELSI experts from all BBMRI-ERIC Member States and National Nodes, reflecting its distributed and pan-European scope. The ELSI team members have very distinct academic backgrounds and experiences and different formal links (if any at all) to the National Nodes, the cooperation and motivation is very high, time-commitment, however, very low (average 0.12 FTE/expert). In order to achieve the tasks in a coordinated and efficient manner, the experts were grouped in Task Forces (as specified above). Additionally, the new position of the ELSI Helpdesk Coordinator will ensure further efficiency in coordinating task forces, requests in the context of the ELSI Helpdesk as well as the operational platform for experience sharing (D5.1-3).

Example: the realization of the findings as specified in the ELSI Concept Paper on the ELSI Knowledge Base require the collaboration of the Task Force ELSI Tools and ELSI Helpdesk. For efficiency reasons, the task forces have been combined into one and placed under the new leadership of the ELSI Helpdesk Coordinator as of 12 September 2017.

Mid-term:



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The expectations from researchers and CS IT were underestimated: The Common Service ELSI was seen as a tool to solve any ELSI issue in the context of the project or linked to the National Node. This realisation led to a clearer focus of tasks and ultimately the creation of the post of ELSI Helpdesk Coordinator, entirely funded by ADOPT BBMRI-ERIC.

Example: The input on public consultations (e.g. Council of Europe) comes from National Nodes and individual/national ELSI experts. The editorial efforts of compiling a joint comment on a public consultation, however, shall be provided by a staff member of BBMRI-ERIC such as the Engagement Officer, Policy Officer or Helpdesk Coordinator. Similarly, ELSI support (practical legal support not academic guidance) needs to be ensured as seen while contributing to the development of the access policy (WP4) and the set-up of the colon cancer study (WP3).

Long-term:

Services (incl. tools) have to be made available, feasible, practicable, usable, reliable and verifiable.

Evaluations of services via surveys, follow up interviews and test users (outside from BBMRI-ERIC and National Nodes). Evaluation results must lead to readjustments, standardized procedures and potentially certified procedures.

Results (consultations, expert opinions, legal texts, reports) must be translated into practical guidance (webinars, youtube clips, education & training activities, FAQs.).

Example: The Common Service ELSI Task Force GDPR contributed to the Position Paper, which was primarily intended for policy makers to highlight the BBMRI-ERIC position on the Council and Parliament version of the GDPR but also as background document for researchers. In reality, the document was far too complex for the average reader. The Task Force GDPR learned from this experience and produced Frequently-Asked Questions on the GDPR (version 2 published in April 2017).

5. Next Steps

- Continue and intensify the work in the task forces (physical and virtual meetings). The next Annual Workshop is foreseen in the context of the European Biobank Week in autumn 2018, Antwerp/Belgium. Topic currently in discussion.
- Launch and analyse the survey on IC (as presented during Global Biobank Week 2017, see Poster in Annex).
- Conceptualise “How-to guides” and FAQs and education & training activities
- Intensify communication across WPs (esp. 2, 3 and 4)
- Increase marketing of the ELSI Helpdesk



6. References

WMA Declaration of Taipei on Ethical Considerations regarding Health Databases and Biobanks, <http://www.wma.net/en/publications/policies>

Access and Sharing Meeting (meeting organized prior to ADOPT BBMRI-ERIC but report completed in the context of the project), see <http://www.bbmri-eric.eu/publications/>

Workshop Report, Towards Mutual REcognition (2016), http://www.bbmri-eric.eu/wp-content/uploads/2016/07/BBMRI_LPC_B3Africa_RECMeetingVienna2016report.pdf

Report on Workshop Ethical and Legal Issues, Athens, http://www.bbmri-eric.eu/wp-content/uploads/Report-workshop-Athens-20-June-2017_FINAL.pdf

FAQs GDPR (Version 2), http://www.bbmri-eric.eu/wp-content/uploads/BBMRI-ERIC_FAQs_on_the_GDPR_V2.0-1.pdf

Code of Conduct for Health Research, <http://code-of-conduct-for-health-research.eu>



Appendix I: Poster

As presented during Global Biobank Week Conference 2017, Stockholm





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DATA IN QUESTION

Survey on ELSI Challenges in Biobank-Based Research

ELSI Challenges for Biobanks

The European biobanking landscape continues to develop and has become a key resource for biomedical research and innovation. The increasing role of biobanks to improve health and fostering innovation is accompanied by questions about the ethical, legal, and societal impacts (ELSI) of these infrastructures.

Researchers and stakeholders in the field of biobanking are facing different social, ethical and legal challenges related to handling and sharing biological samples and health related data. These practices are directly impacted by new technologies and upcoming changes in European law, such as the new EU General Data Protection Regulation (GDPR), which will enhance the rights for data subjects regarding the processing of their personalised data.

Improving informed consent is one of the key challenges in this regard, as samples and data may be shared widely between researchers and projects, with new possibilities for data linkage, particularly in the context of growing public-private partnerships within the health industry.

This raises questions as to whether, and to what extent participants should be involved in future uses of their biomaterial in an emerging research infrastructure, where the exact purposes of samples collected prospectively are unclear at the time of donation and consent. Hence, the increasing possibilities for research, especially with data, emphasises the need to improve practices of informing and re-contacting participants, and to establish new tools for participant engagement.

Aim of the Study

The study aims to identify and better understand ELSI challenges that impact established practices related to samples and health-related data handling and sharing from the perspective of European biobankers and biomedical science researchers. It will explore the effects of the growing demand for engaging with third parties such as industry representatives, patients or citizens. We seek to learn about how informed consent (IC) practices could better adapt to the requirements of different stakeholder and novel legal frameworks (such as the GDPR).

The results of this study will support evidence-based improvements of transnational biobanking practice, for example in the form of guidelines and practical support.

This study is being conducted by BBMRI-ERIC CS ELSI, COST Action CHIP ME, RD-Connect, IMI DO-IT and Biobank Norway.



Research Question

Based on the hypothesis that ELSI challenges, manifested in different local practices of informed consent, private-public partnerships, and engagement of participants are affecting the use of biobanks across Europe, we investigate both professional experiences and opinions about:

- Secondary use of data
- Informing and/or re-contacting participants
- Sharing data with third parties from industry
- Participant engagement
- Collaboration with industrial partners

Research Tool

Data is collected via an online-survey, where our research interest is operationalised in 116 items within 25 questions. The target population of this survey are persons who have experience as researchers or in other professional activities related to biobanks and/or collections of biological samples.

The questionnaire was pre-tested to evaluate comprehensiveness, length and clarity.

Share your expertise! Take part in the survey →



Presenters: Melanie Goisauf & Gillian Martin
Contributors: Martin Boeckhout, Isabelle Budin-Ljøsne, Sara Casati, Anna Durnova, Marialuisa Lavitrano, Liis Leitsalu, Joachim Marti, Deborah Mascalonzi, Michaela Th. Mayrhofer, Maximilian Salcher, Katharine Smith







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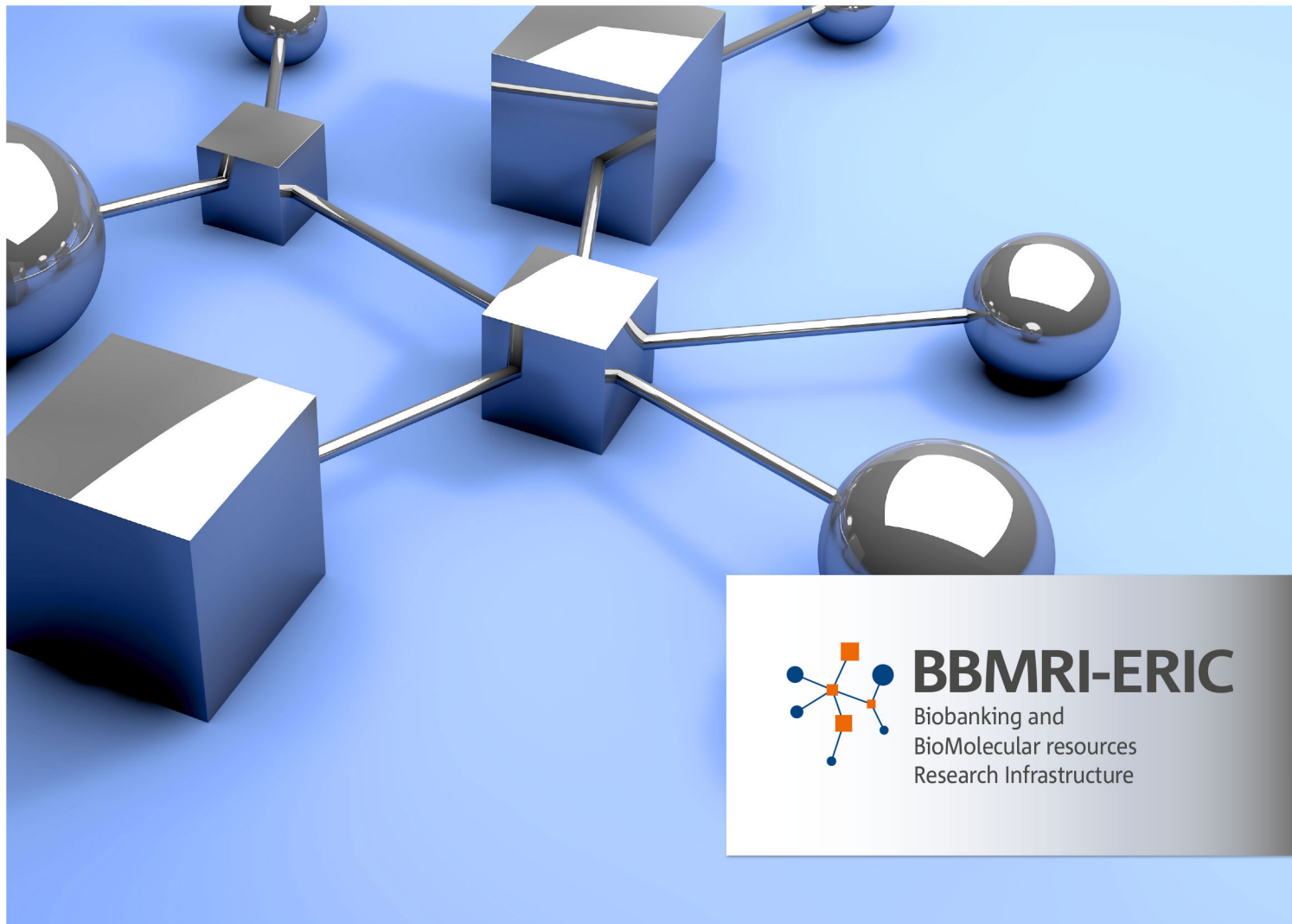
Appendix II: Reports

All publicly available at: <http://www.bbmri-eric.eu/publications/>

- 2015 09 08-09: Access and Sharing Meeting
- 2016 09 12: Towards mutual RECOgnition?
- 2017 06 20: Workshop Ethical and Legal Issues, Athens
- FAQs GDPR (Version 2)



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Biobanking and
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Research Infrastructure

BBMRI ELSI WORKSHOP REPORT

**Sharing and access to data and human biospecimens for
the benefit of patients – Towards a BBMRI-ERIC Policy**

BBMRI ELSI WORKSHOP REPORT

Sharing and access to data and human biospecimens for the benefit of patients – Towards a BBMRI-ERIC Policy: ELSI Workshop

September 08-09, 2015

Paris, France

Prepared by Mats G. Hansson, Moa Kindstrom Dahlin, and Heidi Carmen Howard
Centre for Research Ethics and Bioethics, Uppsala University, Sweden

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I- Short Summary of Workshop

Rational and main objectives

There is a growing international recognition that greater access to, and sharing of research data and bio-specimen collections could help to optimize their long-term value and exploit their potential for health-related discoveries. Currently, the increasing value of data and bio-specimen collections does not correspond with an equal increase in data/sample-sharing and data/sample access. Ideally, data and bio-specimens would be made widely available in an ethically responsible manner to an inclusive group of researchers who could make sound use of them. However, there are logistical, legal and ethical challenges to widespread access. Moreover, there is often resistance by institutions and individuals who fear that they will not receive recognition for their investment in building collections. Since the sharing of data and samples is, in some instances, an essential and/or greatly facilitating element to making novel biomedical discoveries, we must further consider how to further support sharing at all levels (regional, national, international). Furthermore, from a patient perspective, if sharing could lead to a useful discovery, patients may feel that it is a moral imperative for researchers to share samples and data. Indeed, the discussion around sharing and increase access is often held among a select group of stakeholders (often academics) thereby potentially ignoring the values, and agendas of pertinent stakeholders. The discussion around access and sharing should be had with a wide range of stakeholders and different values and needs should be considered.

The main aim of this meeting was to discuss the ethical, legal and social issues surrounding increased access and sharing of biomedical samples and data, including the barriers and potential solutions. In doing so, we also achieved two other important goals to the functioning of BBMRI-ERIC ELSI group: i) members of different national nodes were able to meet, often for the first time; and ii) members were presented with the basic information surrounding the ethical, legal and social implications of sharing data and samples, thus bringing everyone to the same informational level. Both of these sub-goals will facilitate future work in the BBMRI-ERIC ELSI group.

Summary of Agenda

Broad themes addressed during this meeting included were:

- 1- Sharing and access in general
- 2- Human Rights
- 3- Philosophical aspects of sharing
- 4- Cross border sharing and legal aspects
- 5- Informational and Informed consent needs
- 6- Intellectual property
- 7- Alternate ways to provide recognition to biobanks/stakeholders that share
- 8- Patient and Public perspective of sharing
- 9- Transparency and public engagement

10- Governance Structures

11- Codes of practice

Number of presentations: 14 plus conclusion

Detailed Programme

Tuesday 8 September

09.00	Meeting with the BBMRI-ERIC Common service ELSI-Team (that is: all ELSI people who are funded/seconded for BBMRI-ERIC)
12.00	Lunch
13.00	Introduction to workshop on sharing and access – Jan-Eric Litton
13.10	Human Rights and principles for stewardship setting the stage – Mats Hansson
13.40	Philosophical underpinnings for sharing –Berge Solberg
14.10	General discussion
14.30	Coffee
15.00	Sharing biospecimens and health data across borders in EU – Jane Reichel and Olga Tzortzatou
15.40	General discussion
16.00	Information and consent procedures needed for sharing – Emmanuelle Rial-Sebbag, France
16.30	Respect for intellectual property across borders – Tom Southerington, Finland, Gauthier Chassan, France
17.00	Recognition of intellectual investments – BRIF and Authorship – Anne Cambon Thomsen, France and Heidi Howard, Sweden
17.30	General discussion
19.30	Dinner

Wednesday 9 September

09.00	Sharing policies from the perspective of patient and public trust – Gillian Martin, Malta
09.30	Providing transparency of use: the example of Estonia Biobank – TBA
10.00	Coffee
10.30	Examples of governance structures/code of practices: The Global Alliance Code for responsible sharing – Edward Dove, Global Alliance for Genomic Health RD-Connect Code of Practice – Mats Hansson ICGC – Anne Cambon-Thomsen
11.30	Conclusions towards BBMRI-ERIC policy on sharing and access
13.00	Closing, Lunch

Workshop Deliverable:

- Workshop report
- compiled by Heidi Carmen Howard, Moa Kindstrom Dahlin, and Mats G. Hansson, with contributions from Berge Solber, Gillian Martin, Jane Reichel, Isabelle Huys, Roland Jahns, and Anne Cambon-Thomsen.

II- Points to Consider for the access and sharing of human data and biosamples in the biobanking context

Introduction

While biobanking may appear to some (external to the activities) as a homogeneous endeavor where the fundamental purpose(s), composition, configuration, operations and activities are all very similar and/or harmonized between different biobanks, this is currently not the case. Even the main definition of biobanks may differ significantly [1] [2]. More surprisingly perhaps, is the fact that the activity of sharing samples and data between biobanks and researchers – the seemingly “raison d’être” of these institutions – is still not optimal, and in many cases is hindered by a number of challenges and barriers of different nature (for review see Colledge et al. 2013, [3]).

The goal of the BBMRI workshop in Paris was to reflect and discuss regarding the ethical, legal and social aspects surrounding the sharing of samples and data in the biobanking context in order to shed light on the endeavor and help find ways to better conceptualize the activity as well as realize it in practice. Anchored in the presentations and discussions held over the day of the workshop, six international scholars with different areas of expertise from different national BBMRI nodes were asked to elaborate further on themes that are particularly salient to the discussion around the access to, and sharing of human data and biospecimens. (Table 1)

Table 1

Name, country, specialty	Subject
Berge Solberg, Norway philosophy	A background, including policy issues, specific to why sharing is important
Gillian Martin, Malta Sociology and anthropology	What needs to be done for biobanks and researchers to deserve the trust of patients and participants
Jane Reichel, Sweden law	Describe the relevant legal framework in which BBMRI-ERIC is situated/is working.
Roland Jahns, Germany Cardiology, Biobank Director	Information and consent procedures for sharing samples and data.
Isabelle Huys, Belgium Pharmacy and intellectual property	What do we need to pay attention to/have established with respect to IPR and how should it be done?
Anne Cambon-Thomsen, France Immunology and Bioethics and Heidi Carmen Howard, Sweden Genetics and Bioethics	What is important to consider with respect to intellectual and resource investment by researchers and biobanks and how they can be recognized.

A philosophical approach to policy issues regarding reasons why sharing of data and biosamples is important (B. Solberg)

It is clear that sharing can benefit science. There are many reasons for this, including that we get can achieve greater goals faster if we share than if we don't share. Sharing, however, goes deeper than this. From the philosophy and the sociology of science we know that sharing could be regarded as a type of core feature of science. Karl Popper and later Robert Merton would come close to talk about sharing as expressing *the ethos of science*. [4] Popper's idea of an open science in an open society where scientists work together to try to falsify their own hypotheses, presupposes some form of sharing. Merton's norm "communism" refers explicitly to the point that in science we should share everything with everyone. [5] And his norm "universalism" refers to the fact that science is a universal enterprise which involves collaboration. He describes Science as not being a local enterprise for local researchers belonging to a certain culture or religion. Furthermore, he specifies that Science is a universal enterprise where particularities such as class, nationality, gender, ethnicity, etc., should be regarded as irrelevant. [5]

Particularly in the field of genetics and genomics, the Human Genome Project (<https://www.genome.gov/12011238>) highlighted a new dimension of sharing. In addition to the fact that sharing and collaboration was fundamental in order to reach the goal of this ambitious project in the time outlined, there was also a strong belief by some that the human genome represented a type of knowledge that in particular should be collectively owned and collectively accessible. In line with, for instance, developments like Wikipedia, the information from the Human Genome Project was understood by some as a "knowledge commons" (albeit for experts), where the idea of sharing is intimately connected to the important values of human dignity, democracy and access to (parts of) the science. The fear that private interest should claim ownership to the human genome, has been central to the regulation of genomics in many countries, leading for instance, to recent court decisions in the US that naturally occurring DNA is not eligible for a patent.

In addition to these more integral reasons for sharing in genetics/genomics and biobank research, there are also a many more practical reasons for sharing. The UK Data Archive, (<http://www.data-archive.ac.uk>) which acquires, curates and provides access to the UK's largest collection of social and economic data, has for instance, mentioned ten reasons for data sharing. What they all have in common is that they focus on the positive and constructive consequences data sharing will have for science and society. Increased transparency and accountability, increased visibility of research, increased collaboration between data users and data providers and increased scientific inquiry, are only some of the reasons. While this is a databank of information from the social sciences and humanities, these impacts are clearly also those desired in biomedical research.

Indeed, the list of positive reasons to share can be made very long. The ethical focus then perhaps should not be so much on whether there are any ethical reasons for

sharing, but rather the opposite: Are there any ethical reasons for not sharing? An obvious answer to this question concerns the respect for participant autonomy, confidentiality and privacy. Sharing data might be regarded as a privacy threat. On the other hand, data protection is an essential part of all research. Good technical solutions have been suggested as to how to protect privacy in research for years, and there seem to be no reason to believe that we would be less able to find technical solutions for future challenges. A less obvious concern, but maybe a more important one, is how data sharing might impact on the ties between biobank research institutions and individual donors and participants.

Biobank research, internationally, in terms of overall functioning and goals, can be very similar, and clearly illustrate some of the content of Merton's concept of "universalism". On the other hand, almost all biobanks all over the world are also fundamentally *local* in their nature, and they seem to highlight the local above the universal. Very often biobanks or biobank-infrastructures have names that refer to a particular nation, like the UK Biobank, the Danish national biobank, the Estonian Biobank or Biobank Norway. They may also refer to a certain city or a particular region where a cohort study has taken place, like the Tromsø study, The Framingham heart study, the HUNT Biobank, the Guangzhou Biobank, etc. This means that biobanks collect their samples and their data in a context of local and national entities. The research institution might be local, the researchers are local, the information is mediated through the local newspaper and the ethics review will be performed by the local research ethics committee. This local framing of biobanks is partly intentional because among people and participants it can help ensure trust. In addition it can also create pride and thereby increase the participation rates in cohort studies.

Biobank research then might appear to ordinary participants as being of a local nature. But its true nature is universal. This can create a tension between the local context where human biological samples are collected and later use of samples and data in a universalists context. Jane Kaye has formulated the tension in this way: *"Data sharing has the potential to sever the ties between the researcher responsible for participant enrollment and the individual participants in an original study. The onward sharing of data raises questions about who is accountable not only to research ethics committees approving new research but also to the research participants for the secondary uses of data in other studies."* [6]

In order to help ease this tension, research participants must be informed about the value of sharing data and/or samples. They must be informed about the value of thinking globally in science, even though they may have acted locally. The local context in which so many biobanks are situated, should not be downplayed. However, local belonging, local trust and eventually also local pride, might go hand in hand with international data sharing. In fact, it should be possible to build local trust and pride by highlighting the local contribution to a universalist science.

The ethical reasons to be vigilant about sharing are important to address, however, they can not be, in and of themselves, reasons to not share. The benefits of sharing

must be weighed against the potential harms. There are many fundamental reasons *for* international data sharing. However, all the reasons for data sharing can not be considered as common sense for non-expert publics. A major focus in the years to come should be to inform different publics, including patients and research participants about the value of data sharing. With the proper safeguarding procedures in place, data sharing should not be considered as something dubious among the public. Data sharing can contribute to the common good, and could be claimed to be a true expression of the ethos of science.

What needs to be done for biobanks and researchers to deserve the trust of patients and researchers? (G. Martin)

One way to view persons who donate time, samples and information to Biobanks is as participants. They participate in the creation of science by donating these items. In some cases (ie: rare diseases) they can also be viewed as active collaborators within the research process – one in which they are often emotionally and rationally invested. In the case of chronic or rare diseases, it enables otherwise disenfranchised individuals to participate actively in the drive to improve their own and potentially, their kin's situation. In the case of the general public, it allows the enactment of altruistic donation, driven by a sense of empathy, and , in contexts with strong public health systems, a sense of 'payback' or fair return within the norm of reciprocity.

This type of involvement or sharing by participants, donors or collaborators, is the bedrock of a biobank's existence. There are, however, potential hazards entrenched in the action of sharing intimate, personal data - principally the potential breach of data security which may lead to stigma and discrimination. Other key areas of concern highlighted by Hawkins and O'doherty's (2010) include the unknown and unforeseeable consequences of biobanks; concerns associated with vested interests of the researchers related to prestige and profit; the potential misuse of data, results and technology , and the potential sharing and use of research data for unethical purposes unrelated to the original biobank donation. [7] There may be a conscious utility / risk trade off at the core of the individual's decision to donate and consent to share data and bio-tissue, and ultimately trust is an essential factor in taking that step.

Biobank donation is complex because the relationship of trust the participant has with the biobanker is then conjugated down through the network of researchers with whom data and tissues are shared. Trust of actual or potential participants is implicitly rooted in a common denominator of ethical standards and functioning throughout the researcher network, and a clear audit trail of accountability to the governing ethics committee.

The key to building trustworthiness is developing a system of governance based on accountability, transparency and control which accommodates and protects the needs and rights of the multiple players in the process: participants, researchers and political/private sponsors. Of particular importance is that the governing body

should be widely representative of stakeholders, including patients and lay experts on issues such as ethnicity and culture.

Trustworthiness hinges on robust and transparent policies aimed at protecting privacy and anonymity of donors, anchored onto a brief, simple language consent document which is honest about making any potential breaches clear.

Participants' trust in the biobank governance system would benefit if attention is paid to the sense of active collaboration that drives their initial wish to donate. In the ideal situation Biobanks should potentiate empowerment of participants by giving them access to updates on research process, sharing of sample and results, and giving participants option to stop their samples being used for research they consider unethical or undesirable. The use of dynamic consent [8] is an interesting option, however one that hinges on two assumptions: that there is adequate IT technology and IT literacy, and that individuals trust this technology to maintain security and confidentiality.

The idea that the bio-sample and personal data may be commodified and shared with commercial entities may lead to distrust and resentment. Emphasis should be made on the fact that the key step to achieving tangible health benefits from the research process is often the involvement of profit driven pharmaceutical industry and, that health and wealth benefits are not necessarily zero sum ideals.

Trust is rooted in transparency. 'Biobanks should be where the public is' – educational campaigns focused on potential social benefits of biobank participation, and clear emphasis on the rights and privileges of participants, have been shown to valorise the action of donation and augment response. [9] Care should be taken, however not to offer unrealistic promises of feedback, and to work within the limitations of available/accessible technology.

The relevant legal framework for sharing in biobank (J. Reichel)

The European research infrastructures consortia, ERICs, are international organisations set up by the European Commission on the application of at least three EU Member States, according to procedures laid down in the ERIC regulation. Article 15 of the ERIC regulation lists the legal acts relevant to the setting-up and internal functioning of an ERIC:

- EU law, in particular the ERIC regulation, and the decisions taken by the Commission to establish the ERIC,
- the law of the State where the ERIC has its statutory seat,
- the statutes of the ERIC and their implementing rules.

The law applicable to the actual activities carried out by the ERIC will in the first hand be the law of the country where the ERIC has its seat, which in the case of BBMRI-ERIC is Austrian law. However, BBMRI-ERIC is a distributed ERIC, with activities in several states and therefore, it is the law of the land where the activity is actually

conducted that will be applicable to these activities. This issue is not clearly laid down in the ERIC regulation itself, but in paragraph 21 of the preamble it is stated that if the ERIC has a place of operation in another state, the law of that latter state should apply in respect of specific matters defined by the statutes of the ERIC.

Further, in cases where the research is funded via the EU research budget, the EU demands that the values and principles of EU law be respected. According to the Horizon 2020- regulation, all the research and innovation activities carried out is to comply with ethical principles and relevant national, Union and international legislation, including the Charter of Fundamental Rights of the European Union and the European Convention on Human Rights and its Supplementary Protocols. The legal framework for cross-border biobanking within the EU must therefore abide by both EU law and the laws of the land of all participating states.

The BBMRI-ERIC does not in itself have any mandate to change the regulatory framework applicable to the research conducted. It cannot enact acts that supersede the applicable law of the collaborating states, nor replace the decisions of national supervisory bodies such as ethical review boards. However, the BBMRI-ERIC may enact soft law tools such as charters, standards and guidelines that can provide considerable support for researchers conducting cross-border research. The role of soft law and the use of self-regulation within the research policy area have traditionally been outspoken and is to a large extent accepted. These soft law tools can give guidance to researcher on how to achieve a high level of legal and ethical compliance, in accordance to the legal framework applicable to the BBMRI-ERIC and Horizon 2020-projects. On the basis of their persuasive authority, rather than legal force, they may further provide guidance also to national ethical review boards and thereby act as bridges between national jurisdictions. If all partners within the BBMRI-ERIC take common standards into account already from the stage of drafting new research project, future collaboration can become more coherent already from the start. In the long run, BBMRI-ERIC might be able to contribute to a bottoms-up harmonization of a bioethical framework for the EU. A precondition for this, however, is that the framework is drafted with consideration of the role and function of legally binding frameworks of the Member States concerned. If not, a BBMRI-ERIC framework for legal and ethical issues could instead add to the complexity of an already fragmented legal framework.

Intellectual Property Rights in Biobanking: what to consider (I. Huys)

The (legal) role of biobanks within the BBMRI-ERIC network in the (pharmaceutical) scientific innovation process could be manifold, from collector or provider of human biological material (HBM) and data or creator of integrated databases up to co-developer of innovative therapies. To keep up with the desired ethical, legal, and social as well as innovation requirements and excel in quality, biobanks within the BBMRI-ERIC network need to make substantial investments in the creation, organization and maintenance of collections of HBM and data stored in their biobanks. This may result in substantive amounts of research and new innovations. Intellectual Property Rights (IPRs) are designed as tools to protect innovations.

Article 19 of the European 'Commission Implementing Decision of 22 November 2013 on setting up the BBMRI-ERIC as a European Research Infrastructure Consortium' indicates that 'BBMRI-ERIC may claim appropriate IPRs available within applicable national and international jurisdictions over tools, data, products or any other results developed or generated by BBMRI-ERIC while carrying out the Work Programme.'

Types of IPRs relevant for biobanks are mainly copyrights, sui generis database rights, trademarks, patent rights and trade secrets. Copyrights could be held on software and coding systems developed to collect and analyze samples and data, as well as the text and/or structure of health questionnaires. Copyright could protect the manner in which samples and data is selected and structured, or protocols, standard operating procedures or evaluation frameworks (e.g. Bioresource Research Impact Factor (BRIF) parameters), or software to store, process and conduct automatic searches in the collection of HBM and data. One could hold copyright in relation to the appearance or design of databases of samples and data or to the website that provides access to the collection of samples and/or data (e.g. Catalogue of European Biobanks). Copyright could finally be obtained in relation to publications that result from the use of samples and/or data used in the framework of a research project. The particular arrangements or compilation of samples and data in a database (e.g. to guarantee quality) could be the object of sui generis database protection (e.g. MIABIS , Minimum Information About Biobank data Sharing as a standard).

A biobank could apply for a trademark registration in relation to the name, logo or slogan of the biobank – such as the UK Biobank or the BBMRI-ERIC logo –, its products or services, or the database or software it developed. Trade secrets could be held on the (systematic) approach chosen to collect, store, label, process and track HBM and data or the algorithm used to analyse data. Patent rights might be obtained in relation to innovative technology or equipment developed for the improved collection, labelling, processing, storage, tracking and retrieval of HBM and data (e.g. in the Common Services for Biological Resources) , as well as for data analysis and presentations. The use of HBM and data in the framework of a research project could result in patentable inventions further downstream. However, patent rights will, in principle, not be granted in relation to the data resulting from the research project, as such. Only persons that made an essential contribution to the invention are considered as inventors.

Aside from the fact that IPRs may be claimed on inventions or other creations, the exercise of such IPRs needs particular attention. A carefully devised IPR policy could constitute an effective tool to enhance the acknowledgement and protection of the interests of the biobank, while respecting interests of other stakeholders.

First, biobanks could set conditions for access to and use of collections of HBM and data.

Second, any IPR policy must balance the needs to facilitate access to scientific advancements and to ensure the acknowledgment and protection of the interests of biobanks and other stakeholders. The involvement of all stakeholders (e.g. facilitated via the Common Service Stakeholder Forum) in the development of policies on IPRs may create transparency and open the door for continuous dialogues with donors, applicants, funders and biobanks.

Third, IPR policies would include provisions on upstream IPRs held by researchers on research results accruing from use of HBM and data from (publicly funded) biobanks. Such policy could prohibit users from obtaining IPRs on primary HBM and data or upstream data directly derived from the collection of HBM and data. A proper IPR policy should, however, contain sufficient incentives to stimulate innovation. Researchers should maintain the possibility to obtain IPRs on downstream clinical applications or products, such as diagnostic tests, therapies and medicines that arise from using the collection of HBM and data.

The importance of consent in sharing biological samples and data (R. Jahns)

A growing number of biobanks, both in Europe and world-wide, collect human biological materials and related health and personal information for use in biomedical research. They represent important resources for advancement in health research, including basic research, and medical research (e.g. personalized or stratified medicine, diagnostics and treatment development). To foster biomedical research, particularly for rare diseases, where so few samples exist, the research community must develop internationally accepted and applicable strategies in order to facilitate sharing (and access to) data and human bio-specimen across borders. The BBMRI-Common Service ELSI group aims to facilitate, support and guide such endeavors in an ethically responsible manner.

Indeed, one important factor that needs to be addressed in this context is individual level consent of participants donating samples and phenotypic information. Current practices and procedures for consent for the future use of samples and data in biobanking vary widely, including opt-in, and opt-out approaches. Additionally, the amount and type of information provided to individuals regarding the types of research uses may also differ a great deal. These types of consent include blanket, broad, limited, specific, and tiered consent.[10] Broad consent has been defined by Grady and colleagues (2015) as “as consent for an unspecified range of future research subject to a few content and/or process restrictions. Broad consent is less specific than consent for each use, but more narrow than open-ended permission without any limitations (i.e., “blanket” consent).”[11] According to some authors, in order to facilitate sharing and access of human biological materials and related data, a “broad consent” (i.e. as broad as possible, while keeping within ethically acceptable limits, see below) should generally be aimed for. This would allow bio-specimens and data to be made widely available “to the most inclusive and ethically responsible research community”.[12, 13] However, potential risks of discriminating vulnerable patient groups because of health-related data sharing must be considered when striving for broad consent.

A recent workshop regrouping international (including European) experts in research ethics, organized by the NIH Department of Bioethics, argued that broad consent is ethically acceptable as long as participants are provided with sufficient information to make a reasonably informed decision and that additional safeguards are put in place. [11] They “concluded with a proposal for broad initial consent coupled with oversight and, when feasible, ongoing provision of information to donors.” ([11] p. 34) Similarly, in 2015 the WMA published a draft “Declaration on Ethical Considerations regarding Health Databases and Biobanks” considering a broad consent to be ethically acceptable if individuals are “informed about the purpose of the Health Database or Biobank, the nature of the data or material to be collected, and about who will have access to the Health Database or Biobank. The donors must also be informed about the governance arrangements and the means that will be used to protect the privacy of their information.” [14] This exemplifies a crucial factor in the discussion about consent for biobanking research, and more specifically about the acceptability of the use of broad consent: different groups may be using the same term “broad consent” but the conditions attached to its respective use may render its meaning different, at least to some extent (see below). It is important to keep track of such differences and supplemental conditions and not to take for granted that all uses of the term “broad consent” are, in practice, synonymous. (see also BioMedBridges, <http://www.biomedbridges.eu/deliverables/52-0>)

Indeed, the notions related to “broad consent” are increasingly being considered to be the most helpful notions for maximizing the research value of human bio-specimen/data from biobanks. Broad consent and its associated consent-types are gaining ground within the EU in cases where the scope of the biobank cannot be limited to research into specific diseases. Importantly, it is generally accepted that broad consent requires a well-defined ethical and legal framework; nonetheless, in some EU member states it is not yet the prevailing view, perhaps due, in part, to differing values about the concept and/or understanding about the terminology. Because of its breadth and the unpredictability of research purposes, broad types of consent are evidently not the most informative forms of consent for participants. Therefore, it is recommended that any known future research purposes should be explained to the donors as precisely as possible; alternatively, the general aim of the biobank including the potential biomedical fields of research should be indicated in a clear and transparent manner (that is easily and publicly accessible, e.g. a biobank’s homepage). [15]

Beyond the type of consent, there is consensus that any consent for the collection (and cross-border sharing/use) of human biological materials and related health and personal information, should include simple and transparent information about storage, utilization, and processing of the data/samples. Of course, these must be outlined in a transparent manner always respecting the currently applicable national and international ethical and legal framework.

Furthermore, constant technical developments challenge the concept of (privacy-protecting) “anonymisation” of bio-specimen, which may contain genomic sequences. This is especially a concern as whole genome sequencing is becoming

more affordable and accessible to a wide range of researchers. Detailed genetic data, especially whole genome sequence data, is unique to one person and, as such, the general risk of re-identification should be explained to donors. Thus, currently, even with broad consent, any open-access or publication of the full genome of an individual requires a specific, unambiguous consent. [15]

While information and consent documents do not replace the face-to-face discussion between clinician/researcher, biobank and donor, they are an important component of the consent procedure and its documentation, not least legally. Empirical studies have shown that consent forms are often incomprehensive, incomprehensible or impractical, and fail to meet donors' needs. [6] Therefore, appropriate (broad) consent documents must explain the breadth of consent and other elements of the framework for future research such as, for example, cross-border sharing and use of bio-specimen and/or data, property rights,(commercial use if applicable), and data protection, employing a simple and comprehensible language. Moreover, a maximum degree of harmonization of consent forms used for human biobanks is essential for cooperation and networking at the European (at least between BBMRI member states) as well as for other international collaborations. [16]

It is also pertinent that as a mechanism of compensation or adjustment, patients and/or study-participants who are asked under the principles of a broad consent whether they are willing to donate biological materials and related data for medical research should be explicitly informed about their right to refuse or withdraw their consent at any time without any fear of detriment.

Dependent on the scope of the respective biobank/collection the bio-specimen that are stored and may be used for broad medical research purposes should be (A) either tissues and/or body fluids that have been collected for diagnostic/therapeutic purposes which are no longer required and, otherwise, would be destroyed, or (B) body fluids that are add-on collected for broad biomedical utilization in the frame of diagnostic/therapeutic procedures (in that case the exact type and quantity of blood/urine/other samples must be described in details). [17] Related data collected under the principles of a broad consent may comprise selected information about the donor, in particular, medical/ health data but also additional data which then must be specified in the information sheet (e.g. genetic data, life-style data). [17]

Finally, in the context of sharing biomaterials and related data it is strongly recommended that the biobank itself does not host any identifying data and that such data are hosted by the institution (clinic/physician) in which the data/biomaterial was gained. Such conditions are generally preferred, because the subject-identifying data are then protected by medical secrecy and criminal procedural access prohibition. If any other procedure is planned, this must be clearly stated in the donor-information sheet.

Incidental findings regarding undetected health risks or diseases of the donor raise the question of whether there is an obligation to inform the donor. On the other

hand, any 'right not to know' must be respected. This conflict cannot completely be resolved but should, at least, be duly managed through implementing an explicit declaration explaining what will happen regarding the feedback of incidental findings to the sample donor. [15]

The importance of adequately recognizing those who organize and maintain biobanks (A. Cambon-Thomsen, H.C. Howard)

A great deal of biomedical science such as epidemiology, clinical trials, biomarker research and genetics, is currently reliant, to some extent, on samples and data collected and assembled in biobanks. These biobanks include the biological and phenotypic information from a large collection of persons. As mentioned above, the increase access to, and sharing of this information can greatly help make biomedical discoveries. However, there are a wide variety of obstacles to wide and efficient sharing or access to samples and data.[3] One obstacle to sharing biosamples and data has been identified as the recognition of researchers and clinicians who developed the bioresource.[18] That is to say that researchers and even those organizing biobanks may be reluctant to share their collected samples and data due to fear that their contribution to establishing, collecting and maintaining these resources will not be (adequately) recognized. The concept of the Bioresource Research Impact Factor (BRIF) was developed in order to directly address this problem.

The concept of a (BRIF) was first proposed in 2003 (albeit it was originally referred to as the "biobank impact factor" (BIF)) [18] and has since been further developed on its way to becoming a concrete tool for use. As recently described by Mabile et al. (2013)

"The BRIF initiative was set up to construct an adequate framework and provide a set of tools that will allow an objective measure of the actual research utilization of bioresources as a significant component for establishing their reliability and sustainability." [19]

It will be loosely modeled on the concept and functioning of the journal impact factor. The rationale is that if the stakeholders who have set up, maintained and/or contributed to bioresources are properly recognized and acknowledged for their contribution to research (discoveries), they will be more apt to share their samples and data with other researchers. Mabile and co-authors explain that this BRIF would allow for and support a virtuous cycle to occur: the higher the quality of the bioresource(s), the more frequent the solicitations should be; more solicitations means more chances for sharing and the more bioresources would be shared, the more one's impact would increase, "and the more one is inclined to share." [19]

An international working group including experts from 22 countries (primarily from Europe and North America) was developed to address five particularly salient areas relative to the BRIF [19]:

- i) “digital identifiers” address how to identify uniquely and in a persistent way, different bioresources. track, quantify the contribution for and acknowledge
- ii) “Parameters” address the issues surrounding identifying and weighing parameters to be used in metrics aiming at measuring the use of bioresources and at producing indicators of their impact. Basically this addresses the topic of how to measure the utility of a bioresource.
- iii) “Sharing policies” addresses the policies for access and sharing of bioresources which can play a huge role in supporting or hindering wider sharing.
- iv) “Journal editors” includes analysing the role(s) played by journal guidelines and policies for resource citing and referencing and producing a guideline for citing in a standard way in articles the bioresources used in research. The next step is to foster the implementation of such a guideline.
- v) “Dissemination” addresses the needs for outreach and for raising awareness of the BRIF concept and current efforts. For the BRIF to become a concrete framework and for its tools to be useful, stakeholders, must be aware of its existence and must contribute to its development.

For more information on the BRIF, please see Mabile et al. 2013 [19] and Bravo et al. 2015 [20].

III- Conclusion and Future Steps

- The workshop and this report have highlighted the importance of the sharing of, and access to biomaterials and data. They have also addressed the barriers to more wide-spread, efficient and ethically acceptable sharing (e.g. adequate recognition, issues with (broad) consent) as well as aspects that are particularly salient to the activities and context of sharing in biobanking research (e.g. the trust of participants, intellectual property, and the EU legal context).
- Addressing the issues of sharing and access to biomaterials and data is an important activity for the BBMRI ELSI group.
- Future steps could include the consideration of reviewing and mapping out existing current documents that address these issues (e.g. from OECD 2009 guidelines on Human Biobanks and Genetic Research Databanks, Global Alliance 2014 Framework for Responsible Sharing, International Cancer Genome Consortium (ICGC) Goals, Structure, Policies and Guidelines, Consortium Policies and Guidelines, International Charter of principles for sharing bio-specimens and data (RD Connect).
- Should these documents still have gaps and/or do not address fully areas important to BBMRI, a following step could then be to develop a set of recommendations on biomaterial and data sharing and access.

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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
12 September 2016, Messe Wien

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

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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.

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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.

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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

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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	

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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)

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	<i>The problem:</i> <i>Ethics Review for International Data Intensive research - Jasper Bovenberg</i>
10.30-10.45	<i>Solutions: existing Models at EU level:</i> Ethics Review of European Clinical Trials - the European Network of Research Ethics Committees (EUREC) – Professor Elmar Doppelfeld (EUREC Chair)
10.45-11.00	<i>Existing Tools:</i> “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	<i>Expert Perspectives:</i> 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	<i>Case study</i> Data Going Cross Border? Professor Gertjan van Ommen (co-director, BBMRI-LPC)
13.45-15.00	<i>Break-out Session:</i> 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



Biobanking: Ethical and Legal Issues
Workshop Report
(20/06/2017)

www.bbmri-eric.eu

On Tuesday 20 June 2017, at the premises of the Biomedical Research Foundation of the Academy of Athens (BRFAA), BBMRI-ERIC in collaboration with BRFAA and supported by the EU Project ADOPT BBMRI-ERIC, prepared an intensive one-day workshop titled: **“Biobanking: Ethical and Legal Issues”**. This was an initiative which emerged out of the work conducted within the BBMRI-ERIC Common Service ELSI and more specifically the GDPR Task Force which examines the legal and ethical issues related to the personal data protection, within the framework of biobanking research, in view of the implementation of the General Data Protection Regulation (GDPR).

The workshop aimed to increase the awareness of the Greek audience on ethical & legal issues, within the context of biomedical research and more specifically biobanking on a national and regional level. In that context, the way that specific EU countries plan to implement the GDPR in their respective legislations were explored. The workshop was open to all. Researchers, bioethicists, lawyers, students, as well as members of the general public who wished to get informed on ethical & legal issues concerning biobanking were invited to attend.

Experts representing key institutions across Europe & Greece analyzed the changes that the GDPR will bring to biomedical research. Five members of the GDPR Taskforce, analyzed crucial issues concerning data protection in the field of biomedical research focusing in the case of research within biobanks and the recent developments after the GDPR.

Furthermore, during the first half of the workshop, Greek scientists –both from the field of law as well as from that of biomedicine research- presented the recent developments on a national level regarding the above mentioned issues. The workshop started with the opening remarks of the Academician Dr. Dimitris Thanos, President of the Scientific Board of the Foundation and the speech on bridging science to society given by Dr. Olga Tzortzatou, legal and ethics expert of BRFAA and member of the BBMRI-ERIC Common Service ELSI.

The Panteion University Rector, Prof. Kriari Ismini opened the first part of the workshop with a speech on the legal challenges with regards to biobanking, exploring both the Greek as well as the European perspective. Her speech was introductory to the general problematic of the challenges arising from biobanking and gave the opportunity to all attendants to gain an overview of what a biobank is and what are the main relevant legal issues.

Following the Rector’s speech, Dr. Fereniki Panagopoulou–Koutnatzi, Legal Auditor of the Hellenic Data Protection Authority, elaborated the general legal framework regarding health data research in Greece, analyzing in depth the current practices of the Hellenic DPA.

Dr. Catherine Stavropoulos-Giokas, Head of the Hellenic Cord Blood Bank (HCB), presented the experience of the HCB and gave an insight of the role it plays in the Greek society.

Dr. Anastasia Chatzidimitriou, Researcher-Assistant Professor from the Institute of Applied Biosciences, Centre for Research and Technology Hellas, gave a speech on the Greek experience in Biobanking, acting as the scientific representative of the only biobank currently active in Greece.

She informed the audience that currently in Greece there is one Biobank operating based in Thessaloniki conducting research for different types of diseases such as acute leukemia's and lymphomas. Her presentation gave an important insight of the current practical issues which rise on an ethical and legal level when collecting samples from data subjects for biobanking research retrospectively as well as prospectively.

Finally, the experience gained by setting up the Hellenic Biobanks Network BBMRI.gr as well as its vision was thoroughly described by Dr. Sissi Kolyva, from the International Scientific Cooperation Department at the Hellenic Pasteur Institute, who also had an active role in the organization of the workshop, describing in detail the steps already taken for the establishment of the Greek node BBMRI.gr.

At the second part of the workshop the BBMRI-ERIC Common Service ELSI members/GDPR Task Force members gave their presentations.

Gauthier Chassang, lawyer at the BIOBANQUES Infrastructure in Toulouse and member of the BBMRI-ERIC Common Service ELSI, opened the second part of the workshop giving a talk on the implementation of the GDPR in France and the current works regarding data protection in scientific research. His speech gave rise to questions from the audience who wanted to get informed on the current situation in France regarding mostly retrospective research.

The second talk was given by Dr. Victoria Chicco, Lecturer of law at the University of Sheffield and BBMRI.uk's member of the BBMRI-ERIC Common Service ELSI, regarding the reasonable expectations into consent to the use of health data, who thoroughly analyzed the problematic concerning the using and disclosing confidential patient information and what are the information requirements for a valid consent.

Following Dr. Chicco's presentation, Martin Boeckhout, policy advisor on ELSI issues at BBMRI.nl and member of the BBMRI-ERIC Common Service ELSI talked about the new developments in health research infrastructure in the Netherlands and more specifically the ethics of reuse & FAIR data stewardship.

The workshop was finally closed with the presentation of Dr. Michaela Th. Mayrhofer, Chief Policy Officer of BBMRI-ERIC and member of the Common Service ELSI and Irene Schlünder, lawyer-data expert and member of the Common Service ELSI, given by Dr. Mayrhofer, regarding the development of the Code of Conduct that BBMRI-ERIC in collaboration with more than 80 other research and biomedical organisations from academia and industry has undertaken and informing for the first time the Greek audience about the benefits of such an initiative. As legal texts are not easily accessible to non-lawyers, the Code of Conduct aims to translate the requirements of the GDPR to help to guide researchers and administrative staff. If approved by the EU Commission and supported by the national DPAs, the code can reduce fear about wrong compliance and enhance data sharing across countries. This is a long-term project and can lead to further practical guidelines.

The discussion following both parts of the workshop focused mostly on the practical implications both on a legal as well as on an ethical level that are faced when collecting human samples for research and the conditions under which the process of the subject's personal information must be made. The presentations of the members of the Common Service ELSI raised comparative questions regarding the legal and ethical requirements of the personal data processing, from the one hand in the countries which were represented by the invited speakers and from the other hand in Greece. Questions were also addressed to the speakers, regarding the ongoing procedures that the Greek DPA has established for granting permission to Greek researchers in order to process sensitive personal data within the frame of their biomedical research and the problematic around the issue of retrospective research. Further information, see <http://www.bbmri-eric.eu/BBMRI-ERIC/gdpr-code-of-conduct/>

To sum up, this workshop, was a first attempt in Greece to organize such an event regarding ethical and legal issues focusing in the field of biobanking research and even though it did not gather the number of the anticipated audience, it managed however to offer the opportunity to researchers from Greece to engage into a dialogue with legal and ethics experts and get informed about the national DPA requirements and how the GDPR may affect their research after May 2018. Furthermore, this initiative was welcome by Greek law practitioners and members of the governmental committee for the implementation of the GDPR creating a communication canal between [BBMRI.gr](http://www.bbmri.gr) and latest. Hopefully its outcomes will reach the more general public through the dissemination of the present report as well as the speeches already uploaded at the BRFAA website: <http://www.bioacademy.gr/news-details/XsaNtDXU/video-biobanking-ethical-legal-issues-conference> .



The EU General Data Protection Regulation

Answers to Frequently Asked Questions

Updated Version 2.0

Prepared by the BBMRI-ERIC Common Service ELSI

March 1, 2017

www.bbmri-eric.eu

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INTRODUCTION

On May 24, 2016, the Regulation of the European Parliament and of the Council on the Protection of Natural Persons with regard to the Processing of Personal Data and on the Free Movement of such data, and repealing Directive 95/46/EC (the General Data Protection Regulation, also referred to as the “GDPR” or as the “Regulation”) entered into force. The Regulation shall be binding in its entirety and directly applicable in all Member States from May 25, 2018.

The following is an update of answers to Frequently Asked Questions (FAQs) about how the EU General Data Protection Regulation is expected to apply to biobanks, collections of human samples and associated health data, in the EU. The FAQs do not constitute legal advice and may be subject to change, as a result of further analysis or when provisions of the GDPR are being implemented. In applying the GDPR, overlapping obligations contained in other national and European legislation such as EU Clinical Trial Regulation 536/2014 should also be taken into account.

This FAQ expands on the version that was published by the BBMRI-ERIC Common Service ELSI Task Force on the EU General Data Protection Regulation in 2016. The following Task Force members contributed to the FAQ: Jasper Bovenberg, Martin Boeckhout, Gauthier Chassang, Victoria Chico, Michaela Th. Mayrhofer, Irene Schlünder, and Olga Tzortzidou.

WHAT IS THE GENERAL DATA PROTECTION REGULATION (GDPR)?

The EU General Data Protection Regulation is the novel, EU-wide legal framework for the protection of personal data. The objectives of the Regulation are to protect individuals’ rights and freedoms in relation to the processing of their personal data, while also facilitating the free flow of such data within the Union. It provides that the free movement of personal data within the European Union shall be neither restricted nor prohibited for reasons connected with the protection of natural persons with regard to the processing of personal data. The Regulation (the Position of the Council at first reading) can be downloaded in different languages. The official text of the Regulation was published in the Official Journal of the European Union in all official languages on May 4, 2016 and can be downloaded [here](#).

HOW AND WHEN DOES THE REGULATION APPLY?

The Regulation, which was adopted in April 2016, will be binding in its entirety and directly applicable in all Member States as from May 25, 2018. It will repeal the Data Protection Directive (95/46/EC) and will override national data protection legislation based on that Directive. However, the Regulation also provides space for national and EU-level derogations and specifications in some areas, including the use of personal data in scientific research.

DOES THE GDPR AFFECT BIOBANKING?

Yes, because biobanks collect, store and/or process human biological material, in combination with other forms of personal data, including sensitive data, such as genetic and health data.

DOES THE GDPR AFFECT THE TRANSFER OF DATA BETWEEN BIOBANKS WITHIN THE EU?

The GDPR provides that the free movement of personal data within the European Union shall be neither restricted nor prohibited for reasons connected with the protection of natural persons with regard to the processing of personal data. The GDPR allows Member States to maintain or introduce further conditions, including limitations, with regard to the processing of genetic data, biometric data or data concerning health. However, this should not hamper the free flow of personal data within the Union when those conditions apply to cross-border processing of such data.

WHAT IS NEW IN THE GDPR?

Key changes to the existing EU Data Protection Directive include:

- Transparency and accountability are now main principles of data protection
- Special provisions for scientific research
- Enhanced rights for data subjects, such as the right to be forgotten and the right to data portability
- Mandatory procedures for managing data breaches
- Special provisions for protecting data of minors
- Mandatory Data Protection Impact Assessments
- Mandatory appointment of a Data Protection Officer (subject to exceptions)
- Pan-European validation of European Codes of Conduct for non-profit organisations
- Certification mechanisms specifically for data protection
- Remedies, sanctions and fines.

WHAT ARE THE MAIN ELEMENTS OF THE GDPR?

The GDPR contains a number of principles relating to the processing of personal data, the rights of data subjects, and the obligations of data controllers and processors.

The main principle is that personal data need to be processed 'lawfully, fairly and in a transparent manner in relation to the data subject'. For scientific research and biobanking, this will principally require informed consent from individuals whose data are processed, unless the law provides an alternative legal basis for the processing of personal data (i.e. specific permission provided by law). In addition, principles of data minimisation and storage limitation are particularly important to biobanking research.

Data subjects (i.e. patients and participants contributing their data or samples for research) have a number of rights as against the controller(s) and processor(s) of their data. They include the right to consent, to information, to access, to rectification, to erasure (aka 'the right to be forgotten'), to restrict processing, to data portability and to object. A number of these rights may be subject to limitations in the context of scientific research in certain cases.

Obligations of data controllers and processors include the obligation to establish clear and transparent procedures for data protection, security and confidentiality, as well as accountability and demonstration of compliance. Scientific research may enjoy exceptions to some obligations.

DOES THE GDPR CONTAIN EXCEPTIONS FOR BIOBANKS?

Biobanks could be exempted from a number of the GDPR's general principles, obligations and data subject rights, as, if and when processing personal data for the purpose of scientific research purposes. For example, the data storage limitation principle can be modified and personal data can be stored for longer periods provided that they will be processed solely for scientific research purposes in accordance with the provisions of article 89(1) of the GDPR and subject to implementation of technical and organisational measures required by the GDPR. Also, the GDPR retains the presumption of compatibility of use for research purposes, thereby enabling further data processing for scientific research purposes of personal data initially processed for a different purpose, provided that there is a valid legal ground for the initial processing in EU or Member States law exists.

The GDPR also allows for exemptions to various data subjects' rights in so far as the exercise of these rights is likely to render impossible or seriously impair the achievement of the research and such derogations are necessary to the fulfilment of these purposes. A number of these exemptions may directly apply on a case-by-case basis, while others will have to be provided by Union or Member States law. All exemptions are subject to the existence of appropriate technical and organisational measures ensuring in particular the respect of data minimisation principle (including for example pseudonymisation or anonymisation techniques), as mentioned in article 89. For more examples, see the answers relating to the various principles, obligations and rights under the Regulation.

WHAT IS THE RELATIONSHIP BETWEEN DATA PROTECTION AND PRIVACY?

Data protection is the legal terminology central to the Regulation. Privacy encompasses personal data protection but also comprises individuals' rights to private and family life and respect for the confidentiality of their correspondence and communications.

WHAT IS THE RELATIONSHIP BETWEEN DATA PROTECTION AND DATA SECURITY?

Data security is an element in safeguarding the rights and fulfilling the obligations set out in data protection law. More roughly put: data security is a necessary (though not in and of itself sufficient) means to achieve the ends of data protection. Security measures may serve other purposes unrelated to personal data protection as well, such as protecting commercial interests.

WHAT IS ANONYMISED/ANONYMOUS DATA?

The GDPR only applies to personal data, not to anonymised/anonymous (i.e. non-personal) data. The Regulation does not distinguish between anonymous and anonymised data.

Anonymised/anonymous data is defined in opposition to personal data as *‘information which does not relate to an identified or identifiable natural person or to personal data rendered anonymous in such a manner that the data subject is not or no longer identifiable’*.

Anonymity is not a static term, but dependent on context knowledge and ‘all the means reasonably likely to be used’ to re-identify the individual behind a data record. Whether data qualifies as anonymous has to be established on a case-by-case basis, requiring risk assessment. ‘Objective factors’ (such as the costs and the amount of time required for identification, the available technology at the time of processing and technological developments) need to be considered when deciding whether this standard is met in practice.

HOW IS ANONYMISATION ACHIEVED?

There are multiple methods, techniques and strategies to anonymise personal data. The GDPR does not favour a certain method.

In substance, the Regulation did not change the definition of personal and anonymous data. Therefore, methods meeting the standards of the 1995 Data Protection Directive should still hold in the legal sense, although these should always be assessed against the background of constant technical developments. There are many technical methods that can be used, such as deletion, redaction or generalisation, perturbation or dissociation of identifying information. Notably, the Opinion of the Article 29 Working Party on Anonymisation remains relevant under the GDPR.

IS ANONYMISATION REQUIRED IN SCIENTIFIC RESEARCH?

The principle of data minimisation is a requirement under the GDPR. This means that data have to be de-identified to the extent that research objectives can be achieved. However, anonymisation will not always be required. Other means such as pseudonymisation should also be considered. Future research purposes as well as the rights of individuals participating in research should be taken into account as well. Anonymisation makes it impossible to further communicate with the individual behind a data record, for example in order to feedback research results or to ask for follow-up information. In addition, it deprives him or her of the right to withdraw consent.

WHAT IS PSEUDONYMISATION OF DATA?

The GDPR defines pseudonymisation as *‘the processing of personal data in such a manner that the personal data can no longer be attributed to a specific data subject without the use of additional information, provided that such additional information is kept separately and is subject to technical and organisational measures to ensure that the personal data are not attributed to an identified or identifiable natural person.’*

WHAT'S THE DIFFERENCE BETWEEN PSEUDONYMISATION AND ANONYMISATION?

With pseudonymisation, attributing data to individuals remains possible using 'additional information' (e.g. a key or encryption code). For anonymised data, such information is not or no longer available. Pseudonymised data is still considered personal data in principle, whereas anonymised/anonymous data is not.

DOES THE REGULATION REQUIRE PSEUDONYMISATION IN SCIENTIFIC RESEARCH?

Pseudonymisation is promoted in the Regulation as one of the main methods to reduce the risks associated with processing personal data to 'help controllers and processors to meet their data-protection obligations'. However, other safeguards (such as encryption) will need to be considered and implemented as well (recital 28). At the same time, pseudonymisation is not required if it prevents pursuing particular scientific research purposes (according to article 89.1).

WHAT IS CONSENT?

The GDPR defines 'consent' of the data subject as meaning 'any freely given, specific, informed and unambiguous indication of the data subject's wishes by which he or she, by a statement or by a clear affirmative action, signifies agreement to the processing of personal data relating to him or her. Consent is one way to meet the GDPR requirement that processing of personal data must be lawful.

The GDPR specifies the conditions under which data subjects can validly consent to the processing of their personal data.

HOW SHOULD CONSENT BE OBTAINED FROM DATA SUBJECTS?

Where processing is based on consent:

- If the data subject's consent is given in the context of a written declaration which also concerns other matters, the request for consent shall be presented in a manner which is clearly distinguishable from the other matters.
- Consent must be requested in an intelligible and easily accessible form, using clear and plain language.
- Consent must be freely given.
- Consent must be informed, as specified in the GDPR (see FAQs on rights to information).
- Consent must be provided by a clear and affirmative action (silence, pre-ticked boxes or inactivity are not considered valid forms of consent under the GDPR).
- Consent can be provided in writing, by electronic means, as well as orally.

- Consent must represent the specific, informed and unambiguous indication of the data subject's agreement to data processing.
- The controller must be able to demonstrate that consent was lawfully provided, also if consent was provided orally.
- National laws can maintain or introduce further conditions regarding data subjects' consent in specific contexts, for instance with regard to the processing of genetic data.

CAN BIOBANKS USE 'BROAD CONSENT' UNDER THE REGULATION?

The Regulation acknowledges that the purposes of scientific research cannot always be specified at the time of the initial data collection. It therefore allows biobanks to ask individuals for 'consent to certain areas of scientific research when in keeping with recognized ethical standards for scientific research'. However, the Regulation also states that '[d]ata subjects should have the opportunity to give their consent only to certain areas of research or parts of research projects to the extent allowed by the intended purpose' (recital 33).

DO BIOBANKS NEED CONSENT TO PROCESS SENSITIVE DATA?

The GDPR provides that processing of sensitive personal data (such as genetic data or health data) shall be prohibited. However, the Regulation provides for a number of exceptions to this prohibition. One such exception is this prohibition if the data subject has given explicit consent. Consent is not the only exception, however. The prohibition does not apply either when the processing is necessary for scientific research purposes in accordance with Article 89(1) based on Union or Member State law, which shall be proportionate to the aim pursued, respect the essence of the right to data protection and provide for suitable and specific measures to safeguard the fundamental rights and the interests of the data subject.

WHAT ARE THE SPECIFIC PROVISIONS FOR CONSENT IN THE CASE OF CHILDREN?

Children merit specific protection with regard to their personal data, as they may be less aware of the risks, consequences and safeguards concerned and their rights in relation to the processing of personal data. In relation to the offer of information society services directly to a child, Unless Member State Law specifies a lower age, the processing of the personal data of a child shall be lawful where the child is at least 16 years old. Where the child is below the age of 16 years, such processing shall be lawful only if and to the extent that consent is given or authorized by the holder of parental responsibility over the child.

ARE THERE SPECIFIC PROVISIONS REGARDING THE PROCESSING OF DATA OF DECEASED PERSONS?

The Regulation does not apply to the personal data of deceased persons. However, this may be regulated in national law, for instance in law relating to professional secrecy. Moreover, one should keep in mind that constitutional and human rights considerations may be relevant in this regard.

DOES THE GDPR ALSO RULE ON PROFESSIONAL SECRECY?

Professional secrecy law (for health professionals such as doctors, nurses, etc.) may provide additional provisions to be respected next to data protection law (e.g. article 9.2i). The Regulation does not affect obligations of professional secrecy. Wherever applicable, both professional secrecy as well as data protection law need to be respected.

WILL CONSENT OBTAINED UNDER THE CURRENT DIRECTIVE REMAIN VALID UNDER THE NEW REGULATION?

Processing already under way on the date of application of this Regulation should be brought into conformity with this Regulation before this Regulation applies, that is, by mid 2018. It is not necessary for the data subject to give his or her consent again if the manner in which the consent has been given is in line with the conditions of this Regulation.

WHAT ARE THE OBLIGATIONS TO PROVIDE INFORMATION TO DATA SUBJECTS?

Different obligations are involved depending on the situation: whether data is collected from the data subject (article 13); whether data is collected from third parties (article 14); as well as whether data subjects invoke their right to access (article 15).

Under the Regulation, biobanks collecting personal data about their participants must provide their participants with extensive information about how and what data is processed. Obligations to provide data subjects with information about data processing already existed under previous data protection legislation. The GDPR expands on such obligations.

The obligation to provide information may not apply in certain cases:

- when the participant already has the information;
- where the recording or disclosure of the personal data is expressly laid down by law;
- If the personal data have been obtained from a third party: where the provision of information to the data subject proves to be impossible or would involve disproportionate effort. In that regard any appropriate safeguards adopted should be taken into consideration.

WHAT INFORMATION SHOULD BE PROVIDED TO DATA SUBJECTS IF DATA ARE COLLECTED FROM THE DATA SUBJECT?

As specified in article 13, biobanks must provide their participants the following information at the time data is obtained *and* when information is updated (subject to general principles of fair and transparent processing):

- The identity and the contact details of the controller and, where applicable, of the controller's representative;
- the contact details of the data protection officer, where applicable;
- the purposes of the processing for which the personal data are intended as well as the legal basis for the processing;
- the recipients or categories of recipients of the personal data, if any;
- where applicable, the fact that the controller intends to transfer personal data to a third country or international organisation and the existence or absence of an adequacy decision by the Commission, or, as the case may be, reference to the appropriate or suitable safeguards and the means by which their participants can obtain to obtain a copy of these safeguards or where these safeguards have been made available;
- the period for which the personal data will be stored, or if that is not possible, the criteria used to determine that period;
- the existence of the right to request from the controller access to and rectification or erasure of personal data or restriction of processing concerning the data subject or to object to processing as well as the right to data portability;
- where biobanks process personal information on the basis of, inter alia, consent, the existence of the right to withdraw consent at any time, without affecting the lawfulness of processing based on consent before its withdrawal;
- the right of participants to lodge a complaint with a supervisory authority;
- information on any processing of the personal data for a purpose other than that for which the personal data were collected and any relevant further information as referred to above.

WHAT INFORMATION SHOULD BE PROVIDED TO DATA SUBJECTS IF DATA ARE NOT COLLECTED FROM THE DATA SUBJECT?

As specified in article 14, biobanks must provide their participants with the following information:

- the identity and the contact details of the controller and, where applicable, of the controller's representative;
- the contact details of the data protection officer, where applicable;
- the purposes of the processing for which the personal data are intended as well as the legal basis for the processing;

- the recipients or categories of recipients of the personal data, if any;
- where applicable, the fact that the controller intends to transfer personal data to a third country or international organisation and the existence or absence of an adequacy decision by the Commission, or, as the case may be, reference to the appropriate or suitable safeguards and the means by which their participants can obtain to obtain a copy of these safeguards or where these safeguards have been made available;
- the period for which the personal data will be stored, or if that is not possible, the criteria used to determine that period;
- the existence of the right to request from the controller access to and rectification or erasure of personal data or restriction of processing concerning the data subject or to object to processing as well as the right to data portability;
- where biobanks process personal information on the basis of, inter alia, consent, the existence of the right to withdraw consent at any time, without affecting the lawfulness of processing based on consent before its withdrawal;
- the right of participants to lodge a complaint with a supervisory authority;
- where the processing is based on legitimate interests instead of on consent (for instance in some cases of residual or secondary use of data), the legitimate interests pursued by the controller or by a third party;
- if data were collected through third parties: from which source the personal data originate, and if applicable, whether it came from publicly accessible sources.

WHAT INFORMATION SHOULD BE PROVIDED TO DATA SUBJECTS IF DATA SUBJECTS INVOKE THEIR RIGHT TO ACCESS?

As specified in article 15, when data subjects invoke their right to access their data, biobanks must provide participants confirmation as to whether or not personal data concerning him or her are being processed, and, where that is the case, access to the personal data and the following information:

- the purposes of the processing;
- the categories of personal data concerned;
- the recipients or categories of recipient to whom the personal data have been or will be disclosed, in particular recipients in third countries or international organisations;
- where possible, the envisaged period for which the personal data will be stored, or, if not possible, the criteria used to determine that period;
- the existence of the right to request from the controller rectification or erasure of personal data or restriction of processing of personal data concerning the data subject or to object to such processing;
- the right to lodge a complaint with a supervisory authority;
- where the personal data are not collected from the data subject, any available information as to their source;

- the existence of automated decision-making, including profiling, referred to in Article 22(1) and (4) and, at least in those cases, meaningful information about the logic involved, as well as the significance and the envisaged consequences of such processing for the data subject.
- Where personal data are transferred to a third country or to an international organisation, the data subject shall have the right to be informed of the appropriate safeguards pursuant to Article 46 relating to the transfer.
- The controller shall provide a copy of the personal data undergoing processing. For any further copies requested by the data subject, the controller may charge a reasonable fee based on administrative costs. Where the data subject makes the request by electronic means, and unless otherwise requested by the data subject, the information shall be provided in a commonly used electronic form. This right to obtain a copy shall not adversely affect the rights and freedoms of others.

Note that Member States can provide derogations to this right in national law.

HOW SHOULD INFORMATION BE PROVIDED TO DATA SUBJECTS?

Pursuant to Article 12 and according the principle of transparency, any information addressed to the data subject or to the public, must be provided ‘in a concise, transparent, intelligible and easily accessible form, using clear and plain language, and additionally, where appropriate, visualization must be used. In particular for any information addressed to a child any information and communication should be in such a clear and plain language that the child can easily understand. Every single data subject should be provided the information. Information must be provided in writing and/or by electronic means. When requested by the data subject, the information may be provided orally, provided that the identity of the data subject is proven by other means.

The information may be provided in combination with standardized icons in order to give an easily visible and meaningful overview of the intended processing.

WHEN SHOULD INFORMATION BE PROVIDED TO DATA SUBJECTS?

When data are collected from the data subject, the information must be given at the time when the personal data is obtained, as well as when information is updated, subject to general principles of fair and transparent processing. When data are collected through third parties and/or used for secondary purposes, information must be provided (article 14.3):

- ‘within a reasonable period after obtaining the personal data, but at the latest within one month, having regard to the specific circumstances in which the personal data are processed’;
- ‘if the personal data are to be used for communication with the data subject, at the latest at the time of the first communication to that data subject’;
- ‘if a disclosure to another recipient is envisaged, at the latest when the personal data are first disclosed.’

WHAT EXEMPTIONS TO RIGHTS TO INFORMATION MAY APPLY?

Generally, the obligation to provide information does not apply where and insofar as the data subject already has information about processing. In the event the personal data have not been obtained from the data subject (but from a third party source), the obligations to provide individuals with information can be exempted if:

- if the provision of such information proves impossible,
- if the provision of such information would involve a disproportionate effort, and/or
- if the obligation is likely to render impossible or seriously impair achieving the (research) objectives of the processing of personal data.

If a biobank wants to invoke either of these exceptions, it will have to establish that these requirements are met. Moreover, invoking these exceptions is subject to appropriate conditions and safeguards under article 89, such as technical and organisational measures, including pseudonymisation, as well as measures to protect data subjects' rights and freedoms and legitimate interests. At the very least, these measures include making the information publicly available – for instance, through the biobank's website.

These exceptions may usually not be successfully invoked by biobanks which regularly communicate with their participants. For other forms of research, such as residual use tissue banks and patient registries, these clauses may provide some leeway towards operating on the basis of an opt-out system. However, whether this is so will strongly depend on both the specifics of the infrastructure, the research involved, as well as national legislation.

Finally, the obligation to provide information may not apply, where personal data obtained from a third party source is also subject to an obligation of professional secrecy, such as doctors.

ARE THERE ANY NEW RIGHTS FOR DATA SUBJECTS?

Yes. New rights include the right to be forgotten, which amends the existing right to erasure, and the right to data portability'. In addition, a number of existing rights have been specified. These include the right to information, the right to rectification, the right to restriction of processing, the right to object to processing of personal data, and the right not to be subject to legal measures based solely on automated profiling. The GDPR also recognises the need for children as data subjects to be specifically protected regarding the processing of their personal data and provides for an enhanced specification of consent, in particular regarding consent to the processing of sensitive personal data (such as health, genetic, or biometric data). More transparent information and communication about the purposes and forms of data processing, must also be provided when data are processed by third parties.

WILL ALL DATA SUBJECTS' RIGHTS APPLY TO BIOBANKS?

According to article 89, Union or Member State law may provide for derogations from a number of data subject rights, including the rights to access, to rectification, to restriction of processing and to object to processing of personal data, when personal data are processed for scientific research purposes. These further derogations are subject to technical and organizational measures (e.g. pseudonymisation) which need to be in place in particular in order to ensure respect for the principle of data minimisation.

These derogations are only available in so far as the exercise of these rights is likely to render impossible or to seriously impair the achievement of the objectives of that processing. Where those purposes can be fulfilled by further processing which does not permit or no longer permits the identification of data subjects, those purposes have to be fulfilled in that manner.

WILL THE NEW ‘RIGHT TO BE FORGOTTEN’ APPLY TO BIOBANKS?

The right ‘to be forgotten’ shall not apply to the extent that the processing of personal data is necessary for scientific research purposes or statistical purposes in accordance with Article 89(1), in so far as it is likely to render impossible or seriously impair the achievement of the objectives of that processing.

WHAT ABOUT THE NEW ‘RIGHT TO DATA PORTABILITY’?

The GDPR introduces a ‘right to data portability’, i.e. the right for a data subject to receive the personal data concerning him or her, which he or she has provided to a controller, in a structured, commonly used and machine-readable format and the right to transmit those data to another controller without hindrance from the controller to which the personal data have been provided. The data subject also has the right to have his or her personal data transmitted directly from one controller to another controller. This right applies where either the processing is based on consent or on a contract and the processing is carried out by automated means. Notably, the right to data portability is not part of the list of data subject rights which can be derogated from by the Member States under Article 89(2).

“Inferred data” and “derived data” such as data resulting from genetic sequencing of samples could be exempt from this obligation, as suggested by a (non-binding, draft) guideline drawn up by [the EU Article 29 Working Party](#). Further specifications of the reach of the law in this regard remain to be established.

MUST BIOBANKS APPOINT A DATA PROTECTION OFFICER?

Since the core activities of Biobanks consist of processing operations that require regular and systematic monitoring of the data subjects on a large scale, a Data Protection Officer must be delegated by the Biobank controller or the processor/s in order to assist them monitor internal compliance with this Regulation. Such data protection officers, whether or not they are an employee of the controller, should be in a position to perform their duties and tasks in an independent manner.

Organisations with less than 250 employees are exempt from this obligation under the Regulation. Note, however, that it is the number of employees of the organisation of which the biobank forms part which counts towards the total number of employees. For instance, this may be an academic hospital or university of which the biobank is a part.

WHAT DOES THE PRINCIPLE OF ACCOUNTABILITY MEAN IN THE GDPR?

The principle of accountability refers to the responsibility of the data controller to ensure that the fundamental principles relating to processing of personal data are respected, as well as the ability to demonstrate compliance.

WHAT DOES THE PRINCIPLE OF TRANSPARENCY MEAN IN THE GDPR?

Transparency is one of the core principles in the GDPR. It requires in particular that data subjects must be informed about whether, how and by whom data relating to them is processed, as well as a 'right to obtain confirmation and communication of personal data concerning them which are being processed' (recital 39), 'taking into account the specific circumstances and context in which the personal data are processed' (recital 60).

WHAT DOES THE REGULATION SAY ABOUT DATA BREACHES?

According to the GDPR, a personal data breach is 'a breach of security leading to the accidental or unlawful destruction, loss, alteration, unauthorized disclosure of, or access to, personal data transmitted, stored or otherwise processed'.

As soon as the controller becomes aware that a personal data breach has occurred, the controller must notify the personal data breach to the supervisory authority without undue delay and, where feasible, not later than 72 hours after having become aware of it, unless the controller is able to demonstrate, in accordance with the accountability principle, that the personal data breach is unlikely to result in a risk to the rights and freedoms of natural persons. Where such notification cannot be achieved within 72 hours, the reasons for the delay should accompany the notification and information may be provided in phases without undue further delay.

The controller should also communicate to the data subject a personal data breach, without undue delay, where that personal data breach is likely to result in a high risk to the rights and freedoms of the natural person in order to allow him or her to take the necessary precautions.

MUST BIOBANKS DO A DATA PROTECTION IMPACT ASSESSMENT?

Most probably yes, assuming they engage in a type of processing of personal data, in particular using new technologies, which, taking into account the nature, scope, context and purposes of the processing, is likely to result in a high risk to the rights and freedoms of natural persons, e.g. when they are processing on a large scale special categories of data, such as health data and genetic data. The supervisory authority in a Member State shall establish and make public a list of the kind of processing operations which are subject to the requirement for a data protection impact assessment; please refer to your supervisory authority to check whether it has so listed your type of processing. Also, the supervisory authority may establish and make public a list of the kind of processing operations for which no data protection impact assessment is required. Chances that processing by biobanks of sensitive data will be listed on this negative list, are slim but please refer to your supervisory authority. A single assessment may address a set of similar processing operations that present similar high risks.

WILL THE GDPR APPLY IN THE UNITED KINGDOM FOLLOWING BREXIT?

Generally, to provide legal certainty in the UK after exit from the EU, The United Kingdom's exit from and new partnership with the European Union White Paper states that the Government introduce the Great Repeal Bill to remove the European Communities Act 1972 from the statute book and convert the

body of existing EU law into domestic law. This means that, where practical and appropriate, the same rules and laws will apply on the day after the UK leaves the EU as they did before.

The UK will still be a member of the European Union on May 25, 2018, thus the GDPR will automatically become binding in the UK on that date. On Wednesday 1st February the EU Home Affairs Sub-Committee took evidence from Rt Hon Matt Hancock MP, Minister of State for Digital and Culture, Department for Culture, Media and Sport on the EU General Data Protection Regulation. He stated that the British government will fully implement the GDPR for two key reasons:

- "Thanks to some significant negotiating successes during its development we think that it is a good piece of legislation in and of itself,"
- "We are keen to secure the unhindered flow of data between the UK and the EU post-Brexit, and we think that signing up to the GDPR data protection rules is an important part of helping to deliver that."

Even if the UK does fully implement the GDPR post-Brexit, it would become a so-called third country. At that point, the free flow of data between the UK and the EU would be dependent upon arrangements similar to those currently in place to enable data flows to other third countries. outside the EU. One option would be for the UK to apply for an 'adequacy decision' (see further on).

HOW CAN PERSONAL DATA BE TRANSFERRED OUTSIDE THE EU?

Personal data may be transferred to a third country where the Commission has decided that the third country, or one or more specified sectors within that third country, ensures an adequate level of protection. The effect of such an 'adequacy decision' is that personal data can flow from the EU to that third country or sector without further safeguards. Such a transfer shall not require any specific authorization.

In the absence of an adequacy decision of the Commission, a controller or processor may transfer personal data to a third country only if the controller or processor has provided appropriate safeguards, and on condition that enforceable data subject rights and effective legal remedies for data subjects are available. The appropriate safeguards may be provided for by standard data protection clauses adopted by the Commission. They could also be provided for by an approved code of conduct or certification mechanism, together with binding and enforceable commitments of the controller or processor in the third country to apply the appropriate safeguards, including as regards data subjects' rights.

In the absence of an adequacy decision or of appropriate safeguards, a transfer or a set of transfers of personal data to a third country may take place on the condition that the data subject has explicitly consented to the proposed transfer, after having been informed of the possible risks of such transfers for the data subject due to the absence of an adequacy decision and appropriate safeguards.

CAN BIOBANKS CONTINUE TO TRANSFER PERSONAL DATA TO THE UNITED STATES OF AMERICA?

Yes, subject to the general transfer provisions to transferring data outside the EU discussed in the question above. Transfers under the Safe Harbour principles are no longer valid. New specific rules (the EU-US Privacy Shield) are still under negotiation.

CAN BIOBANKS TRANSFER PERSONAL DATA TO THE UNITED STATES OF AMERICA BASED ON THE EU-US PRIVACY SHIELD?

Only if the receiving organisation is listed under the Privacy Shield Framework and the data fall within the covered data of the listing.

On July 12, 2016, the European Commission deemed the EU-U.S. Privacy Shield Framework adequate to enable data transfers from the EU to the USA under EU law (the Privacy Shield replacing previous EU-US Safe Harbour agreements).

Personal data are transferred under the EU-U.S Privacy Shield where they are transferred from the Union to organisations in the United States that are included in the 'Privacy Shield List', maintained and made publicly available by the U.S. Department of Commerce. Transfer of personal data to such an organisation would then qualify as a valid transfer under the Regulation. Any U.S. organisation that is subject to the jurisdiction of the Federal Trade Commission (FTC) or the Department of Transportation (DOT) may participate in the Privacy Shield. Generally, the FTC's jurisdiction covers acts or practices in or affecting commerce. For all practical purposes, academic and not for profit research organisations are unlikely to be eligible for listing under the Privacy Shield Framework and hence biobanks cannot ground any transfer of personal data to such organisations based on the Privacy Shield. This may be different for commercial institutions, provided of course, they are listed and the data to be transferred is covered by the listing; e.g. 23andMe. The Privacy Shield list can be found [here](#).

CAN BIOBANKS TRANSFER PERSONAL DATA TO THE UNITED STATES OF AMERICA BASED ON THE SWISS-US PRIVACY SHIELD?

Regarding Switzerland (non-EU member State), in January 2017, the Federal Council states that a new framework, Privacy Shield, has been established for the transfer of personal data from Switzerland to the USA. With the introduction of Privacy Shield, the same standards apply for Swiss exports of personal data to the USA as for data exports from the EU. The Federal Data Protection and Information Commissioner (FDPIC), as the other supervisory authorities in EU Member States will act as a point of contact for persons in Switzerland in the event of any problems in connection with the transfer of data to the USA.

Regarding the transfer of personal sensitive data (as defined in Article 9(1), including e.g. health, genetic/genomic, biometric data) for research purposes, although it is not obligatory under the GDPR, it is recommended to use additional contractual measures intended to specifically frame the activities in terms of purposes, methodologies, confidential data management and data subjects' rights protection. Such a contract can take the form of a Data Transfer Agreement or a Material Transfer Agreement.

HOW WILL THE REGULATION BE ENFORCED?

The Regulation provides for three types of mechanisms to enforce its provisions: corrective measures, fines and penalties.

Each supervisory authority shall have a set of corrective measures, which include issuing warnings or reprimands, imposing a limitation or even a ban on processing, ordering the rectification or erasure of personal data, and imposing an administrative fine to the controller or the processor.

Infringement of the basic principles for processing, including conditions for consent, but also infringements of the data subjects' rights the transfers of personal data to a recipient in a third country or an international organization, can be subject to administrative fines of up to €20.000.000.

Member States shall lay down the rules on other penalties applicable to infringements of this Regulation, in particular for infringements which are not subject to administrative fines pursuant to Article 83, and shall take all measures necessary to ensure that they are implemented.

