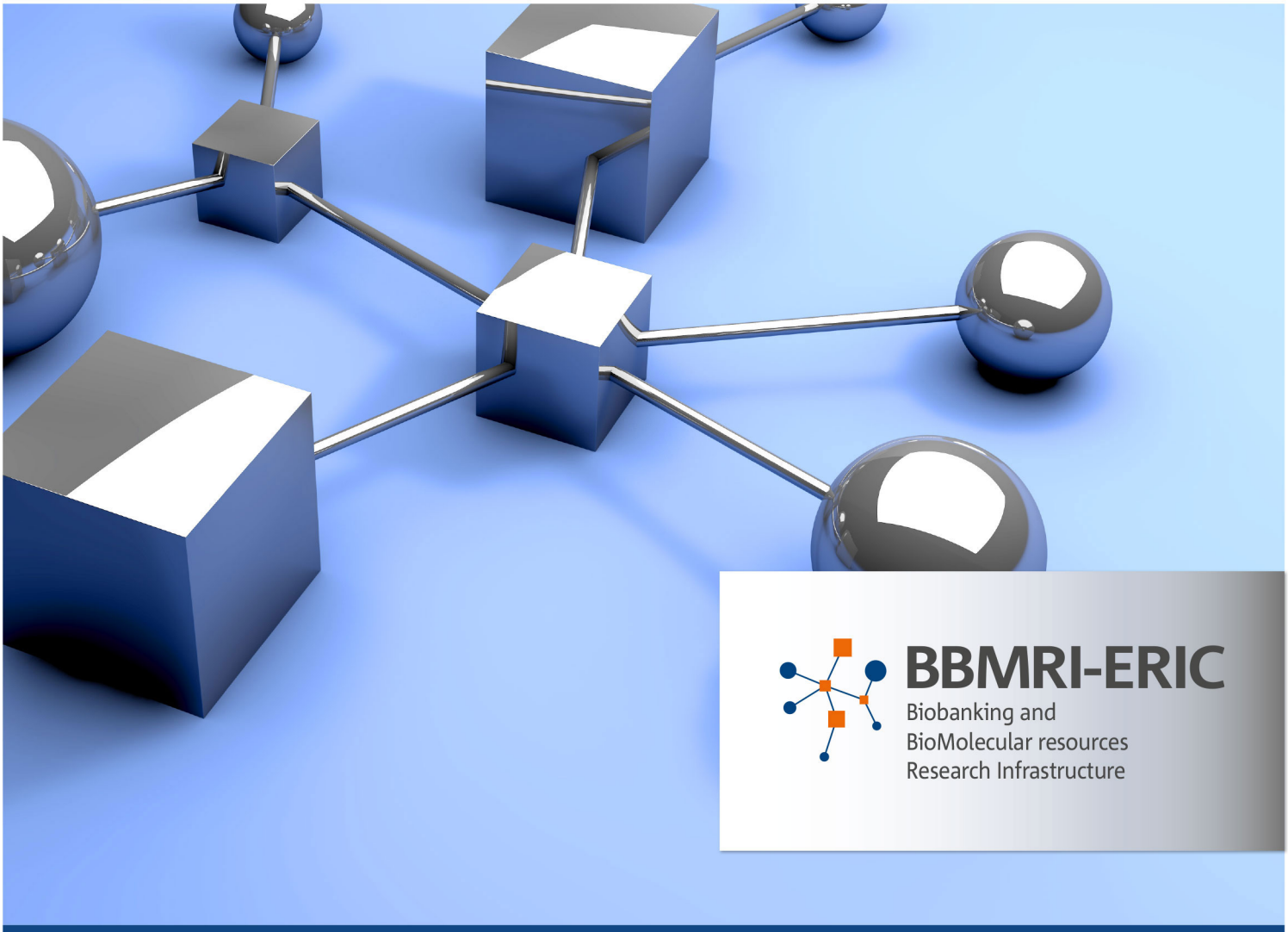

BBMRI-ERIC
Biobanking and
BioMolecular resources
Research Infrastructure

BBMRI ELSI WORKSHOP REPORT

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

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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

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TABLE OF CONTENTS

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 Mertons 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 it's 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 commodifed 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 breath 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]

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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 rational 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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