newsletter

n Q2_2016

Focus ELSI

German Biobank Node
bbmri.de

Editorial

Dear Colleagues and Biobankers,

In addition to the quality of biomaterials and related data, the issues surrounding ethical, legal and social (ELSI) considerations are one of the most important topics for biobanking. Over the last two decades, there have been plenty of discussions – some of which have been very emotionally driven – at the national, European and international levels. There has been some clarification on general issues at this point, but further support is needed for the practical applications in daily biobank operations. To this end, the German AKEK has published a consensus template which can be used for applications of broad consent for donors of health-integrated biobanking. In addition, the AKEK has just recently released another document which defines an ethical framework for the establishment and operation of biobanks. For projects at the European level, the BBMRI-ERIC Common Service ELSI has developed recommendations to facilitate cross-border compilations of collections, and it offers support in various ways to the member nodes. Last but not least, the new GDPR was published this spring, and we would like to outline what this means for biobanking and research in this context. These important ELSI topics are the focus of this edition of the GBN newsletter, and we hope this information will be useful in your work.

We wish you a sunny and relaxed summer!
Michael Hummel & Cornelia Rufenach

"Donors Must Be in a Position to Effectively Assert Their Legal Rights"

Prof. Dr. Roland Jahns (Photo: ibdw)

Prof. Dr. Roland Jahns bears responsibility for public relations and ethical matters within the German Biobank Node (GBN). He is also Director of the Interdisciplinary Bank of Biomaterials and Data in Würzburg (ibdw) and a member of the "Biobanking" working group of the Medical Ethics Committees of Germany.

Prof. Jahns, the increasing centralization and internationalization of biobanks brings completely new ethical questions. Can you describe these?
Biobanks are engaged in a field that affects the interests of medical research on the one hand and the rights and interests of donors on the other, and these interests should be balanced. Ethical considerations are of major importance here. The long-term success of a centralized biobank depends – aside from organizational challenges – to a very considerable degree on the willingness of patients and participants in clinical trials to donate biomaterials and data for a wide range of different medical research purposes. This is achieved today through a so-called broad consent on the part of the donors. This, however, is entirely different from the study-specific consent (informed consent) mostly used in the past for biomaterials. It is necessary, however, to explain to the patient why a broad consent is desirable and necessary for medical research.
Aside from organizational questions,

Topics

BBMRI-ERIC CS ELSI

p. 3

General Data Protection Regulation (GDPR)

p. 4

Ethics committee

p. 5

the internationalization of biobanks primarily raises legal questions of data privacy. In particular, data relating to individuals must be sufficiently protected. The exchange of samples and data between modern biobanks on an international level offers considerable scientific scope for major advances, for example in the treatment of rare diseases because it makes larger sample sizes possible.

Are there national or international recommendations that can help biobanks to deal with ethical, legal and social issues?

The Declaration of Helsinki is a binding international framework. In addition, the Declaration of the World Medical Association (WMA) also embraces the ethically correct handling of biomaterials and data in research projects. The recommendations of the OECD deliver specific information on how human biomaterials and data are to be treated. In addition, at the European level, the Common Service ELSI was launched in 2015 by BBMRI-ERIC as the first BBMRI Common Service (CS) in order to help and advise European biobanks in all kinds of ELSI matters. In addition to acting as a "help desk," CS offers an ethics check for BBMRI research proposals and currently develops recommendations and tools facilitating European cross-border access to biobank resources and data.

At a national level, the German Ethics Council (DER) has issued recommendations for research biobanks hosting human biomaterials. Additionally, there is the TMF, which has published checklists and guidelines on consent documents and legal matters in the field of research. Moreover, the Medical Ethics Committees in Germany Working Group (AMEK) issued templates for standard wording and recommendations on the ethical aspects of biobanking. They offer guidance for the formulation of texts for collections of specimens for specific projects as well as those for research purposes that are not yet determined.

Many biobanks are storing samples and data long-term for use in future research projects, the purpose of which is not yet known. How will the rights of patients be protected with such a broad consent?

The discussion about broad consent is a highly topical one, and for a long time, it was disputed whether it was legal at all. A broad consent is generally accepted today, however, if the recommendations of the German Ethics Council are observed. The broader the consent, the more necessary it becomes to gain the confidence of the donor. The donor must be given clear information, especially with regard to the uncertainty concerning the actual future use. Donors place considerable trust in those who will have access to their sensitive health data. For this reason, the procedures of a biobank and its rules, as well as its scientific and public activities, must be transparent. Donors should be able to inform themselves about the biobank and the use of their samples at any time. Furthermore, donors must be able to assert their legal rights, guaranteed under data privacy laws, such as their right to withdraw their consent.

Studies worldwide have shown that many patients wish to be informed of the outcome of research if there are additional findings or incidental findings. How can biobanks deal with this expectation, and what is the legal framework that governs this situation?

"Incidental" or "unsolicited" findings are mostly not an issue for biobanks, but rather for the researchers who make use of collected biomaterial hosted and provided by biobanks. Thus, in general, it is up to the researcher to decide how to deal with such findings, and this is also true for genetic or "molecular" findings. In this context, I consider it to be ethically problematic if research findings are communicated back to the donor without any form of filter. For example, assume that a person was informed that he had a 20% risk of developing Alzheimer's disease at the age of 80, what should he do with that information? Although it is understandable that people want to know the outcome of genetic analysis, the results can be unsettling for a donor. In a purely research context, the communication of incidental or additional findings is only envisaged in a life-threatening situation which may be circumvented or in which treatment is possible and always with the involvement of the respective treating physician. In addition, if an illness that can be treated is discovered, physicians may have a professional obligation to contact the donor. Moreover, the communication of genetic findings that are relevant to health falls under the Gene Diagnostics Act and generally requires the involvement of a human geneticist. Taken together, I regard a more general feedback on the research subjects and results supported by the biobank in question as being helpful and feasible, but I do not consider the individual communication of research results to be desirable.

Interview Wiebke Lesch

References

Human Biobanks for Research
Deutscher Ethikrat Berlin 2010
http://www.ethikrat.org/

Mustertext zur Spende, Einlagerung und Nutzung von Biomaterialien. Updated version (V.2.0; June 10, 2016)
Arbeitskreis Medizinischer Ethik-Kommissionen in der Bundesrepublik Deutschland e. V. and Arbeitsgruppe Biomaterialbanken der TMF
http://www.ak-med-ethik-komm.de/

Contact: *Prof. Dr Roland Jahns*
Interdisciplinary Bank of Biomaterials and Data Würzburg (ibdw)
Jahns_R@ukw.de

German Biobank Node
bbmri.de

BBMRI-ERIC

A Common Service for Ethical, Legal and Societal Issues

As the proper consideration of ethical, legal and social issues (ELSI) is key to any biobanking activity, BBMRI-ERIC has set up the Common Service ELSI (CS ELSI), which is considered a key asset of the research infrastructure. According to BBMRI-ERIC's Statutes (Statutes, Article 15.1), Common Services shall consist of the facilities of BBMRI-ERIC that provide expertise, services and tools relevant for the pursuance of BBMRI-ERIC's tasks and activities, laid down in the Work Programme. The Common Service ELSI in particular aims to facilitate and support cross-border exchanges of human biological resources and data attached for research uses, collaborations and sharing of knowledge, experiences and best practices. It is co-directed by Anne Cambon-Thomsen, Mats G. Hansson, Jasper Bovenberg and Marialuisa Lavitrano and consists of more than 20 experts from BBMRI-ERIC's 18 Members.

Among the latest achievements of the CS ELSI is a set of Frequently Asked Questions (FAQs) on the General Data Protection Regulation. Consider, exemplarily, the following Q&A:

Will consent obtained under the current directive remain vaild under the new regulation?

Processing already underway on the date of application of this Regulation should be brought into conformity with this Regulation before this Regulation applies, that is, by mid 2 018. 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.

Find out more: www.bbmri-eric.eu

Download of the FAQs:
http://bbmri-eric.eu/elsi

What is the service about?
BBMRI-ERIC provides tools and expertise, as well as knowledge and experience sharing on ethical, legal and societal issues for the biobanking community through its Common Service ELSI.

Who is this service for?
The service offers support on ethical, legal and societal issues related to biobanking activities. It is primarily intended for users located in Member Countries of BBMRI-ERIC.

How can I engage?
Sign up for the e-newsflash!
Sign up in our ELSI expert database!

Who to contact?
BBMRI-ERIC
Chief Policy Officer CS ELSI
Michaela Mayrhofer
michaela.th.mayrhofer@bbmri-eric.eu

Check out our website or contact us directly!

What is BBMRI-ERIC?
BBMRI-ERIC is a distributed research infrastructure of *biobanks and biomolecular resources*. For its Member States, it provides expertise and services on a non-economic basis and facilitates access to collections of partner biobanks and biomolecular resources. BBMRI-ERIC is established for an unlimited period of time.

KEY SERVICES

- Offering practical interpretation of new legislations (e.g., *FAQ on GDPR*)
- Monitoring of relevant ethical and legal frameworks in development (e.g., *Safe Harbour*)
- Coordinating replies to relevant public consultations on the European level (e.g., *Council of Europe Recommendation CM/REC(2016)6*)
- Developing tools to support biobankers in their daily work, especially when addressing legal matters (e.g., WIKI legal & hsern)
- Informing about publications & research results, surveys, and relevant meetings
- Providing an ethics check of ELSI compliance for research proposals
- Organising experience sharing and exchanges regarding ELSI aspects (www.europebiobankweek.org)

➔ Sets up a Help Desk on ELSI issues (forthcoming in 4Q 2016)

German Biobank Node
bbmri.de

Europe

General Data Protection Regulation: What's new for biomedical research?

The General Data Protection Regulation (GDPR) (Regulation (EU) 2016/679) is a regulation by which the European Union intends to strengthen and unify data protection for individuals within the European Union (EU). Irene Schlünder from TMF explains the impact of this new legislation on medical research.

Will there be major changes to data protection or the way in which patient or research participant data can be used for research purposes?
No. The basic concepts of data protection law will not change under the GDPR: Data protection law will only cover personal data, whereas anonymous or anonymized data may be used as before. Health data will still be considered "sensitive"; such data must be handled with special care and diligence. Informed consent remains the main requirement for the use of personal data in research, especially sensitive data. Exemptions from consent must be based on law.

Will the GDPR achieve greater harmonization with respect to exemptions from requirements such as informed consent?
No. The initial aim of the GDPR has been to further harmonize data protection law in Europe. But during the legislation process it became apparent that the national legal frameworks for biomedical research and the national healthcare systems are interwoven in a very complex manner. As a result, the main derogation clauses refer to national legislation. Thus, legal fragmentation with regard to biomedical research will continue within the EU. The research community is now called upon to further harmonize the regulations to facilitate data sharing.

What could the research community do to push forward harmonized regulations?
The GDPR regulates data protection in all conceivable fields and refers to biomedical research only in a quite general way. Many issues remain unresolved and many rules are open to interpretation. A Code of Conduct could help set up common standards for the use and sharing of research participants' data in biomedical research and thus reduce legal uncertainty and bureaucratic burdens for those who have to abide by the law – the biobankers and researchers. In addition, widely-agreed best practices, for example for anonymization and pseudonymization, seem to be needed as well as common concepts and templates for informed consent.

Do Research Ethics Committees (RECs) have a role under the GDPR?
RECs are not explicitly mentioned in the GDPR, but "ethical standards" are, for example as a prerequisite for biobanking on the basis of a consent that covers as yet unknown research projects. RECs indeed play a major role in the development of agreed standards with regard to data protection, since every research project needs the approval of a REC and such approval takes a participant's privacy into consideration as provided for not only in the GDPR, but also in the Helsinki Declaration. Fragmented review practices seem to be a major hurdle for collaborative research projects and sample and data sharing in Europe.

How do biobanks and researchers have to prepare for the implementation of the GDPR?
The GDPR will come into force in June 2018. Meanwhile, national legislators will have to adapt national statutes to make them compatible with the GDPR. The derogation clauses for national legislation make it is very difficult to say what the exact changes for biomedical research will be before this process is complete. With regard to German legislation, there will probably be only minor changes since the standards in Germany have always been quite high. But some changes might be necessary with respect to organizational measures, since the GDPR sets an emphasis on the enforcement of data protection requirements and possible fines for breaches have been increased considerably.

Should researchers just wait until 2018?
No. Biobankers and researchers, or their national organizations, should pay careful attention to national legislation to make certain that the derogation clauses in the GDPR are used to find sustainable solutions to make progress in biomedical research whilst protecting privacy at its best.

Contact: *Irene Schlünder*
BBMRI-ERIC Common Service ELSI and TMF
Irene.Schluender@bbmri-eric.eu

German Biobank Node
bbmri.de

Ethics Committee

"The advice of an ethics committee is very helpful for many researchers"

Prof. Dr. Wolfgang Eisenmenger, Chairman of the Ethics Committee of Ludwig-Maximilians University in Munich, outlines the tasks and roles of an ethics committee in biobank research.

Prof. Dr. Wolfgang Eisenmenger

How are the duties of an ethics committee defined?
The Good Clinical Practice guidelines define an ethics committee as an independent body constituted of medical professionals and non-medical members, whose responsibility it is to protect the rights, safety and well-being of human subjects involved in a clinical trial. Most importantly, this includes an approval of the suitability of the investigators involved in the trial and the adequacy of facilities, and the methods and documents used to inform trial subjects and obtain their informed consent.[1]
Over and above these duties, the ethics committee provides advice to the applicant in scientific and legal matters.

How does one become a member of an ethics committee?
The Public Health and Consumer Protection Act in Bavaria and the EU Clinical Trials Directive specify the composition of the ethics committee. According this Act, the ethics committee must have at least 5 members and an appropriate number of representatives and be interdisciplinary in its make-up. One member should be a lawyer who is qualified to hold the position of a judge, and a further member should have scientific or professional experience in the field of medical ethics. At least 3 members should be doctors who work in a clinical environment, and one member should have experience in the design of trial protocols and in statistics, as well as theoretical medicine.
The EU Directive requires that the committee also include at least one layperson, which is not a requirement in the Bavarian regulations.

How do you evaluate research projects that use biomaterial samples and require a broad consent?
If the broad consent has been obtained under the stipulation that the biobanks are purely scientific and are not commercial operations, then it must be ensured that they abide by these conditions. Samples must not be passed on to pharmaceutical companies or for-profit organizations within a transfer agreement. Moreover, to be approved, biobanks must pledge to present future research projects, which cannot yet be specified in detail, to the ethics committee that is responsible for the researchers. A further absolute condition is that the samples are double-coded as a minimum when they are stored for such future research. Any samples or data from the biobank that are passed on to other countries that have less stringent data privacy standards than the German ones must be in an anonymous form.

Some researchers regard the requirement that they seek approval from an ethics committee as an onerous formality. How would you convince them that it is something positive?
The advice of an ethics committee is very helpful for many researchers. In many cases, questions can be formulated differently or goals defined differently so that the research project is not subject to the requirements of the Medicinal Products Act. In addition, any questions or suggestions from the ethics committee, for example on the design of the study or on how to deal with confounders and/or avoid bias, are reasons to view the research project from the perspective of the ethics committee and ultimately to make improvements and at least clarify any confusing language.

Finally, if the ethics committee takes a positive view of the proposed study, then the researchers will have a greater chance of the results being published in a highly respected journal.

[1]GCP-Verordnung vom 9. August 2004 (BGBl. I S. 2081)

Contact: *Prof. Dr. med. Wolfgang Eisenmenger*
LMU Munich, Institute of Legal Medicine
Wolfgang.Eisenmenger@med.uni-muenchen.de

German Biobank Node
bbmri.de

Publications

Strech, D *et al.* (2016) A template for broad consent in biobank research. Results and explanation of an evidence and consensus-based development Process. European Journal of Medical Genetics 59, 295-309.

Sariyar, M and Schlünder, I (2016) Reconsidering Anonymization-Related Concepts and the Term „Identification" Against the Backdrop of the European Legal Framework. Biopreservation and Biobanking 14(2).

Merino-Martinez, R *et al.* (2016) Toward Global Biobank Integration by Implementation of the Minimum Information About Data Sharing (MIABIS 2.0 Core). Biopreservation and Biobanking 14(2).

Jahns, R (2016) Errichtung und Betrieb von Humanbiobanken. Bundesgesundheitsblatt - Gesundheitsforschung - Gesundheitsschutz 59(3), 311-316.

Link tip

BBMRI.se and the **Centre for Research Ethics & Bioethics (CRB)** of the University Uppsala compiled a list of publications about how to deal with ethical aspects of research using human tissue material and personal data. The "Report on ethical and legal aspects of biobank and registry research" and their current newsletter can be found at http://www.crb.uu.se/biobank-perspectives/

Forthcoming Events

Data integration & data sharing in the era of 'Big Data' - Quo vadis, Medical Informatics?
joint Workshop of TMF & GMDS
12. - 13. July 2016
Berlin, TMF
http://www.tmf-ev.de

Europe Biobank Week 2016 (BBMRI / ESBB)
Biobanking for Health Innovation
13.-16. September 2016
Vienna/Austria
http://europebiobankweek.eu/

➔ The abstract submission deadline for oral presentations has been extended to 15. July 2016.

Big Data in Biology and Health
EMBL–Welcome Genome Campus Conference
25.- 27. September 2016
Heidelberg, EMBL
http://www.embl.de/training/events/2016/BIG16-01/

5th National Biobank Symposium
7. - 8. December 2016
Berlin, Mercure Hotel MOA Berlin
http://www.biobanken.de/de-de/symposium.aspx

The **German Biobank Node (GBN)** is the central contact and exchange point for the German Biobank community - not only for researchers, but also for other stakeholder groups. Our aim is to facilitate exchanges of experience between national biobanks but also the participation in the European network of biobanks (BBMRI-ERIC). The development of standards for quality assurance as well as the elaboration of an IT concept for the sample and data exchange are our major projects.

Imprint

German Biobank Node
Newsletter Q2 June 2016

National Coordinator:
Prof. Michael Hummel

Executive Director:
Dr. Cornelia Rufenach

Charité -
Universitätsmedizin Berlin
Institut für Pathologie | CBF
Hindenburgdamm 30
D-12203 Berlin

Contact:
germanbiobanknode@charite.de

www.bbmri.de