



BBMRI-ERIC[®]
Biobanking and
BioMolecular resources
Research Infrastructure

Biobanking: Ethical and Legal Issues
Workshop Report
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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> .