PROCEEDINGS OF THE 1ST ELSI SYMPOSIUM: ETHICAL, LEGAL AND SOCIETAL INSIGHTS & OUTLOOK FOR BIOBANKS AND MEDICAL RESEARCH

4-6 June, 2024

LYON

Table of Contents

ABOUT THE SYMPOSIUM

From June 4-6th 2024, the Symposium "Ethical, Legal and Societal Insights & Outlook for Biobanks and Medical Research" took place at the headquarters of the International Agency for Research on Cancer (IARC) in Lyon.

Over 2 ½ days, seven keynotes and 30 unique presentations showcased state of the art insight and outlook on ethical, legal, and societal implications (ELSI) relevant for biobanks and biomedical research. It celebrated the faceted plurality of ELSI expertise across countries and disciplines, stemming from both interdisciplinary service provision and research such as GDPR compliance, genetic counselling, science and technology studies, ethics, or social sciences.

Whereas the ELSI experts across BBMRI's National Nodes have been meeting annually over the past decade, this meeting was the first public symposium bringing together 80 participants from around the globe for an in-depth exchange.

Organized in eight sessions, the ELSI Symposium encompassed aspects such as data privacy, EHDS, ethics of AI, genetics and genomics, gender, governance, regulatory compliance or datafication. It closed with the Young Researchers Awards for presentations and a poster, committing to make such gatherings a regular event.

Stay tuned to join us in Bilbao, Spain in 2025.

Programme Committee

Michaela Th. Mayrhofer (BBMRI-ERIC)
Zisis Kozlakidis (IARC/WHO)
Marialuisa Lavitrano (UNIMIB)

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Tracy Wootton (IARC/WHO)
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Acknowledgements Reference

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Reference & DOI

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PROGRAMME

TUESDAY – 4 JUNE 2024

12:30 Registration

14:00 ***Welcome & Setting the Scene***
Elisabete Weiderpass (IARC/WHO), Zisis Kozlakidis (IARC/WHO), Michaela Th. Mayrhofer (BBMRI-ERIC)

14:00 ***SESSION 1: GENETICS AND GENOMICS***
Chaired by Zisis Kozlakidis (IARC/WHO)
Keynote: Biobank Advancement in Egypt – Medical Ethical Evolution
Amany Maher (MASRI)
The Concept of Genetic Privacy: Insights from Empirical Research in Cyprus
Georgia Charalambidou (biobank.cy, University of Cyprus)
Empowering Change: The Role of the BBMRI National Node ELSI Working Group towards Modernizing Biobanking Regulations in Hungary
Eszter Tuboly (Hungarian Pediatric Oncology Network), Regina Felső (Szentágothai Research Centre) et al.
Research Fields and Data Modes of Emergence: Insights for Biobanking, Genomics and AI
Kaya Akyüz (BBMRI-ERIC/University of Vienna)
Panel Discussion

16:00 Coffee Break

16:30 ***SESSION 2: "FROM GUT TO SPACE"***
Chaired by Erdina Ene (BBMRI-ERIC)
Keynote: IARC's Experiences with Ethics over the Last Decade
Chiara Scoccianti (IARC/WHO)
Navigating New Waters: Implications and Challenges for Biobanks in the European Health Data Space
Isabel Huys (University of Leuven, Belgium) et al.
Ethical and Legal Implications of Research with Microbiome Samples
Catarina Almeida (University of Vienna, Austria)
Polish Experience in Creating a Legal, Social and Ethical Framework for Biobanking
Dorota Krekora-Zając (University of Warsaw, Poland)
Panel Discussion

18:30 End of Day 1

19:30 Reception

WEDNESDAY – 5 JUNE 2024

8:00 Registration

9:00 ***SESSION 3: "IT'S THE DATA, STUPID!"***
Chaired by Michaela Th. Mayrhofer (BBMRI-ERIC)
Keynote: "All the Data from Everywhere all at Once": Visions and Practicalities in Data Integration
Klaus Høyer (University of Copenhagen)
International Data Sharing for Optimal Patient Care
Tom Southerington (University of Turku/FINBB)
The Importance of Integrating an Inclusive Sex- and Gender-Sensitive Perspective in Data Driven Biomedical Research
Mónica Cano Abadía (BBMRI-ERIC)
MMCI's Biobank and Increasing Usage of Next-Generation Sequencing
Radek Halouzka, Jan Kuran (Masaryk University)

Panel Discussion

11:00 Coffee Break

11:15 ***SESSION 4: "BACK TO THE FUTURE!"***
Chaired by Verena Borecky (BBMRI-ERIC)
Podium Discussion
Anne Cambon-Thomsen (University of Toulouse), Zisis Kozlakidis (IARC/WHO), Marialuisa Lavitrano (University Milano-Bicocca), Michaela Th. Mayrhofer (BBMRI-ERIC)

13:00 Lunch Break

14:00 ***SESSION 5: "REQUESTING AGENCY"***
Chaired by Irene Schlünder (BBMRI-ERIC)
Keynote: The WHO Office of Bioethics: Projects and Priorities
Andreas Alois Reis (WHO)
MyGenome Portal: A Comprehensive Platform for Return of Results over 200,000 Estonian Biobank's Participants
Liis Leitsalu (University of Tartu) et al.
The Nagoya Protocol Applied to Swiss Biobanks
Joséphine Uldry (Swiss Biobanking Platform/EPFL) et al.
Constitution and Distribution of Organoids and Experimental Models. Legal Implications for Biobanks in Spain
Pilar Nicolás (University of the Basque Country)
Panel Discussion

16:00 Coffee Break

16:30 ***SESSION 6: "ASSESS – ENABLE – TRUST"***
Chaired by Tracy Wootton (IARC/WHO)
Keynote: How Has Oncology Practice Changed Over the Pandemic?
Brenda Boegard (University of Lausanne)
Managing Incidental Findings at Hospital-Based Biobanks
Roland Jahns (Universitätsklinikum Würzburg)
Reporting Incidental Findings: Qatar Biobank - Challenge Accepted
Eleni Fthenou et al. (Qatar Biobank, Qatar Precision Health Institute)
Ethical Challenges in the Era of Medical AI: Biobanks Trustworthiness, and Societal Implications
Melanie Goisauf (BBMRI-ERIC)
Panel Discussion

18:30 End of Day 2

THURSDAY – 6 JUNE 2024

8:00 Registration

9:00 ***SESSION 7: "AT LEAST, ASK!"***

Chaired by Elodie Caboux (IARC/WHO)

Keynote: Bringing Divergence into the Room: The Use of Seemingly Unconnected Fields to Promote a Common Understanding

Mat Clum (Royal Academy of the Arts)

Biobanking with Children – Ethical, Legal and Social Issues in the Maltese Context

Gillian M Martin and Bridget Ellul (University of Malta) et al.

Implementing Broad Consent for Research with Routinely Collected Clinical Data and Residual Biosamples in a Cancer Hospital: Does this Lead to Underrepresented Groups in Research?

Miriam Beusink (Antoni van Leeuwenhoek Hospital) et al.

Strengthening a Biobanking Participatory Ecosystem, Cocreating a Biobank APP with a Digital Informed Consent/Assent Matrix Integrated in the Biobank BIMS

Sara Casati (CNR) et al.

Towards a More General Consent for the Use of Patient's Biological Material and Health Information for Medical Research – The Patient Perspective

Isabelle Budin-Ljøsne, Rebecca Bruu Carver (NIPH)

Panel Discussion

11:00 Coffee Break

11:30 ***SESSION 8: "NEW HORIZONS"***

Chaired by Marialuisa Lavitrano (University Milano-Bicocca)

SCIence outreach: The example of BIObanks in Europe

Olga Tzortzatou-Nanopoulos (BRFAA)

Ethical, Legal, and Social Implications (ELSI) of Biobanking in Turkey

Yücel Erbilgin (University of Istanbul)

Presentations by Young Researchers and Young Researchers Award

Ethical Implications of Different Healthcare Systems for Transatlantic Data Exchange Between the US and the EU

Anna Sierawska (Technical University of Munich)

Perception of Biobanking among Professionals at Medical Research Council/Uganda Virus Research Institute and London School of Hygiene & Tropical Medicine Uganda Research Unit

Sandra Nanyonga (Université Cote D'Azur)

Envisioning the European Health Data Space: Implications upon the Reshaping of Biobanking Infrastructure

Anders Korsgaard (National and Kapodistrian University of Athens)

13:00 Lunch Break

14:00 ***Closing: …And Now to Something Completely Different!***

Michaela Th. Mayrhofer (BBMRI-ERIC), Zisis Kozlakidis (IARC/WHO), Marialuisa Lavitrano (University Milano-Bicocca)

15:00 End of Meeting

ABSTRACTS

Presentations in order of appearance in the programme & posters.

Session 1: Genetics and Genomics

Keynote: Biobank Advancement in Egypt – Medical Ethical Evolution

Author: *Amany Maher (MASRI)*

Egypt has made significant strides in establishing and developing biobanks, driven by collaborative efforts between government institutions, research organizations, and healthcare facilities. The Egyptian government has recognized the importance of biobanking and has provided support for infrastructure and regulatory frameworks, leading to the creation of several biobanks across the country. These advancements in biobanking have had a substantial impact on medical research and the development of personalized healthcare solutions in Egypt. The establishment of the Egyptian Genome project, in collaboration with the Academy of Scientific Research and Technology, aims to position Egypt at the forefront of personalized medicine and gene therapy. However, the growth of biobanks has also raised important ethical considerations that must be addressed. Egypt's regulatory framework, including the Clinical Research Law and Data Protection Law, plays a pivotal role in ensuring compliance and protecting patients and research participants. Ethical principles, such as informed consent, confidentiality, and data security, are central to the operation of Egyptian biobanks. To further strengthen biobanking practices, Egypt has established the Egyptian Biobank Alliance (EBA), a joint network among national biobanks, which aims to create a research platform for new medicines. The benefits of such biobank networks include increased sample size and diversity, harmonization of activities, and improved efficiency and cost-effectiveness. Looking ahead, the future of biobanking in Egypt holds promise for continued advancements in medical research, personalized healthcare, and ethical practices. Through collaborative efforts and adherence to ethical principles, Egypt has positioned itself as a key player in the global biobanking community, contributing to the betterment of healthcare and scientific knowledge.

The Concept of Genetic Privacy: Insights from Empirical Research in Cyprus

Author: *Georgia Charalambidou (biobank.cy, University of Cyprus)*

The article focuses primarily on the concept of genetic privacy as it has evolved in light of scientific advancements in medical research. It commences by examining the concept of privacy, setting a foundation for understanding the concept of genetic privacy. Then, it proceeds to consider the genetic rights held by patients, research participants, genetic relatives, and genetic groups. By examining the genetic rights held by these different parties, it provides insights into the complex landscape of genetic privacy and elucidates how their genetic rights may be affected. The article also considers the multifaceted issues arising from sharing genetic data across different contexts/settings. It navigates through ethical dilemmas, legal complexities, and broader societal impacts in the sharing of genetic information. The discussion is anchored in a study conducted in Cyprus, providing empirical insights into the

attitudes and perceptions of the Cypriot population regarding genetic testing, access to genetic results, genetic counseling, data privacy, control of genetic information, participation in genetic research, and trust in healthcare practitioners and researchers.

Empowering Change: The Role of the BBMRI National Node ELSI Working Group Towards Modernizing Biobanking Regulations in Hungary

Authors: *Eszter Tuboly (Hungarian Pediatric Oncology Network), Regina Felső (Szentágothai Research Centre), Hajnalka Andrikovics (National Institute for Infectology and Haematology), Zoltán Veréb (Interdisciplinary Centre of Excellence Biobank), Márta Szegedi (Semmelweis University), Orsolya Varga, (University of Debrecen), Oguz Kelemen (University of Szeged), Mária Judit Molnár (Semmelweis University)*

Introduction/Problem Statement: The current legal framework governing biobanking in Hungary emerged in 2008 in the form of the Human Genetic Research Act (Act No. XXI of 2008). Focused primarily on human genetic testing, research and the protection of human genetic data, it humbly states the rules of biobank operations, as storage facilities of genetic biomaterial. While considered rather progressive at the time, this legislation ultimately fell short in keeping pace with the dynamic and rapid evolution of biobanking, particularly in relation to the complex activities and landscape within the field.

Methods: An extensive review of biobanking regulations in Hungary and in other European countries were conducted. Areas that were not or partially covered in the existing Hungarian legislation were addressed alongside selected standpoints of European practices. Simultaneously, collaborative discussions identified key regulatory components of infrastructure, technology, ethics, and quality management, along with the formulation of new terms and definitions to underscore the necessity for change.

Results/Proposed Solution: In the dedicated Biobank Law, the establishment and scope of biobanking activities should be expanded beyond genetic analysis to foster a broad range of biomedical research using quality biological samples and associated data. The culture of ethical material-and data-sharing should be embraced by the new legislation together with the core operational and resource requirements, and minimum technical standards.

Conclusion: Our proposal advocates for a fundamental shift in Hungary. By integrating international precedents and resolving the specific challenges within the Hungarian context, our proposed regulatory framework seeks to support researchers and the biobanking community while safeguarding the latest ethical principles.

Research Fields and Data Modes of Emergence: Insights for Biobanking, Genomics and AI

Author: *Kaya Akyüz (BBMRI-ERIC/University of Vienna)*

Genopolitics and social genomics are emerging fields where methods from behavioural genetics, genetics and genomics are employed for researching phenomena relevant for political science and social sciences, respectively. Based on an analysis of pre-histories, methods used, infrastructures and data practices, the two fields-in-the-making are identified to have different dynamics of emergence. In terms of methodological paths, genopolitics is characterized by the divergence of methods over time while exhibiting the practices of dealing with controversy similar to behavioural genetics from where the major data/methods are borrowed. Social genomics can be characterized as a phenomenon that aligns itself with

postgenomic, big data knowledge production practices, where work around the production of a data object (polygenic score) orders the emerging community in terms of data practices, communication and control. Both fields-in-the-making were restricted by the available data; however, they differed in their data modes of emergence which could be broadly characterized as 'accumulating' for genopolitics and 'prototyping' for social genomics. Such characterizations are tied to how the modes of emergences align with the prevailing regimes of knowledge production and contributes to better understanding of the contemporary dynamics in epistemic and social organization in science. Finally, the paper presents insights from an ELSI perspective on biobanking and the potential impact on genomics and AI research in life sciences and medicine.

Session 2: "From Gut to Space"

Keynote: IARC's Experiences with Ethics over the Last Decade

Author: *Chiara Scoccianti (IARC/WHO)*

IARC/WHO is a sponsor of research as well as a practitioner, and thus has a duty to show leadership in ensuring that its studies are beyond ethical reproach. Research at IARC/WHO relates to public health with epidemiology as its core discipline. There is well documented agreement that epidemiological studies involving patients or participants from healthy populations should receive the same rigour of ethical review as any clinical study.

The major role of IARC/WHO is the assurance to the international community that whatever constitutes ethical approval, transparently demonstrates the fundamental principles of doing no harm, respect, beneficence and justice. This presentation will provide a series of examples from the IARC/WHO studies over the last ten years, the ethical challenges that have emerged and the ways in which they have been successfully addressed.

Navigating New Waters: Implications and Challenges for Biobanks in the European Health Data Space

Authors: *Janos Meszaros (KU Leuven), Teodora Lalova-Spinks (UGent), Sofie Bekaert (UGent), Isabelle Huys (KU Leuven)*

Introduction: The European Health Data Space Regulation (EHDS) aims to increase the control of individuals over their electronic health data, while also making more data available for healthcare and scientific research. The law introduces new roles and responsibilities, most notably the concepts of health data access bodies (they will be responsible for authorizing access to data), data holders (they have the right or obligation to make data available), and data users (they can have access to data). However, the integration of biobanks as data holders within this framework introduces a complex layer of consideration, given the current heterogeneity of biobank regulations across Member States.

Material & methods: Legal desk research.

Results: Our presentation will unfold in four key sections: the overview of the EHDS, a comparison of biobank regulations across Member States, the potential benefits of EHDS for biobanking (such as promoting standardization in data access and reuse, thereby encouraging cross-border research), and an exploration of the possible risks (for instance, uncertainty

regarding how the EHDS framework will align with existing research oversight regulations in Member States, particularly concerning ethical review processes and civil society involvement in governance).

Discussion & conclusion: Uncertainties remain regarding the interaction between the EHDS provisions and current national biobank regulations. Careful consideration is required to avoid further fragmentation of the European biobank framework. For biobanks, the transition into this new regulatory landscape offers both opportunities and challenges, which our contribution aims to untangle.

Ethical and Legal Implications of Research with Microbiome Samples

Author: *Catarina Almeida (University of Vienna – BBMRI.at#3)*

As members of BBMRI´s Austrian node dealing with Legal and Regulatory Challenges, it has been brought to our attention that microbiome samples remain a point of specific concern, since they raise important ethical and legal issues including – but not limited to – those relating to the *privacy of data subjects* who provide these samples. Microbiome samples present features that are unique to each individual, akin to genetic and biometric data, resulting in a heightened risk of re-identification of the data subjects.

While these samples come with great diagnostic and therapeutic potential – including opportunities for the development of *personalized medicine* and use as *forensic tools* – the fact that they can be traced back to an individual highlights the need for those who store them (biobanks or healthcare facilities) to have measures to resolve issues of compelled disclosure, "ownership", data protection (such as under which conditions microbiome-related data is to be seen as sensitive under the General Data Protection Regulation), product liability, and security/safety. Also, the legal status of such samples (and the related rights and obligations of those who are users and/or handlers of such samples) may vary: they could remain a sample for research, be minimally processed and used for human application – and thus find a legal framework within the upcoming "SoHO Regulation" – or be deemed a medicinal product, when they are further processed. The hybrid character of microbiome samples in between biological material, (personal) data and information will trigger questions on the impact of recent data related European Union (EU) legislation such as, in particular, the Data Governance Act and the European Health Data Space (EHDS) Regulation proposal.

Additionally, seeking *informed consent* from donors, especially at a point in time where there is limited knowledge of what can be achieved by researching on a sample, may also prove to be a challenge for biobanks. The research would benefit from exploring these issues in light of new legislative developments such as the EHDS and the SoHO Regulation Proposal, with the aim of influencing the current debates and legislative developments at both the EU and Member State levels.

Polish Experience in Creating a Legal, Social and Ethical Framework for Biobanking

Author: *Dorota Krekora-Zając (University of Warsaw)*

Polish representatives have participated in the work of BBMRI-ERIC from the very beginning. Initially, Poland was an observer, later a full member. During this time, the Polish members of ELSI group managed to develop a project of the Code of Conduct for the processing of personal data by biobanks in Poland, Quality Standards for biobanks including ELSI issues, and

publicly available legal, ethical and social analyses regarding biobanking in Poland. Research on the psychosocial determinants of social attitudes towards biobanking has also been carried out on representative national sample. ELSI groups of BBMRI.pl organized several trainings, national and international conferences, and its representatives took an active part in many events by BBMRI-ERIC. The subject of the presentation will be a description of the activities undertaken by BBMRI.pl to prepare recommendations regarding future development of biobanking in Poland taking into account ELSI determinants.

Session 3: "It's the Data, Stupid!"

Keynote: "All the Data from Everywhere all at Once": Visions and Practicalities in Data Integration

Author: *Klaus Høyer (University of Copenhagen)*

On March 30th, The Economist had a special issue on data and artificial intelligence (AI) in healthcare. It was not the first, and will probably not be the last. When outlining what it takes to realize the proclaimed potential of AI, the issue featured a familiar trope, namely the dream of having "All the data from everywhere all at once" (p. 10). The particular formulation has an uncanny resemblance to the award-winning movie 'Everything Everywhere All at Once' (2022) about a pressured woman feeling forced to tackle everything everywhere all at once, and who is sucked into an ontological multiplicity where what happens in one world has life and death implications in other worlds, and where powerful forces struggle for ultimate control. In this talk, I will use the trope of having all data available in total compression of time and distance. I will suggest that it too comes about as a result of powerful forces, and that it can indeed lead to a form of ontological multiplicity, albeit of a very different nature from that suggested in the movie. Drawing on my recent book (Data Paradoxes. The Politics of Intensified Data Sourcing in Contemporary Healthcare, MIT Press 2023), I describe the impact and effect of data integration initiatives over the past decades in Denmark and relate these experiences to current cross-border data initiatives. My key message will be that we may need to put limits to certain forms of integration to make others work according to purpose.

International Data Sharing for Optimal Patient Care

Author: *Tom Southerington (University of Turku/FINBB)*

Sharing patient data enables research and quality control for better patient care. The need to be able to combine data from several sources to follow and improve is particularly imperative in rare diseases and small patient groups. The few patient cases in one's own institution or even country will not provide the numbers for reliable analyses. Comparing outcomes between institutions and countries gives invaluable insights into the efficiency and standards of care or the participating institutions and countries. A European example of data sharing infrastructures in are the European Reference Networks (ERNs) for rare and complex diseases. An international example is the Vermont Oxford Network (VON) for improving neonatal care, concentrating on paediatric patients with very low birth weight and intensive care. Sharing patient data is governed by the European General Data Protection Regulation, GDPR, as well as complementing national legislation, and the legal bases for data sharing are not always clear. We will examine how well the present European and Finnish national regulatory

frameworks, including the expected European Health Data Space Regulation support patient data sharing for improving patient care and outline recommendations based on the findings.

The Importance of Integrating an Inclusive Sex- and Gender-Sensitive Perspective in Data-Driven Biomedical Research

Author: *Mónica Cano Abadía (BBMRI-ERIC)*

This presentation delves into the crucial significance of incorporating a sex- and gender-sensitive perspective in biomedical research. The European Commission has underscored in the Gender Equality Strategy the necessity of integrating this perspective into current research endeavours.

Moreover, the EC emphasizes the importance of an intersectional perspective that considers the interplay of various factors such as sex, gender, race, ethnicity, and socio-economic status. While imperative for promoting inclusivity and accuracy in research outcomes, adopting an intersectional perspective adds complexity to study designs and data analysis. It is also essential to consider sex and gender beyond binary classifications, recognizing the diversity and fluidity of these categories.

One crucial example to be analyzed in this presentation will be the application of AI and big data in biomedical research. By examining how these technologies can both enhance and potentially perpetuate biases related to sex, gender, and other intersecting factors, this presentation aims to highlight the challenges and opportunities in leveraging AI and big data to advance a more inclusive and equitable approach to data-driven biomedical research.

MMCI's Biobank and Increasing Usage of Next-Generation Sequencing (NGS)

Authors: *Radek Halouzka, Jan Kuran (Masaryk University)*

Masaryk Memorial Cancer Institute (MMCI) operates a well-established biobank where the biological material of cancer patients is stored. With rapidly increasing usage of Next-Generation Sequencing (NGS) in cancer treatment there has been a need to ensure proper storage for such massive data volume in a secure processing environment. This has been ensured by the usage of secured cloud storage administered by a third party.

Since NGS data together with rich descriptive metadata and/or clinical data are very useful for secondary usage in research, there has been also the need to create a system for their integration with biobanking and clinical data and for making them easily findable and reusable for research. This NGS data have been stored longitudinally at the MMCI, but not well described and curated.

With respect to the principles of data FAIRification a team of IT workers and molecular pathologists of MMCI has developed an online catalogue of NGS (meta) data together with sample and donor information. The aim of this project is to make data stored at secured cloud storage easily findable by researchers who wish to reuse them for research.

In our presentation we would like to briefly describe the developed system and data flow from MMCI biobank to researcher with use of the BBMRI.cz (meta)data catalogue. After that we will focus in more detail on ethical and legal aspects related to the creation of a (meta)data catalogue, adopted access policy to (meta)data catalogue by researchers, processing of researchers´ data requests and last but not least also on ethical and legal conditions for transferring requested data to researchers.

Session 4: "Back to the Future!"

Podium Discussion

Panellists: *Anne Cambon-Thomsen (University of Toulouse), Zisis Kozlakidis (IARC/WHO), Marialuisa Lavitrano (UNIMIB), Michaela Th. Mayrhofer (BBMRI-ERIC)*

The discussants look back on decades of the study of ethical, legal, and societal implications or aspects (ELSI or ELSA), highlighting the importance to continuously raise awareness and remain, through both ethical compliance and state of the art research, cautious whilst balancing the rights, considering ethical standards with the needs of research. They highlight the importance of training on ethical principles, legal frameworks and socio-economic considerations by experts for those who need to apply it in research practice. ELSI support, as provided by research infrastructures and organisations, requires a multidisciplinary effort and is never a tick-boxing, but rather a constant weighing of principles.

Session 5: "Requesting Agency"

Keynote: The WHO Office of Bioethics: Projects and Priorities

Author: *Andreas Alois Reis (WHO)*

The World Health Organization (WHO) Health Ethics and Governance Unit provides a focal point for the examination of ethical issues raised by activities throughout the WHO, as well as supporting Member States in addressing emerging ethical issues. This includes a range of global bioethics topics from public health surveillance to developments in genomics, and from research with human beings to fair access to health services.

This unit's work is particularly important in the context of contemporary health challenges and raises and addresses difficult questions in areas such as resource allocation, new technologies, decision-making in clinical care and public health. The unit's work consists of developing normative guidance, producing ethics tools and resources, capacity building, ethical oversight on WHO's research projects and public health interventions, and hosting the secretariat of the biennial Global Summit of National Ethics/Bioethics Committees. The presentation will provide an overview of these functions and present the recent work of the unit and its global impact.

MyGenome Portal: A Comprehensive Platform for Return of Results to over 200,000 Estonian Biobank's Participants

Authors: *Liis Leitsalu, Natalia Pervjakova, Kristjan Metsalu, Karoniina Kruusmaa, Priit Pärkson, Kersti Teder, Kaarel Kaasla, Lars Johannes Sissas, Krista Fischer, Viktorija Kukushkina, Priit Kleemann, Anu Reigo, Helene Alavere Kristi Krebs, Sulev Reisberg, Georgi Hudjashov, Vasili Pankratov, Mari Nelis, Sirje Lind, Kadri Maal, Kristi Läll, Diana Sokurova, Reedik Mägi, Silvia Kasela, Laura Birgit Luitva, Andres Metspalu, Mait Metspalu, Lili Milani (University of Tartu)*

Estonian Biobank's research platform, MyGenome Portal (MGP), objectives include providing individual results to over 200,000 biobank participants; ensuring transparency regarding the

use of participants' data; improving genomic literacy and public health; serving as a platform for research; and supporting precision medicine initiatives.

The MGP is structured into three sections: personalized results, educational content, and studies. The portal incorporates dynamic consent that allows participants to choose specific categories for the return of results and which research projects they wish to join. The results section currently includes polygenic risk scores, pharmacogenomics and ancestry. The studies section offers a solution for data collection. Among the first projects is an investigation into the perceived impact of genetic information reported through the portal. Participant feedback gathered informs us how risk information communicated through a portal is perceived and helps planning future report generation.

The development of the MGP involved consulting with expert groups and a qualitative study to assess user experience. A preliminary launch with invites sent to 1000 participants was initiated in February 2024 and is planned to be expanded to 10,000 participants by 2024 spring. The MGP will eventually be available to all Estonian Biobank participants. The MGP is envisioned to empower individuals and promote research, while also contributing to the ongoing transformation of healthcare.

The Nagoya Protocol Applied to Swiss Biobanks

Authors: *Josephine Uldry, Sabine Bavamian, Camille Doras, Christine Joye (Swiss Biobanking Platform)*

As a research infrastructure funded by the Swiss National Science Foundation, Swiss Biobanking Platform (SBP) plays a pivotal role in coordinating both human and non-human biobanking nationally. In its mission to support the biobanks in working according to best practices and in adhering to applicable ethical and legal standards, SBP is dedicated to developing national guidance, harmonized documentation and services.

The Nagoya protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (ABS) was ratified by Switzerland in 2014. The essence of the ABS lies in the fair and equitable sharing of benefits arising from the utilization of genetic resources. Specifically, the agreement aims to establish the legal framework that governs the interaction between providers and users of non-human genetic resources and associated traditional knowledge held by indigenous and local communities. Its primary objective is to clarify the terms and conditions governing access to these resources and ensure the equitable sharing of benefits among the involved parties.

Each country that has ratified the Nagoya Protocol has incorporated it into its national legislation, leading to varied implications for biobanks. Consequently, SBP has developed a comprehensive guideline that addresses the specificities of Switzerland's implementation. This guideline offers a practical approach, detailing considerations, procedures, and documentation required for accessing or sharing genetic resources from international sources.

Through its step-by-step guidance on the Nagoya Protocol, SBP enables Swiss biobanks to meet international ethical and legal requirements, thereby facilitating their participation in global non-human research collaborations.

Constitution and Distribution of Organoids and Experimental Models. Legal Implications for Biobanks (in Spain)

Author: *Pilar Nicolás (University of the Basque Country)*

The generation of organoids and PDX (patient-derived xenografts) poses no particular issues regarding the use of human material, as the control and authorization pathways are well defined in regulation. However, some specificities regarding the information that the subject must receive should be considered: if the use of samples involves animal experimentation, generation of cell lines, and economic exploitation. Standard information documents should be reviewed for adaptation.

As the product my contain personal information, relevant regulations must be applied, including their transfer. It is important to define the purpose of data processing to identify the legal bases for data processing. Likewise, the legal positions of those involved and their obligations should be established beforehand.

Once the experimental model is established, its application for purposes other than biomedical research falls outside the regulatory framework for sample use for research purposes, and the relevant regulations must be considered: invasive research, in vitro research, conducting clinical trials with advanced therapy medicinal products or medical devices, use for transplantation, or other therapeutic acts.

Since the organoid or PDX is not a biological sample or a separate part of the body but a different product, there is no legal prohibition regarding its commercialization, although there may be a patent requiring a license for commercial exploitation.

Regarding the patent, it should be noted that its object would not be the organoid or the PDX model as such, but the intellectual creation that can be materialized in said material. Therefore, there must be a creative and innovative act to identify a patentable object. If the product generated is the result of the application of scientific techniques of general knowledge, patentability cannot be claimed. Neither would be patentable an innovative procedure whose patentability is legally restricted, for example, a procedure that requires the destruction of human embryos.

Session 6: "Assess – Enable – Trust"

Keynote: How Has Oncology Practice Changed Over the Pandemic?

Author: *Brenda Boegard (University of Lausanne)*

This presentation will elaborate how oncology care and research was adapted during the COVID-19 pandemic in the Metropole of Lyon (France), including the lasting innovations that came out of the crisis. The research method involved 22 semi-structured qualitative interviews of healthcare professionals, managers, and researchers in the Lyon, France region coming from both public and private academic hospitals. The interviews took place from February 2021-December 2022 in order to assess the long-term adaptations and innovations in cancer care organization in the post-COVID era, as cancer care was severely affected during the pandemic.

The main results show adaptations and innovations in 1) new processes and resources to facilitate disciplinary and interdisciplinary work; 2) harmonization and streamlining of patient

journeys. Our analysis utilized the capabilities approach, an interdisciplinary social sciences approach that focuses on the capabilities of persons to *be* and to *do*, to elaborate the conditions by which local actors were able to be agile, to adapt and to innovate in spite of the healthcare emergency and in coherence with their professional and personal values.

Managing Incidental Findings at Hospital-Based Biobanks

Authors: *Jörg Geiger, Jörg Fuchs, Michael Neumann (ibdw/Universitätsklinikum Würzburg), Ronny Baber (University Leipzig), Michael Kiehntopf (Jena University Hospital), Cornelia Specht, Michael Hummel (German Biobank Node, Charité - Universitätsmedizin Berlin), Roland Jahns (ibdw/Universitätsklinikum Würzburg)*

Background: With the recent progress in genetic diagnostics and predictive biomarkers, the management of incidental findings has become an important issue. In the last decade, hospital-based biobanks have become increasingly relevant as brokers of samples and data, in particular for large research projects or multicenter trials. Scenarios where a biobank acts as a mediator between clinician and researcher entail additional responsibilities and requirements: Key requirements to consider are privacy, self-determination, ethics, and medical responsibility and accountability.

Methods: The German Biobank Alliance, coordinated by the German Biobank Node (GBN) has endeavoured to set up a procedure for hospital-based research biobanks accomplishing the legal and regulatory framework, professional regulations, and ethical standards. In a joint action, the centralized biobank of the medical faculty Würzburg (ibdw) together with the local authorities (data protection officer/legal department/ethics committee) drafted a concept to manage incidental research findings in full compliance with relevant ethical and data privacy regulations.

Results: Traceability of the process is ensured by comprehensive documentation of each of the process-steps. Unnecessary action is avoided by advising the incidental finding to be evaluated prior to re-identifying the respective individual. The individual's "right not to know" is respected as required by informed consent. As a rule, all communication with the individual will be through the hospital and by competent physicians with appropriate knowledge and communication skills.

Conclusion: The procedure presented is designed to be adaptable to most settings of academic hospital-based biobanks and may therefore serve as blueprint for other biobanks facing the requirement to implement appropriate measures for handling incidental research findings.

Reporting Incidental Findings: Qatar Biobank - Challenge Accepted

Authors: *Eleni Fthenou, Marwa El Deeb, and Fatima Qafoud (Qatar Biobank, Qatar Precision Health Institute)*

The reporting of incidental findings (IFs) presents a unique set of challenges and opportunities in the context of biobanking. Qatar Biobank (QBB) is committed to addressing these challenges and ensuring maximum benefit for the community. The challenge mainly lies in the accurate interpretation of these findings and their potential impact on participants' health and life. This abstract outlines the processes and protocols established by QBB to manage incidental findings, ensuring ethical considerations, participant engagement, and data integrity are maintained.

QBB has established a comprehensive framework that encompasses physicians/clinicians, genetic counselors, diagnostic laboratories, the healthcare system, and bioethicists. Within this framework, QBB has implemented a board consent model, empowering participants to make informed decisions regarding the receipt of incidental findings. This model upholds participant autonomy and adheres to international ethical standards. Researchers are required to incorporate a plan for identifying and evaluating incidental findings that may have clinical significance. Researchers are also responsible for reporting any IF back to QBB facilitating referrals to relevant clinics.

QBB is reporting back to its participants IF found i) on MRI scans (n=470,38.8%), ii) based on abnormal laboratory results or clinical assessments (n=24,401, 54%), mental health issues (n=3) or the discovery of actionable genetic findings (n=10). The majority of IF were newly diagnosed cases (n=23,314 referrals, 77% of total referrals).

In conclusion, numerous challenges persist regarding the classification of incidental findings, and there is ongoing debate within the research ethics community regarding the clinical significance of certain results. However, at QBB, the establishment of a multidisciplinary team comprising various experts and stakeholders has facilitated the identification of opportunities to contribute positively to our community.

Ethical Challenges in the Era of Medical AI: Biobanks, Trustworthiness, and Societal Implications

Author: *Melanie Goisauf (BBMRI-ERIC)*

The increasing datafication in the life sciences together with advancements in AI technologies is transforming medical knowledge production, healthcare practices, and major infrastructures, such as biobanks. Biobanks often serve as crucial infrastructures facilitating data sharing and flows, supporting access to diverse datasets crucial for training algorithms, encompassing imaging, pathological, genomic, and clinical data. AI holds promise in enhancing diagnostic accuracy and treatment efficiency, particularly in identifying biomedically relevant patterns, thereby facilitating progress towards individually tailored preventative and therapeutic interventions. However, the integration of AI into healthcare also raises ethical and societal concerns, necessitating careful considered to avoid harmful consequences for vulnerable populations. Drawing upon foundational ethical principles, various guidelines have been formulated to uphold values such as transparency, fairness, accountability, and equity throughout the development and deployment of medical AI. Current discourses underscore the imperative of establishing trustworthy AI and mitigating associated risks within healthcare domains. Concerns have been raised regarding the potential amplification of ethical and societal injustices by AI technologies. This presentation advocates for a nuanced understanding of trust as a multifaceted, context-specific, and relational concept. It emphasizes the necessity of identifying and addressing biases stemming from human, systemic, institutional, and societal factors, which could imperil the equitable adoption of medical AI and its impact on societies.

Session 7: "At least, Ask!"

Keynote: Bringing Divergence into the Room: The Use of Seemingly Unconnected Fields to Promote a Common Understanding

Author: *Mat Clum (Royal Academy of the Arts)*

This presentation is based on the experiences of the events created over the last decade through TickbirdandRhino, an organisation that takes big ideas and make them accessible in different ways – from simple socials and salon-like evenings to workshops and collaborations. This approach is grounded in the concept of performative science, a methodology that dissolves the boundaries between researcher, observer and system, giving all participants parity and providing equal access to, and impact upon, the results.

Eliminating the boundaries between disciplines and using a common audio-visual language to bring participants together creates greater potential for emergent knowledge, to express itself in ways that generate ideas from multiple perspectives and return useful results that are not necessarily contingent upon previously held knowledge.

Crucially, we believe that the creativity and imagination used by artists makes them particularly adept at inventive problem-solving, and their experience working across disciplines gives them the unique ability to explore a wider landscape of potential solutions to any problem.

Biobanking with Children: Ethical, Legal and Social Issues in the Maltese Context

Authors: *Gillian M Martin, Bridget Ellul (Unversity of Malta, BBMRI.mt ELSI)*

Biobanking with children offers a robust practical way to maximize research effort, enhance research benefits and increase the potential for developing clinical applications for minors. DwarnaBio, the national biobank in Malta, is addressing ELSI challenges in this respect, and this presentation aims to share our experience and introduce work in progress. Focus on ethical and legal aspects will include issues related to informed consent and assent, return of results and sharing of samples and data as they affect minors and their families - keeping in mind the child's development and maturity, as well as the child's future. Discussion will be in the context of international guidelines and regulatory instruments, with consideration of applicable legislation, both local and international, to ensure the protection of children's rights.

Societal implications will be discussed by referring to qualitative research in progress - My DNA my say: beliefs and attitudes towards biobanking with children in Malta. In this study a scripted puppet show is used as an interactive educational activity which then serves as an elicitation tool in follow-up focus group discussions. Key research questions: What beliefs and 'feelings' do children hold in relation to giving their blood and DNA for research? What beliefs, understandings and expectations do children hold related to voluntariness, 'fairness' and control in research? How do children conceptualize confidentiality? Thematic analysis on the emerging qualitative data will be used to explore the process of embodiment related to blood/DNA in young children, and their attitudes and expectations in relation to the ethicality of donating their blood/DNA to biobanking for genomic research.

Implementing Broad Consent for Research with Routinely Collected Clinical Data and Residual Biosamples in a Cancer Hospital: Does this Lead to Insufficient Data and Samples or Underrepresented Groups in Research?

Authors: *Miriam Beusink, Annegien Broeks, Robbert Hardenberg, Susanne Rebers, Marjanka K Schmidt (Netherlands Cancer Institute-Antoni van Leeuwenhoek Hospital)*

Broad consent procedures for research with routinely collected data and biosamples may lead to consent bias and less availability of data and samples. We investigated these aspects after implementation of a broad consent procedure in the Antoni-van-Leeuwenhoek, a specialized cancer hospital and research institute. Scope of this broad consent is limited to scientific research into cancer and related disorders and to improve care. Hospital record data and consent decisions of 59,813 patients recorded during the implementation of the procedure between May 2018 and December 2020 were included. Using multivariable logistic regression analyses (consent versus no consent or no decision), we specifically investigated which demographic and treatment characteristics affected the patients' consent decision.

Of all patients 92.4% provided consent (the majority at first hospital visit), 2.3% gave no consent and for 5.3% we had no response. All included demographic and treatment-related characteristics affected the consent decision with statistical significance, although they explained only a small portion (2% to 7.5%) of the variance in consent decisions. Of the demographic characteristics, being born in the Netherlands instead of elsewhere (15.4% of patients) had the largest positive impact on likelihood to consent. Visiting the hospital just once (instead of more often), had the largest negative impact on the likelihood to consent. We conclude that it is feasible to implement a broad consent procedure that, due to high consent and weak associations with patient characteristics, is unlikely to bias research data. However, it is unsure whether these results are representative for other hospitals as well.

Strengthening a Biobanking Participatory Ecosystem, Cocreating a Biobank APP with a Digital Informed Consent/Assent Matrix Integrated in the Biobank BIMS.

Authors: *Sara Casati (CNR-IEOS), Sabato Mellone (Università degli studi di Bologna), Antonella Mirabile (CNR-IEOS), Manuel Ottaviano (AOSP di Bologna), Marialuisa Lavitrano (University Milano-Bicocca), Matto Pallocca (CNR-IEOS), on behalf of the digitized consent/assent BBMRI.it working group (BBMRI.it)*

Our challenge: strengthening a participatory ecosystem of biobanking and translational research through the shared digitisation of consent/assent pathways and the cocreation of ELSI tools and platforms to foster citizen proactive participation, open science and the BBMRI.it community of practice (CoP).Our core action is to prototype and validate a biobank APP integrated with a digital informed consent/assent matrix to characterize samples with participant's preferences, facilitate third-party access and interaction between biobank and participant. Thanks to the "Strengthening BBMRI.it" project, in April we launched an open ELSI call among the biobanks; essential requirement to join was the institutional endorsement for integrating the biobank data set with the consent/assent options in format compatible with the BBMRI catalogue, based on CCEs. BBMRI.it selected nine biobanks, representatives of the different biobanking fields and regional biobank distribution. We are currently planning a two-phase work programme, the first mapping ELSI/RRI requirements for improving responsible digital good practice in informing, consenting/assenting, accessing data and samples, returning results, facilitating re-contact. This phase will also be a pilot for the CoP platform.

The second phase will validate the biobank APP with the integrated digitized consent/assent thanks to three pilots: one involving adolescents with rare disease conditions and high school students, a second with citizens engaging in citizenship biobanking, the last with persons with a cancer condition. In parallel, the IT biobank services will integrate the IT structure of consent options into the biobank BIMS. Work is underway; the living labs with all the players will start in May.

Towards a More General Consent for the Use of Patients' Biological Material and Health Information for Medical Research - The Patient Perspective

Authors: *Rebecca Bruu Carver (NIPH), Matthias Kolberg, Wenche Reed (Oslo University Hospital), Birgitte Wirum Sand (University of Oslo), Isabelle Budin-Ljøsne (NIPH)*

Biological material and health information from patients are valuable in medical research. Under a "broad" consent model, hospital patients in Norway can consent to their biological material and health information being stored in research biobanks and used for "specific, broadly defined research purposes" within a specified medical research area, but not for medical research in general. This limits the researchers' ability to use such resources. This study investigated patient representatives' views on general consent for medical research without limitation to specific research purposes, preferences for the storage of biological samples, consent collection and timing, and factors motivating or hindering consent. A digital, anonymous survey was shared with patient representatives from patient advisory councils at national hospitals in Norway, who answered on behalf of patients. 157 representatives completed the survey (response rate of 41%). A majority (66.2%) supported general consent for medical research and the use of surplus material (63.7%) without limitation to specific research purposes. 65% supported biological samples storage without time limitation. Most (56%) believed patient consent should be collected before the patients are hospitalized and recommended offering digital or paper consent alternatives. Factors motivating consent included the desire to contribute to medical research (89.8%) and faith in scientific progress (24.2%). Main hindrances included the fear that health information may be misused (49%), uncertainty regarding uses (43.9%) and lack of information (31.8%). Regulations in Norway should support a broader, more general consent than currently feasible to comply with patients' wishes and maximize research potential.

Session 8: "New Horizons"

SCIence Outreach: The Example of BIObanks in Europe

Author: *Olga Tzortzatou-Nanopoulos (BRFAA)*

Public involvement is essential in biobanking for medical research. Biobanks depend on public trust and citizen participation, but limited awareness due to poor scientific communication highlights the need for better community engagement programs by biobanks and researchers or even students. The "SCIence outreach: The example of BIObanks in Europe" (SCIBIOEU) project, conducted by seven BBMRI-ERIC node partners in five European countries (Austria, Cyprus, Finland, Greece, Italy), aims to fill this gap. To map existing educational resources, online courses and serious games for students, young researchers and citizens on biobanking were searched and summarized in an inventory. In addition, focus groups involving the public

and selected stakeholders (including students, professors, researchers, developers and designers, biobanking professionals), were performed. An online course is engineered using Moodle, the serious game developed in Unity, with WebGL enabling online browser accessibility. The focus groups provided insights into target group's needs and important elements for the development of the course and serious game. An online multimedia course, incorporating texts, videos, and user self-evaluation mechanisms, is developed. Additionally, a 3-D online serious game that navigates users through a virtual biobank, is designed. This interactive experience is enhanced with the assistance of an AI service, providing multiple stages and customization options. SCIBIOEU, an ERASMUS+ funded initiative, seeks to bridge the communicative divide between scientists and the public about biobanking. It equips scientists with effective strategies for scientific outreach and boosts public knowledge of biobanking, through an online course and a serious game.

Ethical, Legal, and Social Implications (ELSI) of Biobanking in Turkey

Author: *Yücel Erbilgin (University of Istanbul)*

In recent years, the storage of data and biological samples of patients with rare diseases for research purposes has gained significant momentum in Turkey. As these biobanks play a crucial role in advancing biomedical research, it has become crucial to understand and address the ethical, legal and social implications (ELSI) associated with them. With the rapid development of genomic technologies and the increasingly complex nature of biobanking, new ethical challenges are being faced, especially in data storage and sharing. For now, there is no specific legal regulation on biobanking in Turkey yet. However, the Law on the Protection of Personal Data (KVKK) published on April 7, 2016, and health-specific regulations cover the protection, recording, processing and sharing of personal data within the scope of fundamental rights and freedoms within the constitutional framework. Recently, the Personal Data Protection Authority published a guideline on the Considerations to be Considered in the Processing of Genetic Data. Within the scope of the guideline, genetic data controllers and data subjects, conditions for processing genetic data, obligations of data controllers, genetic data security and finally the recommendations and suggestions of the institution are regulated. In addition, there are efforts to improve the ethical and legal framework for the establishment of sustainable biobank structures in Turkey.

Presentations by Young Researchers and Young Researchers Award

Envisioning the European Health Data Space: Implications upon the Reshaping of Biobanking Infrastructure

Author: *Anders Korsgaard (National and Kapodistrian University of Athens)*

The European Health Data Space (EHDS) is envisioned to establish a common framework for data sharing, aiming at capitalizing on the imagined potential of a safe and secure cross-border exchange, use and re-use of health data. Visions for better health and biomedical research in Europe thus become key arguments in favour of sharing health data. Within this framework, biobanks and biobanking networks, like the BBMRI-ERIC, are endorsed as key infrastructures with expectations to generate value through biomedical research, made possible by the creation, storing, and sharing of samples and data. However, reshaping biobanking to fit under the EHDS could be translated into tension with old practices and arrangements. Being attentive to visions in data practices and research infrastructures means to explore how they lead to sociotechnical rearrangements. Pooling of health data for research in many ways rests on the infrastructuring of biobanks, i.e. building enabling environments for quality data sharing. It therefore becomes important to look at how the EHDS affects the infrastructure of biobanks (and BBMRI-ERIC). Looking into infrastructuring means bringing the practices of a set of actors – ranging from researchers, up to policy makers - into one socio-technical network. The paper will present interview data from actors connected with the research infrastructure of BBMRI-ERIC in Greece and Norway, focusing on the uses of visions specifically in the discussions surrounding biobanking, while providing preliminary findings regarding the ways the EHDS visions are being contested and/or stabilized and how the actors themselves envision health data sharing going forward.

Perception of Biobanking among Professionals at Medical Research Council/Uganda Virus Research Institute and London School of Hygiene & Tropical Medicine Uganda Research Unit

Author: *Sandra Nanyonga (Université Cote D'Azur)*

Introduction: Biobanking is crucial for medical research, yet there is a lack of understanding among professionals involved in the process. This study aims to explore the perceptions of biobanking among sample collectors, transporters, laboratory staff, and biobank personnel. Objective: To investigate the perceptions of biobanking among professionals at Medical Research Council/Uganda Virus Research Institute and London School of Hygiene & Tropical Medicine Uganda Research Unit. Methodology: The study examines the views of sample collectors, transporters, laboratory staff, and biobank personnel through structured interviews and surveys. Results: While biobanking is recognized, there is a lack of standardized knowledge among professionals. Efforts are needed to ensure transparency and standardization within biobanking activities to facilitate stronger engagement, commitment, and advocacy with stakeholders. Conclusion: This research fills a significant knowledge gap within the biobanking field and underscores the necessity for transparent and standardized biobanking practices to manage biobanks effectively.

Ethical Implications of Different Healthcare Systems for Transatlantic Data Exchange between the US and the EU

Author: *Anna Sierawska (Technical University of Munich)*

Transatlantic data sharing has a potential to significantly advance healthcare in the EU and the US, and globally. The strict data protection regulations (GDPR) in the EU have been identified as primary barrier hindering of sharing patient data between EU and US. The sluggish progress in data sharing partnerships is unethical as it impedes the development of better-informed therapies and treatments for patients on both continents. However, one aspect that is missing in this discussion is the significant difference in healthcare systems between those two countries, particularly concerning their private and public financing regulations, and overall access to healthcare. While the European approach emphasizes social solidarity and recognizes healthcare as a fundamental right, the US one the other hand tends to favor individualistic and private insurance-based healthcare model. The principle of solidarity plays a key role in the sharing of patient data, as it is only by recognizing collective, solidarity-based action the individual person can benefit. Public healthcare in the EU is an example of a solidarity-based approach that does not exist to the same extent in the US. The question arises as to how this solidarity-based incompatibility could be reflected in the sharing of patient data, which is based on similar solidarity-based concepts. The main focus of this project is to compare the EU and US healthcare systems and their impact on the type and quality on patients' data sharing.

POSTERS


BBMRI-ERIC®
Ethical, Legal and Societal Insights and Outlook for Biobanks and Medical Research Lyons June, 4 -7/24
From the Tumor Bank to the scientific Biobank - Hospital Eva Perón, Buenos Aires Province, Argentina
Cartography of a life: historical-social evolution of biotechnoscience and the ethical-legal aspects
PHD Liliana Virginia Siede, PHD. Inés Bravo; Dr. Alejandra Trinchero, Design: Jorge Sánchez
Biobanks for research with human biological samples in Argentina represent a resource that has transcended the borders of scientific knowledge in areas such as forensic science (identity), social sciences and health sciences. The present work proposes to reflect on advances and challenges in the life of the Eva Perón Hospital Biobank for research with human biological samples in a historical perspective based on a cartography that includes biotechnoscience and ethical-legal aspects.
1954
1964
1964
1997
2004
The Hospital Tumor Bank is created
2010
1 Genealogy of pathological anatomy
Las mitocondrias pasan de madre a hija a nieta ...
Macroscopic Structural- Autopsies
Histopathological structure – Biopsies - Studies of tissues
Cell Study - Clinical and Basic Citology
Molecular Study
Translational Research
2 Human Biological Sample
It is a sample of biological substance (blood, skin, bone cells or blood plasma) that contents nucleic acids and contains the characteristic genetic makeup of a person.
It is constituted as part and as a whole (International Declaration on Human Genetic Data UNESCO, 2003)
It contains genetic information from one person or another.
3 Mutations Of Biopolitics- N. Ross
Molecularization
Susceptibility
Optimization improvement
New mobility
The new pastorate
The Bioethics
Biological citizens
individually
collectively
Paradigm of hope
Regime of truth
Regimen of hope
Biovalue – Bioeconomic
4 Ethics, Bioethics, regulations
Anglo-SaxonTradition
European Tradition
Latin AmericanTradition
Convergent ethics
Fundamental Intellectuals Relational Affective:
. Next
. Social
. Other living being
Values: basic human values, human rights, capabilities.
Principles: guidelines for practical moral action
Rules or norms: determine the action- facilitate the decision.
Laws Proffesional Code of Ethics
5 The Biological Sample Incidence of Bioethics and Human Rights
Biological samples Residual remains? human
objects of study for science
They have the status of human parts
With research they have global potential value for future generations
Value for each person
Value as a social group
EVA PERON HOSPITAL BIOBANK
It is a BB that has a healthcare function that began with anonymization aimed at standardizing molecular techniques for future diagnostic applications in 2004 and research from the Molecular Profile Project in 2010.The human biological samples stored are mainly breast cancer tissue, blood, serum, rare pathological tumors, among others. Conducts bio-medical and population research.
Networks
Eva Perón Hospital (EPH)
Roffo Institute (RI)
Maria Curie Hospital (CH)
Patient recruitment
Epidemiological study
Histological characterization
Clinical evaluation
Sample collection
Biobanking
Data processing (epidemiological/clinical)
Fundation Leloir Institute (FLI)
Molecular profiling
Córdoba Catholic University (CCU)
Data processing (molecular profiling)
Data management
Challenges
Computer security risks (Extraction, circulation)
¿Achieves Informed Consent and Assents to protec the rights of people in the health process?
Digital Technologies do not offer a guarantee of respect for confidentiality and the right to privacy of patients
The data is not exhausted. They can be reused and increase in value when connected with other data
¿The public versus Patents?
¿How the common good and the protection of people's information are protected in global science ?
Conclusion
1.- From the ethics of care and responsibility we must promote empowerment for the participation of patients and families.
2.- From the ethics of care and responsibility. we must promote that researchers and other health professionals urge effective dialogue to generate this empowerment .
3.- This requires going beyond the information in a Consent or assent.
4.-Take into account the rights of the populations in decision-making, with the north in a governance that includes the population in clinical and scientific development.

The IARC Biobank: A Research Infrastructure for Global Operations

C. Lallemand, E. Caboux, S. Villar, E. Colney, H. Cordier, S. Guillot, G. Tchoua, T. Wootton and Z. Kozlakidis

IARC/WHO - Laboratory Services and Biobank group

The IARC Laboratory Services and Biobank Group (LSB)

The Laboratory Services and Biobanking unit was created over 10 years ago, centralizing biospecimen collections and laboratory services activities across the Agency. The unit's activities fall into three categories:

1) Maintain high-class Laboratory Services and a Biobanking facility

2) Generate data from interdisciplinary research and

Synthesize information for global guidelines production

3) Build local capacity for research infrastructure in LMICs

Biobanks are research infrastructure facilities, containing high-quality, standardized, research-ready and auditable material. They consist of three groups of distinct information: Biological samples, attached or associated data and legal and ethical aspects. The IARC Biobank contains almost 6 million samples from across the world.

Standards, Guidelines and Protocols

- The Biobank produced a Global Reference Book in Biobanking

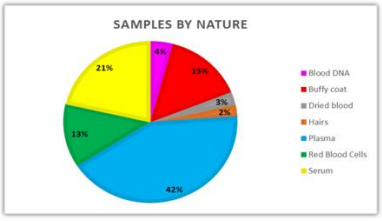
Common Minimum Technical Standards and Protocols for Biobanks Dedicated to Cancer Research, IARC Technical Publication No. 44. Mendy M, Caboux E, Lawlor RT, Wright, J and Wild CP. (2017)

- The Biobank represents IARC at the International Standards Organization (ISO/TC276)
- The Biobank takes part in the Proficiency Testing Programme (IBBL Luxembourg)
  - Annual participation of IBB since 2014 to ensure consistency of performance year- on-year

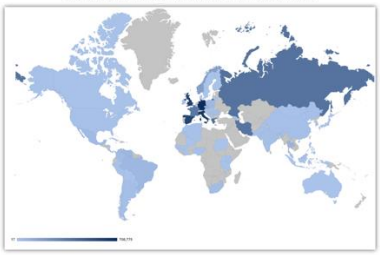
In 2024,the IARC Biobank has achieved the French National IBiSA label

- Quality control

All new tanks at the IARC Biobank are equipped with:
- Liquid nitrogen level detectors for automated filling
- All new installed freezers are connected to a temperature control monitoring system.



Geographical distribution of IARC Biobanked samples

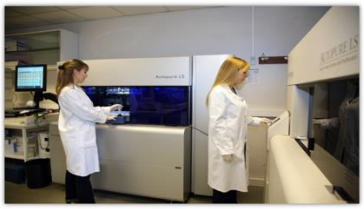


IARC Biobank's activity during 2022-2023

- shipment of 150 parcels to 28 countries worldwide
- reception of 124 parcels of biological and/or laboratory material

- 27 projects supported
- 64,895 samples retrieved
- 8,407 DNA extractions
- 13,413 DNA aliquots
- 5,026 non-DNA aliquots
- 17,195 samples inventoried

IBiSA Infrastructures en Biologie Santé et Agronomie



Automated DNA extraction systems

Sample retrieval in liquid nitrogen tank

Biological Sample Management System: SAMI

The IARC Biobank operates a Sample Management System (SAMI) developed in-house.
SAMI2.0 based on Oracle APEX was launched in 2019:

- Total number of samples registered: **5,901,628**
- Total number of sample movements: **1,739,150**
- Total number of projects registered: **387**

Ethical and Legal aspects

The IARC Biobank co-ordinates the Material Transfer Agreements (MTA) and Fast-Track MTAs between IARC and providing/receiving Institutes in collaboration with SSR

- IATA compliance (International Air Transport Association): Dangerous Goods Regulation (DGR)
- CODECOH training: application of the French norm (Loi Jardé)

Biobank services

- Sample retrieval from storage units
- Inventories and quality control
- Sample reception and shipment
- Non-DNA aliquoting (plasma, serum, RBC…)
- DNA extraction, DNA quantification, DNA aliquoting
  - 2 automated DNA extraction systems (Autopure LS)
    - Autopure LS (QIAGEN)
    - QIAsymphony (QIAGEN)
  - DNA quantification
    - spectrophotometry (Nanodrop-8000)
    - fluorometry by Picogreen (InfinitePRO 200)
  - Liquid handling system (FreedomEVO 150)

Upgrade of the DNA extraction platform
- Plans for acquisition of a new DNA extraction robot and other equipment: barcode rack reader, heat sealing system and thermomixer (2021)

International Agency for Research on Cancer

World Health Organization

For more information:

IARC Biobank (https://ibb.iarc.fr/)

Biobank and Cohort Building Network (BCNet) (https://bcnet.iarc.fr/)

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National legal framework and ELSI impact in Biobanks' activity: Italy vs Spain comparison

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BBMRI-ERIC ACADEMY | International Agency for Research on Cancer | World Health Organization | Università degli Studi di Milano Bicocca

SYMPOSIUM: ETHICAL, LEGAL AND SOCIETAL INSIGHTS & OUTLOOK FOR BIOBANKS AND MEDICAL RESEARCH

Biobanks' activity and national regulation: Italy vs. Spain

The activity of biobanks imply the management of a great amount of sensitive data. Given the fast-paced evolution of technology, interdisciplinary skills around data management are required from the professionals of these infrastructures. The lack of efficiency of laws and regulation to keep the pace with the upcoming challenges, leave researchers and managers in a grey area of uncertainty and risk

After the itroduction of the European General Data Protection Act (GDPR) every country has adopeted his own approach in further regulating the subject:

Italy: "Hibryd model" that combine general national and international provisions with a decisive role of the italian DPA (Data Protection Agency)

Spain: specific regulation on scientific research and Biobanks' activity (Ley 14/2007 de Investigación Biomédica, Real Decreto 1716/2011, Ley Orgánica 3/2018 on data protection)

Does the presence of a specific legislation actually simplify Biobanks' activity?

Objective: understand if the present needs and challenges that biobanks' professionals face in their everyday activity are receiving coverage through the legal framework of their country and identify possible improvements in regulation and interdisciplinary skills provided to these professionals.

Contacting biobanks through National nodes → Qualitative interviews to BBs' managers and researchers → Comparison of the two legal framework and design of possible trainings

How to do it?

Design of a possible training path for professionals and researchers operating in the Biobanks' field in order to tackle the ELSI challenges of their every-day activity

ISCIII Biomodel and Biobanks Platform Consultation among Spanish BBs

BBMRI.it node Consultation among Italian BBs

Interviews will evaluate how governance and ethical issues are managed in different BBs within the infrastructure

11 Biobanks expressed interest in partecipating to the interviews

10 Biobanks expressed interest in partecipating to the interviews

Through the comparison of the two sistems possible improvement to the Italian framework will be considered

Frontal qualitative semi-structured interviews performed with managers and representatives

The evaluation of the results will take into account the impact of legal regulation

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Citizen science in biomedicine: Attitudes of the general public and researchers in Latvia

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Introduction

UNESCO "Recommendation on Open Science" emphasizes the importance of opening the processes of scientific research to societal actors beyond the traditional scientific community. Broadly defined, citizen science includes the participation of laypeople at any phase of a research project.

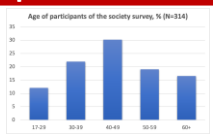
The study aims to evaluate **the concerns and motivation of the Latvian general population and researchers towards citizen-science** research projects.

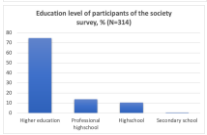
Methods

We developed an **online questionnaire** based on literature analysis on the existing citizen science projects in biomedicine. The questionnaire consisted of **seven vignettes** including descriptions of potential citizen science projects and questions. The questionnaire for the general public mainly included questions about attitudes, motivations and concerns towards participation in each type of citizen science project. Scientists were asked about their attitudes, motivations and concerns to conduct each type of citizen science study and engagement of citizen scientists.

Study groups

The **survey for the general public** was filled in by 314 respondents. Most of them had attained a higher level of education (75%). Respondents represented all age groups with a slightly more participants in the age of 30-49. The gender division of the participants was unequal with a lot more women than men participating. Most of the respondents (70%) did not have previous experience of participation in citizen science projects.





The **survey for scientists** was filled by 49 respondents. Most of them identified primarily as researchers (86%), less as academic staff (8%). Main fields of research represented were biology, medicine, pharmacology, chemistry. Almost all participants (94%) were in the age of 19-49. 81% of the participants were Latvians and 71% were females. A bit more than half of the participating scientists had no experience with citizen science and/or have heard about it for the first time.

Results: general public

Only 18.5% of the general public sample had previous experience of participation in citizen science projects.

	Question	Answer	N, %
General public	Have you ever participated in a citizen science project (for example, collecting nature data, microbiome research, deciphering folklore records)?	Yes	58 (18.5)
		No	219 (69.7)
		Don't know/don't remember/not sure	37 (11.8)
Scientists	Have you ever participated in a citizen science project (for example, collecting nature data, microbiome research, deciphering folklore records)?	Yes	20 (40.8)
		No	26 (53.1)
		First time hearing about citizen science	2 (4.1)
		I am planning to take part	1 (2.0)
	Have you ever engaged citizen scientists in your research?	Yes	8 (16.3)
		No	40 (81.6)
		I don't know	1 (2.0)
	Would you like to engage citizen scientists in your research?	Yes	31 (63.3)
		No	4 (8.2)
		I don't know	14 (28.6)

The general public was mainly motivated by **individual benefits** from participation in citizen science activities: opportunity to get new knowledge about themselves or their own health, followed by opportuninty to benefit society and to help scientists in their research.

The most often mentioned **concerns** of the general public were lack of time to participate, data safety and lack of interest.

Biological **sample donation** raised concerns for 17.2% of participants in the case of faecal samples and 5.4% in the case of saliva.

For the vignettes where the **co-payment** was required this was the biggest concern regarding participation for general public. When asked what amount of money participants would be willing to spend to participate in specific studies most would be open to participate if the participation cost would be under 50 EUR, and about 15% would not participate in any citizen science project if this would require co-payment.

In the vignettes where where gamification was involved the respondents were **concerned about their IT skills** to participate successfully.

Results: scientists

The main motivation of researchers to include elements of citizen-science in their studies was an opportunity to collect more data and do it faster, as well as potential to lower the data collection costs and attract co-funding.

Why Would You Like to Engage Citizen Scientists in Your Research?	Rank Points *
It is an opportunity to collect more data (attract more research participants)	99
It is an opportunity to collect data faster	44
It is an opportunity to collect data with less costs	55
To democratize science (make it more accessible to the general public)	37
To increase the public's level of understanding of my research field	43

* Higher rank points mean higher relevance to the scientists.

Researchers' **most important concerns** about using citizen-science were lack of control of data collection procedures, data protection, and potential problems to publish research results in higher impact journals.

What Would be Your Concerns When Engaging Citizen Scientists in Your Research?	Rank Points *
Quality and traceability of data	148
Lack of control in data collection process	253
Ethical aspects	127
Data protection and normative aspects	234
Public's disinterest in participation, low participation	68
Need for additional resources: coordination, communication with volunteers	148
Difficulty in publishing the obtained results in higher class journals	153
No concerns regarding engagement of citizen scientists in research	98

* Higher rank points mean higher relevance to the scientists.

Most of the scientists who answered open questions on the role of citizen science saw it as potentially beneficial and of high importance. They acknowledged having little experience with citizen science in their research, but at the same time, most of them showed motivation to learn more about citizen science and to try using its methods in their scientific work.

Conclusions

The results of our study provide important information for organizing communication campaigns for citizen science projects in biomedicine. On the one hand, it is clear that emphasizing individual benefits available in citizen science projects might help to attract more citizen scientists, at least in a short time. On the other hand, the survey results show that in Latvia, it is necessary to empower science literacy in society and to educate citizens about the role of science and the public benefits of scientific research.

The differences between the attitudes of the general public and scientists should be taken into account when developing future citizen science projects in Latvia.

Acknowledgements

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LINK TO THE PUBLICATION

Authors: Anne Costello[1]; Emily Vereker[1]; National Irish COVID-19 Biobank Research Ethics Committee[1] (NICB-REC)
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Assembling the right expertise for an emerging area in research ethics

Biobanking, ethics, and biostatistics: to review ethical aspects specifically related to biobanking processes

Bioinformatics and data protection: to ensure that data are appropriately used and adequately safeguarded

Legal and regulatory: to review compliance with legislative and regulatory frameworks

Epidemiology, population and public health: To ethically assess the NICB's potential impact on public health and pandemic preparedness.

Genetics and genomics, immunology, pathology, virology, and vaccine development: to inform the ethical review as it relates to pertinent areas of research and science

Clinical, respiratory, and infectious disease medicine; geriatric and paediatric medicine: to inform the ethical review of clinically related aspects

Patient, public and carer involvement (PPI) representatives: PPI members who will contribute their insights from the perspective of patients or members of the public.

A targeted approach identified a range of members who encompass the broad spectrum of expertise and experiences required to ethically assess a biobank.

Ethics assessment

All members contributed written ethics assessment reports before convening to discuss the NICB ethics application in a section-by-section structured format.

Key focus points included (not exhaustive):

- Human rights
- Informed consent and assent
- Withdrawal of consent/assent
- Vulnerable participants
- Regulatory compliance
- Research Scope
- Governance and operations
- Standardisation and harmonisation of processes across sites
- Risk mitigation
- Data protection
- Genetic data considerations
- Data integrity and FAIR data
- Technical safeguarding of biosamples and data
- Access and transfer of data and bio-samples
- Patient, public and carer involvement (PPI)
- Pathway to research translation towards improved public health
- Protection or destruction plans for bio-samples and data in the event the biobank closes.

All member contributions were considered equally valid regardless of Clinical, Academic, Lay or PPI background.

A phased and partitioned ethics opinion model

Separate ethics opinions on different aspects of biobank operations.

1. **Governance**: Biobank governance and oversight
2. **Participant recruitment**: Identification of potential participants; participant facing information and consent protocols.
3. **Biological samples and data**: Collection, storage, processing, cataloguing, general curation, and security aspects.
4. **Researcher access, downstream impact and commercialisation:** Legal agreements for biosample and data access/transfer, public health impact and pathway to research translation.

The implementation of a phased and partitioned ethics opinion model enables the NICB-REC to facilitate NICB operations in a timely and ethically robust way. It also allows an iterative ethics review process aligned to the biobank's expected milestones towards being fully operational.

There are committee members with biobanking specific expertise in: bioethics specific to biobanking; biobanking operations; law and regulatory requirements for biobanking; and biobanking specific data protection expertise.

The biobanking experts on the committee were involved in the development of the opinion model which was then discussed with, and endorsed by all members of the NICB-REC.

Information required to ethically assess a national biobank

Operations, governance and access rights: Governance structures; harmonised NICB site processes and access agreement templates

Biological samples, associated data and research scope: Collection/curation/ storage and all associated processes including data protection. research scope; genetics and genomics research.

Biobank participants: Recruitment, Informed consent and assent forms and participant information leaflets.

Public engagement, patient and public involvement (PPI), sustainability and societal impact: PPI, economical sustainability, pathway to commercialisation and biobank impact on society and research.

Local Site Approvals*. Information regarding all local REC approvals in place and the associated conditions of those approvals.
*National Opinion, upon issue, supersedes all local ethical opinions.

Documentation: Governance Structure, Patient information leaflets & Informed Consent forms (PIL/ICFs), Protocol, DPIA, etc

Operational Framework:

The NICB-REC operational framework captures all aspects of the ethics assessment process, which was developed to ensure that the NICB would operate to the highest of ethical standards. This document is available to download on the NICB-REC website.

Conclusion

Ethical safeguarding ensures that the confidentiality and autonomy of biobank participants are protected while also facilitating truly impactful research which can benefit society. This ethics framework, developed specifically for a national, multisite, biobanking infrastructure, may serve as a blueprint or reference for any future ethics assessments of biobanking infrastructures in Ireland and beyond.

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