BOOK OF ABSTRACTS

BIOSAMPLES AND BIODATA IN MEDICAL RESEARCH ELSI CHALLENGES

24 – 26 November 2021

"REALIZACJA USŁUGA ORGANIZACJI MIĘDZYNARODOWEJ KONFERENCJI ONLINE Z ZAKRESU ETYCZNYCH, PRAWNYCH I SPOŁECZNYCH ASPEKTÓW WYKORZYSTYWANIA BIOPRÓBEK I BIODANYCH POCHODZENIA LUDZKIEGO W BADANIACH NAUKOWYCH W RAMACH PROJEKTU PN. „UTWORZENIE SIECI BIOBANKÓW W POLSCE W OBRĘBIE INFRASTRUKTURY BADAWCZEJ BIOBANKÓW I ZASOBÓW BIOMOLEKULARNYCH BBMRI-ERIC" REALIZOWANEGO NA PODSTAWIE DECYZJI MINISTRA NAUKI I SZKOLNICTWA WYŻSZEGO NR DIR/WK/2017/2018/01-1 Z DNIA 12.12.2018 R. ZMIENIAJĄCEJ DECYZJĘ NR DIR/WK/2017/01 Z DNIA 27.01.2017 R. O PRZYZNANIU ŚRODKÓW FINANSOWYCH NA FINANSOWANIE KOSZTÓW WKŁADU KRAJOWEGO WNOSZONEGO NA RZECZ UDZIAŁU WE WSPÓLNYM MIĘDZYNARODOWYM PRZEDSIĘWZIĘCIU PN. „INFRASTRUKTURA BADAWCZA BIOBANKÓW I ZASOBÓW BIOMOLEKULARNYCH BBMRI-ERIC".

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Biosamples and Biodata in Medical Research
- **ELSI challenges**

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held from **24 - 26 November 2021**

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HUMAN GENOME EDITING: THE MESSAGES, MYTHS AND REALITIES.

Feeney Oliver[1]

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The revolutionary potential of the CRISPR-Cas9 gene editing technique has created a resurgence in enthusiasm and concern in genetic research perhaps not seen since the mapping of the human genome at the turn of the century. Some such concerns and anxieties revolve around crossing lines between somatic and germline interventions as well as treatment and enhancement applications. Underpinning these concerns, there are familiar concepts of safety, unintended consequences and damage to genetic identity and the creation of designer children through pursuing human enhancement and eugenics. In the policy realm, these morally laden distinctions and anxieties are emerging as the basis for making important and applied measures to respond to the fast-evolving scientific developments. This paper will reflect upon some key issues arising in the potential use of human genome editing in the context of reproductive medicine or assisted reproduction. By critically reflecting upon the 2021 Report from the World Health Organisation and the 2018 Report from the Nuffield Council on Bioethics, this paper will emphasise the importance not only on what human genome editing can potentially bring about in science and medicine (both good and bad), but also on how it emphasises and potentially recreates multiple messages about 'who we are', for instance, in the context of respect for future generations, human enhancement and regarding persons with disabilities. The paper will conclude with important suggestions on how we move from discussions of ethics of human genome editing to discussions of its governance.

ARE WE PREPARED IN POLAND TO PROMOTE GENETIC TESTING?

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The extremely rapid development of modern techniques for analyzing the human genome, both in the field of scientific research and diagnostic applications, entails a variety of problems whose solution lags far behind our current technological capabilities. These problems appear in the ethical, social, legal or religious spheres and include such detailed issues as e.g. examination of children for diseases manifested in adulthood, accidental (secondary) results being a side effect of the analysis of the whole genome, the growing offer of tests directed directly to the recipient, patenting of genetic information, confidentiality of genetic data and their availability to third parties, availability of genetic counselling, etc. The legal regulation of these problems, the list of which is growing at an alarming rate, still remains in the sphere of declarations, and its shift to the sphere of real.
actions seems to be lagging further and further back in time. Do patients, laboratory diagnoses, doctors still have to be held hostage by the legislative impotence?

MAKING BIORESOURCES AVAILABLE IN THE CONTEXT OF OPEN SCIENCE

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The open science movement broadly states that science must be done in an open, and reproducible manner where all components of research are open. In many fields it has now been recognised that research data sharing is crucial, and global initiatives have been taken to this aim, highly promoted at EU level. The domain of bioresources where not only data but the physical samples, are to be shared is no exception and the FAIR principles (Findable, accessible, interoperable and reusable) also apply to bioresources. The tension between an open policy and a required protection is real. However obstacles to openness and sharing include multiple dimensions. Defining what can be shared, may be challenging as well as organising informative meta data. But the work to make the biosamples suitable to be shared is still hardly recognised. The Open Journal of Bioresources (OJB) was created in 2014 as a peer-reviewed open access journal with short papers describing bioresources dedicated to human biomedical research, providing the authors with a citable informative reference and a DOI (Digital Object Identifier). This is fully part of the recognition and rewarding of such an important work, and allow to trace the use of such resources that need to be promoted. BBMRI is working towards such a recognition but other institutions should give more importance to such aspects. The French national plan for open science has made one of its priorities to better recognise and incentivise sharing and re-use in research assessment.

CLINICAL TRIAL DATA SHARING

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Tens of thousands of clinical trials take place every year, subjecting participants to various experimental treatments, and generating vast amounts of research data. To use that data efficiently and broadly seems like an ethical imperative, but there can be pros and cons and sharing large amounts of potentially very sensitive data is not straightforward. Industry consortia and associations have sought to build responsible data sharing schemes. One of the fundamental considerations is naturally protecting participant privacy. In Europe the GDPR can be a source of uncertainty in data sharing.

POLISH BIOBANKS - A RELIABLE SOURCE OF MATERIAL BEING THE SUBJECT OF THE NATIONAL AND INTERNATIONAL COOPERATION

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The biobanking situation in Poland is more and more advanced. This is due to the growing awareness of the essence of biological material, not only in the broadly understood scientific community but above all in society. The new opportunities offered by, among others, being a member of the Polish Biobanking Network (PBN), also have an impact on this.

Since 2016, Poland as BBMRI.pl is a member of the pan-European network BBMRI-ERIC. Thanks to this, Polish biobanks can publish information about their collections in the European catalog (BBMRI-ERIC Directory). The Detailed Survey conducted by us showed that so far 28% of the PBN members have already placed information about their resources in it, and 56% intend to do so.

Polish biobanks show a willingness to cooperate with other units. 50% of the surveyed biobanks declare willingness for sharing their resources, of which 47% consider the possibility of transferring samples to a company or scientists outside Poland. However, the majority of units to which Polish biobanks share their collections (56%) are not obliged to provide them with the obtained research results after conducting scientific research.
The research shows the enormous potential of cooperation between Polish biobanks and both national and international units. Nevertheless, most units do not receive feedback information about the results of research carried out on shared material. We believe that wide information/education action connected to the ethical and legal aspects of biobanking would be desirable by the Polish biobanking society, and it should be provided by BBMRI.pl ELSI experts.

ETHICS OF AI IN RADIOLOGY: A REVIEW OF THE ETHICAL AND SOCIETAL IMPLICATION

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Introduction

Artificial Intelligence (AI) applications in medicine are hoped to improve healthcare and to advance health equity. The application of AI-based technologies in radiology is expected to improve diagnostic performance in terms of accuracy and personalized decision-making. While the technology carries the potential to improve health services, the ethical and societal implications need to be carefully considered to avoid harmful consequences for individuals and groups, especially for the most vulnerable. It is therefore inevitable to (1) identify what types of ethical issues are raised by AI, and to (2) analyse how these issues are tackled in biomedical research, especially in radiology and cancer imaging.

Methods

A comprehensive and systematic review of academic literature was conducted. Five electronic databases were searched for peer reviewed articles published since 2017 focusing on ethics of AI in radiology. Search results were screened and analysed using thematic analysis.

Outcome

The paper gives an overview of the results of this literature review, focusing on the topics that have been identified to be relevant within ethical discussions on AI in radiology. Building on this review, we will problematise approaches such as 'trustworthy AI' and 'explainable AI' that shape the ethics discourse on AI.

Conclusions

Based on the issues identified, the paper concludes with a reflection on the topics identified that shape the understanding of 'Ethics of AI' and the gaps in the discourse from a philosophical and STS perspective.

SELECTED LEGAL, ETHICAL AND ECONOMIC ASPECTS OF BIOBANKING FOR THE DEVELOPMENT OF DIGITAL PATHOLOGY.

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Over the past few years, breakthroughs in the field of artificial intelligence (AI) have had a huge impact on society worldwide.

Widespread use of AI in pathology will be possible once AI-based computer algorithms have been developed and validated. For this, large amounts of patient data are required to enable annotation-based training of algorithms. Annotations can mean both manual descriptions of pathomorphological image regions or objects and clinical annotations. Clinical annotations require access to pathology reports and electronic patient records, either from the hospital or from regional or national registries and can be provided by authorised clinicians or data managers.

Pathology departments have at their disposal huge amounts of pathomorphological slides and paraffin-embedded archival biological material which can be very helpful, and sometimes indispensible in the proces of development of AI-based applications. Without clear and well-balanced regulations concerning the possibility of accessing tchem by both research and medical industry entities, progres in the area of digital pathology will be severely limited.

Issues such as anonymisation and pseudo-anonymisation of pathology images, patient consent to use archival material and ethical considerations, including patient traumatization in relations to patient consent will be discussed. We will also discuss the issues of market inequality between research and development units operating in a restrictive legal environment versus those operating in a less restrictive one as well as issues of patient rights, in relations to personal data protection confronted with the possibilities to develop new life-saving diagnostic tools.

Ligia Kornowska

Abstract available soon...

SOCIO-ETHICAL FORESIGHT OF BIOINFORMATIONS

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The developments of technologies that constitute gathering and digitalisation of medical and biological information sets new challenges to the society. By embracing patient-cantered idea of care, which is becoming worldwide standard, we have to foresee solutions and answers that would have ethical aspects of subject and sociological impact on society in mind. Bioinformations as clusters of data might be used to breach one's privacy. On the other hand, research that uses tremendous amounts of information should not be restricted. This classical problem of consent within research is still actual in modern times.

Center for Technology Assessment plans to analyse the socio-ethical aspect of gathering and digitalizing information. Introduction will mention background of current situation and globally recognised problems of said topic. By employing social studies, we are able to access wider scope of issues, including social impact of medical research. Directly involved will be ethical aspect, implying necessity of setting certain values and duties of not only participant of experiments, but also researcher. By including directives and approaches set by state institutions and international organisations we see additional research field in said topic. Researchers from CTA plan to employ foresight methods to select optimal development paths for safe data management technologies and also shaping the direction of national policies.

Wide-scope approach towards topic of biobanking and bioinformation is gaining popularity worldwide. Skills and knowledge of medical teams is now often assisted by sociological and ethical studies. CTA in its actions tries to uphold said values and approach.

CAN THE COLLECTION AND USE OF HUMAN BIOLOGICAL MATERIAL AND DATA BE CARRIED OUT IN ACCORDANCE WITH ETHICAL STANDARDS?

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The research ethics of human biological material and associated data is a new field of knowledge that has developed over the past 20-30 years. Traditional and unquestionable ethical principles applied in the ethics of research on humans required certain modifications in relation to research on human biological material. The separation of the process of collecting human biological material from the planning and implementation of subsequent scientific research on the same collections, drew attention to the need to indicate new ethical principles. The ethical evaluation of the collection, storage and transfer of human biological material and data for research purposes plays a key role in the protection of the rights and interests of the donors of human biological material. The way this evaluation is organized in individual countries has not been standardized. RECs based on national law have specific responsibilities that do not correspond specifically to the needs of biobanks that collect human biological material. Therefore, there is a need to establish additional independent ethical committees that would fill the gaps in the current system of ethical protection of the rights and interests of research participants. This presentation aims to indicate those tasks that should be carried out by independent ethical committees for the protection of the rights and interests of donors of human biological material and data.

POPULATION BIOBANK AS A „BIOFENCING": FROM ARTIFICIAL INTELLIGENCE TO ARTIFICIAL SOCIETY

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Population biobanks create a space for interactions between donors, researchers, scientific institutions and the society. In this regard, there is a certain analogy to the idea of geofensing, especially as biobanking institutions use artificial intelligence technologies. Nowadays, it is expected that biodata from biobanks will enable researchers to identify genetic and environmental factors influencing on the course of diseases. One of the possible applications of the population-based „biofencing" is the possibility of using biodata for searching related persons. This application is importance for the development of genealogical genetics. The question is whether reconstructing social relations in this way will not create a kind of "artificial society". It is worthy to analysys technological and social issues related to the development of population biobanking.

GOVERNANCE OF RESEARCH BIOBANKS IN LATVIA: PUBLIC ATTITUDES AND TRUST

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Background. Our paper will give the overview about recent activities in establishing ethically and socially responsible governance of research biobanks in Latvia. We will analyse the process of development of the new Biobank law in Latvia, as well as present results of our recent study. The aim of our study (2018-2021) was to analyse attitudes, concerns, and needs of the general public, donors and researchers. Methods. We developed a 12-question survey repeating seven questions about biobanks from the 2010 Eurobarometer questionnaire and adding five additional questions (N=1017). We also performed 40 qualitative semi-structured interviews with biobank donors and researchers.

Results. The general public in Latvia is still not well informed about research biobanks. Fewer respondents have heard about research biobanks than in 2010. At the same time, the number of respondents who are willing to donate samples and data has increased. Overall, concerns about the donation of different types of biological samples and data to a biobank have slightly decreased.

Conclusion. More information on biobanks and biobank-based research should be made available to the public in Latvia to demonstrate the results and benefits of donation of biological samples. Our results also show a lack of information about or trust in research ethics committees in Latvia, which needs clarification by further research and a discussion about possible ways of strengthening the role of ethics committees in the context of development of the new Biobank law.

BIOLOGICAL MATERIAL OBTAINED FROM CHILDREN – WHO SHOULD DECIDE ABOUT IT?

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Polish biobanks collect diverse human biological material and data related to it. The operation of a biobank is inseparably connected with the issue of obtaining consents for the collection, processing, and sharing of biological material.

In 2016 was established Polish Biobanking Network. Its main role is to integrate polish biobanks, get knowledge about their characteristics, assess their capabilities, and increase the quality level of the biological material collected in them.

A questionnaire was prepared, the purpose of which was, among others, to verify whether Polish biobanks collect biological material from children and who sign consents in such cases. 38% of the polish biobanks collect material obtained from children. 50% of it comes from children between 16-18 years. The question of who is responsible for giving the consent for samples obtained from children was a multiple-choice question. The respondents indicated that 83% comes from a parent/guardian, 33% from a child, 33% is issued on the basis of an opinion obtained from a bioethical commission, 17% of biobanks do not obtain such consent.

The research has shown that Polish biobanks are a good source of material obtained from children. The main source of consent for obtaining material from children between 16-18 years of age are their parents/guardians. It should be considered whether, in the case of children of this age, they should not decide on their own about the fate of their biological material. The fact of collecting consents in case of gathering material from children should be further explored.

SOCIAL ATTITUDES TOWARDS BIOBANKING- STUDY RESULTS AMONG PHARMACY AND MEDICAL DIAGNOSTIC STUDENTS QUESTIONAIRES

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Since 3 years Wroclaw Medical University has performed new elective course „ABC Biobanking" for 1st 3rd-year pharmacy and medical diagnostic students. Course aimed to learning the following aspects of biobanking: general information, ELSI, processes, quality of biological material and data, scientific and industrial cooperation.

Respondents were asked to complete an anonymous questionnaire at the end of the course. Participation was voluntary and was not related to payment. The questionnaire consisted of 45 survey questions including: open, semi-open and multiple-choice questions

Students were divided into groups of: field of study, year of study, gender and origin. 100% of the students were aware of the term "biobank". Despite knowledge why biobank is collecting samples (90.1%), only 62.4 % of the students would recommend donating biological material to their family. The data collected from survey shows contingency of the yes/no responses to the biospecimens donate willingness before and after participating in the courses. Willingness of donation after courses increased significantly in groups of pharmacy students, 1st, 2nd and 3rd year of study, male and female, and origin. When asked about donating biospecimens, before attending to the classes, 43% of the students would agree. Attending to the classes changed their opinion, and 93% of the students would donate biological samples.

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SOCIAL ATTITUDES TOWARD HUMAN BODY, BIOSAMPLES AND BIOBANKING IN POLAND

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Introduction

The success of biobanking for scientific purposes depends, inter alia, on social attitudes towards biobanks and the willingness to donate human biological material. A number of available studies indicate significant role of sociodemographic factors in shaping the attitudes of potential donors. Cultural factors, including stereotypes about one's own body, the organs that determine its functioning and that constitute humanity, may play a significant role in the decision-making process to donate biological material. It was interesting to find out how beliefs about one's own body influence the willingness to donate biological material.

Material and Methods

Quantitative research was conducted on a sample of 1,100 adult Poles. The computer aided personal interview (CAPI – 96%) and Paper over Pencil Interview (PAPI) - 4%. techniques were used to collect the data.

Results

According to the study, Poles associate humans with the following parts of the body: heart (71.0%), brain (51.6%), kidney (11.5%), limbs (hand, leg, fingers, foot) - 10, 5% and head (8.6%). At the same time, they would be most willing to donate for scientific research: urine (73.9%), blood (69.7%), hair (69.6%) and tears (69.0%)

Conclusions

According to the research, the more an organ is associated with a human being, the less likely it is to be donated for scientific research. Information campaigns to encourage the donation of samples should therefore take into account not only sociodemographic variables, but also beliefs and stereotypes deeply embedded in human consciousness.

SUPPORTING BIOBANKING THROUGH ONLINE TOOLS COVERING ETHICAL AND LEGAL ASPECTS FOR REUSE OF SAMPLES AND DATA

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Since the accessibility of biological samples and comprehensive data sets are crucial to conduct biomedical studies, their reuse and change of primary research objectives have deep impact on increasing value of such resources for development of novel diagnostic and therapeutic applications. Cooperation in the field of exchange of biospecimens and data, especially in assays requiring large sets of these resources is recognized as vital for advancing translational research based on omics approaches.

Together with reuse of biological samples and data comes the ethical, legal, and social aspects focusing on assurance of privacy and protection of personal sensitive data. Accordingly, experts are preparing and issuing rules regulating process of biobanking with respect of donor privacy. Having the variety of regulations covering exchange of specimens and data across the world, biobankers meet multiple issues with complex data protection laws that may significantly influence global cooperation.

Among tools available online, serving as a guide for researchers on ethical and legal issues regarding sharing and reuse of biological material, there are several applications worth mentioning: Legal Assessment Tool developed as BioMedBridges project, Biobanking and BioMolecular resources Research Infrastructure WIKI Legal Platform, Human Sample Exchange Regulatory Navigator, International Policy interoperability and data Access Clearing House promoted by Public Population Project in Genetics.

To provide user-friendly interface for all biobankers, using such tools should require only minimal knowledge of legal regulations. Moreover, applications should be updated on regular basis together with highlighting the need for expert consultation to support researchers in ethical and legal aspects.

BROAD CONSENT: ELSI-CHALLENGES IN HOSPITAL-INTEGRATED BIOBANKING - EXPERIENCE FROM A LARGE FACULTY-WIDE OPERATING GBA-B

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One of the essential preconditions for the acquisition & storage of human biological samples for multiple medical research purposes is the informed broad consent form signed by the donor after comprehensive written and oral information, as stated in the GDPR (Art. 7+9). A major challenge for hospital-integrated biobanks is the faculty-wide rollout and involvement of all departments in the process of biosampling and in obtaining the respective patient's consent.

Methods: From 2012 to 2014, the Working Party of the German Medical Ethics-Committees (WP-GMEC) has developed a nation-wide consented template for the broad use of human biosamples and data, which in 2014 has been implemented in the University Hospital of Würzburg.

Results: To date, the faculty-wide rollout comprises 19 out of 25 departments. Consent information is electronically documented in the hospital's IT system and the biosampling-workflow is differentially but fully integrated into each department's routine workflow. Broad consent biosampling in a large University Hospital needs the involvement of many stakeholders, in particular a comprehensive training of the clinicians & involved hospital staff on the scope & relevance of broad consent biosampling for medical research. This is necessary, because patients have to be informed clearly on the broad medical scope of the intended use of their biosamples and data.

Conclusion. The WP-GMEC template for the broad use of human biosamples and data fulfils the current WMA-recommendations for human biobanks. The template furnishes a framework that permits hospital-integrated biobanks to store & use human biosamples without restrictions regarding the scope of biomedical research.

ETHICS AND TRUST IN RESEARCH BIOBANKS

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In the presentation, the concept of trust will be tackled and some ethical considerations will be proposed also concerning the consent.

BIOSAMPLES AND BIODATA DURING COVID-19 PANDEMIC – THE ROLE OF BIOBANKING INFRASTRUCTURE BBMRI-ERIC

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The COVID-19 pandemic required a change of priorities and full mobilization from clinical and scientific community. BBMRI-ERIC as one of the largest biomedical and biobanking research infrastructure has responded quickly to provide support and state of the art expertise in preservation of valuable biological material accompanied with detailed clinical and laboratory data. The presentation will focus and discuss the BBMRI-ERIC response to facilitate access to biological samples and relevant data via: gathering the information on available European as well as non-European biobank resources related to COVID-19, facilitating access to biological resources through the BBMRI-ERIC Negotiator platform; providing support to harmonize data and biological material collection guidelines, providing trainings and guidelines on handling infectious and providing a pan-European exchange platform on ethical, legal and social (ELSI) issues specific to biological and data collection during the COVID-19 pandemic. Effective access to the biobanking resources plays a fundamental role in in strengthening and accelerating research into effective measures to combat pandemics.

DATA AND SAMPLES SHARING AGREEMENTS - NEW CHALLENGES FOR BIOBANKS

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The harmonization of the European data protection law (GDPR Regulation) and the amendment to the Polish law on the professions of a doctor and a dentist made it necessary to adapt samples of Material Transfer Agreement (MTA) and Data Transfer Agreements (DTA) to the new regulation. An additional challenge for biobanks in this regard has also become the Commission implementing decision(EU) 2021/914 of 4 June 2021 on standard contractual clauses for the transfer of personal data to third countries pursuant to Regulation (EU) 2016/679 of the European Parliament and of the Council. The subject of the presentation will be to show the most important provisions of such agreements in the context of international exchange of samples and data for scientific purposes.

Sara Casati

Abstract available soon...

APPROPRIATE SAFEGUARDS UNDER ARTICLE 89 GDPR IN RESEARCH BIOBANKS

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The use of biological samples and data stored in a biobank or databank for research must be rooted in human rights. Indeed, sharing genetic and health data for research impacts on many fundamental rights. Among these, the right to the protection of personal data in research has attracted increasing attention with the entry into force of the GDPR.

The GDPR applies to all personal data, devoting specific attention to special categories of data, such as health and genetic data. Thus, the GDPR directly impacts the use of such data in research. Simultaneously the GDPR outlines several exemptions from many of the strict processing requirements for research. These exemptions are allowed if "appropriate safeguards" are implemented. Article 89 states that these must be "in accordance" with the GDPR "for the rights and freedoms of the data subject", ensuring "respect for the principle of data minimisation". However, the GDPR does not specify the measures that could be implemented to meet these requirements.

In this paper, we first consider each of the requirements for safeguards to be legitimate, particularly the meaning of "in accordance" with the GDPR. We then examine the numerous regulatory instruments developed in the field of biobank, genetic research, and medical research more broadly to protect research participants. The safeguards outlined in such instruments are identified and examined to assess whether they can be legitimate safeguards under Article 89 GDPR.

BIOSAMPLES & BIODATA: THE CZECH LEGAL PERSPECTIVE

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BBMRI-CZ is a network of biobanks which are coordinated by national node in Masaryk Memorial Cancer Institute in (Brno, Czech Republic). It is aimed at collection and storage of human biological material and data (HMB/D) from patients with wide range of civilization diseases for future medical and biological research. Management of biosamples and data for research in the Czech Republic is connected with challenges which mainly arise from the absence of complex legislation in area of biobanking. We would like to point out issues: 1. Fragmented legal rules for collection and use of HMB/D – different laws apply for material and data. Basic rules for collection of HMB during providing healthcare are stated in Act No. 372/2011 Coll., on Health Services. However, there are no specific rules for collection of HMB from healthy individuals as well as for collection of data in research. Therefore, different legal bases for collection of material and data may apply. This can be confusing both for scientists and patients. 2. Requirements for informed consent – Act on Health Services states that consent must be documented. Absence of other requirements leads to legal uncertainty about the extent of information which must be given to patient to keep consent legally valid. 3. Conditions of transfer of HMB/D – there are no specific national legal rules for transfer HBM/D (such as Ethics committee approval). Rules must be set up by biobanks themselves with respect to BBMRI-ERIC policies. For data transfer GDPR provisions apply. MTA/DTA is not mandatory.

Olga Tzortzatou

Abstract available soon...

CONTROLLER-PROCESSOR OR JOINT-CONTROLLER? RIGHTS AND RESPONSIBILITIES IN
Ciara Staunton, Deborah Mascalzoni, Andrea Parziale

Medical research is increasingly reliant on access to large quantities of samples and these materials are often obtained through data sharing arrangements. This sharing of data raises considerable legal and ethical complexities, including issues of consent, benefit sharing, risks of discrimination and stigmatization, and privacy concerns.
The General Data Protection Regulation (GDPR) has impacted this sharing of data. In addition to the conditions that must be met in the processing of personal data that includes genetic data, the GDPR sets out lines of responsibilities, notably in relation to the data controller, the data processor, and joint controllers. It is the data controller who will decide the means and processing of personal data and the data processor who processes data on behalf of the data controller. The responsibilities of both parties differ; therefore, it is essential that prior to the sharing of data, the relationship on which the samples and data are shared (i.e., controller-processor or joint controllership) is established.
The implementation of the GDPR at a national level has been fragmented in the context of research and this has challenged the identification of the appropriate data and sample sharing relationship. In this paper we discuss these relationships and unpack the data and sample sharing relationship in four contexts: a contract for services, collaborations between institutions, research consortia, and research databases.

GENETIC DATA AS SENSITIVE DATA AND THE DEMAND FOR ITS PROTECTION ON THE BASIS OF FUNDAMENTAL RIGHTS

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There is no data more unique and personal than our genetic data. As particularly sensitive data, it should be subject to special legal protection, which should be ensured when it is acquired, collected [gathered] and used, inter alia [i.a.], for scientific research. The basis is the protection of fundamental rights, in particular the right to privacy, and the closely related information autonomy (information self-determination). However, due to the specific value of genetic data, it requires a specialized system of protection. However, the question arises whether the protection of genetic data as part of personal data in the form of the Regulation of the European Parliament and of the Council (EU) of 28.04.2016 referred to as GDPR [General Data Protection Regulation] is sufficient? It seems that, for the time being, there is also a need for actions that contribute to the development of "genetic awareness", allowing the importance of the problem to be appreciated outside scientific circles. Postulated principles related to the protection of the human genetic code:

trust
transparency
the right to consent and withdraw consent regarding the collection and use of genetic data
the right to information for the sample donor
the right to respect for privacy and confidentiality in relation to genetic information
the prohibition of discrimination based on genetic characteristics
the order to exclude the samples taken from commercial circulation
the enabling data exchange between research centres

MODELS OF THE HUMAN EPIDERMIS IN RESEARCH

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In vitro models of human skin are the best research tools in the pharmaceutical and cosmetic industries. Due to its various functions, skin has an equally complex structure. Models in in vitro tests can be used to analyze the basic cellular mechanisms, signaling pathways, assess the safety of tested products or histological changes under the influence of various factors. The best models for research are biopsy tissues, corpse skin or tissues removed as a result of plastic surgery, but the high price, low availability and legal and ethical aspects make finding artificial equivalents a key solution. At the same time, Regulation (WE) 1223/2009 restricts animal testing of cosmetic products. Artificial models are required to be as similar as possible to the structure and features of a natural model. Due to the complexity of the tissue, it is difficult to obtain a model comparable to natural skin. Currently, bioengineering methods allow to obtain full-thickness tissue with proper architecture and barrier properties. Keratinocytes in epidermal equivalents, similarly to natural tissue, are differentiated into 5 different layers, they are also subject to keratinization processes. Compared to native tissue, the models should contain, in addition to keratinocytes and fibroblasts, other cells present in the epidermis, which significantly increases the complexity of such a structure. The available models of the epidermis show a very high similarity to the morphology of the native tissue, but the lack of the dermis and the subcutaneous network of vessels may significantly affect the obtained test results.

THE HISTORY OF IMMUNOLOGY

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The aim of this speech is to present the social background which led to the development of immunology. In 19th century the large number of epidemic diseases forced doctors to find the reasons of the diseases prevalence. They were putting attention on the sanitary conditions. By hygienic education, they were trying to eradicate the outbreak. Some of the scientist put attention to find relations between microbes, infections and the methods of prevention. The researches on microorganisms were started in the 30s of 19th century. Although Louis Pasteur discovered bacteria, it was in 1895 that the existence of organisms smaller than bacteria was proven. The organism was named "the virus". From another perspective, from the 30s of 19th century scientist started their researches on cells and created the cell theory. Due to the development of the organic chemistry in the second half of the nineteenth century, the tissue engineering was also started. The researches dated from the mid-twentieth century led to the creation of a new perspective in medical science. Many contagious diseases and epidemics were eliminated with a combination of sanitation, nutrition, the basic medical care and vaccinations. The immunological theory of contagious diseases was then created. The basics of genetic studies put attention to heredity in general and to genes in particular. All of the experiences and research have created the opportunities for the development of a new paradigm of medicine designed for the treatment of chronic diseases.

PROHIBITION OF COMMECIALIZATION OF HUMAN BODY AND ITS PART AND COMMODIFICATION OF HUMAN BIOLOGAL MATERIAL

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The prohibition of the commercialization of the human body and its parts has been an ethical and legal standard in democratic countries for several decades. On the other side, products based on human biological material (HMB) are being traded and patented. The problem of the limits of commercialization of HBM applies in particular to biobanks (both commercial and non-commercial), which collect, storage and use huge amounts of HBM from participants based on ethical rule of “altruistic donor”.