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Summary of the doctoral dissertation entitled

Biobanking of human biological material: dispute over the model of rational law in biomedical research

The issue of biobanking is related to the dynamic development of molecular biology, medicine and informatics, which nowadays enable to learn about the structure and function of genes, as well as to develop innovative drugs and therapeutic methods. DNA analysis is widely used in diagnostic tests, disease prevention, genealogical research, the determination or denial of paternity and maternity and in identifying biological material of suspects or victims of accidents. The establishing of biobanks, which are structured collections of human biological material and related data, for future research or clinical purposes, gives new opportunities and potential risks. The main aim of this dissertation is to answer the question, how should the legislator regulate the risk in modern biobanking activities in order to optimize the safety and effectiveness of future biomedical research? The main research goal requires identifying instruments for protecting the fundamental rights of research participants in biobanks, reconstructing consent models of people donating biological material to a biobank and the current trends in European biopolitics in genomic research.

The reason for undertaking research on this subject is the need to define the legal nature and the framework for the functioning of biobanking, in the context of biomedical research. Many authors dealing with the indicated issues (in Polish literature, for example, Julia Kapelańska-Pręgowska, Atina Krajewska, Dorota Krekora-Zając, Jakub Pawlikowski) describe detailed issues related to the practice of collecting human biological material – genetic discrimination, patent protection, consent of the research participant, security biological material, biobank management. Despite this, there are still no comprehensive studies on the legal aspects of biobanking.

The research problems undertaken and the adopted methodological assumptions determined the structure of the dissertation. The doctoral dissertation has been divided into five chapters. The first chapter, which is an introduction to the main part of the discussion, analyzes the genesis of modern biobanks, terminological issues of biobanking, basic types of existing

collections of human biological material and the importance of modern genetic research and biobanking. The main research goal of this chapter is to reconstruct the concept of biobanking on the basis of scientific literature and the content of normative acts, as well as the typology and significance of modern biobanking for the development of scientific research, diagnostics and therapy.

The second chapter is devoted to the analysis of normative regulations of human rights protection systems in biomedical research, both at the universal level (soft law acts: the Universal Declaration on the Human Genome and Human Rights of 1997, the International Declaration on Human Genetic Data of 2003, the Universal Declaration on Bioethics and Human Rights of 2005) and regional (documents of the Council of Europe and the European Union). The research was supplemented with comments of the current legal status of biomedical research in Poland – various aspects of biobanking activities are regulated in several acts, which are fragmented. The adopted method of normative analysis finds its justification in the context of the multicentric nature of the legal system, when one legal order is governed by normative acts originating from different legislative entities. The main research objective is to answer the question whether the current regulations on genetic testing remain mutually harmonized and what is the minimum standard of protection of the rights of research participants in biobanks?

In the third chapter of the dissertation, the issues concerning the basic aspects of protection of the rights of research participants in biobanks were analyzed, including in the context of the right to privacy. Due to the relevance of the consent of the participant in the research procedure, its constitutive features were identified and the basic variants of consent were distinguished. This preliminary analysis of consent to participate in biobanking activities anticipates further reflection, developed in the next chapter of this work. Due to the multifaceted activity of modern biobanks, research has been undertaken on the normative situation of people incapable of giving their consent and deceased individuals, property law protection of human biological material and databases. The necessity to implement normative instruments to protect the fundamental rights and interests of participants was emphasized (the right to know and not to know about genetic characteristics, the right to withdraw consent, anonymization of samples and data). The final element of this part of the dissertation is an attempt to reinterpret the principle of solidarity in the perspective of biobanking, including respect for the genetic heritage of local communities, fair access and benefit sharing of genomic research and the role of intergenerational communication. The research objective of this chapter is to identify the

main risks associated with biobanking activities and measures to optimize the protection of the fundamental rights of research participants.

The fourth chapter serves to reconstruct the consent models for participation in biobanking activities in selected European national orders. The analysis covers fourteen countries with comprehensive legal solutions in the field of biobanks. These countries were assigned to three different model groups (taking as a criterion the scope of consent, the purpose of collecting samples and data and the information obligation of participants):

a) two-variant consent model in the biobanking system: informed consent and presumed consent – Iceland, Norway, Denmark, Belgium, Hungary;
b) broad consent model in the biobanking system – Estonia, Latvia, Great Britain, Spain, Finland;
c) informed consent model in the biobanking system: explicit and specific consent – Lithuania, Portugal, Sweden, France.

In order to check whether certain national regulations on biobanking activities are coherent with international legal acts and guidelines, a comparison was made of the ways of regulating such issues as: the formula of consent of a participant in scientific and clinical research, the purpose and scope of applications of human biological material, protection of the fundamental rights of research participants. genetic, ways to protect the stored biological material.

Chapter five is devoted to examining the mutual relations between ethics and biopolitics in the context of genomic research in biobanks. It was assumed that the existing regulatory framework for the protection of participants is created in a specific socio-political environment, which has a significant impact on the current legal solutions. Creation a coherent axiological foundation of biobanking at the regional level is a serious challenge due to the existence of many interested entities: research participants, scientific institutions, political institutions, entrepreneurs and the government. In order to present a broader perspective, different ethical positions were presented: consequentialism (utilitarianism), deontology, principialism, virtue ethics, communitarianism and personalism. This chapter attempts to answer the question of how the existing research procedures in biobanks can be standardized within the framework of biopolitical and bioethical discourse.

While preparing this dissertation the formal-dogmatic, theoretical-legal, historical and comparative methods were used. Each chapter ended with a summary, and the research conclusions presented at the end of the dissertation, both of a general and application character:

1. the practice of banking biological samples and related data implies the presence of various types of risk in several areas – privacy and confidentiality of research participants, scope of consent, commercialization of human biological material, genetic discrimination and stigmatization, re-contact of the biobank with research participants, financing of the biobanking;

2. The activity of biobanks generates new types of risks related to the potential violation of the fundamental rights of the donor, therefore it is necessary to apply adequate protection in the biobank, e.g. the requirement of free, informed consent of the research participant to precisely defined research activities, rules for recruiting people to biobanks „one consent – one research project", the possibility of withdrawing consent at every stage of the research, providing the participant with full information about the planned research project, securing biological samples and data collected in biobank, guaranteeing the right to know or not to know on the research results, obligation to obtain a special certificate by the entity which manage the biobank, obtaining a positive opinion of the bioethical commission for the implementation of a specific research project;

3. conducting genomic research with the use of isolated human biological material and biobank data requires the adoption of a new – in comparision to traditional scientific experiment – research methodology, based on the acquisition, storage, collection, preparation, preservation, analysis, testing or distribution of biological samples and data from a representative of the population that could be used for future research projects;

4. the requirement to obtain the consent of the statutory representatives of persons with no or limited capacity to express informed consent, taking into account the „best interest" and the absence of objection of such persons; the requirement to obtain the consent of the closest family members of the deceased, from whom samples and data were collected for the biobank before their death (similarly also in the case of *ex mortuo* collection of biological material);

5. the prohibition of using the human body and its individual elements as a source of profit, excluding the possibility of commercializing isolated human samples in their natural state (i.e. not genetically modified), while limiting such possibility to genetically

modified human DNA sequences or cell lines, even if the structure of that element is identical to that of a natural element;

6. the prohibition of genetic discrimination by excluding the possibility of using individual genetic data in employment and social security relations.