

In the 19th and 20th centuries, the development of medicine, pharmacy and associated knowledge of human being was enormous. These sciences may be developed only thanks to scientific research conducted on biological samples deriving from very different groups of donors. No scientist may independently collect a sufficient quantity of samples to carry out veracious research and, therefore, around the world, biobanks are created for the purpose of collecting, safeguarding, storing and making available for scientific purposes vast collections of biological samples. The idea of biobanking has been recognised by the Time Magazine as one of the leading ideas which may change the world.

The development of biobanks has generated also the development of the entire biomedical industry based on high technologies. It is estimated that the value of the biobank market in 2014 was 14.4 milliard USD, and in 2018 it will reach 22.7 milliard USD. An exceptionally large quantity of biological samples incorporating information on genetic, health and genotype features, thus contributing to the development of personalised medicine, may cause numerous threats related to eugenics, discrimination and respect for dignity of human being. Furthermore, the lack of legal rules governing agreements concluded by biobanks causes uncertainty in terms of legality of agreements of this type. This uncertainty directly affects limitations in conducting scientific research and, consequently, moderates the development of the science of human being. The subject matter of the analysis covered by the grant applied for will be agreements on biobanking for scientific purposes. According to the definition formulated by the European Group on Ethics in Science and New Technologies, biobank is a term defining various types of collections of biological samples with associated data bases, which are to a certain extent available, attainable and exchangeable for scientific purposes. The absence of legal regulations governing the rules for the operation of biobanks in Poland is illegitimate and harmful from the point of view of legal trading, freedom of research and, primarily, protection of rights of donors of biological samples. The research project I present will enable the carrying out of a comprehensive doctrinal study of agreements on the biobanking of human biological material and reaching conclusions in respect of future legal regulations.

The first scientific goal of the research is to describe the merits and legal nature of the rights and duties of donors, biobanks and scientists, related to the use of human biological samples for scientific purposes. The second goal is to determine the rules governing permissibility of donating biological samples by donors, their delivery by biobanks to scientists and transfer between biobanks. The third research goal is the analysis of Polish and European laws with respect to the rights and duties of donors, biobanks and scientists using biological samples deriving from biobanks. The fourth major research goal is to determine a relation between a legal regulation of the issue in question and agreements concluded by biobanks. The analyses will be aimed at determining a legal framework for agreements concluded by biobanks. The said goal will be attained by way of a legal analysis of all agreements concluded by biobanks within the scope of donation and delivery of a human biological sample. The necessity to analyse these contract-related issues stems from the lack of legal regulations in this respect. All attempts for develop statutory laws have failed. The research conducted as part of the project is not limited to Polish law and will cover also European regulations, including those developed by a biobank association. Furthermore, the analysis will cover also agreements concluded in Great Britain by the UK Biobank, one of the largest biobanks in the world, and Swedish biobanks, which are among the oldest biobanks. The necessity to carry out extensive legal comparative research stems also from the fact that, in Polish law, which lacks provisions in this respect, these issues are not the subject matter of a scientific debate and, as shown in the research conducted by J. Pawlikowski, are often a matter of concern in the Polish society. The research applied for is in its nature fundamental and innovative for the activity of biobanks and also for the development of genetics, medicine, pharmacy or biotechnology. This is the first research on civil law aspects of biobanking in Poland and the publishing of its results will enhance social awareness of biobanking, which will contribute to greater legal awareness of donors and their greater number. In the research, different research methods will be applied depending on the subject matter and goal of the research. Applying inter alia a legal comparative method, I will describe legal regulations relating to civil law aspects of biobanking in countries such as Sweden and Great Britain.

The aim of this research will be to depict differences and similarities in contractual provisions relating to biobanking in these countries and to draw conclusions *de lege ferenda* in respect of future Polish regulations governing the issue in question.