

ABSTRACT

The objective of the scientific research conducted within the framework of this doctoral dissertation is to determine the extent to which the most recent amendment to the Act on the Professions of Physician and Dentist complies with international standards governing scientific research involving human biological material. Furthermore, the study seeks to assess whether, in light of these standards, Polish legal regulations adequately and comprehensively address the issue of medical experiments conducted on biological material obtained from individuals for scientific purposes. As a result of the amendment to the Act on the Professions of Physician and Dentist, since 2021, the statutory catalogue of medical experiments has been expanded to include an additional category, namely, *the examination of biological material, including genetic material, collected from individuals for scientific purposes*.

The considerations presented in this dissertation focus on the analysis of legal issues related to the conduct of research on biological material in accordance with the provisions of the current Act on the Professions of Physician and Dentist. Legal regulations establishing the principles for conducting medical experiments *in genere* often do not directly apply to research involving biological material derived from the human body. A necessary condition for determining the legal status and assessing its completeness and adequacy in relation to international ethical and legal standards is the resolution of numerous interpretative doubts arising from the provisions of the Act on the Professions of Physician and Dentist following its amendment. These doubts pertain to the very notion of a medical experiment involving human biological material, the activities constituting such an experiment, issues related to participation in such experiments, and the obligations arising therefrom. The analysis of the current legal framework also raises questions regarding the relationship between the present wording of the Act on the Professions of Physician and Dentist and regulations concerning biobanking, as well as other issues related to the permissibility and principles of collection, storage, and distribution of human biological material.

The new legal conditions, which *de lege lata* subject research on biological material collected from individuals for scientific purposes to the regime of medical experiments, have given rise to a number of legal uncertainties regarding their proper interpretation. The numerous interpretative doubts identified in connection with the introduction of a new category of medical experiment have necessitated the formulation of possible interpretative

variants of the amended Act's provisions and the presentation of solutions which *de lege lata*, appear to be the most justified.

The possibility of applying various interpretative approaches to the provisions of the Act on the Professions of Physician and Dentist demonstrates the complexity of the issues associated with its application. From a legal perspective, it appears correct to base one's interpretation either on the literal meaning of the Act—which, *prima facie* does not seem to pose significant interpretative difficulties, although it does not account for all possible uses of biological material for scientific research purposes—or on an interpretation that departs from the literal wording in favour of a purposive approach. In such a case, it is possible to recognise any research on biological material meeting the statutory criteria as a medical experiment, or, alternatively, to adopt the position that research not fulfilling at least one of the conditions set out in Article 21(4) of the Act on the Professions of Physician and Dentist falls outside the scope of this Act. At the same time, it also appears correct to conclude that such research should not be regarded as a separate category of medical experiment distinct from experiments conducted “on humans,” but rather as a form of research experiment.

The findings of this dissertation clearly indicate that the most recent amendment to the Act on the Professions of Physician and Dentist has not achieved the intended legal effects in addressing the regulatory gap previously existing in the area of scientific research. The currently binding provisions generate more legal uncertainties regarding the conduct of research on biological material than the previous legal state, which did not *de lege lata* regulate this area. Polish legal regulations do not comprehensively govern the issue of medical experiments conducted on biological material obtained from individuals for scientific purposes, resulting not only in fundamental normative doubts as to the scope of application of the amended Act and, consequently, the correct derivation of legal obligations therefrom, but above all, leaving many legal aspects related to the use of human biological material for research purposes outside the scope of any statutory regulation. Therefore, the direction of changes introduced by the most recent amendment must be regarded as inappropriate, insufficiently aligned with international standards for conducting scientific research on human biological material, and divergent from the legal regulations of other European countries, thereby revealing numerous deficiencies in the current provisions.