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Abstract

mBiobanks are collections of human tissue and related personal data of the donors. German legislation has, in contrast to other countries, not passed any special legal provisions on biobanking yet. The German Ethics Council published an opinion in 2010 on the need for legislative action. The Council proposed a five-pillar-concept whose main elements include a biobank-secrecy that aims to prevent access to biobanks and their information by all non-research third parties including state authorities; the biobank-secrecy is seen as the "price" for the validity of a broad consent of the donors of the tissue that allows researchers to use the samples and data without specifying the future uses in advance. In this article, the recommended elements of the biobank-secrecy, a duty of professional discretion, a right to refuse to give evidence and the prohibition of seizure are examined in respect of their constitutionality. A constitutional balance between the legally protected interests of donors and researchers on the one side and the general interest in the prosecution of crimes, public order and security on the other is, in our opinion, only possible, if access in cases of serious crime and serious danger for the public remains lawful. Furthermore, the article discusses the validity of a global

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consent of the donors of human tissue and deals with criticism by the scientific community concerning the recommendations by the German Ethics Council. Furthermore, the main problem of the five-pillar-concept will be the legislative implementation of the different recommendations. It is shown that a legal regulation of global consent falls into the responsibility of both federal and state legislation, depending on the areas of application of the different data protection laws in Germany. As a result, a single uniform biobank law including all provisions of the five-pillar-concept cannot be passed. (HRK / Abstract übernommen)