Abstract

Since the turn of the millennium biobanks – stores of biological samples and associated data for research – have become increasingly important aspects of medical research infrastructure. Yet, with this growth in importance has come ever greater legal and ethical scrutiny. One set of critical questions concerns privacy. Questions have been raised as to how privacy might be best protected given biobanks facilitate the processing of huge quantities of genetic data: Questions of genetic privacy. Thusfar, the EU legal situation regarding the protection of genetic privacy has been criticized. Yet, there is one area of law whose applicability is unquestioned, yet whose capacity has been scarcely considered: Data protection. Currently, EU data protection law is outlined by Directive 95/46. On 25th May, 2018, the Directive will be replaced by Regulation 2016/679: The General Data Protection Regulation. This thesis considers the role the Regulation could play in the protection of genetic privacy in biobanking.

To start, the thesis clarifies the legitimate genetic privacy rights engaged by biobanking. These include rights held by research subjects – concerning restricting access to samples and data and the return of data produced in research – and by genetic relatives and genetic groups. In relation to these rights, the thesis outlines a base line standard of protection via an analysis of international law. Against this base line, the thesis highlights the inadequacies of other EU approaches and thereby the logic of looking to the Regulation. Accordingly, the thesis provides a detailed descriptive analysis of the applicability of the Regulation to biobanking and a critical analysis of its ability to protect genetic privacy. These analyses show an instrument providing comparatively extensive applicability and protection. Yet, they also show an instrument with multiple problems. Fortunately, a deeper consideration of these problems shows none are critical for the efficacy of the Regulation.