

DATA PROTECTION, GENETICS AND PATENTS FOR BIOTECHNOLOGY

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This paper has three parts. In Part One, we argue that while biological samples and genetic information extracted from them are not (in terms of Directive 95/46/EC) personal data in and of themselves, each is capable of being personal data in appropriate contexts, and we consider the consequences of this position for data controllers and data subjects. In Part Two, we argue that if this is correct, then the requirement for sources of human biological samples to give informed consent for any use of their samples (which the ECJ has maintained to be a fundamental principle of EC law but not one to be enforced via patent law) must be enforced by data protection law in the EU. Furthermore, we argue that, because Directive 95/46/EC does not clearly prohibit regarding biological samples and genetic information extracted from them as personal data, the premise that the requirement for such consent is a fundamental principle of EC law supports our thesis that biological samples and genetic formation extracted from them are to be regarded personal data. Finally, in Part Three, we consider the implications of our position for the capacity of Directive 95/46/EC to adequately protect third party interests given the shared nature of genetic data