

Table of Contents

Part I of the legal opinions: Lawfulness of Processing	1
1 Executive Summary	3
2 Legal requirements of data collection and migration	5
2.1 Preliminary note	5
2.2 Applicability of data protection law	6
2.3 Collection of personal data concerning health of patients for the registry in Germany	8
2.4 Data migration	20
Part II of the legal opinions: Detailed Questions on organisational and technical measures	21
1 Transparency	23
2 Auditing	26
3 Erasure of Personal Data	28
3.1 The right to be forgotten	28
3.2 Erasure of Personal Data in backups	29
4 Information Duty	31
5 Consent	32
5.1 Informed Consent	32
5.2 Consents (before 25/05/2018)	39
5.3 Consent (after 25/05/2018)	44
5.4 Dealing with different consent versions	45
5.5 Withdrawal of a Declaration of Consent/Study Exclusions	47
6 Legal consequences of withdrawal	51
7 Standard Operating Procedure (SOP)	55
8 Ethics Committee Vote	56
9 Quality assurance in the Trusted Third Party	59
10 Authorisation of Study Leaders	61
11 Dealing with deceased study participants	63
12 Studies within the European Union	66
13 Storage limitation	70
14 Purpose limitation	72
15 End of a project	75

Table of Contents

16 Possession and ownership of data	78
16.1 “Dateneigentum”/“data ownership”	78
16.2 “Datenhalter”/“data holder”/“data possessor”	79
16.3 “Datenverarbeiter”/“data processor”	79
17 Data Protection Management System	81
18 Privacy by Design	83
19 Use of eGK number or KV number	85
19.1 General Information on the eGK and the KVNR	85
19.2 Special legal significance of an unchangeable identifier	86
19.3 Additional sensitivity as a Data about health?	87
19.4 Non-validated issuing process	88
19.5 Special restrictions of use according to the SGB V	89
19.6 Conclusion	91
20 Technical and Organisational Measures (TOM)	92
21 Data usage by industrial partners	97
22 Necessity of documents	99
23 Responsible supervisory authority	101
24 Release From Obligation To Secrecy	102
25 Necessity of a contract on data processing	104
Appendix	111
List of Questions	113
Keywords Glossary	123