## Contents

Ab	Abbreviations		
Tai	le of Cases and Legislation	xi	
1.	Introduction	1	
2.	Genetic Data, Genome Understanding, and Socially Relevant Informa	tion 7	
	A. Introduction	7	
	B. Types of Genetic Data	7	
	C. Types of Socially Significant Information Revealed via Genetic Analysis	9	
	D. The Range of Genetic Analyses Potentially Applicable to Genetic Data	12	
	E. The Accuracy of Information Produced via Genetic Analysis	14	
	F. The Range of Parties Implicated by Genetic Analyses	16	
	G. Conclusion	17	
3.	The Context and State of the Art in European Biobanking	19	
	A. Introduction	19	
	B. The Human Genome Project: Where It All Began	19	
	C. Organisational Legacies of the Human Genome Project	21	
	D. Methodological Legacies of the Human Genome Project	22	
	E. The Promises of Genomic Research	24	
	F. The Unfulfillable Promises of Genomic Research?	25	
	G. Defining Biobanks: A Loose Definition for a Heterogeneous Class	26	
	H. Variations in European Biobanking: Scientific Approach	29	
	I. Variations in European Biobanking: Organisational Structure	31	
	J. Variations in European Biobanking: Substance Ownership and Intellectu	al	
	Property	33	
	K. Variations in European Biobanking: Approach to Research Subjects	34	
	L. Future Trends in European Biobanking	36	
	M. Conclusion	38	
4.	Genetic Privacy and Other Interests in Biobanking: Conflict		
	and Confluence	40	
	A. Introduction	40	
	B. Privacy: As a Condition and as a Right	40	
	C. Genetic Privacy Rights: A Subset of Privacy Rights	43	
	D. Mapping Genetic Privacy Rights Engaged by Biobanking: The Research		
	Subject's Genetic Privacy Rights on the Transactional Axis	46	
	E. Mapping Genetic Privacy Rights Engaged by Biobanking: Genetic Relative	ves'	
	and Genetic Groups' Genetic Privacy Rights on the Relational Axis	51	
	F. Genetic Classes and Genetic Categories: Two Different Kinds of		
	Genetic Groups	54	
	G. Mapping Other Interests Engaged by Biobanking: Interests Tied Up with	the	
	Conduct and Outcome of Biobank Research	56	

## vi CONTENTS

	H.	Mapping Other Interests Engaged by Biobanking: Third-Party Non-Research	
		Interests in Accessing Biobanking Substances	59
	1.	Mapping the Relationships between Genetic Privacy Rights and Other	-
		Interests: Conflicts	63
	J.	Mapping the Relationships between Genetic Privacy Rights and Other	
	**	Interests: Confluences	65
	K.	Conclusion	66
_	Th	a Protection of Constita Drive av in Diahanking at International	
٥.		e Protection of Genetic Privacy in Biobanking at International	
		vel: Establishing a Baseline Standard for Genetic Privacy Protection in	
		banking	67
		Introduction	67
		The Structure of the International Framework	68
	C.	Common International Principles Regarding Research Subjects' Genetic	
	5	Privacy on the Transactional Axis	71
	D.	Common International Principles Regarding Genetic Relatives' and Groups'	
	~	Genetic Privacy on the Relational Axis	75
	E.	Emerging International Principles Regarding Research Subjects' Genetic	
	-	Privacy on the Transactional Axis	77
	F.	Emerging International Principles Regarding Genetic Relatives' and Groups'	
	-	Genetic Privacy on the Relational Axis	79
		Problems of Structure: The International Framework Is Not Hard Law	80
	H.	Problems Along the Transactional Axis: The International Framework	
		Does Not Provide Protection for the Full Range of Research Subjects'	
	_	Genetic Privacy Rights	82
	I.	Problems Along the Relational Axis: The International Framework	
		Does Not Provide Protection for the Full Range of Genetic Privacy	
		Rights Holders	85
	J.	Problems with the Standard of Protection: The International Framework	
		Provides Incomprehensive Protection	88
	K.	Conclusion	89
-	D	No. J. Data Boots et an at All2 Facilities Boots et a Compti-	
0.		we Need Data Protection at All? Evaluating Protection for Genetic	0.1
		vacy in Biobanking in Europe Excluding Data Protection	91
		Introduction	91
		Selection of European Legal Systems to Analyse	92
		EU Law Excluding Data Protection	93
		Estonian Law Excluding Data Protection	94
		German Law Excluding Data Protection	101
		UK Law Excluding Data Protection	107
	G.	Problems of Structure: No System—Excluding Data Protection—	
		Is Optimally Structured to Protect Genetic Privacy in Biobanking	115
	H.	Problems with the Protection of Research Subjects' Genetic	
		Privacy: Excluding Data Protection, Only Estonia Protects the Full	
		Range of Genetic Privacy Rights	117
	I.	Problems with the Protection of Genetic Relatives' and Genetic Groups'	
		Genetic Privacy: No System—Excluding Data Protection—Protects Genetic	
		Relatives or Groups	119
	J.	Problems with the Adequacy of Protection: No System—Excluding Data	
		Protection—Provides Comprehensive Protection	121

	K.	Problems of Harmony: Systems— <i>Excluding</i> Data Protection—Are Neither Harmonised, Nor Necessarily Compatible	123
	L.	Looking to Data Protection and the GDPR	126
		Conclusion and to some and some and guilless and an extension and some anation and some and some and some and some and some and some and s	128
7.	Tes	sting the GDPR in Relation to Biobanking: When Does the	
	GI	OPR Apply to Biobanking?	129
	A.	Introduction all gnims to a smalder a	129
	B.	The GDPR's General Applicability Principles: Article 2 and Biobanking	129
	C.	Personal Data and Its Constituent Criteria	131
		Which Biobanking Substances Could Potentially Be Personal Data?	135
	E.	Biological Samples as Personal Data? Practical Parallels Between	
		Biological Samples and Sequenced Genomic Data	137
	F.	Biological Samples as Personal Data? Biological Samples Can Be	215 A
		Considered in Terms of Information	138
	G.	Biological Samples as Personal Data? Biological Samples Can Be	
	* *	Considered as Information as the Term Is Used in the GDPR	141
		Which Biobanking Links Qualify as Identified or Identifiable?	143
	1.	Conclusion	146
Q	Tes	sting the GDPR in Relation to Biobanking: How Does the	
0.		OPR classify the Biobanking Process?	148
		Introduction	148
		Two Classifications Systems: The Actor Classification System and	140
	D.	the Personal Data Classification System	148
	C.	The Applicability of the Actor Classification System to Biobanking	152
		The Applicability of the Personal Data Classification System to Biobanking	155
		Conclusion	157
9.	Tes	sting the GDPR in Relation to Biobanking: How Do the GDPR's	
	Sul	bstantive Provisions Apply to Biobanking?	159
	A.	Introduction	159
	B.	Biobanking and Oversight under the GDPR	159
		Biobanking and Legitimate Processing under the GDPR	162
		Biobanking and Data Subject Rights under the GDPR	169
		Biobanking and Data Controller Obligations under the GDPR	175
		Biobanking and Transfers to Third Countries under the GDPR	181
		Biobanking and Sanctions under the GDPR	186
		Biobanking and Derogations under the GDPR	188
	1.	Conclusion	190
10	A (	Critical Analysis of the Efficacy of the GDPR as a Framework for the	
		otection of Genetic Privacy in Biobanking	192
		Introduction	192
		A Framework for the Critical Analysis of the GDPR	193
		Problems Concerning the Structure of the GDPR	196
		Problems Concerning the Protection of Research Subjects' Genetic Privacy	170
		Rights on the Transactional Axis	201
	E.	Problems Concerning the Protection of Genetic Relatives' and Genetic	
		Groups' Genetic Privacy Rights on the Relational Axis	205

## viii CONTENTS

	F.	Problems Concerning the Substantive Protection Offered by the GDPR	212		
		Problems Concerning the Technical Applicability of the GDPR's			
		Provisions to Biobanking	222		
	H.	Problems Concerning the Disproportionate Impact of the GDPR			
		on Research	229		
	I.	Problems Concerning the Practical Applicability of the GDPR			
		to Biobanking	236		
	J.	Problems Concerning the Degree to Which the GDPR			
		Harmonises Protection	247		
	K.	Conclusion	254		
11.	Co	nclusion	256		
Refe	eren	ces	261		
Indi	Index				