

Contents

1	Beyond Data	1
1.1	Introduction	2
1.2	Rise and Fall of Individual Sovereignty Over Data Use	3
1.3	Reconsidering Self-determination: Towards a Safe Environment	10
1.4	A Paradigm Shift: The Focus on Risk Assessment	13
1.5	HRESIA: A Multi-layered Process	15
1.6	The Role of Experts	19
1.7	Assessing the Impact of Data-Intensive AI Applications: HRESIA Versus PIA/DPIA, SIA and EtIA	20
1.8	The HRESIA and Collective Dimension of Data Use	27
1.9	Advantages of the Proposed Approach	30
1.10	Summary	30
	References	32
2	Human Rights Impact Assessment and AI	45
2.1	Introduction	46
2.2	A Legal Approach to AI-Related Risks	48
2.3	Human Rights Impact Assessment of AI in the HRESIA Model	51
	2.3.1 Planning and Scoping	52
	2.3.2 Data Collection and the Risk Analysis Methodology	54
2.4	The Implementation of the Model	60
	2.4.1 A Case Study on Consumer Devices Equipped with AI	61
	2.4.2 A Large-Scale Case Study: Smart City Government	76
2.5	Summary	83
	References	85

3	The Social and Ethical Component in AI Systems Design and Management	93
3.1	Beyond Human Rights Impact Assessment	94
3.1.1	The Socio-ethical Framework: Uncertainty, Heterogeneity and Context Dependence	96
3.1.2	The Risk of a ‘Transplant’ of Ethical Values	97
3.1.3	Embedding Ethical and Societal Values	101
3.1.4	The Role of the Committee of Experts: Corporate Case Studies	104
3.2	Existing Models in Medical Ethics and Research Committees	110
3.2.1	Clinical Ethics Committees	110
3.2.2	Research Ethics Committees	112
3.2.3	Ethics Committees for Clinical Trials	117
3.2.4	Main Inputs in Addressing Ethical and Societal Issues in AI	119
3.3	Ad Hoc HRESIA Committees: Role, Nature, and Composition	121
3.4	Rights-Holder Participation and Stakeholder Engagement	127
3.5	Summary	130
	References	132
4	Regulating AI	139
4.1	Regulating AI: Three Different Approaches to Regulation	140
4.2	The Principles-Based Approach	142
4.2.1	Key Principles from Personal Data Regulation	144
4.2.2	Key Principles from Biomedicine Regulation	152
4.2.3	A Contribution to a Future Principles-Based Regulation of AI	158
4.3	From Design to Law – The European Approaches and the Regulatory Paradox	159
4.3.1	The Council of Europe’s Risk-Based Approach Centred on Human Rights, Democracy and Rule of Law	161
4.3.2	The European Commission’s Proposal (AIA) and Its Conformity-Oriented Approach	166
4.4	The HRESIA Model’s Contribution to the Different Approaches	174
4.5	Summary	176
	References	177

5 Open Issues and Conclusions 185

5.1 Addressing the Challenges of AI 186

5.2 The Global Dimension of AI 188

5.3 Future Scenarios 191

References 195

Index 199