

Contents

<i>List of Figures</i>	<i>page</i> xi
<i>List of Tables</i>	xiii
<i>List of Contributors</i>	xv
<i>Acknowledgements</i>	xix
Introduction	1
Graeme Laune	
PART I CONCEPTS, TOOLS, PROCESSES	
SECTION IA CONCEPTS	
Introduction	13
Annie Sorbie	
1 Vulnerability	17
Wendy A. Rogers	
2 Autonomy: Relational Conceptions	27
Natalie Stoljar	
3 Proportionality in Health Research Regulation	37
Owen Schaefer	
4 Social Value	46
Johannes J. M. van Delden and Rieke van der Graaf	
5 Solidarity in Health Research Regulation	56
Katharina Kieslich and Barbara Prainsack	
6 The Public Interest	65
Annie Sorbie	
7 Privacy	73
David Townend	

8	Trustworthy Institutions in Global Health Research Collaborations Angeliki Kerasidou	81
9	Vulnerabilities and Power: The Political Side of Health Research Iain Brassington	90
	SECTION 1B TOOLS, PROCESSES AND ACTORS	
	Introduction Edward Dove and Nayha Sethi	99
10	Consent Jane Kaye and Megan Pricor	103
11	Forms of Engagement Mhairi Aitken and Sarah Cunningham-Burley	112
12	Participatory Governance in Health Research: Patients and Publics as Stewards of Health Research Systems Kim H. Chuong and Kieran C. O'Doherty	121
13	Risk-Benefit Analysis Carl H. Coleman	130
14	The Regulatory Role of Patents in Innovative Health Research and Its Translation from the Laboratory to the Clinic Dianne Nicol and Jane Nielsen	139
15	Benefit Sharing: From Compensation to Collaboration Kadri Simm	148
16	Taking Failure Seriously: Health Research Regulation for Medical Devices, Technological Risk and Preventing Future Harm Mark L. Flear	158
17	Rules, Principles and the Added Value of Best Practice in Health Research Regulation Nayha Sethi	167
18	Research Ethics Review Edward Dove	177
19	Data Access Governance Mahsa Shabani, Adrian Thorogood and Madeleine Murtagh	187
20	Is the Red Queen Sitting on the Throne? Current Trends and Future Developments in Human Health Research Regulation Stuart G. Nicholls	197
21	Regulatory Authorities and Decision-Making in Health Research: The Institutional Dimension Aisling M. McMahon	205

22	The Once and Future Role of Policy Advice for Health Regulation by Experts and Advisory Committees Eric M. Meslin	215
PART II REIMAGINING HEALTH RESEARCH REGULATION		
SECTION IIA PRIVATE AND PUBLIC DIMENSIONS OF HEALTH RESEARCH REGULATION		
	Introduction Graeme Laurie	227
23	Changing Identities in Disclosure of Research Findings Emily Postan	229
24	Health Research and Privacy through the Lens of Public Interest: A Monocle for the Myopic? Mark Taylor and Tess Whitton	239
25	Mobilising Public Expertise in Health Research Regulation Michael M. Burgess	248
26	Towards Adaptive Governance in Big Data Health Research: Implementing Regulatory Principles Effy Vayena and Alessandro Blasimme	257
27	Regulating Automated Healthcare and Research Technologies: First Do No Harm (to the Commons) Roger Brownsword	266
SECTION IIB WIDENING THE LENS		
	Introduction Agomoni Ganguli-Mitra	275
28	When Learning Is Continuous: Bridging the Research–Therapy Divide in the Regulatory Governance of Artificial Intelligence as Medical Devices Calvin W. L. Ho	277
29	The Oversight of Clinical Innovation in a Medical Marketplace Wendy Lipworth, Miriam Wiersma, Narcyz Ghinea, Tereza Hendl, Ian Kerridge, Tamra Lysaght, Megan Munsie, Chris Rudge, Cameron Stewart and Catherine Waldby	287
30	The Challenge of ‘Evidence’: Research and Regulation of Traditional and Non-Conventional Medicines Nayeli Urquiza Haas and Emilie Cloatre	296
31	Experiences of Ethics, Governance and Scientific Practice in Neuroscience Research Martyn Pickersgill	306

32	Humanitarian Research: Ethical Considerations in Conducting Research during Global Health Emergencies Agomoni Ganguli-Mitra and Matthew Hunt	315
33	A Governance Framework for Advanced Therapies in Argentina: Regenerative Medicine, Advanced Therapies, Foresight, Regulation and Governance Fabiana Arzuaga	324
	SECTION IIC TOWARDS RESPONSIVE REGULATION	
	Introduction Catriona McMillan	333
34	Human Gene Editing: Traversing Normative Systems Rosario Isasi	335
35	Towards a Global Germline Ethics? Human Heritable Genetic Modification and the Future of Health Research Regulation Sarah Chan	344
36	Cells, Animals and Human Subjects: Regulating Interspecies Biomedical Research Amy Hinterberger and Sara Bea	356
37	When Is Human? Rethinking the Fourteen-Day Rule Catriona McMillan	365
38	A Perfect Storm: Non-evidence-Based Medicine in the Fertility Clinic Emily Jackson	373
39	Medical Devices Regulation: New Concepts and Perspectives Needed Shawn H. E. Hamon	382
	Afterword: What Could a Learning Health Research Regulation System Look Like? Graeme Laurie	391
	<i>Index</i>	401