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### Introduction: Towards a learning health research regulation system

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# Introduction

## *Towards a Learning Health Research Regulation System*

*Graeme Laurie*

### 1 INTRODUCTION

The principal objective of this volume is to provide the first-ever integrated, multidisciplinary and cross-cutting analysis of health research regulation, drawing on experiences and expertise from across the globe. The book confronts the gaps between documented law and regulation in action; it demonstrates the relevance and value of ethical and social theories to good governance in research, and it seeks to capture and capitalise on lessons learned from research practice. This chapter provides an account of the changing landscape of health research regulation since the millennium, exposing themes and issues that become the focus of the subsequent sections and chapters of the book. Together, the contributions lay the foundation for the development of a Learning Health Research Regulation System, and the potential elements of such a system are explored in the Afterword.

### 2 WHAT IS HEALTH RESEARCH REGULATION AND WHAT IS THE PROBLEM?

The focus of this volume is the broad field of human activity termed ‘health research regulation’ (hereafter ‘HRR’). This is not a formal term of art, but rather refers to the general ecosystem of activities, laws and regulations that seek to shape the conduct of any and all types of health-related research involving human participants directly, or indirectly using data and biomaterials from them.

It is not appropriate to attempt a unitary definition of ‘regulation’ that would accommodate the range of discussions in the following chapters. Rather, our approach is to suggest that ‘regulation’ can broadly be seen as typified by certain characteristics, such as frames of operation and control that are normally state-led and proscriptive of action; grounded in law; often accompanied by monitoring and legal sanction for failure to comply; and involving clear institutional roles and responsibilities for actors, commonly organised in a formal hierarchical manner. As an example, HRR in the European context involves a complex morass of regulations and actors, with laws passed by the European Union, some of which require implementation in member states, but all reflecting common standards and values that are applicable across the region. Among other areas, this European ecosystem extends to clinical trials, medical devices, data protection and advanced therapy medicinal products (ATMPs).

In contrast, the practice of ‘governance’ is a now common phenomenon in human health research. As above, a single definition is not helpful, but common characteristics include governance arrangements being initiated by actors other than the state (e.g. research funders); non-reliance on law for authority; principles-based modes of conduct to guide action; absence of

formal sanction; and a plethora of diverse context-dependent approaches and actors that are, accordingly, highly contingent. Where individual chapters diverge significantly from these outlines, this is made clear. Together, however, these notions of regulation and governance are an attempt to reflect holistically the extensive range of activities that make up modern health research across the globe.

The project of compiling this volume was motivated by a concern that current literature on HRR fails to capture cross-cutting issues and (inter) disciplinary perspectives from which lessons can be learned for the enterprise of HRR *as a whole interconnected system*. This arises, in part, because regulation is unevenly distributed across the landscape of biomedical practice. For example, some areas may be seen as over-regulated (such as clinical trials), while other areas are seen as under-regulated (such as experimental therapies), or simply not regulated at all in some countries (such as putative stem cells therapies).

By offering an account and a critique of current approaches to regulatory systems, this book provides deep insights into the theory and practice of HRR in national, European and international contexts. While no single work can hope to reach a majority of legal jurisdictions, the editors have identified an array of international contributors to draw out lessons from particular experiences of regulation in action, with the aim of extracting more generalisable lessons across national and international borders. We are most grateful to our contributors who have worked so hard to bring this volume to fruition.

By adopting an approach that is both descriptive and also unashamedly normative, the volume contributes to orienting HRR towards the identification and exploitation of flexibilities within regulatory spaces in order to deliver the benefits of biomedicine more effectively and efficiently.

The overarching objective is to provide a robust platform for the construction and analysis of regulatory normativity through practice. In this regard, the core contribution of this work is to offer insights into the design of a *Learning Health Research Regulation System*, further details of which are offered in the Afterword.

More particularly, the volume addresses the following questions:

- What lessons and insights are revealed when particular regulatory responses and experiences are subject to scrutiny from diverse disciplinary perspectives?

This question is motivated by the current reality that legal frameworks and approaches tend to ‘compartmentalise’ HRR, that is, to fixate on the creation and regulation of certain regulatory objects – such as ‘human tissue’, ‘personal data’, ‘clinical trials’, ‘human embryos’, etc. In doing so, there is little attempt to extrapolate lessons across these regulatory spaces or the particular experiences in different sectors. This volume seeks to do so, where this is appropriate.

- What policy and practice implications flow across areas of health research when we better understand health research regulatory spaces?

This question re-enforces the objective of the volume to draw out and demonstrate lessons from across regulatory sectors and experiences. As explained below, readers will see how the structuring of the volume into sections, for which individual editors have been responsible in stewarding the authors’ contributions, assists this process.

- What are the benefits for health research of re-framing regulation and risk as ethical and co-produced practice?

This question reflects a further objective of the volume to challenge existing assumptions and underlying theories in regulation, particularly command-and-control models of regulation

(i.e. state-led, top-down approaches) that are frequently found in approaches to HRR. While these models are important and valuable in appropriate contexts, many contributions in this volume also focus attention on bottom-up initiatives – e.g. stakeholder-led, funder-led and/or patient-led – thereby revealing a wider pool of options to deliver effective regulation and governance, and with which to gauge impacts of regulatory approaches. The volume seeks to connect abstract models of regulation and governance with actual experience; accordingly, many chapters are anchored in case studies from which the analysis and insights emerge.

The volume arose from an interdisciplinary initiative that brought together scholars from medical anthropology, medical sociology, bioethics and law to address the above research questions. The editors have benefited considerably from a Wellcome-funded research project entitled: *Confronting the Liminal Spaces of Health Research Regulation (2014–2021: the Liminal Spaces Project)*.<sup>1</sup> In accordance with the vision of the Liminal Spaces Project, the cumulative contribution of this volume is to serve as a basis for radical reimagining of HRR and to provide novel insights for framing and informing the future direction of health research itself.

We envisage this volume having wide and significant global reach for several reasons. First, the theoretical and conceptual contributions are of universal appeal and are not tied to any particular country or region. Second, the range of examples and case studies used have resonance across the whole field of HRR, including interventions involving research participants, human tissue, personal data, embryos and more novel approaches to human health research, such as citizen science initiatives and open science projects. Third, to the extent that examples or discussions are focussed on particular countries or legal systems, these are presented to serve as testing grounds for valuable lessons for other countries or jurisdictions. As stated above, we cannot hope – nor do we aspire – to reach all jurisdictions; the approach is one of abstracting lessons from particular regulatory challenges and implemented solutions in particular contexts (while acknowledging the vagaries of the ‘local’ in such accounts).

As to audience, the volume is designed to have both academic and practical appeal. As well as capturing experiences from existing examples of HRR and analysis of failed and successful initiatives, the book offers researchers, regulators and engaged citizens with a rich resource of examples and discussions of regulation tools and practices, and an assessment of their contributions, limits and ultimate value. The aim is to make this volume the ‘Go To’ reference guide both to offer accounts of approaches to HRR and signposts on how to improve on the delivery of scientifically sound, ethically robust human health research.

### 3 HOW HAS THE HEALTH RESEARCH REGULATION LANDSCAPE BEEN CHANGING (AND WHAT ARE WE PREPARED TO DO ABOUT IT)?

In 2017, the United Kingdom’s Academy of Medical Sciences (the Academy, AMS), Cancer Research UK and Wellcome produced a follow-up report to the Academy’s 2011 publication: ‘A New Pathway for the Regulation and Governance of Health Research’.<sup>2</sup> The update report<sup>3</sup> captured the conclusions of a high-level stakeholders’ workshop that took place in November 2016 to explore progress in the regulation and governance landscape for health research. The mission of the Academy of Medical Sciences (AMS) is unashamedly to promote medical

<sup>1</sup> The Liminal Spaces Project: [www.liminalspaces.ed.ac.uk/](http://www.liminalspaces.ed.ac.uk/).

<sup>2</sup> Academy of Medical Sciences, ‘A New Pathway for the Regulation and Governance of Health Research’, (Academy of Medical Sciences, 2011).

<sup>3</sup> Academy of Medical Sciences, Cancer Research UK and Wellcome, ‘Regulation and Governance of Health Research: Five Years On’, (AMS, 2016).

science and its translation into benefits for society. This particular partnership with the world's leading independent cancer charity and a global funder of biomedical science reflected a growing phenomenon of 'self-help' initiatives among stakeholders implicated in navigating the intricacies of HRR and facing the challenges of supporting burgeoning and diverse cohorts of researchers attempting to do the same.

The AMS had previously lamented the advent of the so-called 'consent or anonymise' model of regulation<sup>4</sup> that is prevalent in many legal systems seeking to legitimate health research involving personal data.<sup>5</sup> The limits of consent as an effective protection of individual interests are well documented,<sup>6</sup> as are the significant shortcomings of anonymisation both as a technical security measure<sup>7</sup> and as a robust guardian of citizens' rights to privacy.<sup>8</sup> The clarion call from the AMS was to 'Be Bold!' in interpreting laws and regulations, but this is of little comfort for research sponsors or data protection controllers fearing potential legal liability for any misstep in an increasingly complex legal environment.

These complexities range across all areas of human health research, and these are multiplied when an increasing number of initiatives are now internationally collaborative in nature. This is compounded further by the growing imperative to seek new fields of enquiry for research beyond the 'pure health' realm and into cross-sectoral domains such as social care, welfare, bioengineering, artificial intelligence, machine learning and software development, and further still into citizen science.<sup>9</sup>

For any reader remotely familiar with trends in the HRR environment in the period since the turn of the millennium, it is trite to observe that law and regulation struggle to keep apace. A key challenge is that the regulatory regimes to be navigated have grown up largely piecemeal and divorced from each other: thus, clinical trials are regulated differently to medical devices; reproductive medicine is largely a self-contained world, while data and tissue research – ostensibly similarly in many respects – are often regulated by stand-alone regimes that do not have mechanisms to 'talk' to each other, let alone learn lessons from the common enterprise of seeking to regulate *well*. Each of these siloes is populated by its own actors and often driven by self-regarding agendas.<sup>10</sup> For many of these reasons, a central conclusion of the AMS/Cancer UK/Wellcome report of 2017 was '... [the] importance of a whole systems approach to regulation, supported by metrics spanning the entirety of the research pathway from grant award through to study completion, to promote the UK as a location of choice for research as well as enabling identification of any delays in the pathway'.<sup>11</sup> The workshop found:

Numerous concerns were expressed about the appropriate and timely discharge of responsibilities of upstream actors such as sponsors and R&D offices, where a failure to prepare a study or a research application thoroughly can lead to downstream delays and process blockages ...

<sup>4</sup> M. Mostert et al., 'Big Data in Medical Research and EU Data Protection Law: Challenges to the Consent or Anonymise Approach', (2016) *European Journal of Human Genetics*, 24, 956–960.

<sup>5</sup> Academy of Medical Sciences, 'Personal Data for Public Good: Using Health Information in Medical Research', (Academy of Medical Sciences, 2006).

<sup>6</sup> Classically, see O. O'Neill, 'Some Limits of Informed Consent', (2003) *Journal of Medical Ethics*, 29(1), 4–7.

<sup>7</sup> M. Langarizadeh et al., 'Effectiveness of Anonymization Methods in Preserving Patients' Privacy: A Systematic Literature Review', (2018) *Studies in Health Technology and Informatics*, 248, 80–87.

<sup>8</sup> P. Ohm, 'Broken Promises of Privacy: Responding to the Surprising Failure of Anonymization', (2010) *UCLA Law Review*, 57, 1701–1777.

<sup>9</sup> G. Laurie, 'Cross-Sectoral Big Data', (2019) *Asian Bioethics Review*, 11, 327–339.

<sup>10</sup> G. Laurie, 'Liminality and the Limits of Law in Health Research Regulation: What Are We Missing in the Spaces In-between?', (2017) *Medical Law Review*, 25(1), 47–72, available at: <https://doi.org/10.1093/medlaw/fww029>

<sup>11</sup> AMS, Regulation and Governance of Health Research, 5.

[t]herefore there needs to be a whole systems approach to regulation and governance that facilitates research from design through to health improvement delivery, supported by metrics that reflect the whole pathway to make sure that they capture delays that are simply being shifted and subject to ‘gaming’. This also ensures that all actors in the system are collectively responsible for the smooth and efficient operation of the system.<sup>12</sup>

This volume assumes the mantle of exploring how to deliver such an approach. More particularly, the golden thread that runs through this volume is to examine the contours of what might be called a *Learning Health Research Regulation System* (LHRRS). Clearly, this notion builds on the concept of the learning healthcare system.<sup>13</sup> In the Afterword, we pull together the lessons learned from the cumulative contributions of the chapters in this volume with the aspiration of contributing further to a similar literature in HRR and to processes of systems-level change.

As a catalyst for synthesising the cross-cutting value of the chapters in this volume, the editorial team hosted a symposium in Edinburgh in April 2019. This was attended by many of the authors who contribute to this volume. As can be seen, the full list of contributors is composed of colleagues from an extensive range of disciplines; our multi-disciplinary approach is reflected in a recent review of the literature on large-scale change in healthcare that reveals the considerable disruptive dynamics involved and which points to ways in which sociology and other disciplines can contribute.<sup>14</sup> We seek to do the same for HRR.

Collectively, as demonstrated in the next section, we identified a range of features of HRR that have changed in recent years. Just as importantly, we highlighted elements of HRR that we believe to be insufficiently visible to permit full assessment of current approaches, and/or that are the source of multiple stubborn problems that require to be understood and tackled on the route to delivering a LHRRS. Our discussions formed the basis of the chapters contained herein, and there are multiple junctures for cross-referencing between the individual contributions. This having been said, at the time of going to press, the globe is in the midst of the COVID-19 pandemic. It has not been possible to include any specific chapter on this particular disease nor regulatory responses thereto, but the advent of such an event is precisely the kind of phenomenon for which regulatory systems ought to stand ready to deliver safe, effective and timely outcomes from human health research.

#### 4 THE DYNAMIC CONTOURS OF RESEARCH AND THE CHALLENGES OF REGULATORY CATCH-UP

The clinical trials regulatory paradigm – as typified by the models operating in the European Union, Australasia and North America – is both lauded as a ‘gold standard’ of HRR,<sup>15</sup> as well as a being seen in some quarters as a source of considerable and undue regulatory burden.<sup>16</sup> Typical features of this paradigm are the centrality of securing informed consent from participants to take part in trials, and the importance of robust risk management. While certainly by no means trivial

<sup>12</sup> AMS, Regulation and Governance of Health Research, 10.

<sup>13</sup> A. Budrionis and G. Bellika, ‘The Learning Healthcare System: Where Are We Now? A Systematic Review’, (2016) *Journal of Biomedical Informatics*, 64, 87–92.

<sup>14</sup> See L. Jones et al., ‘Exploring the Neglected and Hidden Dimensions of Large-scale Healthcare Change’, (2019) *Sociology of Health & Illness*, 41(7), 1221–1235.

<sup>15</sup> A. Rosemann, ‘Alter-Standardizing Clinical Trials: The Gold Standard in the Crossfire’, (2019) *Science as Culture*, 28(2), 125–148.

<sup>16</sup> L. Duley et al., ‘What Are the Main Inefficiencies in Trial Conduct: A Survey of UKCRC Registered Clinical Trials Units in the UK’, (2018) *Trials*, 19(15), <https://doi.org/10.1186/s13063-017-2378-5>.

matters and unquestionably of ethical import, the relative importance and viability of these elements of regulatory design have been proven to be problematic and sometimes entirely antithetical to health research beyond the clinical trials context, as illustrated by research involving personal data or human biological materials.<sup>17</sup> The appearance of biobanks in the health research environment around the turn of the century demonstrated this amply, probably best illustrated by the controversy – and then general acceptance – of the notion of broad consent.<sup>18</sup> In regulatory terms, the response in many countries was not to revise regulations on health research, but rather to add to them, either as a matter of bespoke biobank laws or as an additional layer of ethical governance and oversight focussing on particular biobank initiatives.<sup>19</sup> While understandable with respect to biobanks as a then novel phenomenon, the net effect of this ‘regulatory churn’ was arguably to increase compliance concerns for researchers and research managers without sufficient revision and review of the overall regulatory burden. It must be remembered that biobanks have the same objective as all other forms of health research: to generate forms of new data, information, knowledge and understanding towards improving human health.

This having been said, as the distinction between research and clinical care becomes increasingly blurred – as well-demonstrated by the Genomics England initiative<sup>20</sup> – there is an important question to answer: where does *research* begin and end? For us, given the whole system approach that we seek to adopt, we do not see ‘research’ as a closed category, but rather as a series of interconnecting processes and human practices aiming at the realising of social value.<sup>21</sup> Specific instances and examples are given in individual chapters. More holistically, we aim to interrogate overtly the value of attempts to put human activities in artificial regulatory repositories, because this can too easily obfuscate the complexities involved and lead to abrogation of responsibilities.

The examples of the regulation of clinical trials and biobanks also illustrate other key ways in which the regulatory landscape has been changing in recent years. For example, the European Union Clinical Trials Directive<sup>22</sup> (now Regulation<sup>23</sup>) introduced the legal role of the ‘sponsor’: ‘[an] individual, company, institution, organisation or group of organisations that takes on responsibility for initiation, management and financing (or arranging the financing) of the research’. As new actors in the regulatory domain, the function and effectiveness of these entities has largely gone unstudied. However, the AMS/Cancer UK/Wellcome report specifically highlighted concerns about the due discharge of responsibilities of such ‘upstream actors’, including Research & Development offices, whose inaction can result in regulatory blockage or stasis (see above). It is therefore crucial to identify the full range of actors implicated in HRR, particularly those that may be less visible and less overtly engaged in the formal enterprise of

<sup>17</sup> AMS, ‘Personal Data for Public Good: Using Health Information in Medical Research’.

<sup>18</sup> R. B. Mikkelsen et al., ‘Broad Consent for Biobanks is Best – Provided It Is Also Deep’, (2019), *BMC Medical Ethics*, 20(71), <https://doi.org/10.1186/s12910-019-0414-6>.

<sup>19</sup> See for example, J. Kaye et al., ‘Consent for Biobanking: The Legal Frameworks of Countries in the BioSHaRE-EU Project’, (2016) *Biopreservation and Biobanking*, 14(3), 195–200.

<sup>20</sup> Genomics England: [www.genomicsengland.co.uk/](http://www.genomicsengland.co.uk/).

<sup>21</sup> A. Ganguli-Mitra et al., ‘Reconfiguring Social Value in Health Research through the Lens of Liminality’, (2017) *Bioethics*, 31(2), 87–96, <https://doi.org/10.1111/bioe.12324>.

<sup>22</sup> EU Directive 2001/20/EC of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use [2001] OJ L121/34.

<sup>23</sup> Council Regulation (EU) 536/2014 of 16 April 2014 on clinical trials on medicinal products for human use [2014] OJ L158/1.

regulation itself.<sup>24</sup> This is reflected in the focus of one of our sections to the volume and explained below.

Other actors of note in influencing the nature and direction of travel of HRR are those from the commercial sector. As many chapters in this volume illustrate, the relationship of commercial enterprise with human health research is an uneasy one. Extensive social science and public engagement research has repeatedly demonstrated a degree of distrust among some publics about the involvement of private business in health research,<sup>25</sup> but as is so often the case, the picture is a complex one with multiple hues: many publics, and notably many patient groups, actively support commercial engagement with health research because this is commonly seen as an optimal way to secure adequate funding and eventual health benefits. The relationships and influences of the commercial sector therefore bear particular merit in scrutinising the future landscape for human health research.

Publics now have considerable say – and sway – in many examples of good health research practice;<sup>26</sup> but the challenges of involving publics well in this enterprise remain considerable. An over-zealous commitment to public engagement by funders can lead to the unlooked-for consequence that unsuitable research projects seek to engage citizens when this is simply not appropriate for the research in question. At the other end of the spectrum, public engagement exercises, even when well-designed, can fail to capture lay expertise as a valuable source in its own right. At the same time, there are very good reasons to view engagement as a driver for more dynamic research governance and regulatory design. We are privileged to have several world-leading experts in public engagement contributing to this the volume to help us think through how to address issues. Relatedly, involvement of publics in research can lead to, and has led to, important reorientation of regulatory framing with respect to what is at stake at the level of human values. The traditional dominant (western) world view of the liberal individual whose autonomy and ancillary interests must be protected and privileged certainly continues to hold sway; but the regulatory challenges of delivering for collective interests, whether patient groups, genetically related families or heterogenous research participants cohorts, are considerable. Important lessons are available, in particular from the experiences of research with indigenous peoples, and this theme of individual/collective interests permeates the volume. At the same time, the concept of vulnerability of persons and groups is put under particular strain in human health research and we welcome various contributions that examine the dynamics very closely.

Beyond actors, the nature of human health research has changed immeasurably in the last few decades. It may not be an overstatement to suggest that data-driven research has replaced clinical trials as the dominant paradigm that shapes regulatory practices,<sup>27</sup> and associated changes in methods, analytics and data sources from non-health as well as health-related contexts all impact on the nature and scale of research being undertaken. A recent review article in *Nature* makes

<sup>24</sup> We advocate elsewhere for the role of regulatory stewardship involving expert actors who can assist research applicants to navigate complex regulatory frameworks: G. Laurie et al., 'Charting Regulatory Stewardship in Health Research: Making the Invisible Visible', (2018) *Cambridge Quarterly of Healthcare Ethics*, 27(2), 333–347.

<sup>25</sup> G. Haddow et al., 'Tackling Community Concerns about Commercialisation and Genetic Research: A Modest Interdisciplinary Proposal', (2007) *Social Science and Medicine*, 64(2), 272–282; D. Nicol et al., 'Understanding Public Reactions to Commercialization of Biobanks and Use of Biobank Resources', (2016) *Social Science and Medicine*, 162, 79–87; R. Milne et al., 'Trust in Genomic Data Sharing among Members of the General Public in the UK, USA, Canada and Australia', (2019) *Human Genetics*, 138(11–12), 1237–1246.

<sup>26</sup> See Cunningham-Burley and Aitken, Chapter 11, and Burgess, Chapter 25, in this volume.

<sup>27</sup> T. R. Frieden, 'Evidence for Health Decision Making – Beyond Randomized, Controlled Trials', (2017) *New England Journal of Medicine*, 377, 465–475.



the persuasive case that the ‘old’ ethics, as embodied in the ground-breaking Belmont report from 1979,<sup>28</sup> are no longer fit-for-purpose to protect research participants adequately as data science assumes more of a central role in the design, delivery and realisation of value from human health research.<sup>29</sup> In addition to this, health-related research is now more collaborative, networked, platform-based, international and cross-sectoral than at any time in its history. It has been estimated that more than 70,000,000 researchers and other professionals are engaged in data science around the globe, and this led the High Level Expert Group (HLEG) of the European Open Science Cloud (EOSC) to suggest in 2016 that up to 500,000 ‘data experts’ trained in the principles of open science and research data commons will be needed to support them.<sup>30</sup> These seismic scientific shifts pose considerable challenges for regulators, not only because many relevant laws are national in nature, but also because following-the-data can be a near-insurmountable task. For the purposes of this volume, these intricacies require us to consider a range of possible regulatory landscapes in which health research might be conducted, that is, both the health-focussed ecosystem and other ecosystems that are not principally concerned with health but whose data might have health-relevance in research terms. This entails, in turn, an appreciation of diverse approaches and cultures of regulation, not all of which will necessarily reflect the well-versed liberal bioethical framing that places the individual as centre stage. Data per se might be the valued scientific object that is the prize that is won when scientifically sound research is well-conducted; but the generation of data relating to human subjects – even when anonymised to whichever technical standard applies – can never remove the subject from the frame: we must always locate the ‘human’ in human health research. For all of these reasons, the first section of this volume explores core common concepts that sit at the heart of HRR, both in practice and in our discourses. The discussions therein remind us powerfully of what is at stake and also allow us better to take discussions forward about how HRR should evolve into the future.

The data-focussed nature of much modern health research is also impacted by policies that seek to make these data more readily available. We speak here, of course, of agendas of growing influence from the realms of open science<sup>31</sup> and open data<sup>32</sup>. From one perspective – notably, the appeal to human health research as a social or public good – these agendas make perfect sense; but they do not exist in splendid isolation from other factors and values of social significance. Such policies sit in constant tension with rights of citizens to adequate privacy protection, and also to commercial claims to secrecy and the appropriate rewards arising from labour, especially through intellectual property rights. Undoubtedly, these policies impact on *how* health research regulation is interpreted and applied, and also with respect to *whose* interests are recognised and promoted. Regulatory responses such as open data and open science might seem superficially laudable as a counter-point to the worst vagaries of intellectual property rights, but the implications for the whole system of regulation itself must be explored. Emerging research suggests, for example, that motivations behind the phenomenon of ‘my data’ might be more about researchers’ desires to protect participants’ privacy and/or to secure appropriate

<sup>28</sup> The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research (1979).

<sup>29</sup> N. Raymond, ‘Safeguards for Human Studies Can’t Cope with Big Data’, (2019) *Nature*, [www.nature.com/articles/d41586-019-01164-z](http://www.nature.com/articles/d41586-019-01164-z).

<sup>30</sup> High Level Expert Group on the European Open Science Cloud, ‘A Cloud on the 2020 Horizon: Realising the European Open Science Cloud: first report and recommendations’, (High Level Expert Group on the European Open Science Cloud, 2016), [www.eudat.eu/sites/default/files/HLEG%20EOSC%20ofirst%20Report.pdf](http://www.eudat.eu/sites/default/files/HLEG%20EOSC%20ofirst%20Report.pdf).

<sup>31</sup> The Royal Society, ‘Science as an Open Enterprise’, (The Royal Society, 2012), [www.royalsociety.org/topics-policy/projects/science-public-enterprise/report/](http://www.royalsociety.org/topics-policy/projects/science-public-enterprise/report/).

<sup>32</sup> V. Xavis et al., ‘An Ethics Framework for Big Data in Health and Research’ (2019) *Asian Bioethics Review*, 11, 227–254.

recognition in collaborations, and less about some proprietorial claim over the fruits of scientific labour.<sup>33</sup> As such, like the invisible actors mentioned above, there is much that we can miss about what makes regulation work – or not work – if we do not subject the entire system to close scrutiny.

Given all of these factors, it is unsurprising that regulatory systems are often in the invidious position of playing catch-up rather than getting ahead of any technological curve, emerging research trend or global pandemic. In no way does recognition of this denigrate the herculean efforts of many regulators across the globe in attempting to address the myriad challenges; indeed, multiple contributions to this volume attest their efforts. Nonetheless, these ever-changing dynamics represent a significant source of tension in determining how best to proceed in human health research. This is a restatement of the core problem that we face and that we seek to address in this volume.

We believe that it is fitting to end this Introduction with a reminder of the core value that sits at the heart of HRR, and without which there would be no health research. This is trust. And, to paraphrase the words of Onora O’Neill, trust cannot be built, it must be earned.<sup>34</sup> Too often, however, a social engineering-inclined attitude has prevailed among policy and law makers in HRR: make it lawful and they will comply.<sup>35</sup> This is a mistake of considerable proportions, and as O’Neill reminds us, the task is not to build trust but to demonstrate trustworthiness.<sup>36</sup>

Thus, the task for this volume is not only to dissect and analyse lessons from HRR across multiple domains, but also to offer insightful, ethically sound, scientifically robust and trustworthy insights into the possible futures for HRR. Manifestly, this is no easy task, but the editorial team are proud to present the contributions of the excellent cohort of authors who have willingly agreed to take up this task by contributing to this volume. It has been a privilege to work with all of them.

## 5 NAVIGATING THE CAMBRIDGE HANDBOOK OF HEALTH RESEARCH REGULATION

The volume comprises two substantive parts: the first takes stock of the current state of play in HRR, and the second seeks to go beyond current thought and practice. Thus, Part I introduces the reader to existing approaches in HRR, analysing in particular the challenges for regulation. This Part is divided into two sections. Section IA revisits core ‘Concepts’ in HRR because these are central to discussions and practices about what is at stake in regulating human health research, and also because these concepts embody the fundamental values in play. If we are to engage multiple disciplines in tackling the challenges of delivering health research regulation, we must first ensure that we arrive at some common understandings. Section IB brings together contributions on ‘Tools, Processes and Actors’. Here, contributors explore the panoply of actors that may serve a role in regulating health research; the array of tools or devices regulators may employ to achieve desired objectives such as innovation, research promotion and participant protection; and the processes by which regulation may develop and guide

<sup>33</sup> A. Sorbie et al., ‘Examining the Power of the Social Imaginary through Competing Narratives of Data Ownership in Health Research’, (2021) *Journal of Law and the Biosciences*, <https://doi.org/10.1093/jlb/lsaa068>.

<sup>34</sup> See generally, O. O’Neill, *Autonomy and Trust in Bioethics* (Cambridge University Press, 2002).

<sup>35</sup> P. Carter et al., ‘The Social Licence for Research: Why *care.data* Ran into Trouble’, (2015) *Journal of Medical Ethics*, 40(5), 404–409.

<sup>36</sup> O’Neill, *Autonomy and Trust*, p. 45.

human practices towards desirable endpoints while avoiding undesirable consequences. Together, these sections provide a rich critical account of the mechanics of HRR to date.

Part II is styled as 'Reimagining Health Research Regulation'. The three sections here examine and develop novel regulatory approaches through analysis of stubborn or emerging issues in health research. Section IIA invites the reader to rethink the nature of the public–private distinction that is so often at the heart of discussions of, and approach to, HRR. Section IIB brings together contributions that, in diverse ways, demonstrate the importance of understanding the relationship between governance and *time* – a crucial element of a responsive and effective regulatory system. Finally, Section IIC provides particular examples of ways in which regulation is continually disrupted by on-going advances in biomedicine; this lays the groundwork for normative claims that any responsive and effective regulatory system must also be flexible and dynamic in accommodating an ever-shifting landscape.

Each section has a Foreword written by the section editors that guides readers through the respective chapters and teases out cross-cutting themes; where appropriate, cross-references to other chapters in the volume are made to steer readers seeking a more holistic grasp of a particular topic.

Ultimately, the Afterword of this volume brings together the cumulative elements of the contributions to address the question: *What could a learning health research regulation system look like?*