SECTION 1B

Tools, Processes and Actors

Introduction

Edward Dove and Nayha Sethi

This section of the volume explores the tools, processes and actors at play in regulating health research. Regulators rely on a number of tools or regulatory devices to strike a balance between promoting sound research and protecting participants. Some of the paradigmatic examples are (informed) consent and research ethics review of proposed projects; both are explored in this section. Other examples include intellectual property (especially patents), data access governance models, and benefit-sharing mechanisms. Much of the contemporary scholarship on and practice of health research regulation relies on, and criticises, these tools. Relatedly, and arguably, regulation itself is processual; it is about guiding human practices towards desirable endpoints while avoiding undesirable consequences. There has been little discussion of this processual aspect of regulation to date and the specific processes at play in health research. Contributors in this section explore some of the most crucial processes, including risk–benefit analysis, research ethics review and data access governance mechanisms. Further, as becomes apparent, processes can themselves become tools or mechanisms for regulation. Finally, one cannot robustly explore the contours of health research regulation without a consideration of the roles regulatory actors play. Here, several contributors look at the institutional dimension of regulatory authorities and the crucial role experts and science advisory bodies play in constructing health research regulation.

Despite the breadth of topics explored within this section, an overarching theme emerges across the thirteen chapters: that technological change forces us to reassess the suitability of pre-existing tools, processes, and regulatory/governance ecosystems. While a number of tools and processes are long-standing features of health research regulation and are practised by a variety of long-standing actors, they are coming under increasing pressure in twenty-first-century research, driven by pluralistic societal values, learning healthcare systems, Big Data-driven analysis, artificial intelligence and international research collaboration across geographic borders that thrives on harmonised regulation. As considered by the authors, in some cases, new tools, processes or actors are advocated; in other cases, it may be more beneficial to reform them to ensure remain they fit for purpose and provide meaningful value to health research regulation.

Much of the discussion focusses therefore not only on the nature of these long-standing tools, processes, and actors, but also on how they might be sustained – if at all – well into the twenty-first century. For example, the digital-based data turn necessitates reconsidering fundamental principles like consent and developing new digital-based mechanisms to put participants at the heart of decision-making, as discussed by Kaye and Prictor (Chapter 10). Shabani, Thorogood and Murtagh (Chapter 19) also speak to the challenges that data intensive research is presenting

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for governance and in particular the challenges of balancing the need to grant (open) access to databases with the need to protect the rights and interests of patients and participants.

This leads to another related theme emerging within this section: the need to examine more closely the participatory turn in health research regulation. Public and participant involvement is becoming an increasingly emphasised component of health research, as illustrated by public engagement exercises becoming mandatory within many research funding schemes. But, as Aitken and Cunningham-Burley (Chapter 11) note, many different forms of public engagement exist and we need to ask 'why' publics are engaged, rather than simply 'how' they are engaged. They suggest that framing public engagement as a political exercise can help us to answer this question. For Chuong and O'Doherty (Chapter 12), the process of participatory governance also necessitates unpacking, particularly due to the varied approaches taken towards embedding deliberative practices and including patients and participants as *partners* within health research initiatives. Both of these chapters help set up discussion and analysis to come later in this book, specifically the contribution from Burgess (Chapter 25), who makes a case for mobilising public expertise in the design of health research regulation.

Beyond the inclusion of publics and participants in decision-making, many authors in this section raise additional questions about decision-making tools and processes involving other regulatory actors. For example, Dove (Chapter 18) notes how research ethics committees have evolved into regulatory entities in their own right, suggesting that they can play an important role in stewarding projects towards an ethical endpoint. Similarly, McMahon (Chapter 21) explores the ways in which institutions (and their scaffolding) can shape and influence decision-making in health research and argues that this ought to be reflected when drafting legal provisions and guidance. On the question of guidance, Sethi (Chapter 17) lays out different implications that rules, principles and best-practice-based approaches can carry for health research, including the importance of capturing previous lessons learned within regulatory approaches. Sethi's discussion of principles-based regulation helps round out the discussion to come later in this book, specifically Vayena and Blassime's contribution (Chapter 26) on Big Data and a proposed model of adaptive governance. Sethi's chapter also engages with another key theme emerging within this section: the construction of knowledge-bases and expertise. For example, Flear (Chapter 16) suggests that basing current framings of regulatory harm as technological risk marginalises critical stakeholder knowledges of harm, in turn limits knowledge-bases. Indeed, in considering how governments make use of expertise to inform health research regulation, Meslin (Chapter 22) concludes that it will be best served when different stakeholders are empowered to contribute to the process of regulation, and when governments are open to advice from the expertise of experts and non-experts alike.

Many of the authors highlight the need to analyse how we anticipate and manage the outputs (beneficial and harmful) of health research. For example, Coleman (Chapter 13) questions the robustness and objectivity attributed to risk–benefit analysis, despite the heavy reliance placed upon it within health research. Similarly, benefit sharing has become a key requirement for many research projects but, as discussed by Simm (Chapter 15), there are practical challenges to deploying such a complex tool to distinct concrete projects. Patents are also a standard feature of health research and innovation. As considered by Nicol and Nielsen (Chapter 14), these can be used both as a positive incentive to foster innovation and, paradoxically, as a means to stifle collaboration and resource sharing.

Three final cross-cutting themes must be kept in mind as we continue to attempt to improve health research regulation. First, in closing this section, Nicholls (Chapter 20) reminds us that we must be mindful of the constant need to evaluate and adapt our approaches to the varying

contexts and ongoing developments in health research regulation. Second, in recognition of the fragility of public trust and the necessity of public confidence for health research initiatives to succeed, we must continue to strive for transparency, fairness and inclusivity within our practices. Finally, as we seek to refine and develop new approaches to health research regulation, we must acknowledge that no one tool or process can provide a panacea for the complex array of values and interests at stake. All must be kept under constant review as part of a well-functioning learning system, as Laurie argues in the Afterword to this volume.