1. Introduction

I. THE AIMS OF THIS BOOK

Research ethics committees (RECs) occupy a critical position in health research governance. In the United Kingdom (UK), 86 National Health Service (NHS) RECs review approximately 6000 research applications each year[1] that seek to involve potential research participants who are in the NHS system. One of the tasks of NHS RECs is to ensure 'that any anticipated risks, burdens or intrusions will be minimized for the people taking part in the research and are justified by the expected benefits for the participants or for science and society'.[2] Through their discretionary power to modify or reject an applicant's research design, RECs can impact what knowledge is produced and can significantly affect the relationship between researchers and research participants.

In this book, I am interested in the roles and practices of RECs in light of recently implemented health research regulation in the UK that explicitly seeks to promote health research in the country, in part by streamlining regulation itself. It is unclear how these recent regulatory changes, stressing efficiency and maximization of UK competitiveness for health research as well as maximization of return from investment in the UK, may affect the substantive and procedural workings of RECs. It is also unknown whether the modification of research regulation at the level of legal architecture to promote research—seen, for example, in the Care Act 2014 and in the mandate of the Health Research Authority (HRA)—'trickles down' to the day-to-day practices of RECs, which the HRA is responsible for managing directly in England and indirectly across the UK.

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[1] Health Research Authority, 'Research Ethics Committee Members Area' <www.hra.nhs.uk/about-us/committees-and-services/res-and-recs/research-ethics-committee-members-area/> accessed 11 October 2019.

[2] Health Research Authority, *Governance Arrangements for Research Ethics Committees: 2018 Edition* (Health Research Authority 2018) [colloquially known as and cited hereinafter as GAfREC] para 1.2.2.

More granularly, we lack good empirical understanding about how and why RECs make the decisions they do, and how the dynamics of RECs and central 'managing' regulators play into decisions in this evolving regulatory backdrop.[3] This book fills this lacuna by: (1) going inside RECs to ask and examine how they, as individual members and as a collective body, see themselves in a changing regulatory environment; and (2) going inside a managing regulator (the HRA) to gather perspectives on the roles of RECs and the relationship between the HRA and RECs, which in turn provides deeper understanding of the meta-level contributions of these entities as regulatory agents, both in their own right and in an interconnected way.

Thus, this book offers an original, empirical investigation of health research regulation and RECs, examining how these entities, designed to essentially give an ethical 'licence' to researchers, undertake ethics deliberation and work under the umbrella of regulation that is becoming more streamlined and research-promoting. The primary aim of this book is to provide both an original, critical understanding of what RECs and regulators actually do (and see themselves doing), and also to explain and understand the nature of health research regulation. The objective is to provide my intended audience of students, academics, lawyers, regulators, and policymakers a crucial contribution to understanding the roles RECs and members within them (and connected to them) play in regulating health research.

The research findings further offer normative assessments of RECs and health research regulation, thereby informing policy decisions. As I will argue, *regulatory stewardship* is a crucial concept that emerges from the empirical investigation and warrants consideration beyond the health research regulatory landscape. Indeed, a secondary aim of this book is to encourage a reimagining of 'regulatory spaces' if they are seen to be under-delivering in what they set out to achieve. Through theoretical insight and empirical investigation, I will suggest what regulation and regulators across a range of ecosystems—health and non-health—can do to stimulate meaningful research oversight without adding to any burden of pre-existing regulatory measures.

As we go to press, an example of this wider potential influence on regulation is provided by the UK Government in its white paper,

[3] On this point, see e.g. Wellcome Trust, 'A Blueprint for Dynamic Oversight: How the UK Can Take a Global Lead in Emerging Science and Technologies' (2019) <https://wellcome.ac.uk/sites/default/files/blueprint-for-dynamic-oversight.pdf> accessed 11 October 2019.

Regulation for the Fourth Industrial Revolution.[4] In it, the Government sets out plans to transform the UK's regulatory system to support innovation, while protecting citizens and the environment. As part of this plan, it calls for the establishment of a 'digital Regulation Navigator' to help businesses 'find their way through the regulatory landscape and engage with the right regulators at the right time on their proposals'.[5] The concept of regulatory stewardship, as elucidated in this book, can help put platforms such as the Regulation Navigator on firmer policy footing.

In this book, I distinguish law from regulation. Both law and regulation are notoriously tricky to define, not the least because of cultural variation in ascribing meaning to phenomena that are 'legal' or 'regulatory'. I take law to mean a system of rules, codes, and pronouncements promulgated by state or state-like actors within a particular community (e.g. sub-national, national, international) with the aim of regulating the actions of its members and which it may enforce by the imposition of penalties. Examples of law include a statute and statutory instrument or a judgment from a court of law. By contrast, 'regulation is a broader category and includes much more flexible and innovative forms of social control'.[6] I define regulation as a set of rules, principles, mechanisms, strategies, or activities promulgated by state or non-state actors that either affect behaviour as an incidental effect or are designed to steer behaviour in a socially, politically, and/or economically desirable way. It may involve self-regulation, persuasion, and co-regulation. Thus, regulation is broader than law and can encompass anything from codes of practice of professional bodies to traffic lights and signs in a neighbourhood. My definition of regulation does *not* privilege the state; the state is simply one node among many actors sharing control of resources. In turn, law and regulation are components of governance, which refers to the constellation of actors and mechanisms that promulgate, implement, or enforce norms across sites of authority.

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[4] UK Government, 'Regulation for the Fourth Industrial Revolution: White Paper' (2019) <www.gov.uk/government/publications/regulation-for-the-fourth-industrial-revolution> accessed 11 October 2019.

[5] ibid 24.

[6] Neil Gunningham and Cameron Holley, 'Next-Generation Environmental Regulation: Law, Regulation, and Governance' (2016) 12 Annual Review of Law and Social Science 273, 274.

II. ANTHROPOLOGY OF REGULATION

In my investigation, I employ an 'anthropology of regulation' methodology, influenced by regulatory theory and the anthropological concept of liminality. Liminality refers to a threshold phase in social transitions characterized by processual (temporal and spatial) dynamics.[7] Harnessing liminality as a sensitizing concept in an anthropology of health research regulation enables one to examine the ways in which practices, people, and entities are structured in and by regulation, and vice versa. The reasons for this choice of liminality—drawing our attention to processes and experiences of change in human dynamics—are explained more fully below and in Chapter 4.

As I argue in a later chapter, anthropology of regulation transcends the confines of a law-based approach by focusing on what happens within the regulatory spaces and under the layers of regulation across time. In health research, we find that regulation plays as much a crucial role as law. My research explores and explains—through documentary research comprised of historical tracing and present-day regulatory analysis that explicates the internal constitution of regulation, as well as through observation and interviews—the experiences and behaviours of specific individual actors in the health research regulatory space who govern the ethics of health research involving participants, namely RECs and their managing regulators. Anthropology of regulation allows me to investigate both the nature of regulation as a social form (an ontological concern), as well as what regulation does to actors and what actors do to regulation (a functional and experiential concern). Regulatory theory is necessary to help provide potential explanatory background; empirical research is equally necessary to help provide understanding of everyday practice. In essence, anthropology of regulation allows us to bring theory and practice meaningfully together by focusing on capturing the experiences of regulators in their multiple contexts.

III. STRUCTURE OF THE BOOK

This book comprises seven chapters. Following this introductory chapter, in Chapter 2, I offer an overview of the NHS REC system. I raise the question of whether the roles and practices of RECs are shifting in

[7] Samuel Taylor-Alexander and others, 'Beyond Regulatory Compression: Confronting the Liminal Spaces of Health Research Regulation' (2016) 8 Law, Innovation and Technology 149, 150.

response to 'next-generation' regulation (particularly regarding research promotion), and whether modifications to the health research regulatory space at the levels of statutory law and central regulatory authorities 'trickle down' to the day-to-day practices of RECs. At the end of the chapter, I pose several questions that drive the empirical investigation.

Chapter 3 traces the regulatory development of RECs and health research regulation within the UK, with a view to demonstrating both the growth of health research regulation and the increasingly central role that RECs play in regulating health research. While, to a certain degree, research promotion has always been embedded in the regulatory techniques of RECs, it has not until now been instantiated in law with the creation of the HRA and rules promulgated under the Care Act 2014. The subsequent and fundamental research question to explore is whether this instantiation of research promotion in law has a (hitherto absent) trickle-down effect that impacts the day-to-day practices of RECs, and if so, how, or indeed, whether the law is only now coming to reflect an everyday practice that has long existed.

In Chapter 4, I explain the research approach, theoretical underpinnings, and analytical concepts that drive the empirical investigation. I show how regulatory theory provides a solid but ultimately insufficient foundation on its own for the empirical investigation that informs this book. I argue that there is a need for an empirically grounded discussion of regulatory practice. I propose an anthropology of regulation that contributes to socio-legal studies by drawing explicit attention to processes, passages, and change. I further draw on the anthropological concept of liminality, which serves as a sensitizing concept in addition to concepts provided by regulatory theory. Together with regulatory theory, liminality helps us to better understand the nature of transformations of actors within the regulatory space, the form of regulation in this space, as well as the behaviours and experiences of actors as they go through processes of change. Those interested in the research methods undertaken for my empirical work and which define an anthropology of regulation may consult Appendix 1.

In Chapter 5, I engage with the empirical data collected from the interviews and observations and, coupled with the findings from the document analysis, make sense of them through an anthropology of regulation approach. Through investigation of three main themes (the 'black boxes' of ethics review; regulatory connectivity; and regulators as stewards), I explore what happens in REC meetings, consider the operationalization of 'next-generation' health research regulation (particularly in light of the twin aims of protection and promotion), and investigate the procedures and substance behind risk-based regulation. I do this by querying whether

risk-based regulation is being practised by RECs and the HRA, and more fundamentally, by querying the nature and function of the interactions among RECs, researchers, and the HRA. Throughout, I draw on the implications of space and time in ethics review, signifying the contribution of liminality to the normative discussion to come in Chapter 6.

Chapter 6 then further unpacks the significance of liminality of RECs and the ability of actors within the health research regulatory space to serve as 'regulatory stewards'. I do so by suggesting a normative model of what a new regulatory framework for health research oversight ought to look like if it were to explicitly endorse regulatory stewardship. I also chart how participant protection and research promotion can and should work together. I conclude that a reformulated regulatory framework could work to improve regulatory conversations between actors, provide ongoing opportunities for 'regulatory play' to emerge, and shift the burden and emphasis away from more procedural work and towards flexibility and experimentation in ethics review. What I suggest, in other words, is a refinement of the extant regulatory framework, not wholesale change.

The final Chapter 7 reflects on the data, discussion, and regulatory framework presented, and proposes future directions for research. In particular, I suggest the need to further develop and test a regulatory model for health research oversight in the UK that integrates regulatory stewardship and improves regulatory interactions between different stakeholders in health research.

Having laid out the aims of this book and mapped the structure, I now turn to provide a conceptual framework of RECs, setting the scene for 'protection' and 'promotion'.