7. Conclusion

I. INTRODUCTION

This book has provided insight into the everyday workings of RECs and other regulatory actors in light of 'next-generation' health research regulation that seeks to both protect participants and promote research. It has done so through an empirical investigation—set within an anthropology of regulation—of the nature of health research regulation and of the behaviours and experiences of actors within regulatory spaces, and the ways in which they themselves affect and are affected by processes of regulation. Further, it has positioned liminality and regulatory stewardship as key components in a regulatory framework for health research.

The research set out to explore how and why RECs make the decisions they do, and how the dynamics of RECs and central 'managing' regulators play into decisions in an emerging regulatory backdrop of twinned 'protection and promotion'. It also set out to go inside RECs to ask and examine how they, as individual members and as a collective body, see themselves in a changing regulatory environment. In addition, perspectives were gathered on the roles of RECs and the relationship between the HRA and RECs. In so doing, I queried the precise nature of the interaction between central regulators and RECs, and queried the functional operations and deliberative processes of RECs in an era of twinned regulatory objectives of participant protection and research promotion. To date, this topic has received little coverage in the literature despite its significance, much less through a qualitative study from a regulatory perspective.

This final chapter draws together the findings from this body of work. First, I recap the key research findings. Second, I consider possible next steps for the research.

II. RECAP OF THE BOOK

2.1 Context-Setting Chapters

I began this book by providing a conceptual framework and historical regulatory tracing of RECs. Chapter 2 argued that RECs have been central in regulating the ethical acceptability of health research—and by extension, much of health research's very existence—since the late 1960s. They serve as gatekeepers that determine whether a proposed research project is ethically acceptable and therefore may proceed. Since its formation in late 2011, the HRA has been tasked with both protecting research participants from harm *and* also facilitating a productive research environment by streamlining health research regulation. The HRA is a central regulatory body that is seen to help make the UK once again an attractive place to conduct health research such as clinical trials. The HRA, particularly through its RES, and equivalent bodies such as the CSO in Scotland, is working to make REC processes more effective and efficient. I therefore raised the question of whether the roles and practices of RECs are shifting in response to 'next-generation' regulation such as the Care Act 2014, 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.

Chapter 3 traced 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. Tracing history over the past half-century, we saw that as health research gained prominence in the UK as both a driver of scientific knowledge and economic development, self-regulation of health research—ad hoc peer review by fellow scientists based on professional norms and local customs—gradually gave way to stricter, stronger, more centralized forms of regulation, particularly through policies and guidelines set by the UK's constituent governments. The central claim I made is that 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. Participant protection and research promotion have had an uneasy, unequal, but sustained marriage across the RECs' lifespan. And along the way, REC members have faced the challenging task of working in regulatory spaces that demand that they work with various regulatory actors and that they not only operate within the (shifting) regulatory spaces' confines, but also

help shape their contours. It is this finding that led me to query 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.

2.2 Anthropology of Regulation

In Chapter 4, I explained the research approach, theoretical underpinnings, and analytical concepts that drove the empirical investigation. I proposed an anthropology of regulation that blends the theoretical with the empirical, and which affords critical methodological improvements to common research approaches. As anthropology of regulation draws explicit attention to processes, passages, and change, I further drew on the anthropological concept of liminality, which served as a sensitizing concept, in addition to concepts provided by regulatory theory. Together with regulatory theory, liminality helped me 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.

2.3 The Research Findings and Normative Implications

In Chapter 5, I presented three main themes from my findings: the 'black boxes' of ethics review; regulatory connectivity; and regulators as stewards. I found that RECs serve as liminal actors. Relative to each other and to publics, they are black boxes existing in multiple spaces, despite a surprising degree of group homogeneity in approach and rituals. Significantly, I also found that RECs and other actors can serve as 'regulatory stewards' in helping researchers and others navigate difficult regulatory spaces and improve the overall quality of research. They can play a critical role in assisting researchers navigate the demands of putting an application and protocol together; as regulatory stewards, they can help researchers cross thresholds—serving as 'ethical research promoters'.

Contrary to my early expectations, and critically for the purposes of this book, the empirical data suggest that modifications to the health research regulatory space at the levels of statutory law and central regulatory authorities have not so much 'trickled down' to the day-to-day practices of RECs, as the day-to-day practices have long reflected what has only recently been enacted in law. The data also suggest that RECs, managing regulators, and researchers share a common goal of promoting research that is safe and of high quality. Actors in these regulatory spaces

carry similar interests and shared responsibilities, helping each other to cross boundaries and deal with major moments of transition in the research lifecycle. This led me to further investigate how, normatively speaking, protection and promotion ought to be worked through, as practised by RECs, the HRA, and other actors, and what a model of a new regulatory framework for health research oversight ought to look like if it were to explicitly endorse regulatory stewardship.

Chapter 6 unpacked the significance of the liminality of RECs and the ability of actors within the health research regulatory space to serve as 'regulatory stewards'. I charted how protection and promotion can and should work together. Specifically, I argued that protection and promotion *should* be treated as twin objectives for regulators. The liminality of RECs suggests that there is a need for a deliberative space within which RECs can both negotiate the risks relevant to a research application and also work with researchers to get to a point where the application can be deemed ethically acceptable. This deliberative space ought to be protected to capture and promote the fluid, processual nature of those deliberations. Within this space, REC members should feel comfortable debating the strengths and weaknesses of a research project, and achieving a consensual position on how much risk they are willing to tolerate. This risk toleration, in turn, needs to be considered relative to the notion of research promotion. Thus, rather than viewing protection as a bright-line test, a tolerance perspective accommodates the fluid nature of ethics deliberation and the relative nature of risk, that is, a higher tolerance of greater risk if it is seen as reasonable in relation to the benefits to participants and society.

I concluded 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. Three principal elements, flowing from the empirical research, were offered to improve the extant framework and were organized by starting with those less potentially disruptive to the current system:

- **Flexibility**
  I argued that the regulatory framework should provide RECs with sufficient room to roam in an ethics of space that accommodates diversity, disagreement, and dissent across applications and across time. This requires little change to the current system, as RECs are already permitted to protect and promote. However, room for improvement is called for in two areas, namely feedback loops and

enhanced connectivity between the regulatory spaces of law, science, and ethics.

- **Conversations**
  I argued that, to foster greater regulatory responsiveness, RECs should be encouraged to engage in discussions and negotiations with researchers, sponsors, and other actors before submission to the REC as well as after a proposal has received a favourable opinion. These conversations may revolve around ethical concerns that have arisen during the course of the project, but they may also go beyond this. RECs are not expected to play a role in each element of the research lifecycle. Rather, I suggested that RECs, along with other actors, should be encouraged to engage in regulatory conversations with each other, before, during, and after the launch of a research project, clarifying both their respective roles and when they should intervene to assist in helping move research across the stages of the lifecycle.
- **Stewardship**
  I argued that regulatory stewardship involves different actors helping researchers and sponsors navigate complex regulatory pathways and work through the thresholds of regulatory approvals. Collective responsibility, as a component of regulatory stewardship, requires relevant actors to work together to design and conduct research that is ethical and socially and scientifically valuable and that ultimately aims to improve human health. This can only be accomplished if a framework delineates how and when regulators and regulatees should communicate with one another and makes clear who has what responsibility and role to be played (if any) at each stage in the research lifecycle. To this end, I suggested that a regulatory framework for health research could chart different kinds of regulatory stewards, such as operational stewards (e.g. REC Managers or Scientific Officers that help usher researchers through the complexity of established procedures such as ethics application processes) and ethics stewards (e.g. RECs that deliberate in an ethics of space to protect participants and promote research).

Summarizing the research findings, while there has been reform in the health research regulatory space at the level of legal architecture to foster an environment that promotes health research in addition to protecting participants (particularly through the method of streamlining perceived regulatory barriers), there has not been a consequential change in how RECs act among themselves. Legal reform such as the Care Act 2014

reflects already-existing, everyday workings of RECs. RECs are remarkably similar to each other in terms of demographics and practices, yet they are relatively black-boxed to each other; they operate in fairly splendid isolation despite having a fair degree of homogeneity in culture. This said, an area of concern in light of recent regulatory reform is the nature of the interaction between RECs and their managing regulators, namely the HRA. Perhaps because of their homogeneity in culture, there is a strong desire by RECs, including REC Managers, to preserve the sanctity of *their* black box and ethics of space. Initiatives by the HRA that try to improve the regulatory pathways for researchers can backfire if there is improper consultation with RECs. As we saw, regulatory tension or failures are more likely to exist between regulators than between regulators and regulatees.

We can also say that, while the bond of research and ethics remains strong, there is some room for improving the regulatory framework. RECs, managing regulators, and researchers share a common goal of promoting research that is safe and of high quality. Actors in this health research regulatory space carry similar interests and shared responsibilities, helping each other to cross boundaries and deal with major moments of transition in the research lifecycle. The respective roles, competencies, and influences among the actors in these spaces are not always clear, and the regulatory conversations are sporadic and at times weak between regulators, though relatively strong between regulators and regulatees. To avoid dangerous spaces from appearing *within* the health research regulatory space where hazards may occur, in Chapter 6 I suggested several elements to improve the regulatory framework and prevent these spaces from appearing or opening too widely or disjointedly.

III. FUTURE DIRECTIONS FOR RESEARCH

Having considered the core contribution which this book makes, a final task lies in considering how this work can be further developed. Areas for future investigation include:

- evaluation of the added value Scientific Officers bring to health research regulation and consideration of how they can be brought into the RESs in the three other nations;

- assessment of how NHS R&D offices are coping in light of HRA Approval (e.g. how do R&D officers now see their role; what is their relationship with HRA Assessors and other regulatory actors?);
- cross-jurisdictional comparisons of health research regulation to evaluate similarities and differences among RECs, managing regulators, and other actors. Such an assessment may lead to formulation of best practices for health research ethics oversight;
- horizon-scanning to assess the potential impact of 'Brexit' on UK regulatory flexibility (i.e. will a formal de-coupling from EU regulation lead to regulatory fragmentation, harmonization, or something else?);
- how regulatory flexibility might afford opportunities for 'regulatory play', that is, opportunities to think beyond rules and engage in innovation and experimentation ('sandboxes' to design and experiment without fear of falling foul of regulatory infraction);
- deeper understanding, through empirical investigation, of the actual blockages and perceived impediments to health research so as to promote a culture of confidence and proportionate regulatory practices; and
- charting a path for collective responsibility for the (co-)design and delivery of health research and health improvements therefrom. Such investigation may explore how actors other than regulators (e.g. researchers, sponsors, publics) can view themselves as responsible for designing and delivering ethical and scientifically robust health research.

In each of these areas, anthropology of regulation can play an invaluable role in investigating empirically the form and function of regulation across different contexts (e.g. locales, cultures, time periods). It allows us to uncover the experiences and practices of regulators and regulatees and the ways in which they understand themselves and their roles. In so doing, it can also problematize the notion of regulation, challenging us to consider the multiple phenomena that it may constitute and the ways in which it manifests and shapes behaviours. Anthropology of regulation, underpinned by regulatory theory and liminality, helps us make sense of the nature of regulation as a form of social control (an ontological concern), as well as how regulation structures our living in the everyday and in the in-between (a functional concern). Analytically, it has the potential to contribute to deeper understandings of local dynamics and contexts, as well as the multiple roles regulation plays in a complex world as a form of social control. Finally, it can offer normative

prescriptions that are developed from the empirical investigation to guide actors in achieving regulatory goals.

Undoubtedly, there are numerous further lines of enquiry that flow from this book. The findings from the empirical research demonstrate a wide applicability to a diverse array of settings. While such enquiries are left for the future, it is my hope that this book has in its own right contributed to a deeper theoretical and practical understanding of the precise nature of health research regulation; the roles of actors within regulatory spaces; and the processual, iterative realization of the public interest aim of health research oversight—namely to protect the rights, interests, and welfare of research participants *and* to promote valuable research that advances human health for the benefit of the public.