

SECTION IA

Concepts

Introduction

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This volume commences with chapters that address key concepts that are embedded in health research regulation (HRR). Many of the concepts considered – autonomy, proportionality, the public interest – may feel familiar and could even be described as ‘regulatory buzzwords’. However, although they may be often used, they can also be elusive and ill defined. Here, the contributing authors explore these contours and provide the reader with the lie of the land in these areas. However, the chapters in this section go beyond this. The authors also challenge the operation of these concepts and provide their own views on how they may be deployed in HRR. This is not a ‘definitions’ section: the concepts explored may be used in different ways by authors in the course of the volume. However, the value of exposing these to scrutiny at the outset is twofold. First, this orientates the reader (whether they be a researcher, regulator, or engaged citizen) in the context of contemporary HRR and sets the scene for these familiar concepts to be approached with a critical eye. Second, this reveals the range of perspectives that may be brought to bear on these shared concepts in HRR, thus promoting productive interdisciplinary engagement and discourse in this and subsequent sections of this volume.

The section opens with Rogers’ chapter on Vulnerability. Rogers positions vulnerability as a widely accepted and relevant concept in HRR, but one that is also challenging to conceptualise and define. She engages with the difficulties that have arisen in conceptualising vulnerability, reconciling universal and special notions of vulnerability, and identifying the distinct duties and obligations that are triggered. In particular, she points to newer analytic approaches that conceptualise vulnerability as relational and dynamic, and identifies multiple potential sources of vulnerability, thus offering a more nuanced way of thinking about protections against the risks of research-related harm and wrongs. Stoljar’s chapter on Autonomy also addresses a pervasive concept in HRR. Stoljar challenges the individualistic conception of autonomy implicit in the current health research ethics guidelines and outlines a contrasting ‘relational’ approach to autonomy. Stoljar posits that the social conditions that a person inhabits, including their available options and interpersonal contexts, all affect the ability to make autonomous decisions. She identifies some of the implications of this for health research ethics, including the relationship between autonomy and vulnerability, and the claim that informed consent is sufficient for accordingly due respect to autonomy.

A similar interconnectedness can be seen between the next two chapters in this section. Schaefer’s chapter considers Proportionality in the context of HRR. He approaches this in terms of a justificatory relationship and underlines that, while a necessary part of responsible HRR, assessing proportionality is no easy task. In particular, it involves the weighing of different values

that are non-commensurate and often non-quantifiable. Moving forward, Schaefer suggests several procedural approaches that can help improve the reliability and legitimacy of those assessments. Coleman further addresses risk–benefit analysis later in this volume (Chapter 13). Schaefer’s consideration of how to integrate the social value of research into proportionality is also complemented by van Delden and van der Graaf’s chapter that takes Social Value as its focus. The authors define the social value of an intervention as the value that it could eventually have on the well-being of groups of patients and/or society. However, they note, too, that to state a requirement for social value is one thing; to actually evaluate the social value of a research project is another. Overall, they find that social value has matured from an attractive but elusive idea into something that has to be assessed, evaluated and optimised, and can be used to address some of the justice issues in healthcare.

Three chapters follow that speak to the role of the individual and the collective in contemporary HRR. These begin with Kieslich and Prainsack’s chapter on Solidarity. This builds on existing and emerging research to explore the analytical and normative roles solidarity can play when designing HRR regimes. Kieslich and Prainsack illustrate their argument by reference to the European Union regulatory regime for research on rare diseases and orphan drugs. Through this discussion, the authors show how the concept of solidarity can be used to reframe the regulation of research from a market failure problem, which needs to be addressed through financial incentives, to a societal challenge in which the nature of barriers is not just financial. Next, Sorbie considers the Public Interest in HRR. This chapter provides an introduction to this elusive concept and considers two key ways that the public interest is constructed in HRR, namely as a legal device and through empirical evidence of the views of publics. Both conceptualisations are analysed with reference to the key challenges and opportunities that they present before a holistic concept of the public interest in HRR is proposed and consideration given to how this may be operationalised in practice. Townend’s examination on Privacy completes this trio of chapters. Here, he examines privacy as a well-established concept that has become a mainstay of good practice in research, yet also one that remains nebulous in character. Townend offers an explanation of why privacy is a difficult concept to express, how the law approaches the concept, and how it might be explored as a broader normative concept that can be operationalised by researchers. In the course of their analyses, Sorbie and Townend both consider matters at the intersection of governance and public involvement. Readers who wish to know more about the latter in HRR are directed to Aitken and Cunningham-Burley’s chapter, which specifically examines Forms of Engagement (Chapter 11) and to Burgess’ consideration of Mobilizing Public Expertise in Health Research Regulation (Chapter 25) later in this volume.

The final two chapters of the section consider key concepts specifically in their institutional and political contexts. Kerasidou’s chapter on Trustworthy Institutions in Global Health Research Collaborations delineates the differences between trust and trustworthiness, and argues that institutions committed to advancing the aims of global health should aim to promote fair and trusting collaborations. More specifically, she proposes that being trustworthy requires more than just the observation of rules or the incorporation of moral principles in policies and structures; it also demands attention to the relational aspect of trust. Finally, this section concludes as it started: with consideration of vulnerability. In Brassington’s chapter on Vulnerabilities and Power: The Political Side of Health Research, he argues that there is a political dimension to research, and that accounts of health research regulation that ignore political relations between stakeholders are therefore incomplete. He concludes that research promises us a way to address human vulnerabilities, but it may exacerbate others in the process

and that the relationship between researcher and participant can only really be understood when its own inherent political dynamic is acknowledged too.

Each of the chapters in this section illustrate that HRR provides a dynamic area of study where even well-established concepts may be in various ways disputed and unsettled. In examining these dynamics many of the authors also address the relationship between the individual and the collective in HRR. As these and subsequent chapters show, this tension at the heart of HRR is accentuated by the drive towards data-driven and population-level biomedical research. Finally, many authors call for further work to deepen both how these concepts are understood in context and how they are operationalised in the health research endeavour. A response to this can be found in the pages that follow.

