

Balanced Ethics Review: A Guide for Institutional Review Board Members

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Pp xvii + 131. Springer, 2016
ISBN 978-3-319-20704-9

The aim of this pocketbook-size manual is to assist Institutional Review Board (IRB) members and chairs to conduct ethics reviews by balancing the two major morally relevant considerations in health research: that of protecting research participants and that of the benefits of health research, namely, societal well-being and progress. The recurring refrain throughout the book is that many IRBs today have misplaced both balance and focus, and while the primary function of IRBs is to protect participants, many today protect scientists, try to forestall controversies, attempt to prevent lawsuits and aspire to improve the methodology of the science they review. These activities as claimed by the author are 'all manifestations of the curse of power' and IRBs should avoid these distractions and focus on protecting participants. As someone who has been engaged in ethics review for many years, involving collaborative studies with researchers from the USA, and having been on the receiving end of the IRBs' attempts to interfere with our local review processes, I can understand all too well the author's disquiet with regard to the all-too-powerful IRB.

The manual focuses on ethics review in the USA, and hence concentrates on federal policy highlighting when that policy restricts the IRB's ability to adapt to the changing scientific and moral landscape. The manual can be used in other countries because the challenges to ethics review are global and also because many countries, especially resource-poor ones, depend on funding from the USA when conducting research, which is often collaborative involving researchers from the sponsor states and is subject to federal policies and guidelines. The manual covers mostly core issues, but omits others such as proxy consent, research involving some vulnerable groups, and placebo-controlled trials. It focuses on ethical principles and how to apply them during the review process and not on procedures, and therefore omits the mechanical details of IRB operations, for example, the number of members necessary for the composition of the committee.

Comprising nine chapters, the manual is summarised in chapter 1, the introductory chapter, which is keyed in such a way that the reader can easily turn to the appropriate section later in the book for more detail. Chapter 1 includes the critical questions that IRBs need to consider when conducting ethics review. The analyses and differing points of view are provided in later chapters. The importance of drawing on evidence and not speculating, is stressed as are the two foundational ethical obligations: doing no harm and helping others. These translate to the two goals of ethics review: protecting participants and enabling research that will benefit society. Eight rather helpful principles in the IRB process are briefly described: respectfulness – treating investigators as valued colleagues; transparency – with IRB operations being open to public view; efficiency – minimising the review costs in time and money; clarity – using language appropriately; accountability – providing for an appeals process; judiciousness – acting only when the benefits justify the costs; rationality – striving to improve the public interests in ways that are evidence-based; and restraint – remaining within the bounds of the IRB authority. These principles are detailed in chapter 3. While the focus of the book is on biomedical research, conducted in the medical school or hospital, chapter 6 is specific to research ethics review in the social sciences and the duty of the IRB to approve research that is ethical and will help ground public debate in evidence is emphasised.

The book is written in easy-to-read language and would be understandable to all members of the IRB, including the lay member. It does not always provide answers, especially to complex issues, but it does suggest ways of thinking that will assist IRB members to reach morally justified decisions that take the balance into consideration – respecting both participant welfare and society's need for the benefits of research. It is compact, pocket sized and also available in eBook.

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S Afr J Bioethics Law 2016;10(2):93.