

Preface

This manual will help you, the IRB member or chair, conduct ethics review that balances the two major moral considerations in research with human subjects.

Balance

This guide would not have been needed when the IRB system was formed, for ethical pioneers like Hans Jonas, Paul Ramsey, and Henry Beecher took balance for granted. They recognized that research ethics should aim to promote both the rights and welfare of research subjects and our shared interest in better treatments for disease. In the past half century, however, theory and practice have turned away from the balanced perspective of the early ethicists and toward an exclusive focus on subject protection.

Today's error has virtuous roots. Scholars in the mid-twentieth century were drawn to research ethics by grievously unethical experiments like the Tuskegee syphilis study and the Jewish Chronic Disease Hospital cancer cell injections. Early ethicists focused on protecting subjects from serious hazards. When study subjects risked death, any benefit to society was rightly dismissed as unimportant.

Once the foundations were laid—once the moral contours of injury and abuse were charted and a regulatory system established to guard against those perils—later ethicists turned to lesser risks, ultimately creating a literature that paid increasing attention to diminishing hazards.

The result is today's unbalanced ethics, in which the benefits research brings to society are discounted as morally irrelevant.

This manual will give you the tools to restore the balance that the early ethicists saw as fundamental.

The Curse of Power

Many contemporary IRBs have lost both balance and focus. The system was created to protect subjects, but IRBs today sometimes seek to protect scientists, to forestall controversy, to prevent lawsuits, and to improve the methodology of the science they review. These activities are all manifestations of the curse of power—the belief that the IRB has an open-ended mandate to take any action that would improve the research enterprise. IRBs should shun these distractions and focus on protecting subjects.

Changing Ethics and Unchanging Regulation

Ethical principles may be universal, but ethical practice is contextual. Early scholarship assumed, for instance, that enrollment in a randomized trial jeopardized subjects' welfare and was therefore morally questionable. This assumption was overturned when patients with AIDS demanded inclusion in trials of new drugs. The realization that trial participation can be a benefit does not displace our older concern about participation as a burden; each is valid in the appropriate circumstance.

New research methods expose deficiencies in the ethical canon. The Nuremberg Code states unconditionally that the consent of the subject is essential, but a stubborn insistence on consent can make research less ethical. We must question fixed principles that arise from archetypal abuses and embrace the new and more nuanced morality that leading scholars now propose.

This new morality overruns the bounds of today's regulatory structure. The regulations might be interpreted in a way that permits IRBs to follow contemporary ethical theory, but creative ethical

solutions are not welcomed by the federal oversight agencies. This manual candidly explains when federal policy restricts your IRB's ability to adapt to our changing scientific and moral landscape.

Still there is much to celebrate. Ethicists find new ways to help science; science finds new ways to help us all. Your IRB will play an important role in these advances.

This manual focuses on ethics review in the USA. But the challenges of ethics review are international, so I hope that it may be of some use in other countries that recognize that subjects and society both matter.

About this Manual

This guide is filled with the insights of dozens of scholars. If you want to learn more about any topic in this manual, start with the references. I host a website, <http://balancedethicsreview.com>, and invite you to participate in the ongoing discussion there.

No guide can provide the final answer for ethical uncertainty. This manual covers some core issues but omits others, such as proxy consent to research, research with prisoners, research with children, and placebo-controlled trials; it considers federal, but not state or local, regulations. And because it focuses on ethics, not procedures, this manual omits the mechanical details of IRB operations like how many members a committee must have and what kinds of research qualify for exempt or expedited review; your IRB chair or administrator will guide you in these matters. Robert Amdur and Elizabeth Bankert's *Institutional Review Board Member Handbook* (2011c) provides an excellent discussion of how an effective IRB functions.

I mention individual authors when there are one or two; in the interests of readability, when there are three or more I sometimes mention only the first author and dispense with the customary but cumbersome "*et al*" or "and colleagues."

The people who make research possible are commonly referred to as "subjects," although some authors believe it is more respectful to refer to them as "participants." I follow the more common usage of "subject" while applauding the individuals who, far from being passive objects of study, are active partners in the research.

This guide has benefited from candid review by my friends, family, and colleagues, and it is as accurate and sensible as I know how to make it, but I do not imagine that it is without error or beyond improvement. If you have comments or criticisms, please email me at swhitney@bcm.edu.

Where to Start Reading

This manual is meant to be useful to the IRB member at any level of experience. Chapter 1 summarizes the entire guide. The remainder of the book provides the reasoning, authorities, arguments, and counterarguments.

If you are contemplating joining the IRB but have not yet done so, be advised that the IRB is like no other committee. It deals with issues of vital importance to your university, medical school, or hospital, and it may require correspondingly outsize effort from you. Please read Sect. 2.6, “Your IRB Service,” which reviews the terms of your IRB service.

If you are a new IRB member I suggest you begin with Chap. 1, the Introduction, which includes a compact summary of the book and the essential ethical concepts any member needs to know.

If you are a community member, please see especially Sect. 2.6.3, “The Community Member.”

If your IRB is dedicated to research in the social sciences, Chap. 6 is for you. Browsing through Chap. 1 will help you find additional relevant material.

If you are an experienced IRB member or chair, you can start with Chap. 1 for a rapid overview, or Chap. 2, which begins the detailed discussion of ethics review.

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Balanced Ethics Review

A Guide for Institutional Review Board Members

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2016, XVII, 131 p., Softcover

ISBN: 978-3-319-20704-9