

# Book review: *Balanced Ethics Review: A Guide for Institutional Review Board Members*

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## ***Balanced Ethics Review: A Guide for Institutional Review Board Members***

by Simon N. Whitney MD JD<sup>a</sup>  
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*Balanced Ethics Review* is intended to be a guide for members of Institutional Review Boards [IRBs (in Canada, Research Ethics Boards)], those interdisciplinary committees that are tasked with reviewing the ethical probity of research involving human participants. The theme of the book is that reviews conducted by IRBs should balance the principle of “protecting human research participants” with the principle of “enabling research that will benefit society” (p. 15). The central issue raised is that the regulations that IRBs are obliged to follow often emphasize the protection of research participants regardless of the potential effect on research. *Balanced Ethics Review* is a plea to expand the focus of IRBs to include valuing research on an equal level with the protection of research participants. That is not to say that research is more important than the protection of research participants. However, the traditional focus of IRBs has been the protection of research participants, leading to delay or rejection of important research projects that could ultimately benefit future patients.

Taken together, the 9 chapters—Introduction, Ethics and the IRB, IRB Process, Evaluating Biomedical Research, Consent in Biomedical Research, The Social Sciences, Biomedical Research Topics, FDA and OHRP, and The Future—provide a fairly comprehensive overview of the most common issues faced by IRBs.

Subliminally or not, the reader will very quickly adduce that Dr. Whitney, like many of those involved in this process, is extremely frustrated with the current IRB model. In fact, he refers to IRBs as being endowed with the “curse of power.” When a scientist submits a research protocol to an IRB, that IRB has the power to authorize, reject, or require modifications to the research project. Institutional review boards are notorious for exceeding the boundaries of their mandates and delaying research for spurious reasons such as trying to protect researchers, trying to protect the institution, requiring changes that go beyond what is found in the regulations, conducting a scientific review, and requiring literature reviews, among many others.

The emphasis of *Balanced Ethics Review* is that those types of considerations are beyond the mandate of the IRB review and are therefore not areas in which IRBs should comment. Although IRBs have the power to withhold approval until such concerns are addressed, Whitney suggests that they should exercise their power in an ethical manner and resist the temptation to extemporize. There is wisdom in the venerable adage “Power corrupts and absolute power corrupts absolutely.”

One of the most original, and yet unorthodox, ideas proposed is the model of “consent before approval,” which is presented in Chapter 4. The problem Whitney tries to solve is that IRB members not uncommonly find themselves in a dilemma in which they are struggling to determine whether the risks to participants from participation in a particular research project are justified by the value of the knowledge to be gained if the study is successfully completed—known as the risk–benefit ratio. In this type of situation, Whitney presents a detailed process that is consistent with the regulations and that might help IRBs to determine whether research participants are truly willing to accept the risks. The process (p. 45) reads as follows:

- The IRB approves the consent form.
- The researcher uses the consent form to enrol some subjects.
- The IRB discusses the enrolment process with the investigator, or meets with the subjects, or both.
- The IRB decides whether to approve the protocol.
- If the protocol is approved, the researcher begins the investigation.

Whitney acknowledges that this model of approving the informed consent form before approving or rejecting the protocol is not explicit in the regulations; however, it is at least compatible with his reading of them.

Although I appreciate this book and am sympathetic to the problem that the author is trying to address, I was

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not convinced by the fundamental premise that the social value of research should be considered an equal ethical principle with protecting human research subjects and participants. I understand that elevating research to such status would be appealing for many researchers who are frustrated with the IRB process. However, it is not clear that the author has provided a compelling ethical justification for accepting that premise, which is fundamental to the book.

The issue replicates the long-standing consequentialist versus deontologist debate. In other words, within the context of IRBs, what is more important: Producing a societal good by conducting important research? Or protecting research participants? Whitney's approach is to suggest that both principles are important and that they should be balanced. His insight is that the IRB process thus far has been biased in favour of protecting research participants regardless of the impact on science. Unfortunately, his justification for that important conclusion is simply a reiteration of consequentialist reasons, which might convince the consequentialists, but certainly not the deontologists. No amount of finger wagging on the part of a consequentialist regarding the beneficial consequences of an act will convince a deontologist of the rightness of that act.

Finally, there are almost two hundred references scattered throughout the work and yet very little explanation

for their use. The author does not report conducting any form of systematic literature review, nor does he report the criteria for including or not including a reference. As a result, it is hard to avoid the impression that references are used simply because they are convenient. It would be useful if the reader could be assured that the references provide a clear overview of the scholarship in a particular area rather than simply bolster the point the author wishes to make.

*Balanced Ethics Review: A Guide for Institutional Review Board Members* is an insightful exposition of the "curse of power" tantalizing IRBs. Simply because IRBs have the power to exceed their mandate does not mean that they are ethically justified in doing so. In fact, such an abuse of power in any other discipline, without the convenient disguise of being an ethics committee, would be considered egregious. This book provides practical advice to IRB members on how to resist the proverbial "wolf in sheep's clothing" otherwise known as the "curse of power."

#### CONFLICT OF INTEREST DISCLOSURES

I have read and understood *Current Oncology's* policy on disclosing conflict of interest, and I declare that I have none.

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