Book review

Simon N. Whitney

Balanced Ethics Review: A Guide for Institutional Review Board Members

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Preface, Acknowledgments, Contents (xvii) + 110pp + References and Index

When several decades ago the IRB system was established trying to balance major moral consideration in research with human subjects, the main impetus were severe cases of unethical behaviour and experiences, often protected by state and institutional administration. The first phase of the IRB aimed at protecting subjects from serious hazards, while in later stages the IRB turned to „lesser risks, ultimately creating a literature that paid increasing attention to diminishing hazards" (vii). With the constant rise of the number and varieties of research being submitted to ethical review, raising number and scale of people being involved in the IRB settings as members, the need for continuos ethical education and corresponding literature manual is evidently present today. In this manner, book *Balanced Ethics Review: A Guide for Institutional Review Board* Members written by Simon N. Whitney can serve as the valuable contribution towards filling this gap.

The book is divided in 9 main chapters (1. Introduction; 2. Ethics and the IRB; 3. IRB process; 4. Evaluating Biomedical Research; 5. Consent in Biomedical Research; 6. Social Sciences; 7. Biomedical Research Topics; 8. FDA and OHRP; 9. The Future), with the titles suggesting several cores, but also alternative topics for the typical IRB literature. As the author himself emphasizes, the entire manual is summarized in the introductory chapter; if you are officially appointed to the institutional IRB, lacking knowledge and interests, and avoid time consuming readings, this part could be a good start (however, even a less demanding reader should not deceive him/herself that they can find everything they need here, but some basic information is provided,

hopefully incentive for follow-up reading). When someone realizes that being a member of the IRB is not a coincidence and ethical work needs to be done, Chapter 2. („You're on the Institutional Review Bord. Congratulations!", p. 11) provides basic historical review of the core IRB idea (always welcomed!), including scandals and research ethics foundations, as well as Belmont Report contribution. Although the book is planned as a manual for the „modern" IRB members, Whitney only refrains to two (traditional) ethical principles: do not harm, and help others (p. 13), while omitting bioethical autonomy from his review (justice is a part of the chapter 7, p. 86). Also present is the „balance aspiration", combining subjects protection with permitting research to proceed, although there is no answer whether the balance is always achievable in "subject welfare versus scientific advances" (p. 16) settings. If someone needs more information on "community members" of the IRB, the last part of the second chapter provides basic instructions (especially useful in countries lacking lay person members in the IRB, as Croatia does). Once IRB starts to work, according to Whitney, several principles can be useful in facilitating responsible decisions: respectfulness, transparency (including open meetings), efficiency, clarity, accountability, judiciousness, rationality, restraint. Principles sometimes lack practical aspects; to avoid this the author has included the rules for the IRB authority: *Do Not Protect Third Parties. Do Not Protect Scientists. Do Not Protect Research Assistants. Do Not Protect Communities. Do Not Protect Companies.* (p. 28–29). It sounds so simple, but sometimes it is so difficult being an IRB member, isn't it?

Evaluating Biomedical Research (Chapter 4) covers the core of the book – basic research in biomedical sciences, including also some other topics (bias, need for peer-review literature readings, influence on scientific protocols, estimation of the value of research etc.). "Risk issue" (p. 38–40) is also known in relevant literature on the IRB system, being here well elaborated. Although we would expect "zero-risk tolerance", Whitney pleads for "balanced approach", allowing subjects to take some risks (as the author himself points, although theories for making balance do exist, they are often replaced by "gut feeling", "intuition", "sniff test", p. 43). There is a good chance scientists would support such approach, at least as long as they are the one performing research, and not being the subject. Chapter 5 (Consent in Biomedical Research) deals probably with the most relevant and most unclear term in research – subject consent, described in two sentences: "Consent covers subjects." and "Consent covers societies." (p. 47). Although a great part of the literature has been devoted to the consent issue, additional instructions are always welcomed, especially for the IRB beginners. If you think the preparation of a unified consent form is an easy part, there is still plenty of time to change your mind (p. 52–55).

There is no doubt biomedical research is the most demanding part of the IRB system, but as Whitney shows, social sciences need their place under the same sky. Or, do

they? Namely, the introductory part of the Chapter 6 very clearly suggest "avoiding" the humanities reviews – even if we presume the reasons for such an attitude, the message for the potential IRB members (both biomedical and non-biomedical) is doubtful ("If a higher institutional official requires you to do so, you are a victim of *their* power. This manual's advice on how to review the humanities consists of a single word: *don't*".) (p. 57). After reading this, not only was the question raised of when was the IRB system declared to be only a biomedical research application, but also it raises the question of when and where interdisciplinarity efforts have disappeared? After all, in the same chapter the author makes an effort to point to the potential risk for the subjects in social research (threat to self-esteem, deception, risks of the survey and interviews etc.), showing the need for the IRB. Easier way (avoid IRB humanities), could hardly be a better way.

What are the typical biomedical research topics is the question of the Chapter 7. Archive research is very common today, not only for biomedical researchers, but for all healthcare professionals, like nurses. Still, even today many believe such research do not need review, forgetting privacy and confidentiality, as well as power of historical process of the IRB system development in the last few decades (p. 72–73). This chapter also covers ways of integrating research with clinical care (in so called learning health care system, p. 78-79), risks and benefits of randomized controlled trials (valuing risk(s) of staying inside-outside of a trials), comparative effectiveness trials comparing two or more accepted interventions. Regarding the last one, especially valuable is the part 7.4.2. on Faden's ethical principle in learning health care system; or introduction of "a substitute for informed consent for carefully selected studies" (p. 84). Even bearing in mind limitations from the last sentences of the paragraph, we can ask ourselves are we facing here the so called "slippery slope", specially having in mind researches which are still not performed in officially recognized learning health care system (university clinics)? As previously mentioned, the Chapter 7 also includes an issue on justice, but there is a doubt is this the best option. After all, understanding all previous chapters and topics would be easier with at least limited introduction of justice principle (especially in IRB United States setting). Following this, Whitney elaborates in this chapter other "edging questions", like vulnerable subjects, paying issue, emergency research etc.; this is of course valuable part, but current chapter 7 title (Biomedical research topics), maybe is not the best solution. Chapter 8 (FDA and OHRP) is dominantly useful for the American IRB members. Whitney is very aware of their public agencies character (Food and Drug Administration and Office for Human Research Participants), consequently their role, political power and limits. In this complex relations, balance has different (or should we say or maybe altered meaning, reconciling subjects with protocols, federal sanctions with institutional reputation, the investors with IRB chair, not forgetting all the staff. This

situation not only shows everlasting problems on (biomedical) research in the USA (elsewhere as well), but also ambiguity(ies) of normative regulations – ethics relation ("While there may be dispute over ethical judgements, there is no disagreement on the need for careful documentation.") (p. 102). Still, errors do happen, even with careful documentation and good intentions ("… about five unexpected deaths of many millions of research subjects in America in the last 15 years", p. 103.) – what to do in situation like this, with different stakeholders (agencies, funder, media, court), could be the most readable part of this book. Let just hope that injuries and fatalities would remain so "rare".

The last chapter of the book, The Future, has a long term perspective. If the Chapter 1 was introductory manual, this could serve as a conclusion summary, including the most important guidelines and keeping you open for novelties (importance of evidence in IRB work, willingness and duty to reform, challenges of avoiding any kind of influences and manipulation).

In addition, find very good Reference list (p. 111–121), and Index (p. 123–131).

It is not easy to write a short but at the same time useful book on IRB, especially when you want to emphasize a balanced approach. Even whilst a reader could disagree with the author on several points, there is a strong impression that Whitney has done serious research work, and has included relevant practical experience. It is maybe not the most comprehensive IRB book, but there is no doubt it is good IRB manual and "must read" balanced review book.

Iva Rinčić