BOOK REVIEW

Evaluating the science and ethics of research on humans - a guide for IRB members

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Dennis J Mazur. *Evaluating the science and ethics of research on humans - a guide for IRB members.* The Johns Hopkins University Press, USA. 2007, pp 252. ISBN 10 : 0-8018-8502-7

Institutional Review Boards (IRBs) are created for the "express purpose of providing safety to participants in clinical trials" and "IRBs exist for the sole formality of passing protocols so that drug companies can get legal clearance to start their clinical trials" are two statements that I have actually heard over the past year. Contrary to what you may expect, the first was made by a pharmaceutial company doctor while the latter was made by a cynical physician-investigator in a hospital!

The reality, as always, lies somewhere in the middle. IRBs were initially established to protect the interests of research subjects, but the fact remains that they also give a licence to a researcher to proceed with a trial. The importance that we give to IRBs is clear from the fact that at the recently concluded National Bioethics Conference in Bangalore, there were well attended workshops devoted to IRBs - either in establishing them or in answering the IRB's questions.

All of us in research and ethics in India have learnt IRB-related issues on the job and have, of course, faced problematic decisions from time to time. Most importantly, perhaps, many wonder whether, occasionally, we have missed out on important issues or slipped up. Dennis Mazur has drawn on his rich experience as chairperson of an IRB in the USA to write this invaluable guide for IRB members. I cannot recommend it highly enough - not only for the novice IRB member, but even for old hands and also for those on the other side of the table.

There are introductory chapters on IRBs and their work, the terms and concepts used in discussions within IRBs and on their proper functioning. The concepts of risk and informed consent are dealt with in great detail. We learn interesting tidbits such as this - the concept of consent was first discussed in 1767, that of self-determination in 1914 and of informed consent in 1957. The informed consent form should not bear the watermark of the institution or present the benefits of the trial in boldface, as these can be subtle ways to coerce study participants. Because certain drugs cannot be stopped suddenly - as participants may intentionally or inadvertently do during a trial - without disastrous consequences, the IRB may need to insist that the consent form specify these risks [page 98]. Separate chapters are devoted to research involving questionnaires and surveys because they are no less risky than clinical research, and on the protection of participants' privacy and their data.

Because much time and effort go into reviewing protocols, the author suggests ways to manage workload effectively. Pre-screening of protocols is one such way. He suggests that individual members develop areas of expertise so as to improve review. Examples of areas of expertise are in the role of placebo in trials, privacy of participants and their data, etc. A point that is made repeatedly is that all members of an IRB must attend its meetings. He illustrates how, in borderline cases, even a few absentees can change the vote. For this, he suggests the possibility of having a proxy vote in absentia. Accurate, reasonably detailed minutes of meetings must be kept which justify the decision taken by the IRB. This may be crucial at a later date. Finally, the author also stresses that IRB members must search the biomedical literature to verify facts rather than accept the investigator's protocol because an investigator "may frame a scientific hypothesis to appear less risky..." [page 190]. Continuing review of research studies, within a year of the trial starting, is important because additional risks and new issues may come to light during the course of the research. Useful checklists for reviewing the scientific protocol and the informed consent form are provided.

If I have to find fault with this book, it is that practically all references are to American books and journals [even given that this book deals mainly with American issues] and that most of the references are general in nature. Perhaps in a later edition the author will consider using some data-based papers to prove some of his points. The use of papers from journals such as the *Journal of Medical Ethics, BMC Medical Ethics and the Indian Journal of Medical Ethics* would show that many of the problems faced by IRB members are similar across the globe.

Every IRB member must read this book so that the participants of clinical trials benefit from it. After all, as the author states on page 98, "some research studies [have] limited scientific value and possible ulterior motives".