book reviews

Manual for research ethics committees.

Edited by Sue Eckstein. Cambridge University Press, Cambridge 2003. 578pp. £120.

The *Manual for research ethics committees* from King's College, London, was first produced by Clare Foster in 1992 as a compendium of guidance issued by sundry professional bodies, and accompanied by some short essays to assist a basic understanding of ethical review. The manual grew with each edition: one folder became two large ones. The old format has now been dispensed with and this new sixth edition is a hardback book of 578 pages. Its two parts (the essays and the guidance) are divided into four sections: fundamental ethical and legal considerations; the research process; protecting the interests of research participants; and international research.

What might the research ethics committee (REC) member want from such a manual? First and foremost, the collection of published guidance. Some has been abbreviated in order to save space, but the essentials have been kept with the full text included in references. The most notable and explicit omissions are those (admittedly now outdated) from the Royal College of Physicians. Chapter 69 of the book provides an astonishing list of international codes, declarations, guidelines etc, with advice on how to track down this information. There are lots of web addresses.

Given the international differences in ethical review structures, this is a very British book. Key European documents including the EU Directive 2001/20/EC are reproduced. I looked in vain for significant omissions of published guidance: it's all here and as up to date as one could reasonably expect – the Council for International Organizations of Medical Sciences (CIOMS) 2002 revision included.

Some areas have attracted more attention than others. For example, apart from that of the National Union of Students, there is no guidance on non-patient human volunteer studies from a professional body. The Association of the British Pharmaceutical Industry guidance is excellent, but there is surely a role for independent advice.

Reservations grow when one turns back to Part 1. The book would surely have been improved by reversing the two parts, so that the essays supplement the guidance. It is the latter that makes the manual indispensible, rather than just another multi-author book. The quality of the essays is highly variable. Utilitarianism is not the best starting point and the opening chapter disappoints. A 'right to be included' in research appears without any justification; while the primary moral duty when recruiting to research is surely not consent, still less non-discriminatory subject selection. Rather it is to ensure either equipoise or – notably in non-therapeutic studies – minimal risk. Without equipoise/minimal risk, no research can be ethical, with or without consent. A chapter on the history of research regulation avoids any mention of the seminal contribution of the RCP, omits the Department of Health's 1991 guidance and makes the extraordinary assertion that in the UK the making of regulations on the conduct of medical research has depended on having a scandal. But the 'scandal' of the Griffiths Inquiry of 2000 was the lack of a research governance framework and not primarily a research ethics issue. In fact the development of research ethics review in the UK is a less exciting story. The chapter on complementary medicine fails to discuss how research that cannot be scientifically justified can be ethically justified; and makes the assertion that NHS RECs are 'arguably obliged' to vet research on any application affecting the well-being of human subjects. A justification would be nice. The vexed issue of differentiating between audit and research gets half a page, with no discussion – yet this is a common problem for RECs. There is much of value in these chapters but the link to the published guidance is often unclear.

How might this be improved for a seventh edition? One of the needs of REC members is to understand the structures of research. Experimental designs may be pragmatic or explanatory or mixed; cluster trials generate different questions to individual randomisations; epidemiology has its own methods. Some classification and description would help. Ethical decisions are often simple if the issue or method is understood. Secondly, the individual contributions need to be more even, with a better link to the guidance that is the book's main strength. Thus if the first item of guidance in the section on fundamental legal and ethical considerations is the Declaration of Helsinki, the starting point might be the moral desirability of good research, the protection of the patient, the nature of the doctor's duty and what it means to say that medical research 'must conform to generally accepted scientific principles'. Nevertheless, this single volume compendium is enormously valuable. It should be in the hands of all those with an interest in the regulation of research in human subjects in the UK and will have much of interest to those in other countries as well.

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Science: a history 1543–2001.

By John Gribbin. Penguin, London 2003. 672pp. £8.99.

John Gribbin, an astrophysicist with a track record as an author of readable popular science books, has set out to cover the history of science in a single volume. He has deliberately ignored the work of the Ancients, and Islamic and Chinese scientists and concentrated only on the development of modern Western science. The year 1543, which at first glance seems a strange choice of starting point, marks, as Gribbin cogently argues, the birth of science as we understand it today. In that year Andreas Vesalius published *De Humani Corporis Fabrica* ('On the structure of the human body'), the text that marked the beginning of the breaking of medicine's ties