Human subjects research regulation: perspectives on the future.

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BOOK REVIEW

Human subjects research regulation: perspectives on the future, edited by I. Glen Cohen and Holly Fernandez Lynch, Cambridge, MA, Massachusetts Institute of Technology, July 2014, 392 pp., £27.95 (paperback), ISBN 9780262526210

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This book is the 43rd in a series entitled 'Basic bioethics', and is intended to make work in bioethics accessible to a broad audience. This volume looks at the regulations safeguarding research involving human participants, and explores the legislative framework governing research in the US, in particular the 'Common Rule for the Protection of Human Subjects'. The reason for this focus is that there have been a number of proposed changes (described within the Advanced Notice for Proposed Rulemaking, or ANPRM) which aim to take a risk-based approach to targeting regulatory oversight, as well as modifying regulations to keep pace with research, particularly regarding multi-site trials and the challenges facing research involving use of biological specimens. One of the points made in the introduction is that at the time of writing (late 2013) little progress had been made in terms of this legislative review. Indeed, at the time of writing this review, the process is far from complete. The aim of the book, therefore, is to stimulate dialogue around the proposed changes.

This book is likely to have broad appeal. Despite the US context, these issues have worldwide relevance. Furthermore, the book revisits two primary themes throughout, both of which are likely to be of interest to both Human Factors/ Ergonomics researchers and practitioners. The first of these themes is risk, its regulation and its management, while the second concerns the importance of taking a participatory approach and engaging human subjects as partners in research. These themes are key elements of any HFE approach, and readers will often find themselves on familiar territory.

The book is divided into five sections, each concerning a facet of the ANPRM and considering its strengths and weaknesses. Risk is a central tenet of the proposed amendments, and this is dealt with in the first section. The current framework has evolved over the last few decades, originally arising as a response to the appalling revelations of the doctors' trials at Nuremberg following the Second World War. The 'Common Rule' has remained unchanged for two decades and is designed to protect human participants from unacceptable risk. However, it is recognised that many studies are very safe and there is an argument that research regulation is only necessary when risks are considered substantial. The ANPRM thus proposes the elimination of regulatory oversight when the risks are deemed to be minimal. In one chapter, Rhodes suggests taking this further, and including an even lower risk category ('de minimis'). Iltis provides a counter-argument to this proposal which will resonate with HFE specialists: the proposals are based on a flawed assumption that there will be no errors in decisions to classify studies as minimal risk and lower. If we also consider that – in an ethical research project – the benefits should outweigh the risks, we can spot another flawed assumption: that risks and benefits can be calculated at the start of a project and will remain the same throughout. The book contends that it is this analysis

of whether or not ‘low-risk’ projects require regulatory oversight and how these decisions are made that illuminates the more general aspects of research regulation.

Part II looks specifically at the protection of vulnerable groups, described as those most at risk of exploitation from research. While general aspects of ‘vulnerability’ are considered, there is a closer focus on three specific cases: military personnel, children and prisoners. Military personnel are not currently considered vulnerable, but Parasidis creates a compelling argument for re-classification, pointing out the much lower protection available when drugs are being ‘field tested’ rather than as part of clinical drug trials. Furthermore, she (check) describes current research programmes which seem horrific to the civilian observer, such as ‘Persistence in Combat’, a project which exploits medical developments to produce soldiers who are ‘unstoppable because pain, wounds and bleeding are kept under their control’. Others might argue that ‘military necessity’ trumps a soldier’s human rights: this is an unsavoury – but wholly necessary – discussion and this book opens that dialogue. Similarly, uncomfortable discussions are raised in the chapter that reflects on a recent Institute of Medicine report that suggested relaxing the regulation with respect to prisoners as research participants. While these proposals are – again – risk-based (the IOM is not suggesting that prisoners should be participating in anything other than low-risk studies), it seems a rather frightening drift back to Nuremburg. These are exactly the type of developments that need exposure through texts such as this, ensuring that legislation is progressive, not regressive. The chapter concerning paediatric research participation is an example of the former, suggesting that such research is best served by developing community partnerships with children, fostering trust between researchers and participants and per- haps improving research accountability.

The third section of the book extends this concept of research participation as an active process, suggesting a more participant-centred approach. The authors of all the chapters in this section emphasise the sole reason for regulation in the first place is because there is the potential for the research to impact on the participants and there is no one better placed to judge this. By involving participants, we can assess whether or not regulation has achieved its purpose of protecting participants whilst not needlessly impeding beneficial research. As HFE specialists will be aware, full stakeholder engagements raises researchers’ awareness of risks that may not have been apparent to them. This section also explores the responsibilities of investigators and sponsors. One of the potential problems with the proposed changes at the lower end of the perceived risk spectrum is that once a study has been identified as low risk, that is the end of the researchers’ responsibilities to the participants.

A natural extension of this argument continues in Part IV, with a look at the contemporary issues surrounding the collection of biospecimens. Currently, ‘de-identification’ of samples is the cornerstone argument as to why it is acceptable to use specimens in later research studies (for which the original participant has not consented, and using technology that perhaps did not exist at the time of consent). The ANPRM addresses this by referring to studies by research groups that have demonstrated that ‘re-identification’ is possible and consequently consent should be obtained for all studies. This section of the book argues that the best way to achieve this is to work in partnership with potential participants.

The final section deals with ‘paradigm shifts’ in research ethics: the authors feel that the current regulation was an emergent outcome of a research system centred on biomedical and behavioural research, and doesn’t really fit with the more modern research landscape where social research

has become more prominent.

In summary, this (highly readable) book presents a multifaceted view of current US ethical regulation and the proposed changes and, in doing so, challenges the reader to consider some often uncomfortable risks associated with research involving human participants. Furthermore, the primary arguments contained within the text concern effective risk management and the use of participant-centred research: a good argument for involving HFE specialists on the research team!