Book Review

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Writing Clinical Research Protocols: Ethical Considerations
by Evan DeRenzo, Joel Moss
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Writing Clinical Research Protocols was written for the novice as well as the experienced clinical researcher. Authors Drs. Evan DeRenzo and Joel Moss divided the book into four sections: The Basics; Preparing the Protocol; Procedures, Methods, Statistics, Data Management, and Record Keeping; and Special Issues. In all aspects of the book, the theme that emerges involves the ethical issues to be considered when undertaking clinical research.

In the section entitled The Basics, the authors provide background information as well as the history of clinical research. They present the regulatory issues that apply to clinical research and tie it back to historical happenings. As is often the case, abuse led to regulations.

Preparing the Protocol focuses on the research subject. These chapters stress the importance of evaluating the risk and benefits of the study as well as the selection of the subject. To illustrate their points, the authors tie in excellent examples. Certainly for the novice clinical researcher this section is a must-read. As a clinical laboratory scientist, Preparing the Protocol was interesting but did not present information applicable to our role in clinical research as it exists today. However, with the potential broadening of the field to encompass clinical research, this section could provide pertinent background information.

The section on Procedures, Methods, Statistics, Data Management, and Record Keeping fills fewer than 30 pages. Ethically, clinical research can not follow experimental research format. A mixture of qualitative and quantitative research methods are discussed, with a heavier emphasis on the qualitative. The authors advise the clinical researcher to consult a statistician in determining the appropriate number of subjects and the selection of statistics for the study. The section does not address how to select appropriate statistics for the design of the research study. In all, it is probably sound advice for a clinical researcher performing a study. As clinical laboratory scientists, our interest is more on the outcome of the study (e.g., whether it was valid), while the clinical researcher's interest focuses more on the study's process. For that reason, this book would not serve the needs of clinical laboratory science educators in teaching students how to evaluate a research article.

The Special Issues section introduces evolving areas that in the future will present additional required approaches in clinical research.

The book is well-written and should be required reading for anyone conducting clinical research. For clinical laboratory science faculty, it will provide excellent insight. For the clinical laboratory science program, it could serve as a reference.

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