Foreword

The Institutional Review Board and You

Clinical research has known both tremendous highs and lows with regard to the ethical conduct of human-subjects research. This RESPIRATORY CARE Journal Symposium, "The Institutional Review Board and You," was a special opportunity to review the history of clinical trials and discuss past and current challenges. Featured on Tuesday, December 4, 2007, it provided an opportunity for colleagues gathered in Orlando for the 53rd International Respiratory Congress of the American Association for Respiratory Care to hear about and discuss issues related to human subjects protections in research. This is a topic that affects all researchers, whether basic science, clinical, or translational. In the past, regulations were less clear about when institutional review board (IRB) review was required, but it's now very apparent that any access of a clinical record, even if not part of an interventional study, requires regulatory review. Exact rules are guided by federal, state, and local requirements and are still being shaped in an attempt to keep pace with current technology and to answer questions about topics of investigation less obviously researched, such as quality-improvement projects and case reports.

Starting off the symposium was Todd Rice, who provided the historical, ethical, and legal background of research with human subjects. This helped put the challenges facing investigators into a larger context. Jonathon Truwit followed this talk with further information about the makeup of an IRB and its responsibilities. I had an opportunity to share thoughts about informed consent, and particularly how important the process is—more so than just the consent form. Karen Schwenzer shined light on the topic of research with specially protected populations, including children, pregnant women, prisoners, and employees. Schwenzer, Rice, and I then finished up the morning with discussion about special regulatory issues, including chart reviews and case reports, how to work with your IRB, and what to do if your institution doesn't have an IRB. By the end, we all had a nice perspective on the history of the regulations on human-subjects research, some of the special challenges that our IRBs and investigators face today, and tools to navigate through the IRB process and succeed in conducting safe and effective research.

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