

Virtual Mentor

American Medical Association Journal of Ethics
April 2009, Volume 11, Number 4: 277-278.

FROM THE EDITOR

The Escalating Importance of Clinical Research

In 2004, the National Institutes of Health (NIH) launched its NIH Roadmap for Medical Research, an ambitious plan to delineate the agency's priorities and to serve as a guide for scientific research in the coming years [1]. Central to this plan is the promotion of clinical and translational research. Since then, the NIH has shifted more extramural funding to these areas and added funding for didactic-degree programs in clinical research at academic institutions around the country to train the next generation of clinical researchers. As part of recent economic stimulus efforts, the American Recovery and Reinvestment Act of 2009 will infuse the NIH with hundreds of millions of dollars, much of it slated for clinical-research endeavors [2].

Opportunities in clinical research abound for medical students and residents. And as the focus of the leading scientific agency in the country shifts more toward research involving human subjects, there is little doubt that increasing conflicts between the agenda of scientific advancement and biomedical ethics will surface. This issue of *Virtual Mentor* explores a number of these aspects of clinical research.

The three clinical cases in this issue describe scenarios that are particularly salient for medical trainees engaged in clinical research. In the first case, Julie Freischlag explains how to avoid faculty favoritism in recognizing the efforts of a resident who enrolls patients in a clinical trial being conducted by his department chair. The second case commentary, written by Mark T. Hughes, charts the course a research trainee should take when asked to add honorary authors to a scientific publication. Timothy M. Pawlik tackles the thorny issue of how to handle suspected research misconduct in the final clinical case.

This month's journal discussion and clinical pearl relate to the ethics of statistics. In the former, Garrett M. Sparks reviews a 2008 article from the *New England Journal of Medicine* that describes the negative publication bias in studies of antidepressants and its effect on the public's perception of their efficacy [3]. The clinical pearl by Chandra Y. Osborn focuses on the importance of statistical literacy and explains how to interpret several frequently misunderstood statistical concepts.

As alluded to earlier, the NIH is funding many programs to develop future clinical researchers. In the medical education section, Emily Abdoler writes about some of the opportunities available to medical students and residents and the efforts to ensure that ethics is an integral part of that training. In the medicine and society section, Rebecca Dresser takes up the question of how the NIH determines its research priorities and the ethical considerations that must be part of those decisions.

The medical history and medical narrative sections this month highlight the human side of clinical experimentation. In the narrative section, Amanda Redig interviews participants in human-research studies and explores their motivations for subjecting themselves to pain and possible side effects of treatment, often with no known benefit. In a similar vein, Akhil Mehra writes about the incentives for participation in Walter Reed's historic yellow-fever experiments in the beginning of the 20th century.

Inherent to the conduct of clinical research in this day and age is the role of the institutional review board (IRB)—the oversight body responsible for the protection of human subjects involved in clinical experimentation. In a two-part policy forum, Margaret R. Moon and Felix Khin-Maung-Gyi explore the role of IRBs and debate the pros and cons of for-profit “central” IRBs and not-for-profit, academic institution-based “local” IRBs. Finally, Micah R. Onixt and Robyn L. Sterling review the liability and scrutiny that IRBs face when adverse events do occur in the course of clinical research.

I would like to thank all the distinguished authors for their contributions to this month's issue of *Virtual Mentor*. In addition, many thanks are owed to the staff at the American Medical Association—Audiey Kao, Faith Lagay, Phil Perry, and Jennifer Schooley—for their creative input, editorial efforts, and administrative support. It is our sincere hope that you enjoy reading about the aspects of clinical-research ethics covered in this issue and that you find it challenging and educational.

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