Keeping a Focus on Research Ethics

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research ethics, IRB, compensation, expanded access, vulnerable populations

Those of us who work in clinical research and drug development understand that navigation of ethical questions and challenges is always part of our work. While making ethical choices should be implicit in everything we do, it's also occasionally necessary to focus specifically on those ethical questions—and sometimes, to consider whether it's time to change our practices. In this issue of TIRS, we are taking a special look at four topics that raise ethical considerations for drug development teams.

Two of these topics—payment to research participants, and participation in research by persons who are unable to make their own decisions—are ones that we've encountered and discussed often over many years, but the evolving attitudes and opinions of ethicists and society lead us to take a fresh look at our old policies. Gelinas and colleagues have written a number of papers encouraging reconsideration of our long-held conservative practices in compensating research participants.^{1,2} In their paper “Truth in Advertising: Disclosure of Participant Payment in Research Recruitment Materials,” they explore the regulatory prohibition against “emphasizing” payment in advertising for research subjects, and propose guidance for sponsors and for institutional review boards (IRBs) to assist in the development of recruitment materials that are both effective and ethically appropriate. In “Adults Lacking the Capacity to Consent—When Is It Appropriate to Include Them in Research?” authors Forster and Borasky review common beliefs about including people in research studies who cannot provide informed consent. They put forward a new practical framework for the assessment of when decisionally impaired adults can be included in research, designed both for the sponsors and researchers who are writing the protocol and the IRBs who will review them. Their framework is scaled against the potential risks and potential benefits to participants, and based on the ethical principles of respect for persons as well as beneficence and justice.

The other two topics are relatively new issues encountered in the field of drug development. As the United States grapples with the current epidemic of opioid use and overdose, the number of clinical studies exploring ways to effectively treat opioid addiction continues to grow. In our paper “Ethical Issues in

Research Involving Participants With Opioid Use Disorder,” Anderson and I look at issues of consent, compensation, and novel research risks when working with a research population that is becoming more and more common. Finally, while the United States Food and Drug Administration (FDA) has had established policies for expanded access/compassionate use of investigational drugs for many years, the recent advancement of state and federal Right-To-Try legislation has brought expanded access policies and programs into the public eye. IRB review is required as part of the pathway for preapproval access to investigational drugs. Authors Folkers and Bateman-House have previously looked at many aspects of the expanded access process.³ In their paper “Improving Expanded Access in the United States: The Role of the Institutional Review Board,” they survey and assess IRB policies on the review of expanded access applications, and question whether variation in policies impacts patient access to investigational drugs outside of clinical trials.

We hope that this special issue, and this chance to look more closely—and perhaps, from a different perspective—at some of the ethical questions you may encounter proves interesting and thought-provoking. And should you have thoughts or comments about any of these papers, please reach out to the authors; I know they would be pleased to hear your thoughts and to keep these conversations going.

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