

Report on Research Compliance Volume 15, Number 4. April 30, 2018 Payment Is 'Not a Dirty Word': Paper Offers Framework to Support Subjects

By Theresa Defino

When, and how, to pay research subjects are among the more vexing issues principal investigators (PIs) and institutional review boards (IRBs) face. Both want studies to reach recruitment goals and not place unacceptable burdens on subjects. Yet proffers of payments to potential study participants can't lead to coercion or "undue influence" on them.

To help piece this puzzle together, a working group of "ethicists, members of IRBs, investigators, regulators, research participants, and industry representatives" met in 2016 to consider "payments in publicly and privately funded research, at academic institutions and elsewhere, and in various phases of research." Their efforts led to the publication of an article in *The New England Journal of Medicine (NEJM)*, "A Framework for Ethical Payment to Research Participants."

Despite being "ubiquitous," these payments "continue to engender controversy, and the payment-related policies and practices of [IRB] often reflect some discomfort with payment," according to the paper, coauthored by Holly Fernandez Lynch, an assistant professor in the University of Pennsylvania's Department of Medical Ethics and Health Policy, and Barbara Bierer, whose titles include faculty director of the Multi-Regional Clinical Trials Center of Brigham and Women's Hospital. Their coauthors are four other ethicists and translational science researchers. The article appears in the *NEJM* under the "Sounding Board" category. The paper includes two boxes: "Considerations for Investigators Proposing Payment Offers" and "Considerations for IRBs Reviewing Payment Offers" (see page 8).

As part of a discussion about the paper, RRC asked Fernandez Lynch what prompted the group to tackle this topic now. "Our main driver was evidence that many clinical trials have difficulty recruiting enough participants to meet their enrollment targets in a timely fashion," she told RRC. "Although more data is needed about whether payment can help address this problem, it seems intuitively likely. Therefore, we are concerned that an important recruitment tool is not being sufficiently utilized out of concern regarding coercion and undue inducement."

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