



## Conflict of Interest Notifications Study

Following the death of Jesse Gelsinger in a trial of genetic therapy at the University of Pennsylvania, and then the controversy over pulling Vioxx from the market, regulators and the media have focused considerable attention on potential conflicts of interest in research settings. Both the FDA and the DHHS require investigators to disclose financial relationships connected with their research, and the DHHS requires IRBs to manage potential conflicts of interest in order to minimize harms to participants. These rulings have created considerable uncertainty about which financial relationships require disclosure and management, and how best to do so. Also, medical institutions are concerned about whether disclosing financial relationships to research participants will affect participation and trust.

To examine these issues empirically, we obtained NIH-funding to conduct the COINS study (Conflict Of Interest Notification Study) study (1 R01 HL075538-01). Our group at Johns Hopkins, Duke, and Wake Forest Universities has already conducted multiple studies, including: a review of conflict of interest policies at 120 US academic medical centers; interviews with 37 IRB and Conflict of Interest Committee (COIC) chairs; 16 focus groups and 10 cognitive interviews with patients; an online survey of 3,623 asthma or diabetes patients who were presented a hypothetical clinical trial scenario; and a similar study by phone with 470 cardiology patients.

Our research findings revealed that academic medical centers have well-developed procedures and policies in place to learn about and manage investigators' financial relationships. Outside academic settings, however, we have discovered a much greater need for policy guidance and evidence-based practices. The concern is that policies adopted by or for academic institutions do not adequately consider the special or different considerations elsewhere. Yet, if well-adapted policies and guidelines are not developed separately for non-academic settings, the academic policies will likely apply by default.

The purpose of this phase of the COINS study is to learn more about the issues that non-academic institutions face regarding researchers' financial relationships, in order to help develop better guidance. We will begin with a series of pilot, exploratory interviews to inform ourselves about the range of issues, practices, and policies that currently exist across different types of non-academic institutions. Then, we will devise a more systematic study or survey focused on the more critical issues requiring guidance.

We seek the advice of this group about how best to focus our efforts.

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