

Conflict of Interest: Implications for Clinical Research Sites

The federal government is increasing its scrutiny of the relationships that investigators and physicians have with drug companies and clinical trial sponsors. While there is still debate in the scientific community over whether increased transparency guarantees scientific independence, the reality is that researchers and their sponsoring organizations are facing tighter regulations. The amounts of money have raised the attention not only of NIH and FDA; the IRS is also reviewing financial relationships between investigators and sponsors.

Private sponsorship of research plays a significant role in the development of drugs and devices, as well as contributes to the advancement of science. The U.S. pharmaceutical and biotechnology research companies invested a record \$58.8 billion in 2007 toward research and development, an increase of nearly \$3 billion since 2006.¹ However, over the last year, R&D for publicly traded biotech companies has decreased over the last two years, according to a study by BDO.²

This roller coaster of activity in industry-funded research occurred at the same time of increased regulations over the last several years. Several egregious examples of possible conflict of interest have been cited in the news media as well as Congressional testimony. The most infamous is the U.S. Senate Financial Committee's investigation of Emory University Professor Charles Nemeroff, who failed to report hundreds of thousands of dollars in payments from GlaxoSmithKline while researching that same company's drugs with an NIH grant.

The new regulations impact virtually anyone involved in human subjects research. Starting in 2013, the Patient Protection and Affordable Care Act (PPACA) sunshine provisions require pharmaceutical, medical device, biological and medi-

cal supply manufacturers to report certain types of payments to "covered recipients," specifically physicians.

Now the Department of Health and Human Services (HHS) has issued its latest guidance, or "final rule," regarding objectivity in research. If your institution receives any public funding for research, you will need to become familiar with the changes. Some of the new rules represent an increased burden of documentation and reporting, primarily:

- Lower financial disclosure thresholds
- New conflict of interest training
- New public accessibility requirements
- Increased transparency for travel reimbursement

While these policies do not go into effect until August 2012, institutions are required to revise their policies, establish procedures for compliance and train investigators in the interim.

Then, starting in 2012, the following key provisions go into effect:

- Disclosure – No longer will Investigators make determinations about which significant financial interests are related to PHS. All significant financial interests, regardless of the relationship to PHS funding, must be reported to the institution. In turn the institution will determine if the disclosure is a financial conflict of interest that requires reporting to PHS. Organizations must report all significant financial interests, regardless of its relationship to the Public Health Service (PHS) funded research.
- Public accessibility – The institution's policy must be made available via a publicly accessible Web site, or within five days of a written request.

1 PHRMA 2008

2 bdo.com/news/pr/1768

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- Training – Training will be required for all investigators before engaging in PHS-funded research, and every four years thereafter. Some institutions have more formal and comprehensive programs than others. While researchers and staff often have general knowledge about conflict of interest policies and procedures, these new guidelines will require them to understand how the information must be collected and evaluated. Also they will need additional training to develop effective mitigation plans.

While the guidelines specifically say that investigators will require the training, because so many people are involved in the clinical trial process, some organizations may be well-served by including others in their training. In fact, the final rule does expand the definition of “investigator” to include those involved in research and have a certain degree of autonomy.

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Filling the gap

There is still a significant gap within research organizations regarding their conflict of interest policies. The HHS reported in January that among NIH grantees *fewer than half* had written institutional policies.³ This presents a significant vulnerability for organizations, and means they will be busy over the next several months preparing their policies and posting them publicly. They also must consider the best approach for training investigators, and for tracking and documenting compliance.

Organizations that do not have explicit conflict of interest policies – and even those who do but may now need to revise them to comply with the new regulations – should consider outside professional help to ensure compliance.

Additionally, setting up and executing a new education requirement for investigators can be a challenge.

The cost of non-compliance can be the suspension of funding for research, as well as ill will and negative publicity.

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BRANY offers compliance services to help organizations meet the demands of the new regulations, including customized training for investigators and strategies for collecting and documenting compliance.

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3 <http://oig.hhs.gov/oei/reports/oei-03-09-00480.pdf>