Opinions Vary Widely on Financial Disclosures

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Officials in charge of disclosing financial interests in research agree that disclosure is important, but are confused about how to do so effectively and appropriately, Kevin P. Weinfurt, Ph.D., and his colleagues reported.

Their survey of 42 such officials revealed widely varying opinions on when disclosure should be made, the financial limits that should trigger it, and how much information to share with prospective research subjects, said Dr. Weinfurt of the department of psychiatry at Duke University, Durham, N.C., and his coinvestigators.

"Part of their struggle relates to a lack of clarity regarding the ultimate goals of disclosure," the researchers wrote. "There is also a lack of systematic data regarding how potential research participants can and will use such information in their decision-making" (J. Law Med. Ethics 2006;34:581-91).

About 80% of respondents said disclosure should include the name of the funding source, but some said the name of the source wasn't as important as a description of it.

The study was based on detailed personal interviews with eight investigators, 23 review board chairs, and 14 conflict of interest committee chairs. The survey was designed to elicit respondents' understandings of how disclosure is done at their institutions and their thoughts on the importance of disclosure, including its risks and benefits to the institution and research subjects.

More than half of those interviewed agreed that disclosure should occur under all circumstances; the rest said disclosure would depend on the degree of the financial relationship. The most commonly expressed reason for disclosing a financial relationship was to facilitate better-informed decision making for potential subjects. Other reasons included trust and transparency issues, reducing liability risk, and managing public perception of the institution.

About 80% of respondents said the disclosure should include the name of the funding source. But some said the name of the company or organization wasn't as important as a description—whether it was a nonprofit organization, pharmaceutical company, or government body, for instance.

They also differed on whether the amount of financial interest should be disclosed. Conflict of interest committee chairs were most likely to want to share this information (93%), while investigators were least likely (63%). Those who expressed concern about disclosing the amount felt that level of detail could become cumbersome or confusing in the informed consent statement, and that research subjects might overestimate the impact that particular amounts might actually have on research outcomes. There was no consensus on what amount should trigger disclosure—the lower limit ranged from $1 to $50,000.

There was general agreement that the nature of the relationship should be disclosed, but no agreement about whether the disclosure should explain the possible impact of those relationships. Again, concern about overcomplicating the consent statement semed to be at the root of these issues. Some respondents said the disclosure should include an explanation of how an unscrupulous investigator might alter the research results.

Most respondents dismissed the idea that disclosure could lower enrollment. There was little sympathy among the group for researchers who complained that full disclosure was an invasion of their financial privacy.

There was also concern about how to best highlight disclosure information without overemphasizing its importance or potential risk to a study's integrity. Some respondents said their consent form highlights the information in bold type, while others place it strategically in the document—at the very beginning, for example. Many also emphasized that the informed consent process should include a discussion of conflict of interest, not just a read-through of the document.

"Our data suggest that it will be difficult to achieve agreement on the issue of substantial understanding of financial interests," the researchers concluded. ■