NIH Provides Policy Clarification Concerning Disclosure Requirements for Reimbursed and Sponsored Travel - 42 CFR Part 50 Subpart F, "Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought"

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Key Dates

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National Institutes of Health (NIH)

Purpose

NIH is providing policy clarification concerning Investigator disclosure of reimbursed or sponsored travel under the Final Rule at 42 CFR Part 50 Subpart F, "Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought."

Consistent with NIH's March 2012 policy clarification concerning disclosure requirements for reimbursed and sponsored travel (See Frequently Asked Questions E.1. posted on NIH's Office of Extramural Research, Financial Conflict of Interest (FCOI) Web site), Investigators who are planning to participate in PHS-funded research must disclose their Significant Financial Interests (SFIs) over the previous twelve-month period to their Institution no later than at the time of application for PHS-funded research. As with other SFIs defined in 42 CFR 50.603, the Investigator must disclose his/her interests, as well as those of the Investigator's spouse and dependent children, that reasonably appear to be related to the Investigator's institutional responsibilities.

During the rule making process, we considered how to best balance the need for the Institution to have information on an Investigator's reimbursed or sponsored travel versus the added burden on the Investigator to disclose the value of travel reimbursements. Particularly in the case of sponsored travel, which is paid on behalf of the Investigator, the exact monetary value may not be readily available to the Investigator. The Final Rule, therefore, does not require Investigators to disclose the monetary value of the sponsored or reimbursed travel; rather, it is the Institution's responsibility to determine upon review if further information, such as the monetary value of the travel, is needed. Accordingly, the Final Rule does not impose a general requirement to apply the de minimis threshold to all reimbursed or sponsored travel disclosure. With that said, in response to requests for further clarification, we want to make clear that Institutions may, within the discretion afforded by the Final Rule, impose the \$5,000 de minimis threshold to reimbursed or sponsored travel disclosure in their institutional policies which specify the disclosure details. For example, consistent with the requirement for other types of financial interests within the regulatory definition of SFI, Institutions could apply the de minimis threshold when aggregated per entity. Disclosure of reimbursed or sponsored travel is also subject to the exclusions described in 50.603(3). However, it remains NIH's position that Investigators must disclose their SFIs, including reimbursed or sponsored travel, no later than at the time of application over the previous twelve-month period (initial disclosure), which is also the same disclosure requirement that applies to all other SFIs. The initial disclosure of SFIs over the previous twelve-month period provides baseline information that allows Institutions to take into account whether Investigators have an ongoing financial relationship with an entity providing a payment or reimbursement or whether the payment or reimbursement was limited in duration. Once Investigators have made their initial disclosure, they are required to update their disclosures within 30 days of discovering or acquiring a new SFI and annually during the period of award. We believe that these disclosure requirements provide Institutions with a comprehensive understanding of an Investigator's SFIs related to the PHS-funded research project.

In addition to this Notice, NIH will post and update FAQs on the NIH Office of Extramural Research, Financial Conflict of Interest Web site for reference by the grantee community to capture the clarification provided above.

Inquiries

Please direct all inquiries to:

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