

## The Third OIG Risk Area: Reporting Financial Support from Other Sources—Overview and Risk Assessment

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*This article is the third of a three-part series addressing the research compliance risk areas highlighted by the Office of the Inspector General of the Department of Health and Human Services in its Nov. 2005 proposed guidance on compliance programs in the federal research area. The articles are intended to provide an overview of the applicable federal rules in each risk area and to identify the issues in each area that present the greatest problems for grantees.*

*The January issue of Report on Research Compliance discussed time and effort reporting; the February issue reviewed allocating charges to federal awards.*

The reporting of financial support from other sources is the third risk area in the Office of Inspector General (OIG) of the Department of Health and Human Services (HHS) proposed compliance guidance for recipients of Public Health Service Awards.<sup>1</sup> This risk area has not been the focal point of any of the recently reported federal investigations of universities and research institutions, but the issue has been raised in several of them. It is an issue that deserves close attention, if only because the potential risks of systematic noncompliance are very high and the consequences may be severe.

This article addresses the reporting of research support from other sources as required by the policies of the National Institutes of Health (NIH).

### NIH Policy Guidance on the Reporting of 'Other Support'

When applying for an award from the NIH, the applicant must report all active and pending sources of other financial support for the research projects of the key personnel listed in the grant application. "Active" support includes funded research projects on which the researcher is currently working. "Pending" support refers to proposed research projects to which the researcher intends to devote effort if they are funded. Key personnel include the principal investigator (PI) and other individuals "who contribute to the scientific development or execution of a project in a substantive, measurable way, whether or not they receive salaries or compensation under the grant."<sup>2</sup>

NIH defines this category of funding from other sources (commonly referred to as "other support") to include

all financial resources, whether Federal, non-Federal, commercial or institutional, available in direct support of an individual's research endeavors, including, but not limited to, research grants, cooperative agreements, contracts, and/or institutional awards. Training awards, prizes, or gifts are not included.<sup>3</sup>

Applicants must submit complete and up-to-date other support information for key personnel (excluding consultants) before an award may be made. Pursuant to NIH's "just-in-time" procedures, other support information is submitted upon the request of NIH staff when the award application is under consideration for funding. Once an award is funded, grantees must report any changes in other support for key personnel as part of the annual progress report to NIH.

The reporting of other support at the initial application phase helps the NIH awarding officials to assess whether federal dollars should be awarded to the applicant for the proposed research, or whether because of budgetary, commitment, or scientific overlap, federal investment in the project is unwarranted. NIH does not permit overlap of any kind. By identifying and eliminating overlap, NIH aims to ensure the following:

- (1) Sufficient and appropriate levels of effort are committed to the project.
- (2) There is no duplication of funding for scientific aims, specific budgetary items, or an individual's level of effort.
- (3) Only funds necessary to the conduct of the approved project are included in the award.<sup>4</sup>

### Three Overlap Categories

NIH has identified three different categories of overlap — (1) commitment, (2) budgetary, and (3) scientific — and defined them as explained below.

**Commitment Overlap.** Commitment overlap occurs when an individual's time commitment to research projects exceeds 100 percent, regardless of whether salary is requested for that individual in the application. This rule is consistent with NIH's overall requirement that no individual on the project is permitted to have commitments exceeding 100 percent of total effort.

**Budgetary Overlap.** Budgetary overlap occurs when an application includes budgetary items, such as equipment or salary, that have already been provided for by another source.

**Scientific Overlap.** Scientific overlap occurs when: "(1) substantially the same research is proposed in more than one application or is submitted to two or more different funding sources for review and funding consideration, or (2) a specific research objective and the research design for accomplishing that objective are the same or closely related in two or more applications or awards, regardless of funding source."<sup>5</sup>

NIH instructs individuals to include a summary of whether an active or pending award overlaps in scientific, budgetary, or commitment terms with the work proposed in the application.

If there is no overlap, a simple statement indicating as much will be sufficient.

If there is overlap, the applicant should include an explanation of how the overlap would be eliminated should the application be funded. NIH staff consult with the principal investigator and other applicant institution officials to resolve any overlap issues at the time an award is made. Annual reporting of changes in other support for key personnel by the grantee to NIH helps to ensure that overlap does not become an issue in later grant budget periods.

### **Compliance Risks**

As the HHS OIG noted in its proposed guidance, materially misrepresenting other support information or failing to provide other support information could subject an institution to civil or criminal fraud liability under the False Claims Act or other fraud statutes. Both the principal investigator and representative of the applicant institution certify that the grant application, including just-in-time submissions, contain true, complete, and accurate information. In its proposed compliance guidance, the HHS OIG characterized the provision of "complete and accurate" other support information as "critical" to an awarding agency's ability to determine whether a particular application should receive funding.

**Risk to Entire Award.** Unlike effort reporting or cost allocation errors, which generally result only in disallowance of particular unsupported charges to an award, misrepresenting other support could put the entire award at risk. To the extent that an applicant's misrepresentation of other support information prevents an agency from recognizing scientific overlap—an issue that potentially could cause the agency to modify the award or not fund it at all—it is conceivable that federal officials would deem the entire award invalid.<sup>6</sup>

### **The Scope of 'Other Support' Reporting**

The scope of the "other support" reporting requirement is quite broad but does have some limits.

**Research Endeavors.** First, NIH requires applicants to list only other sources of financial support related to individuals' "research endeavors." The HHS OIG's proposed guidance incorrectly describes the scope of the other support reporting requirement when it states that the applicant institution "must disclose all compensation and salary support."<sup>7</sup> As the NIH policy guidance makes clear, the reporting of other support does not include salary or compensation received for teaching, training, or other nonresearch endeavors.

Second, the NIH grant application instructions indicate that an individual researcher should list *all* research endeavors in which he or she is involved, regardless of whether salary is received for any effort contributed. Specifically, the NIH instructions state that "[c]ommitment overlap occurs when a person's time commitment exceeds 100 percent, whether or not salary support is requested in the application."<sup>8</sup>

While this directive appears to refer only to whether salary support is requested in the application under review, the overall objective of NIH is to use the other support information to determine whether an individual's time commitment is greater than 100 percent. Therefore, individuals must list all research endeavors, including those for which they do not receive compensation.

This instruction may seem to be at odds with the NIH definition of "other support," which is expressed in terms of the receipt of "financial resources," but it is important to note that even if an individual is not receiving financial support in the form of salary for his effort on a research grant, he is likely still using the outside financial resources in the form of equipment or supplies.

Third, in the past applicant institutions and individuals may have felt obligated to report only other support that an individual researcher receives through the applicant institution. Now NIH expects applicants to report *all* financial support from other sources that are available to an individual researcher, even if the other support does not flow through the applicant institution, but, instead, is awarded directly to the individual researcher or to another institution with which the researcher is also associated.

This requirement puts the applicant institution in the difficult position of having to certify the accuracy of the scientific, commitment, and budgetary terms of the outside support, even though the institution itself does not hold the relevant records and is not a party to the research agreement under which that support is provided. For example, it may be difficult for the applicant institution to verify an individual's effort spent on research grants awarded through another institution, be-

cause grantees are required to report and certify only the effort spent by an individual on activities performed directly for the institution. Consequently, time spent on "outside" research projects generally will not be included in an individual's total institutional effort. Nonetheless, NIH at least has been quite clear in stating that key personnel must include in "other support" not only institutional awards, but also "outside" research projects funded by others.

**Reporting Clinical Trials as Other Support.** A final issue worth discussing with respect to the scope of "other support" is how an individual researcher should account for his involvement in industry-sponsored clinical trials. Many researchers are engaged in multiple industry-sponsored clinical trials, most of which require very little effort or time on the part of the researcher. It is sometimes difficult to measure precisely the effort associated with each of the clinical trials because the effort amounts are generally so small and because they vary greatly depending on the phase of a particular trial. An individual researcher may question whether it is necessary to include in his list of "other support" dozens of clinical trials in which he spends less than 1 percent of effort in any given time period.

Nonetheless, NIH makes it clear that in order to comply with the reporting requirements for other support, individuals must include such clinical trials in their list of funded research endeavors. One way of doing so without listing each individual project is to report aggregate effort on the industry clinical trials as a group. This approach appears to be acceptable to NIH, as long as the aggregate effort does not exceed 10 percent. To do so, the researcher should list each clinical trial sponsor separately and provide an explanation as to why he has determined it is best to report his involvement in an aggregate form.

### **Commitment and Scientific Overlap**

The HHS OIG's proposed guidance raised several issues regarding the propriety of submitting multiple applications to different awarding agencies, and whether doing so violates restrictions on commitment and scientific overlap. Given the competition for federal research dollars, it is not unusual for investigators to have multiple applications pending with different awarding agencies. While this practice is generally acceptable, there are certain guidelines that applicants must follow in order to prevent commitment and scientific overlap.

**Commitment Overlap.** As an example of commitment overlap, the OIG stated that it would be "clearly improper for researchers in award applications to separately report to three awarding agencies that they intend

to spend 50 percent of their effort on each of the three awards." The OIG seems to presume that if all three applications were awarded, there would be a clear violation of NIH's policy that an individual's commitments may not exceed 100 percent.

Aside from the fact that there is usually no assurance or even likelihood in such circumstances that all three proposals will be funded, this assumption ignores the interactive way in which NIH finalizes award decisions through discussion with the applicant institution and principal investigator. During this process adjustments are often made to the research proposal, including changes to level of effort for key personnel if commitment overlap is a concern. By handling the proposal review process in this way, NIH enables applicants to have multiple applications pending at one time, and doing so is acceptable as long as certain guidelines and restrictions are followed.

When submitting other support information to NIH, researchers should list the actual effort for the current budget period of active research awards. The other support information should also include all pending awards, and researchers should list their proposed effort for the initial budget period of each pending award.

As explained in the NIH grant application instructions and the policy guidance regarding other support, resolution of the overlap occurs at the time of an award through discussions with the applicant institution officials, the principal investigator, and awarding agency staff.

If resolving the commitment overlap would require an individual to reduce his effort on a different NIH grant for which he is considered "key personnel," he may need to secure advance approval from the appropriate NIH official for that award. Grantees must notify the NIH grant officer in writing if the principal investigator or other key personnel specifically named in the notice of grant award will withdraw from the project entirely, be absent from the project for a continuous period of three months or more, or reduce time devoted to the project by 25 percent or more from the level that was approved at the time of the award. NIH must approve any alternate arrangement proposed by the grantee.<sup>9</sup>

Finally, it is important to note that although the reporting of other support information helps NIH and grantee institutions to monitor an individual's commitments to research projects, it does not always provide an accurate portrayal of overall effort by an individual on an institutional basis because it does not include instruction or other nonresearch activities. Grantee institutions

should ensure through their internal proposal review procedures that the effort to which the researcher committed in a proposal is consistent with all of the researcher's other commitments, not just his research commitments.

**Scientific Overlap.** In its discussion of reporting financial support from other sources, the HHS OIG expressed particular concern that without accurate and complete information, NIH may provide duplicate funding to a project whose research aims are already being supported by another source. NIH and the National Science Foundation (NSF) are particularly sensitive to this issue, because the two agencies sometimes have related research funding interests.<sup>10</sup>

NIH's policy on scientific overlap clearly prohibits applicants from proposing identical or substantially similar research projects to two or more different funding sources. The two exceptions to this general rule are K-series training awards and individual research projects that are identical to a subproject that is part of a P-series grant.

This rule does not, however, prohibit an individual from submitting applications proposing to conduct research in related but distinct parts of a larger research question. If this is the case, an applicant must take care to ensure that "a specific research objective and the research design for accomplishing that objective" are not the same or closely related in two or more applications for awards, regardless of the funding source.<sup>11</sup> One way to help assure the awarding agency that a particular proposal is distinct from other related proposals would be to include a brief explanation of the relationship between the two in the other support information.<sup>12</sup>

### Issue Merits Renewed Attention

In some respects the requirement to report "other support" is a relatively straightforward compliance matter. Upon close examination, however, the requirement is not without ambiguity, and the HHS OIG's recent focus on it suggests that it deserves renewed attention. NIH considers the review of an applicant's active and pending other-support information to be an important part of the funding decision process, as well as a method for monitoring the ongoing commitments of key personnel. Institutions, therefore, must make it a priority to ensure that individual researchers properly include and describe all their research activities, including those only in the proposal stage. Institutional policies and procedures related to the reporting of other support should serve as a safeguard to prevent scientific, budgetary, and commitment overlap by investigators and their institutions.

### Footnotes

1. 70 Fed. Reg. 71312. (Nov. 28, 2005).
2. *NIH Grants Policy Statement*, Part I, at p. 11 (Dec. 2003).
3. NIH NOT-OD-03-029, "Reminder to Applicants About Requirement to Submit Complete and Up-to-Date Other Support Information" (Feb. 13, 2003); *NIH Grants Policy Statement* (Dec. 2003).
4. *Id.*
5. *Id.*
6. At NSF, the OIG has been known to suggest that the misrepresentation of other support may constitute scientific misconduct, because it is a misstatement in a proposal for an NSF award.
7. 70 Fed. Reg. 71312, 71316.
8. PHS 398 Instructions, Part III, p.6.
9. *NIH Grants Policy Statement*, Part II, p. 107.
10. The NSF policy on "other support" is very similar to NIH, although not set out in as much detail. Although the *NSF Grant Proposal Guide* refers only to listing current and pending other "project support," this requirement is commonly understood to refer to research activities. *NSF Grant Proposal Guide*, II. C.2.h, p. 31. Applicants should provide the total award amount (not just the initial budget period), as well as the effort devoted to the project per year. If the combined effort on current and pending research projects would exceed 100 percent effort by the researcher, he should include a statement explaining how effort would be adjusted if the pending application is funded.
11. PHS 398 Grant Application Instructions, Part III, p. 6.
12. Unlike NIH, nearly all NSF directorates permit applicants to submit the same proposal to more than one funding source. NSF explicitly states that "[c]oncurrent submission of a proposal to other organizations will not prejudice its review by NSF." The Biological Sciences Directorate, however, will not accept proposals that are also being submitted to other federal agencies for simultaneous consideration. Presumably, awards submitted to this directorate would be the ones most likely to duplicate NIH proposals. The only exceptions to the directorate's rule are: (1) when the applicants and program officers at the relevant federal agencies have already agreed to joint review and possible joint funding of the proposal, and (2) when the award is proposed by a "beginning investigator," i.e., one who has never served as a principal investigator or co-principal investigator on a federal award. *NSF Grant Proposal Guide*, "Overview," p. 10.