FEDERAL GRANTS NEWS
for Colleges and Universities

In This Issue

NIH Conducts Site Visits to Review Conflict-of-Interest Management Practices

The National Institutes of Health (NIH) has concluded its visits to three Chicago-area universities to review compliance with the "objectivity-in-research" regulations (42 CFR §§ 601–607). The objectivity-in-research regulations, which have been in place since July 1995, ensure that PHS-funded research is not compromised by financial interests of investigators that could "be reasonably expected to bias the design, conduct or reporting of the research." The regulations require institutions to: (1) disclose potential sources of significant financial interest; (2) manage, reduce or eliminate those financial interests if they would "reasonably appear to be directly and significantly affected by the research funded by PHS"; and (3) report the management and elimination of potential conflicts to PHS.

The site visits are targeting conflict-of-interest management, and one of NIH's goals is to determine whether institutions are notifying NIH of conflicts that have been managed or eliminated. NIH wants to know what procedures universities follow to comply with this requirement.

continued on p. 4

Universities Raise Concerns about NIH Electronic Proposal Submission

After sponsored research administrators had time to digest the impact of the National Institutes of Health (NIH) announcement in late August of its plans to transition all proposal submissions to Grants.gov by FY 2007, many of them needed to sit down.

Most colleges and universities had submitted at least one proposal through the Grants.gov portal, using the government-specified PureEdge software, and many found the submission process time-consuming. Still, sponsored research administrators believed it was suitable for solicitations where an institution was likely to submit only a few proposals. But with the NIH announcement, they realized that in FY 2006, they would have to submit approximately 75 percent of all their federal funding proposals through the electronic portal.

In addition, the new SF424 Research and Related (R&R) would serve as the electronic application. The new form requires institutions to report budget and other data in a very different way than the current PHS 398. For example, instead of reporting percent of effort, as the PHS 398 now requires, salaries will be shown on the SF424 (R&R) as person-months. These changes could result in more corrections to applications than were the norm in the past, and institutions only learned how to correct the SF424 (R&R) when NIH released the *NIH Grants.gov Application Guide (SF424 (R&R))* on October 27. The submission procedures explained in the application guide add a significant amount of time to the process and, in effect, change the concept of "deadline."

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Consequently, college and university representatives met with officials from the NIH at a recent Council on Governmental Relations session to express their concerns. The university representatives told NIH that the campus community has few resources to test the electronic submission process, and the transition period to learn to use Grants.gov for large numbers of proposal submissions is short.

Submission Will Be a Two-Step Process

The NIH application guide explains a two-step process for application submission. First, the electronic SF424 (R&R) is submitted using the Grants.gov portal, and an e-mail is sent to confirm receipt. Then, the application is downloaded into the eRA Commons (formerly the NIH Commons), for validation.

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Once the validation is complete, the Commons sends an e-mail to the principal investigator (PI) and the signing official (SO) indicating whether the validation process yielded any errors or warnings. At that point, the PI and SO have two business days to verify the proposal or correct any errors that make the proposal unacceptable under NIH guidelines and resubmit it. If resubmission is necessary, the two-step process begins again.

The university representatives questioned whether verification by the SO was necessary, and NIH indicated that it would reconsider that requirement. Verification by the PI, however, cannot be eliminated because Grants.gov cannot accept PI certifications. NIH officials are discussing the PI certification requirement with legal counsel to try to find an alternative.

NIH also clarified that the PI and SO may not change or correct the technical portion of the application until the validation of the submission is complete. In fact, the first time an applicant will be able to see the proposal in its final form and make corrections is after validation through the eRA Commons.

What Is a Timely Proposal?

One confusing aspect of the NIH process is what constitutes a timely proposal. For example, if an application is submitted through Grants.gov on the deadline, and the subsequent review/validation requirement reveals a "fatal" flaw in the proposal, would the proposal still be considered timely if the correction and resubmission were made two days after the deadline?

NIH's response was clear: If errors found during the Commons' validation process are addressed after the deadline, the changed or corrected application would be considered late. It will allow some flexibility during the early learning phases of the process, but applicants will need to explain the reasons for the delay in a cover letter.

Verification Process Affects Deadlines

This process, from receipt of the first e-mail from Grants.gov to download into the Commons for verification, is estimated to take between 24 and 72 hours after submission of the proposal, and the verification must be completed in two business days. The result is that an October 1 submission deadline really means a deadline at least four to five days earlier to ensure time to verify or correct errors.

Institutions will need to clearly communicate this circumstance to their faculty and administrators and set internal deadlines to mitigate the risk of late proposals.

No Change in Proposal Time Deadline

The application guide requires proposals to be submitted by 8:00 p.m. Eastern time on the day of the deadline. While the NIH officials agreed to consider changing this, NIH subsequently decided to maintain the time deadline. Now institutions will need to establish their own deadlines to reflect their time zone.

Web Page Provides Assistance

Overall, the NIH officials were receptive to the universities' concerns. The application guide, they said, was a "work in progress," and they will consider other suggestions from the grantee community. For example, they will begin work on various reports in the Commons that should assist institutions in assessing the verification status of all of their proposal submissions.

NIH also has posted various presentations, form samples, and demonstration information on its Web site — http://era.nih.gov/ElectronicReceipt/training.htm. It also plans to host a video conference on the SF424 (R&R) and the transition to electronic submission. (The tentative date is Jan. 11, 2006). Finally, the NIH officials have been working on plans to place a "test" funding opportunity announcement in Grants.gov. Institutions could use this announcement to "submit" test applications that would go through the entire submission process to Grants.gov and continue to the eRA Commons.

It should be noted that in FY 2005, approximately 16,000 proposals were submitted through Grants.gov to all funding agencies. The approximately 1,000 small business proposals that are anticipated for the first NIH submission (SBIR/STTR) in December will serve as a real test for the system and the application process. ✧

Commerce Publishes Final CREATE Act Implementation Rule

The Department of Commerce's Patent and Trademark Office has amended the patent laws to implement the Cooperative Research and Technology Enhancement Act of 2004 (CREATE Act). The CREATE Act was designed to encourage collaborative research between teams of researchers from different organizations.

Under patent law, an invention may be deemed obvious because of the amount of information or prior art available before the patent application. The CREATE Act amended the patent laws to provide an exemption from the "prior art" invalidation rules for confidential disclosures among collaborators. This safe harbor is already available to collaborators with the same employer.

The rule defines "joint research agreement" as "a written contract, grant, or cooperative agreement entered into by two or more persons or entities for the performance of experimental, developmental, or research work in the field of the claimed invention."

Three conditions must be met in order to allow recognition of an invention:

(1) The claimed invention was made by or on behalf of parties to a joint research agreement that was in effect on or before the date the claimed invention was made.

NEWS FROM THE ANIMAL FRONT

◆ **Class B Dealers.** A proposal that would have placed greater restrictions on where research facilities could purchase lab animals has been dropped from the final language of the 2006 Agriculture appropriations bill. Sen. Daniel Akaka, D-Hawaii, had incorporated the provision into the Senate version of the bill. The provision would have prohibited funding by the U.S. Department of Agriculture (USDA) or the Food and Drug Administration to institutions that acquire animals from "Class B" animal sellers, who collect animals from sources such as pounds. The amendment was based on the assumption that dogs and cats are routinely stolen and sold to research facilities. If it had passed, the amendment would have had a chilling effect on animal research, because many types of animals are acquired through Class B dealers, including nonhuman primates.

◆ **Publication of Annual Reports.** Research facilities are required to submit an annual report to the Department of Agriculture's Animal and Plant Health Inspection Service (APHIS). APHIS has been publishing these reports on its Web site, but on advice of legal council, has stopped withholding confidential business information, such as the name of the institution's responsible official (the person signing the report). There is concern in the animal research community that the publication of the administrative official's name, while it is probably available elsewhere, may give rise to harassment by various groups opposing research involving the use of animals.

(2) The claimed invention was made as a result of activities undertaken within the scope of the joint research agreement.

(3) The application for patent for the claimed invention discloses, or is amended to disclose, the names of the parties to the joint invention.

Review Policies, Other Agreements

As research collaborations continue to increase, particularly between faculty at different institutions, the sponsored programs administrator will want to revisit policies addressing collaborative agreements. To take advantage of the CREATE Act safe harbor in new or existing research collaborations, the work scope should be examined carefully and written or amended to reflect the broadest scope of the project. The standard wording states that any invention in the project would be subject to the CREATE Act provisions. Faculty should be made aware of the act as they contemplate research collaborations.

In addition to research agreements, institutions also should consider the effect of the act on any material transfer agreements or cooperative research and development agreements. Finally, the institution should consult with the institution's patent counsel or technology transfer office to confirm that the institution is taking the best course of action to take advantage of the CREATE safe harbor. The rule appears in 70 Fed. Reg. 54259 (Sept. 14, 2005). It applies to any patent granted on or after December 10, 2004. ✧

Conflict-of-Interest Site Visits

continued from p. 1

NIH Expects Mandatory Training

The initial feedback from the Chicago institutions is that the one-day site visits were cordial and constructive. The visits consisted of a process-and-documentation review and faculty/staff interviews. For the most part, the institutions set the agenda with NIH input.

One of the outcomes of the reviews is that NIH expects institutions to conduct some type of "mandatory" conflict-of-interest training for investigators, even though training is not required by any regulation or policy. For training purposes, NIH applies a broader definition of "investigator" than institutions. The NIH definition includes anyone participating in funded research (e.g., postdoctoral fellows, graduate students, and laboratory technicians); normally institutions would include only "key personnel."

NIH also focused on the institutions' ongoing maintenance or monitoring of the management plan. Institutions should assess their practices in this area, regardless of whether they use a series of questions at the anniversary date of the management plan or fold the monitoring into the annual review for faculty. Finally, NIH reviewed how the prime institution receives information on subgrantee conflict of interests and what follow-up procedures it uses with subgrantees.

Visits May Not Continue

All participants seemed to agree that the Chicago visits were constructive and that NIH had a positive impression of the universities' conflict -of-interest management practices. Whether NIH will continue these site visits or whether the Chicago experience was enough to show it that institutions were making good faith efforts toward compliance remains to be seen. ✧

NIH Site Visits Are Not New

NIH began conducting reviews of institutional conflict-of-interest policies in FY 2000 as one of five focus areas in its proactive compliance site visits. During these site visits, NIH reviewed documentation that included: the institution's written, enforced policy; organizational charts that showed where the conflict-of-interest function was housed; conflict-of-interest files maintained by the institution; minutes of conflict-of-interest meetings; determinations or findings made by the designated official; conflict-of-interest management plans; and correspondence, if any, between the institution and NIH relating to the conflict-of-interest process. The compendium of its findings and observations from the past visits is found at http://grants2.nih.gov/grants/compliance/compendium_2002.htm#rpt .

In 2004 NIH collected financial conflict-of-interest policies from grantee institutions across the country. In its assessment of these policies, NIH found that, in general, "institutions have developed policies that reflect a serious desire to inform and assist their investigators in complying with the regulation. Some policies provide more helpful information than others." NIH offered suggestions for strengthening policies concluding that "a complete, single institutional policy document, replete with citations and weblinks to supporting institutional policies and federal and state regulations, provides the greatest source of information and guidance to investigators."