

FEDERAL GRANTS NEWS

for Colleges and Universities

In This Issue

- 2** Agencies Require Terrorism and Prostitution Certifications
- 2** What Were Those FOIA Requirements?
- 3** 'Other' Agreements — How They Impact Grant Compliance
- 3** DKT Sues USAID Over Certification
- 4** Important Correction

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NIH Announces Its Transition Timetable for Electronic Submission of SF424 (R&R)

The National Institutes of Health (NIH) has changed the timetable for its transition to the electronic submission of SF424 Research and Related (R&R) through Grants.gov, and some colleges and universities may have to scramble to meet the new deadlines. SF424(R&R) is the new grant application form tailored to research funding.

NIH made its long-awaited announcement in the *NIH Guide* on August 19. It set out a transition timetable for five research program/funding mechanisms. For other programs, NIH promises to provide at least four-to-six-months' notice before transitioning them to electronic submission of the SF424 (R&R). However, to prepare for the transition, it advised institutions to make sure they are registered with both the NIH Commons and Grants.gov. The NIH Commons will remain a communication vehicle for interactions between NIH, Grants.gov, and the grantee community. (See <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-067.html> for the notice).

By the end of 2007, the agency will require electronic submission of all applications through Grants.gov using the SF424 (R&R) in lieu of the PHS 398 application. According to the announcement, once each transition date passes, NIH will require use of Grants.gov, and there will be no other submission options for that particular mechanism. It will accomplish the transition in steps, based on the following timetable:

continued on p. 4

OMB Moves Cost Principles Circulars, Debarment/Suspension Guidance to 2 CFR

The Office of Management and Budget (OMB) has jump started its effort to locate grant policy guidance in Title 2 of the Code of Federal Regulations (CFR) by announcing the move of the cost principles circulars and the debarment and suspension guidance. 70 Fed. Reg. 51862 (Aug. 31, 2005). OMB originally announced its intent to house all the guidance as well as agency regulations in 2 CFR in May 2004 as part of the streamlining initiative mandated by the Federal Financial Assistance Management Improvement Act of 1999 (Pub. L. 106-107). At that time, it published Circular A-110 as 2 CFR Part 215 but had not made any other changes.

Circular A-21, *Cost Principles for Educational Institutions*, is now Part 220 in 2 CFR (2 CFR 220); the circular itself (with its exhibits and attachments) is Appendix A. 70 Fed Reg. 51880 (Aug. 31, 2005). OMB placed A-21, as well as the other cost circulars, in Chapter II of Subtitle A, Title 2, without revision, because it is awaiting proposals from an interagency work group with additional streamlining changes. Once any changes are finalized, following a comment period, then the circulars will move into Chapter I, which houses final OMB guidance.

In addition to designating A-21 as 2 CFR 220, Circular A-87, *Cost Principles for State, Local, and Indian Tribal Governments*, moves to 2 CFR 225, and Circular A-122, *Cost Principles for Non-Profit Organizations*, to 2 CFR 230.



The A-21 announcement also updated citations and references in, and made corrections to, OMB Circular A-110. The primary change to A-110 reinstates the Freedom of Information Act (FOIA) requirements that were previously in A-110 but were inadvertently left out of the circular when it moved to 2 CFR 215. The FOIA requirements themselves did not change. See box, next column.

Debarment and Suspension Now in Part 180

On the same day it issued the other notices, OMB published updated guidance for agencies on nonprocurement debarment and suspension. 70 Fed. Reg. 51863 (Aug. 31, 2005). The guidance now reflects the provisions of the Common Rule, as updated on November 26, 2003. Because the debarment and suspension regulations were revised recently, OMB does not expect

What Were Those FOIA Requirements?

As a reminder, these FOIA requirements, now in 2 CFR 215.36(d), address the availability of research data in the possession of grantees and subject that research data to a FOIA request if it is related “to published research findings produced under an award that was used by the Federal Government in developing an agency action that has the force and effect of law.”

any changes in the near term and has located them as Part 180 in Chapter I of Subtitle A of 2 CFR. The debarment and suspension guidance applies to federal agencies and to transactions colleges and universities make with federal funds. In most cases, this applies to subawards and to purchase orders of \$25,000 or more where federal funds are involved. ✧

Agencies Require Terrorism and Prostitution Certifications

College and university sponsored program administrators are used to the variety of regulations that apply to federally funded grants and contracts—many of which have very little to do with research and research-related projects. Some requirements are universal and imposed by all agencies; others have limited scope. Certifications regarding terrorism, prostitution, and sex trafficking fall into the latter category.

USAID Imposes Terrorism Certification

The U. S. Agency for International Development (USAID) requires certification regarding terrorist financing. The certification implements Executive Order (EO) 13224, “Blocking Property and Prohibiting Transactions with Persons Who Commit, Threaten to Commit, or Support Terrorism. “ The EO prohibits “the making or receiving of any contribution of funds, goods, or services to or for the benefit of” persons who are either named in the order or who are determined to be subject to the order.

The certification requirements, which first became effective December 31, 2002, under Acquisition and Assistance Policy Directive (AAPD) 02-19, are set out in AAPD 04-14 (Sept. 24, 2004). AAPD 04-14, which replaced AAPD 04-07 (March 24, 2004), clarifies for applicants what they are certifying, specifically that “to the best of its current knowledge,” the applicant did not provide funds to terrorist organizations “within the previous ten years” and that it will take “reasonable steps” and use all information that is

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“reasonably available” to ensure that it does not support terrorist activity. The applicant also must verify that a person or entity does not appear on two lists:

(1) OFAC’s master list, Specifically Designated Nationals and Blocked Persons (www.treats.gov/offices/eotffc/ofac/sdn) and (2) the U.N. Security Sanctions Committee list, www.un.org/Docs/sc/committees/1267/1267ListEng.htm.

USAID is the only agency that has formally implemented the EO by requiring certification at the time of proposal submission. The AAPDs are posted at www.usaid.gov/business/business_opportunities/cib/year/2004.html.

New CDC and USAID Certifications

Recent program announcements from the Centers for Disease Control (CDC) and USAID require a fund applicant or recipient to certify that it has a policy explicitly opposing prostitution and sex trafficking. The certification has its roots in Pub. L. 108-25, United States Leadership against HIV/AIDS, Tuberculosis, and Malaria Act of 2003. USAID has implemented the requirements through AAPD 05-04 (June 9, 2005) (www.usaid.gov/business/business_opportunities/cib/year/2005.html). The certification, which is applicable to both new and existing awards, is included as a standard provision for assistance agreements and contracts with HIV/AIDS program funding. See box, next column, for related story.

CDC has inserted essentially the same requirements in recent funding announcements under “Funding Restrictions.” ♦

‘Other’ Agreements — How They Impact Grant Compliance

As most college and university research administrators are aware, faculty researchers often fund their activities through a number of sources, including grants and other agreements from the federal and/or state and local governments, funding from private

DKT Sues USAID Over Certification

The Council on Governmental Relations is reporting that organizations and agencies that provide direct service to HIV/AIDS patients have significant concerns about the requirement that awardees have a policy opposing prostitution and sex trafficking. On August 11, 2005, DKT International, a large nonprofit, Washington-based organization that provides family planning and AIDS prevention contraceptive social marketing programs in Africa, Asia, and Latin America, filed suit against USAID, challenging the policy as an “unconstitutional infringement of speech that undermines efforts to stem the spread of HIV/AIDS.” For more information, go to www.dktinternational.org/dkt_sues_usaid.htm.

foundations, and agreements with private industry. Because most faculty research programs follow one line of inquiry with different branches for different funding, faculty research activities often are so intertwined that it is difficult to clearly separate the product of one research project from another.

Protect Ownership Rights under Bayh-Dole

Despite the tangle, it is important that the institution ensure that it protects the federal intellectual property rights granted under 37 CFR 401 (commonly referred to as “Bayh-Dole”), including the right to retain title to an invention. 37 CFR 401 does not allow the transfer of ownership of inventions to another entity without agency approval and requires that the government receive a nonexclusive royalty-free license to any invention made with federal funds. If the federal rights are not adequately protected in any agreement with a nonfederal source, there may be adverse consequences if the faculty member has or plans to use federal funding.

Subawards made by another college or university or state or local government utilizing federal flow-through funding are not a concern because Bayh-Dole

ELECTRONIC ROUNDUP

♦ **NIH Manuscript Submission System.** The NIH is providing new functionality in its Manuscript Submission System to allow third parties, with the author’s permission, to upload manuscripts into the system. Information about the system and the new functionality can be found at www.nihms.nih.gov.

♦ **NSF FAQ.** The National Science Foundation has published a very useful list of frequently asked questions and answers on proposal preparation and award administration on its Web site — www.nsf.gov/pubs/gpg/faqs.pdf.

Important Correction

In the July / August issue of *Federal Grants News*, on p. 3, "NSF Revises Grant Guidance," the first bullet should have read "Requests for prior approval must *now* be submitted electronically via FastLane."

applies to these awards. However, agreements with foundations and other nonprofit organizations as well as commercial entities will need scrutiny.

These funding agreements may contain patent terms that are contradictory to Bayh-Dole. For example, some organizations require, at a minimum, joint ownership, or sometimes assignment, of patents developed under their awards. The college or university either must modify these agreements to meet the federal requirements, or it must assess the relationship between a researcher's privately funded and federally funded projects for potential conflicts. In the case of commercial entities, the college or university may need to negotiate terms with the company. While this may be difficult, it is usually successful.

The Materials Transfer Agreement

In addition to direct grants or agreements for project funding, several other types of agreements should be considered in light of Bayh-Dole. One of these is the Materials Transfer Agreement or MTA. MTAs govern the transfer of materials from one entity to another and set forth the conditions under which the materials may be used and the obligations of the recipient, particularly in the area of intellectual property.

MTAs with commercial concerns often present a challenge. Typically the materials being transferred are needed to conduct a federally funded research project, but the company is likely to consider the materials proprietary. The MTA may contain intellectual property terms that are contrary to Bayh-Dole. Many MTAs require any patents developed using the transferred materials to remain the property of the supplying company; however, if the materials are used on a federally funded project, the fund recipient is not permitted to give ownership away. The only solution is to negotiate terms and conditions that do not infringe on Bayh-Dole rights. Most of the time this can be done, but not always.

Consulting Agreements Cause Headaches

Consulting agreements with for-profit companies also may conflict with Bayh-Dole. These are further complicated by the fact that the terms and conditions of

consulting agreements are usually a private matter between the company and the faculty member. The college or university is not a party to these agreements and, with some exceptions, will not even review the agreements.

Most consulting agreements contain intellectual property language that gives ownership of any work produced under the agreement, including inventions, to the company. Yet, because the faculty member's research interests are so intertwined, the work undertaken for a private company under a consulting agreement may brush against that same faculty member's federally funded research. Conflicts with Bayh-Dole requirements are usually the result.

Many institutions have had success with faculty awareness programs regarding consulting arrangements and intellectual property terms. Some even require the addition of language to the consulting agreement, stating, in effect, that the faculty member is an employee of the institution and subject to institutional policies, including those reflecting the Bayh-Dole intellectual property requirements. ✧

NIH Electronic Submission Timetable

continued from p. 1

- ◆ *December 1, 2005*: Proposals for the Small Business Innovative Research (SBIR) and Small Business Technology Transfer Programs (STTR)
 - ◆ *December 15, 2005*: Proposals for conferences and scientific meetings
 - ◆ *January 25, 2006*: Academic Research Enhancement Awards programs
- The next two deadlines have particular significance for colleges and universities:
- ◆ *June 1, 2006*: Small Grant Programs and Exploratory / Development Research Grant Awards (mechanisms R03 and R21)
 - ◆ *October 1, 2006*: The massive Research Project Grant Program (mechanism R01)

For the R01 transition, institutions had expected an October 2007 deadline to implement institutional upfront proposal submission systems using SF424 (R&R). Now the R01 transition is mandatory as of October 2006. Clearly, institutions need to step up their electronic submission plans if those plans include anything other than submitting through Grants.gov via PureEdge or using a service provider. ✧