

RESEARCH COMPLIANCE

News and Analysis for Colleges, Universities and Teaching Hospitals

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As NIH Debates New COI Regulations, IOM Declares That Institutions Must Lead

Any research institution that doesn't yet have a comprehensive program to eliminate or strictly manage both individual researcher, as well as institutional, conflicts of interest (COI) had better get one going soon.

Consensus is building in Congress, among medical leaders, and at academic associations that, "It is time to end a number of long-accepted practices that create unacceptable conflicts of interest, threaten the integrity of the medical profession and erode public trust while providing no meaningful benefits to patients or society."

Bernard Lo, a professor of medicine and director of the program in medical ethics at the University of California-San Francisco, made that statement as the Institute of Medicine (IOM) committee he chaired issued *Conflict of Interest in Medical Research, Education, and Practice*. The 350-plus-page report, described in the press as "scathing" and "scolding," proposed a series of 16 recommendations to root out such conflicts.

While the committee stated that all participants in the health care venture are accountable — recommendations address researchers, practicing physicians, medical societies, and publishers — it placed the prime responsibility squarely on institutions' shoulders, saying they must lead by example.

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After Creating System for ARRA Reports, OMB Pledges Fixes to Existing Database

The federal government is delaying fixes to the subaward reporting problems vexing its public Web site, USAspending.gov, until it establishes a workable system for posting data regarding grants and contracts issued through the American Recovery and Reinvestment Act (ARRA).

But the Office of Management and Budget's (OMB) approach doesn't mean universities can stop collecting subaward data, which OMB said eventually will be posted — it just failed to say when.

Under a 2006 law, federal agencies are required to post prime award data on USAspending.gov, and the prime awardees, in turn, are required to post subaward information. However, OMB never established an electronic pathway for the subaward data, despite a Jan. 1, 2009, deadline, so none of this data currently appears on the site.

ARRA itself has many reporting requirements, the cost of which universities are being asked to bear (see box, p. 3).

OMB laid out its position on USAspending.gov in a letter to Sen. Tom Coburn (R-Okla.). RCC obtained a copy of the letter late last month; Coburn posted it on his Web site May 1. The letter has not been widely circulated, and it appears OMB has not shared it with the university community at large or other federal grantees or contrac-

tors, who have been wondering when — and how — to submit the subaward data.

Dated April 27, the letter was written by OMB Director Peter Orszag, in response to a March 19 letter from Coburn seeking answers as to why OMB had blown the Jan. 1 deadline (*RRC 11/08, p. 1*).

Along with now-President Obama, Coburn co-sponsored the Federal Funding Accountability and Transparency Act of 2006 (FFATA), which established USAspending.gov and the reporting requirements.

OMB did make a Jan. 1, 2008, deadline for reporting on prime awards, but Orszag's letter confirms there are serious concerns about the reliability of this data — a criticism leveled by universities for months with no official response.

A handful of universities that participated in a pilot test of subaward reporting that concluded in November has also been left hanging as to the pilot's findings, which Orszag's letter also addresses.

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High Error Rate in Existing Database

In his letter, Coburn complained about problems with both prime and subaward reporting, saying “there appear to be several agencies, including the Economic Development Administration, the Nuclear Regulatory Commission, and the Department of the Treasury” that were experiencing “consistent problems fully reporting” as required under FFATA.

Orszag acknowledged this situation, writing that “significant data quality and completeness issues remain. ... This is especially true for assistance data (primarily grants and loans),” which he said “lack the same level of business process standardization and data quality assurance as exists for federal contract data.”

Specifically, he said that as of the writing of his letter, 21 of 24 federal agencies required to report “have valid assistance data submissions, up from 15 in September of 2008.”

He said that agencies “in the past” may not have “understood the importance” of sending in their data, and as such, “did not properly allocate staff and other resources to provide timely and accurate data submissions.”

Perhaps more disturbing than incomplete data is the error rate. “The total error rate for assistance data submissions has dropped from 15% to 13% over the past year,” Orszag wrote. He added that OMB is undertaking “aggressive steps to improve the completeness and accuracy of usaspending.gov and close remaining gaps.”

Some of these steps include offering technical assistance to agencies that hadn't posted data before and now are having problems; OMB also intends to prepare “updated guidance” for issuance in the near future that will “make file submissions and data corrections easier for agencies,” Orszag said.

Orszag assured Coburn that “the administration is committed to the full implementation” of FFATA. But he said OMB's priority now is complying with ARRA's reporting requirements, which are many (*RRC 3/09, p. 1*).

“Our first priority is to enhance and expand the current Transparency Act reporting model for funds expended under ARRA,” Orszag wrote.

Problems With Both Subaward Pilots

Orszag acknowledged that there had been pilots to test reporting of subgrants and subcontracts, but each failed in some way. The grant pilot ran from Oct. 8 to Nov. 14, 2008, and consisted of 18 participants who entered 516 awards.

The subcontract pilot, run by the General Services Administration, began in April 2008 and “required minor system modifications and the establishment of a contracts clause to require the prime contractors to submit

data." However, this pilot "was not completed due to the lack of a contract mandate for the prime recipient's sub-awardees to report their data," Orszag said.

The pilots failed to "generate sufficient information on which to base an operation model or project plan for how subaward information should be collected" or to provide "sufficient information on which to base an ac-

curate assessment of the burden placed on award recipients," the letter stated.

Yet, the pilots "did underscore that the central collection and reporting of subaward information from hundreds of thousands of federal award recipients will require significant data and process standardization across federal and non-federal entities, and investments in our informa-

NIH Says No to ARRA Administrative Costs

An addition to frequently asked questions (FAQ) that appeared without notice on an NIH Web page May 15 gave a thumbs-down to universities that were hoping to allocate some funds received under the American Recovery and Reinvestment Act (ARRA) to help pay for the law's many reporting requirements.

Under the section "Recovery Act Terms of Award" on NIH's "Recovery" funds page, the question is asked: "Can ARRA grant budgets include direct costs to address ARRA administrative and reporting requirements?"

And the answer is ... "No."

"It has been determined that ARRA requirements do not provide sufficient justification to support the provision of direct costs for administrative support in addition to the facilities and administrative (F&A) costs in the awarded budget. NIH staff will continue to evaluate direct costs requested for administrative support using the guidance provided in OMB Circular A-21 F.6.b.(2)," the answer states.

But it goes on to add that, "However, ARRA requirements will not be considered in this determination, because they are incorporated within the core administrative support for the project, which is reimbursed to the institution through the provision of F&A costs. When direct costs have been requested to address ARRA administrative and reporting requirements in requested budgets, NIH staff will make appropriate adjustments."

The FAQ suggests that institutions should not submit a new budget deleting any hoped-for administrative costs that were already included in the original grant application. "Revised budgets submitted solely to remove administrative costs will not be accepted," NIH said.

NIH's denial of an automatic F&A cost for ARRA compliance is a defeat for the Council on Governmental Relations (COGR), which represents research universities, but it is not done fighting. On Feb. 27, just 10 days

after the law was signed, COGR wrote a letter to the Office of Management and Budget requesting permission to charge for compliance costs (*RRC 3/09, p.1*).

After OMB put out a May 13 memorandum specifying how states and localities could charge 0.5% of the ARRA funds received for compliance costs, COGR fired off another letter.

"Universities have been grossly under-reimbursed for administrative costs ever since the 26% administrative cap was imposed in 1991," COGR President Anthony DeCrappeo wrote. "Only colleges and universities are subject to this restriction; non-profit organizations, state and local governments, and private industry are not. And while colleges and universities will recover the 26% administrative portion of their indirect rate on Recovery Act funds, the additional indirect cost reimbursement still will not cover the normal costs of research administration and compliance, let alone the important accountability and reporting requirements necessary under the Recovery Act."

DeCrappeo requested that Orszag grant universities a "2% increment, applicable to Recovery Act funded research, to be added to each institution's indirect cost rate" and meet with him and his staff. He also stressed the urgency of his request.

"The historic growth in research activity and the accompanying significant new reporting requirements will severely strain the current system if the requested relief is not granted," DeCrappeo wrote. "Quick action by OMB on our request will be crucial so that institutions can retain or hire the staff necessary to achieve the transparency and accountability required under the Recovery Act."

As of press time, OMB had not responded to COGR or to interview requests by *RRC*.

Links: http://grants.nih.gov/recovery/faqs_recovery.html#If4 (FAQ); <http://206.151.87.67/docs/OrszagLetterAdministrativeRelief.doc> (COGR letter). ↵

tion technology infrastructure," Orszag wrote. "The pilots also emphasized the need to give appropriate guidance to recipients on how they account for awards utilizing both federal and non-federal resources, and to put in place a robust data quality assurance model."

However, addressing these issues will have to wait because of ARRA. "Instead of further delaying implementing and pursuing new pilots, the administration is working closely with the Recovery Act Transparency and Accountability Board to move forward aggressively on meeting the subaward reporting requirements of the Recovery Act and displaying this information on Recovery.gov," Orszag's letter said.

After OMB gets this figured out, it can go back to focusing on subaward data for non-ARRA funds, he said.

"Once subaward reporting capabilities are in place for Recovery Act funds and these data are displayed on Recovery.gov, the administration intends to begin broadening subaward reporting requirements to all federal funding, to comply with the Transparency Act," Orszag said.

Some of the bugs still to be worked out with ARRA reporting include roles and responsibilities for primary awardees and subrecipients; data standards and definitions; the process for information flow from "subrecipients to the federal environment"; and data quality and assurance.

OMB did not respond to requests for follow-on comments on Orszag's letter.

Universities Are Frustrated

The University of Michigan was among those participating in the FFATA subgrant pilot, and its representative, Bob Beattie, has been outspoken in his criticism of how OMB has managed compliance with this law. Beatty, the university's liaison to Grants.gov and a member of its electronic research administration, termed the government's attempts to run two separate FFATA pilots — for subawards and subcontracts — "a huge mistake."

And he decried the lack of communication between OMB and universities. "In the implementation of a project to provide transparency, OMB has been very opaque," Beattie said. He also noted that in his letter, Orszag blamed the failure of the grant subaward pilot on the previous administration, yet it appears that now the same individuals are charged with FFATA/ARRA reporting compliance.

"The current administration has had since November to get involved. What has been done? This is Mr. Obama's project; why the delay?" Beattie asked.

Going forward, what the government needs to avoid is "Big Brotherism," Beatty told RRC.

"This is not the time for OMB to just impose some half-thought-out system on users," he said. "The stakeholders — those reporting the data — must be involved in the design and testing of the system."

He suggested that OMB "immediately" develop a "user advisory committee" in consultation with the National Grants Partnership and the Federal Demonstration Partnership, two organizations that include both institutional representatives as well as those from local governments and U.S. agencies.

Link to Coburn letter (provides link to Orszag letter): <http://tinyurl.com/o2jzpg> ✧

NIH Draft Stem Cell Guidelines Draw Cheers, Tough Criticisms

The NIH guidelines mark a new chapter in divorcing biomedical research from its ethical foundation ... respect for life at all stages. —U.S. Council of Catholic Bishops

While the comment period for NIH's draft guidelines for human stem cell research doesn't close until May 26 and no feedback received will be available from NIH until after that date, a few groups — like the bishops — have already made their positions known.

The draft guidelines, published in the April 23 *Federal Register*, will be re-issued in final form after the agency sifts through the comments. NIH is under a mandate, included in President Obama's March 9 executive order on stem cell research, to issue final guidelines by July 1. While it is doubtful that the majority of comments will be as damning or dramatic as that from the bishops, it is fair to say that some scientific groups and research organizations are also dismayed by aspects of the guidelines, and they, too, have gone public with their concerns.

Even so, after eight years of tight restrictions, followed by so much speculation and anticipation of what President Obama might do regarding stem cell research, the guidelines are welcome news to many — even if they disagree with some of the specifics.

ESC Must Meet Certain Requirements

"Most important, scientists now know exactly what they have to do in order to create an embryo stem cell (ESC) line that will be eligible for federal funding," bioethicist Thomas Murray, told RRC. Murray, president of The Hastings Center, a bioethics research institution in New York, and a member of several prominent stem cell organizations, including the International Stem Cell Forum, was briefed by NIH on the draft guidelines prior to their release.

In general, according to the guidelines, the stem cells must have been derived from embryos created for reproductive purposes and then not used for this

purpose, informed consent must have been obtained, and there can be no financial inducements associated with the ESC donation. The draft guidelines replace requirements put in place in 2001 by former President Bush, which had the effect of limiting research to just 21 stem cell lines, and implement Obama's executive order (*RRC 3/09, p. 5*).

Certain Documentation Required

Specifically, ESCs are eligible to be "used in research using NIH funds," if they originated from "human embryos that were created for reproductive purposes, were no longer needed for this purpose, were donated for research purposes, and for which documentation for all of the following can be assured:

- (1) All options pertaining to use of embryos no longer needed for reproductive purposes were explained to the potential donor(s).
- (2) No inducements were offered for the donation.
- (3) A policy was in place at the health care facility where the embryos were donated that neither consenting nor refusing to donate embryos for research would affect the quality of care provided to potential donor(s).
- (4) There was a clear separation between the prospective donor(s)'s decision to create human embryos for reproductive purposes and the prospective donor(s)'s decision to donate human embryos for research purposes.
- (5) At the time of donation, consent for that donation was obtained from the individual(s) who had sought reproductive services. That is, even if potential donor(s) had given prior indication of their intent to donate to research any embryos that remained after reproductive treatment, consent for the donation should have been given at the time of the donation. Donor(s) were informed that they retained the right to withdraw consent until the embryos were actually used for research.
- (6) Decisions related to the creation of human embryos for reproductive purposes were made free from the influence of researchers proposing to derive or utilize human embryonic stem cells in research. Whenever it was practicable, the attending physician responsible for reproductive clinical care and the researcher deriving and/or proposing to utilize human embryonic stem cells should not have been the same person."

In addition, the draft guidelines would not allow funding if the ESCs had been "introduced into non-human primate blastocysts" or came from animal breeding

research "where the introduction of human embryonic stem cells (even if derived according to these guidelines) or human induced pluripotent stem cells may have contributed to the germ line."

The draft also spells out responsibilities for an institution receiving stem cell funding, which is technically the funding "recipient," not the investigator. Prior to using any funds, recipients must ensure that the ESCs originated from the approved sources, the agency said.

In addition, NIH specifically states that "grantee institutions" must maintain "appropriate documentation demonstrating such consistency in accordance with 45 CFR 74.53, which also details rights of access by NIH," which implies NIH officials may actually physically inspect research sites to ensure compliance.

Elements in Consents Described

NIH also proposes requiring a written consent form that includes a number of specific elements and states that these must be discussed with "potential donor(s) in the informed consent process."

Consent forms must contain the following:

- ◆ A statement that donation of the embryos for research was voluntary.
- ◆ A statement that donor(s) understood alternative options pertaining to use of the embryos.
- ◆ A statement that the embryos would be used to derive human embryonic stem cells for research.
- ◆ Information about what would happen to the embryos in the derivation of human embryonic stem cells for research.
- ◆ A statement that human embryonic stem cells derived from the embryos might be maintained for many years.
- ◆ A statement that the donation was made without any restriction or direction regarding the individual(s) who may receive medical benefit from the use of the stem cells.
- ◆ A statement that the research was not intended to provide direct medical benefit to the donor(s).
- ◆ A statement as to whether or not information that could identify the donor(s) would be retained prior to the derivation or the use of the human embryonic stem cells.
- ◆ A statement that the results of research using the human embryonic stem cells may have commercial potential and a statement that the donor(s) would not receive financial or any other benefits from any such commercial development.

Murray described the draft guidelines as "an effort to articulate a clear and consistent standard for embryonic stem cell research."

continued

The agency's choice of which ESCs to fund was "a reasonable judgment that will permit greatly expanded funding for ESC research without needlessly offending people with strong moral convictions about the moral status of embryos," Murray said.

He also noted that NIH can revise the policy in the future should the now-prohibited embryo cell creation techniques "become exceptionally promising."

But some organizations, such as the California Institute for Regenerative Medicine, created by state law in 2004 and funded with \$3 billion for stem cell research, opposed a few of the requirements. The institute's comments to NIH, which it posted on its Web page, asked the agency to refrain from retroactively imposing its guidelines, echoing a fear that others have raised.

Unknown: Fate of Bush Lines

The institute asked instead that NIH "explicitly permit the continued use of the established pre-2001 ESC lines that meet Common Rule requirements on donor consent."

There has been a concern in the research community that the draft guidelines are so strict they could knock out the use of even some of the old lines. NIH spokesman Don Ralbovsky said NIH was aware of these concerns but would not address them during the comment period and prior to the issuance of final guidelines.

Murray said the previous administration seemed "to have not been overly concerned with the quality of informed consent, with how much time elapsed between the creation of the embryo and the request for donation to research, and similar matters. It won't surprise me in the least if some of those [pre-2001] lines are disqualified under the draft guidelines."

When asked what changes he expected NIH to make, Murray said, "The most likely major change will be grandfathering of the [Bush] cell lines."

"If the scientific community can argue persuasively for grandfathering those lines, then I hope and expect the final guidelines would accommodate this change," he said. "I urge scientists to write to NIH, not to complain, but to explain why it is important scientifically to have federal funding for research on the legacy lines. And I would expect NIH to pay attention to such arguments."

Some groups also want NIH to open up funding for ESCs made through somatic cell nuclear transfer and a process called parthenogenesis, and those created specifically for research purposes. They are likely to face a tougher battle on these fronts.

Link to NIH draft policy: <http://stemcells.nih.gov/policy/2009draft>. **Link to California Institute comments:** <http://tinyurl.com/oahnl9>. ↵

Higher Ed Groups Support Bills That Would Reform Patent System

In every nation or jurisdiction with a patent issuing system — except the United States — the first "inventor" who beats a path to the patent and trademark office wins. That's a bit of a simplification, because years of challenges to a patent may follow.

But the fact is that only America maintains a "first-to-invent" vs. the more common "first-inventor-to-file" patent system. Two congressional bills that have the support of a coalition of higher education institutions would change that, and their sponsors hope, lessen the battles that can occur after a patent is issued.

The bills, S. 515 and H.R. 1260, are the product of many years of negotiation and collaboration between the higher ed groups and members of the House and Senate. A coalition supporting the bills includes the Association of American Universities; the American Council on Education; the Association of American Medical Colleges; the Association of Public and Land-grant Universities; the Association of University Technology Managers; and the Council on Governmental Relations.

Fostering innovation, and being able to obtain and profit from patents on the fruits of their research labors, are vitally important to universities. Yet they and others feel hobbled by an antiquated patent system that has been unchanged since 1952. They are optimistic about the prospects for real change in this legislative session.

"Since it began working to reform the U.S. patent system four years ago, Congress has achieved significant progress in developing legislation that would enhance the capacity of the patent system to promote innovation and strengthen America's economic competitiveness in the 21st century," the groups wrote in a May 7 letter of support for S. 515, which passed the Senate Judiciary Committee, 15-4, on April 2.

As passed by the committee, the bill now represents "a broad and balanced compromise on those difficult issues ... [and] will substantially strengthen the ability of the patent system to foster innovation," the coalition wrote to Sen. Harry Reid (D-Iowa) and Mitch McConnell (R-Ky.).

Bills Have Several Goals

S. 515 was introduced by Sen. Patrick Leahy (D-Vt.) on March 3, while Rep. John Conyers (D-Mich.) introduced the House companion bill the same day.

Upon introduction of his bill, Leahy said moving to a first-to-file system would remove "confusion and inefficiencies for American companies and innovators" that result from the U.S. being out of step with the rest of the world with its first-to-invent system.

Leahy also said the bill, which he previously introduced in 2007, would address a “significant concern that the U.S. Patent and Trademark Office is issuing low quality patents. Patent examiners are facing a difficult task given the explosion in the number of applications and the increasing complexity of those applications. When Congress last overhauled the patent system in 1952, the PTO received approximately 60,000 patent applications; in 2006, it received 440,000. Clearly, this puts a strain on the system and understandably affects the quality of patents issued,” Leahy said.

Another issue that requires attention, Leahy said, is the increasingly complex and expensive process of obtaining, and then defending, a patent once it is issued. “[T]he costs and uncertainty associated with patent litigation have escalated in recent years, and are creating an unbearable drag on innovation. Damage awards are inconsistent and too often fail to focus on the value of the invention to the infringing product. This disconnect and uncertainty is a problem that also leads to unreasonable posturing during licensing negotiations,” he said.

Changes to Filing, Appeal Process

Many of the changes proposed in the bills stem from recommendations contained in the report *A Patent System for the 21st Century*, issued in 2004 by the National Research Council.

One change concerns damages that can be awarded when a patent has been “willfully infringed.” Under the bills, a “court that has determined that an infringer has willfully infringed a patent or patents may increase damages up to three times the amount of the damages found or assessed” under other procedures allowed by law.

Proposed changes in the type of statements an inventor must make when filing should make it easier to submit a patent application, the groups said.

In addition, a new system for challenging the validity of grants would be imposed, and the process for third parties to submit information during the review process would be improved, supporters of the reform effort say.

Changes have been made to both bills since their introduction and currently the groups favor the Senate version, although neither bill addresses all of the concerns they have about the current system. For example, the groups believe that even with the changes, patents might still face successive re-examinations and civil litigation after they are issued.

The House Judiciary Committee held a hearing on April 30, but at this writing, the committee has not scheduled the bill for a full vote. In its letter, the coalition asked the Senate leaders to schedule a vote on its version. The coalition hopes to push for modifications as the bills progress.

“The reason [the coalition] letter went to the Senate is that the Senate Judiciary Committee has marked up a bill that is expected to move to the Senate floor,” Barry Toiv, Association of American Universities vice president for public affairs, told *RRC*. “The timing was right for this coalition to express our views on the bill. As it becomes appropriate, we will communicate with the House, just as we did in the last Congress.”

Link: thomas.loc.gov (search by “Bill Number”).
Link to AAU letter: www.aau.edu/policy/patent_policy.aspx?id=7372.

USDA Orders Improvements After Inspecting New Iberia Chimp Center

Some primates were not adequately monitored following sedation and others were transported in an unsafe manner, while at least two research activities were undertaken apparently without approval by the institutional animal care and use committee (IACUC), the U.S. Department of Agriculture (USDA) concluded in a report on the New Iberia Research Center (NIRC), part of the University of Louisiana at Lafayette.

In all, six areas of noncompliance were noted. In a statement, NIRC Director Thomas Rowell said the center was working “to ensure that corrective actions are taken. As of May 11, 2009, five of the six items have been completely addressed,” he said.

The USDA inspection was triggered by an undercover investigation by the Humane Society of the United States (HSUS), which took video footage of the center from December 2007 to September 2008 that later aired on “Nightline” (*RRC 3/09, p. 1*).

At the time, the society said it had submitted a 108-page complaint to the USDA, alleging a minimum of 338 possible violations of the federal Animal Welfare Act.

Representatives from USDA’s Animal and Plant Health Inspection Service inspected the facility, which houses approximately 6,000 nonhuman primates, on March 17 — less than two weeks after the video aired. It released the findings May 11.

continued

Links in the News

Links to documents referred to in this issue are posted at www.ReportonResearchCompliance.com under “Links in the News.” Back issues of newsletters also are posted at the Web site.

"The complaint filed by HSUS was in regard to the facility's treatment of its nonhuman primates, but APHIS conducted a thorough review of all areas of care and treatment under the agency's authority," the agency said in a news release. "Inspectors cited the facility for issues with its handling of animals as well as its environment enhancement of nonhuman primates. The inspectors also found problems with New Iberia's IACUC, which is tasked with the review and approval of research protocols."

Among the problems related to the IACUC were "incomplete descriptions of protocols and insufficient consideration of alternatives to procedures that may cause distress."

USDA said it was "taking immediate action to ensure that these issues are corrected." The inspection report indicates APHIS requested a series of changes, with a due date for each.

In his response, Rowell noted that the center had until Oct. 30 to "complete corrective action for the sixth issue, which relates to the provision of additional heat in winter for African Greens housed outdoors. The NIRC has provided APHIS with its plan to accomplish this."

Rowell said APHIS made a follow-up inspection on April 30 and found that "all citations on the March 17 inspection report were reviewed and addressed appropriately by the university's IACUC."

Martin Stephens, vice president of animal research issues at HSUS, told RRC the group was "pleased" its concerns were taken seriously by USDA. He is also hopeful USDA will issue other findings from the inspection and is awaiting the conclusion of concurrent investigations by NIH and the Office of Laboratory Animal Welfare, which are ongoing.

"Six categories of violations uncovered during the USDA inspection — when the NIRC knew full well that a USDA inspection was coming — is a serious matter," Stephens said.

Links: www.aphis.usda.gov/animal_welfare/efoia/downloads/inspection/72-r-0007.pdf (inspection report); www.aphis.usda.gov/newsroom/content/2009/05/newiberia.shtml (news release); www.kadn.com/nirc-directors-statement (NIRC statement); <http://tinyurl.com/qwx5ct> (HSUS statement). ↵

Inside NIH

Dates that appear at the end of NIH news briefs indicate the issue of RRC's weekly e-mails in which a news item first appeared, where links for documents may be included. Go to "Recent E-Mail Issues" at the RRC Web site, www.Reporton-ResearchCompliance.com.

◆ **NIH has issued a "reminder" about its long-standing policies not to review the same or very similar application more than once.** According to NIH, these policies are timely due to the recent large number of applications submitted under the Recovery Act, particularly those for the Challenge Grants, and the potential large number of applications expected in the near future. The notice, NOT-OD-09-100, was issued May 15.

◆ **PETA has asked NIH's Office of Laboratory Animal Welfare "to revoke the University of Michigan's 'assurance,' which allows U-M to receive federal funding to perform experiments on animals."** PETA said the action was warranted after reviewing documents it said showed the university's "long history" of noncompliance with federal law. In a statement provided to RRC, the university said, "The information PETA cites is from our own discovery and self-reporting of incidents to an oversight body, through the operation of our internal oversight system. The reported injuries to animals were all rare and isolated events, not routine occurrences. In every

case, the issues that led to these incidents were identified and remedied swiftly. ... [W]e disagree strongly that the incidents cited by PETA warrant the revocation of our NIH animal use assurance." (4/30/09)

◆ **Approximately 15,000 NIH Challenge Grant applications were working their way through the submission process in early May.** Further, according to the most recent issue of *Extramural Nexus*, the newsletter from NIH's Office of Extramural Research, "The number of applications submitted to the Challenge Grants funding opportunity nearly matches the total number of applications NIH receives in a regular Council round. ... While around 200 Challenge Grants will be funded by the NIH Office of the Director through the Common Fund and other monies, it is likely that an equal or greater number of projects will be funded by NIH Institutes and Centers. Awards will be issued no later than Sept. 30." The newsletter also provides links to NIH notices, including information for facilities affected by the H1N1 flu. (5/7/09)

Scrutiny of COI Continues

continued from p. 1

“The intent of the recommendations in this report is to promote a culture in which conflicts of interest are taken seriously by institutions and individuals engaged in medical research, education, and practice and guideline development,” the committee wrote in the report, issued late last month. “For this to happen, institutions must effectively manage their own conflicts and be seen to be doing so. The board and the senior officials set the tone for the institution. They should be accountable for making sure that their own institutional interests are in order.”

The committee didn’t leave it up to the institutions to decide whether to take this step — it recommended the government mandate such a program. NIH should “develop rules governing institutional conflicts of interest for research institutions covered by current U.S. Public Health Service regulations. The rules should require the reporting of identified institutional conflicts of interest and the steps that have been taken to eliminate or manage such conflicts,” the report said.

As surprising as it may be, there are some institutions that don’t have such policies, or may have one kind, such as individual, but not institutional. A study last year by the Association of American Medical Colleges (AAMC) found only 30 of 125 accredited medical schools reported having financial conflict of interest policies that govern the type of arrangements the institution may make with corporations and private investors.

NIH: Institutional COI a ‘Concern’

NIH has been pondering this topic as well. Just 10 days after the IOM report was released, NIH published in the *Federal Register* an advance notice of proposed rule-making, a precursor to regulations, titled “Responsibility of Applicants for Promoting Objectivity in Research for Which Public Health Service (PHS) Funding Is Sought and Responsible Prospective Contractors; Request for Comments” (see box, p. 10).

At the end of the notice, NIH stated that current regulations are silent on institutional COI, and that it was seeking feedback on whether that should change. “Institutional conflict of interest is currently not addressed by the regulations, although there has been movement in the research community toward incorporating institutional standards in conflict of interest policies ... and some institutions have adopted such standards. This is an area of increasing concern,” NIH acknowledged.

If the agency did amend the regulations, “[H]ow would institutional conflict of interest be defined?” NIH asked. And it posed a second question: “[W]hat would

an institutional conflict of interest policy address in order to assure the PHS of objectivity in research?”

IOM also made it clear that while “research partnerships among industry, academia, and government are essential to the discovery and development of new medications and medical devices that improve the prevention, diagnosis, and treatment of health problems,” bad outcomes are occurring as a result of these collaborations.

“Evidence suggests that these relationships have risks, including secrecy, decreased openness in the sharing of data and findings, and the withholding of negative results. These kinds of risks justify additional requirements and incentives, as recommended in this report, for institutions to adopt and implement policies to identify and eliminate or manage conflicts of interest,” the committee said.

Recommendations Offered for Institutions

Borrowing heavily — with attribution — from previous reports by AAMC and the Association of American Universities, the IOM committee made the following recommendations that relate specifically to institutions:

- ◆ Academic medical centers and other research institutions should establish a policy that individuals generally may not conduct research with human participants if they have a significant financial interest in an existing or potential product or a company that could be affected by the outcome of the research. Exceptions to the policy should be made public and should be permitted only if the conflict of interest committee (a) determines that an individual’s participation is essential for the conduct of the research and (b) establishes an effective mechanism for managing the conflict and protecting the integrity of the research.
- ◆ The boards of trustees or the equivalent governing bodies of institutions engaged in medical research, medical education, patient care, or practice guideline development should establish their own standing committees on institutional conflicts of interest. These standing committees should
 - have no members who themselves have conflicts of interest relevant to the activities of the institution;
 - include at least one member who is not a member of the board or an employee or officer of the institution and who has some relevant expertise;
 - create, as needed, administrative arrangements for the day-to-day oversight and management of institutional conflicts of interest, including those involving senior officials; and
 - submit an annual report to the full board, which should be made public but in which the

necessary modifications have been made to protect confidential information.

The committee added that some of its other recommendations would also affect researchers, research institutions, and companies. "These recommendations call for standardization of the procedures used to disclose conflicts of interest to harmonize the requirements of different institutions and reduce the disclosure burdens on individuals; the implementation of methods for the easier verification of certain financial disclosures; limitations on certain relationships with industry (e.g., acceptance of gifts and participation in promotional activities) for academic medical center personnel; and the promotion of reforms in industry policies on consulting and research grants."

The reference to verification of disclosures refers to IOM's recommendation that the Congress "create a national program that requires pharmaceutical, medical device, and biotechnology companies and their foundations to publicly report payments to physicians, researchers, health care institutions, professional societies, patient advocacy and disease-specific groups, providers of continuing medical education, and foundations created by any of these entities."

Links: www8.nationalacademies.org/onpinews/newsitem.aspx?recordid=12598 (press release); <http://national-academies.org/podcast> (podcast of press briefing); www.nap.edu/catalog.php?record_id=12598 (fee). ↵

NIH Seeks Feedback on COI Regs, Issues Research 'Principles'

On May 8, NIH published in the *Federal Register* an advance notice of proposed rulemaking and a request for information, "Responsibility of Applicants for Promoting Objectivity in Research for Which Public Health Service (PHS) Funding Is Sought and Responsible Prospective Contractors; Request for Comments."

The notice and request were expected; in December 2008, NIH officials told the agency's top advisory committee that the agency had already developed the documents and that they were waiting to be published pending approval by the Office of Management and Budget (*RRC 12/08, p. 1*). The notice also contains a set of principles that NIH said should govern research activities and ensure that conflicts of interest (COI) are addressed.

Speaking last year, Raynard Kington, acting NIH director, said he expected Congress to propose new requirements on reporting and managing COI and said the agency itself was struggling with "how to craft regulations that are more responsive to the world as it is today." NIH's intention was also to preempt any congressional action, he said.

His and others' comments implied that whatever changes were made, NIH was unlikely to shift from its historic role of overseeing how institutions handle conflicts on their campuses, rather than directly managing the conflicts itself, as that would be treating researchers as "employees" — something Kington said NIH does not wish to do.

Such a shift also did not have the support of NIH's Advisory Committee to the Director (ACD); it was at the ACD's meeting that the notice was dis-

cussed. ACD members said NIH needed to do a better job enforcing the regulations already on the books, which have been in effect since 1995.

The May 8 notice gave no hint of what NIH might ultimately propose, and the content hued strictly to what Sally Rockey, acting director of NIH's Office of Extramural Research, had described at the December 2008 meeting.

Currently, grantee institutions are generally required to report to NIH when an investigator has a "significant financial interest" of at least \$10,000 or a 5% ownership interest in a single company that would appear to be affected by the research for which funding is sought. Institutions must report a financial conflict of interest to the NIH at the start of any grant and within 60 days of any new COI emerging and assure NIH that it has been managed, reduced, or eliminated.

NIH relies on the institutions to file such reports, and the institutions rely on the investigators to report to them.

In a news release issued about the notice, NIH said it was seeking feedback on proposed changes "with particular interest in potential for expanding the scope of the regulation and disclosure interests; the definition of significant financial interest; identification and management of conflicts by institutions; assuring institutional compliance; requiring institutions to provide additional information to the PHS; and broadening the regulations to address institutional conflicts of interest."

NIH is seeking an array of respondents to weigh in, saying it is interested particularly in receiving com-

NIH Seeks Feedback on COI Regs, continued

ments on the issues presented “from the general public, individual investigators, scientific societies and associations, members of Congress, other federal agencies that support or conduct research, and institutions that receive PHS funds to conduct or support biomedical or behavioral research.”

The agency added, “The complex and controversial issues surrounding FCOI warrant a carefully considered, open dialogue with all affected parties.”

Changing World Necessitates Rethinking

In the notice, NIH said the potential for COI had increased, sparking its review of whether the current regulations were adequate.

“In the intervening years since the publication of these regulations, the pace of translation of new discoveries from the research bench into effective treatment of patients has significantly accelerated. As a result, the biomedical research enterprise in the United States is extensive and growing in size and complexity,” the agency said. “Researchers frequently work in multidisciplinary teams to develop new strategies and approaches for translating basic research into clinical application.”

NIH also noted that the translational and collaborative research that were pushed so hard by former NIH Director Elias Zerhouni have added to the risk of COI.

“In addition, these newer translational strategies often involve complex collaborations between investigators and the private sector,” NIH said. “Together, these factors may generate an increased potential of investigators to hold financial interests in multiple sources which, if not reported and appropriately managed, reduced, or eliminated, could introduce bias into the conduct of their research.”

Given the “growing complexity of biomedical research, the increased interaction between government and the private sector in meeting common public health goals, and recent public scrutiny,” NIH needs to consider “whether a more rigorous approach to investigator disclosure, management of conflicts, and Federal oversight is required,” the notice said.

Guiding ‘Principles’ Outlined

Last December, Kington said NIH saw the need to issue a set of “over-riding principles,” akin to the Belmont Report, which established standards for conducting research on humans, such as obtaining informed consent and respecting individuals’ dignity. The notice

made good on that promise. It contains five principles that NIH said are necessary to ensure “the objectivity of research”:

(1) Research must be conducted with transparency and the highest scientific and ethical standards in a manner that promotes and respects the rights, safety, and welfare of all human research participants.

(2) Appropriate interactions and relationships between government, academia, and industry, which do not compromise objectivity in research, frequently have beneficial outcomes and should be encouraged.

(3) The integrity of the scientific record is critical to the conduct of science.

(4) Risk management is essential in evaluating and managing conflict of interest; risk management should be commensurate with the level of risk of the research.

(5) Complete and timely disclosure of financial interests and effective management of conflicts of interest are essential to ensuring objectivity in research.

Notice Poses Questions About Reforms

As Rockey had said it would, the *Federal Register* notice posed a series of questions about how NIH might alter the current regulations and to what extent it should add new requirements.

For example, NIH asked whether investigators who conduct certain Phase I trials that are now exempt from COI regulations should be required to comply and whether investigators should be “required to disclose to their institutions all significant financial interests that are related to their institutional responsibilities.” It also asked if expanded disclosures might better enable institutions to ascertain whether a significant financial interest constitutes a conflict.

A related question is whether the 5%/\$10,000 threshold for reporting a COI was still valid and whether different thresholds might be appropriate for different sources of income.

A final question in the notice is whether NIH should begin requiring policies that govern COI that occur at the institutional level, which it does not now demand. It also seeks input on what such policies should contain, were they to be mandated.

Comments are being accepted until July 7.

Link: <http://edocket.access.gpo.gov/2009/pdf/E9-10666.pdf>. **To submit comments:** <http://tinyurl.com/pu5bu3> (click on “Add Comments”). ✧

In This Month's E-News

The following are summaries of news transmitted to RRC subscribers this month in e-mail issues, the date of which is indicated in parentheses following each item. Weekly e-mail and monthly print issues of RRC are archived at www.ReportonResearchCompliance.com. Please call 800-521-4323 or e-mail customerserv@aispub.com if you require a password to access RRC's subscriber-only Web site or are not receiving weekly e-mail issues of the newsletter.

◆ **OHRP issued "clarifications" on May 11 relating to IRBs and federal-wide assurances.** One clarification notes the "fact that an IRB or an independent ethics committee (IEC) is registered with OHRP does not mean that OHRP has determined that the IRB reviews research in accordance with the requirements of the Department of Health and Human Services Protection of Human Subjects regulations, 45 CFR part 46, and does not mean that the IRB or IEC has the appropriate competence or expertise to review a particular research project." OHRP issued a similar statement regarding federal-wide assurances. These clarifications are now included on several OHRP Web pages and in FAQs related to IRB registration and assurances. (5/14/09)

◆ **A "fraud reporting service," operated by GAO, "has recently generated more than 25 allegations of misuse of Recovery and other federal funds."** This information was included in a GAO May 5 report detailing the agency's oversight of Recovery Act funding. GAO's "FraudNet" is a means to gather public input and information on waste, fraud, and abuse in the allocation and spending of ARRA funds. The service is also a reporting portal for misuses of funds from the Troubled Asset Relief Program. The Web site address is <http://gao.gov/fraudnet.htm>. (5/7/09)

◆ **DoD, General Services Administration, and NASA have agreed to delay the applicability date of FAR Case 2007-013, Employment Eligibility Verification, to June 30.** According to a notice in the April 17 *Federal Register*, the delay will "permit the new administration an opportunity to review the rule." Agencies may not insert a clause in federal contracts requiring contractors to use the E-Verify employment verification system before June 30. (4/23/09)

◆ **OMB has issued interim final guidance and standard award terms for federal agencies to include in awards funded by the Recovery Act.** In the April 23 *Federal Register* notice, OMB states that the guidance does not cover all award terms that may be needed. Rather, the "focus of the guidance is on implementing Recovery Act provisions that may require greater clarification" in order to foster consistency, according to OMB. "Under the interim final guidance, agencies

would use the standard award terms ... to require recipients and subrecipients (first-tier that are not individuals) to maintain current registrations in the Central Contractor Registration (CCR) database; to require recipients to report quarterly on project or activity status, subgrant and subcontract information; to notify recipients of the domestic sourcing ("Buy American") requirements that apply to certain iron, steel and manufactured goods; to notify recipients of the wage rate requirements that apply to certain projects; and to ensure proper accounting and reporting of Recovery Act expenditures in single audits." The guidance is effective April 23. Comments are due by June 22. (4/23/09)

◆ **OMB should delay reporting requirements for use of ARRA funds until Oct. 10, the Council on Governmental Relations has told the agency.** In response to a request for comments, COGR said research organizations' ability to successfully report "depend on a uniform, standard approach including standard data elements and format and the use of an electronic central government-wide portal. We urge OMB and the federal agencies to implement truly standard reporting requirements without the addition of agency-specific data elements or unique agency-specific reporting formats. Research organizations will receive awards from multiple agencies, as prime grantees as well as subgrantees. Until this government-wide portal is available, federal agencies should defer all reporting until October 10, 2009," COGR wrote. (5/7/09)

◆ **FDA has submitted to OMB for review and clearance a proposed requirement that sponsors of studies regulated by FDA make certain disclosures.** Sponsors should disclose, among other information, "the complete list of clinical investigators for each covered study, not employed by the applicant and/or sponsor of the covered study, and either certify to the absence of certain financial arrangements with clinical investigators or disclose the nature of those arrangements to FDA and the steps taken by the applicant or sponsor to minimize the potential for bias." The announcement appeared in the April 22 *Federal Register*. (4/23/09)

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