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# RESEARCH COMPLIANCE

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# RESEARCH COMPLIANCE

News and Analysis for Colleges, Universities and Teaching Hospitals

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## New Omnibus Uniform Guidance: The Good, the Bad and the (Possibly) Ugly

Institutions feeling a little (OK, truth be told, *a lot*) overwhelmed by the new omnibus circular published in December by the Office of Management and Budget (OMB) may want to take some time to focus on areas where simplifications and positive changes have actually been made.

Fretting this soon doesn't make sense anyway. As Bob Lloyd, principal of Federal Fund Management Advisor, a private consulting firm, notes, the implementation process is "going to take a couple of years to play itself out."

"Many organizations' first fiscal year that will be affected would be the one beginning July 1, 2015, and ending June 30, 2016," Lloyd said during a recent webinar, "What You Need to Know Now: A Strategic Briefing From the Recipient and Subrecipient Perspective," the first in a series to be offered on the new guidance. (See <http://federalfundmanagement.com/webinars>.)

The 759-page final guidance, "Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards," implements reforms applicable to grants, contracts and cooperative agreements and collapses into one document eight circulars, including A-21, A-110 and A-133 (*RRC 1/14, p. 1*). The document finalizes proposed guidance issued in February 2013 (*RRC 3/13, p. 7*). The guidance now appears as Title 2 of the Code of Federal Regulations.

*continued on p. 6*

## A Rare Look Inside a Misconduct Case Shows Fraud Went Undetected for Years

The former Iowa State University (ISU) HIV researcher who recently agreed to the equivalent of a three-year debarment for misconduct began adding HIV-positive human blood to rabbit samples used in his NIH-funded vaccine research at least four years before his misdeeds came to light.

In investigating the misconduct, ISU worked backwards to determine who was responsible, a situation it describes as "atypical compared to most research misconduct cases because it began with proof of research misconduct and only after considerable effort was the responsible party identified." Dong-Pyou Han, Ph.D., who was an associate research professor in ISU's College of Veterinary Medicine, admitted to the misconduct when he was confronted.

The process took just shy of a full year from the time suspicions first arose from a collaborating lab outside of ISU until it concluded with the Dec. 23, 2013, publication in the *Federal Register* of the misconduct finding against Han. These details are found in ISU's "Inquiry Report," typically the first in a two-step investigative process begun when allegations of misconduct arise. ISU provided a redacted copy of the report about Han, and other related documents, including the researcher's written confession, to *RRC*. They were made available under the state's open records laws. In addition,

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Charlotte Bronson, ISU's associate vice president for research and its research integrity officer (RIO), answered questions submitted by *RRC*.

Han worked in the lab of Michael Cho, Ph.D., professor and Lloyd Chair in Biomedical Sciences at ISU's College of Veterinary Medicine and co-director of its Center for Advanced Host Defenses, Immunobiotics, and Translational Comparative Medicine. Both Cho and Han came to ISU from Case Western Reserve University in 2009, and had worked together more than a dozen years in total, Bronson told *RRC*. Han, 56, who has reportedly returned to South Korea, could not be reached for comment.

Because of Han's admission, which came in August and preceded his resignation by three months, ISU did not move his case to the second step in which an "investigation" is begun. As required by law, ISU was working in consultation with the HHS Office for Research Integrity (ORI), which published its finding of misconduct against Han.

Han "falsified results in research to develop a vaccine against human immunodeficiency virus-1 (HIV-1) by intentionally spiking samples of rabbit sera with antibodies to provide the desired results," ORI's notice states. "The falsification made it appear that rabbits immunized with the gp41-54 moiety of the HIV gp41 glycoprotein induced antibodies capable of neutralizing a broad range of HIV-1 strains, when the original sera were weakly or non-reactive in neutralization assays. Falsified neutralization assay results were widely reported in laboratory meetings, seven (7) national and international symposia between 2010 and 2012, and in grant applications and progress reports," which were identified by number.

The notice said Han had agreed to exclude himself from receiving government funding and serving in any advisory capacity for three years. ISU's contact at ORI was John Dahlberg, who recently retired as ORI's deputy director.

Cho's work was funded by NIH. "If all grants are counted in which at least some falsification occurred — at either the progress report stage, the proposal stage, or both — the total was about \$13.2 million," Bronson said. "This is a significant overestimate of the impacted dollars, however, because the grants funded more than just the problematic project and the funding went to multiple institutions." ISU said it had received no requests for repayment of the grant funds. The research at issue had produced findings that were hailed at the time as a "major breakthrough."

### Lab Head Notified RIO

The Inquiry Report describes events that unfolded from January to December 2013. The earliest date among the additional documents provided to *RRC* is March 15. The actions ISU took should prove instructive to organizations, particularly those that have never had a misconduct case proceed to this degree.

RIOs nationwide have long recognized the need to share information and resources as there is little training for the position. A group of RIOs under the direction of Shelia Garrity, director of the Division of Research Integrity in the Office of Policy Coordination at Johns Hopkins University School of Medicine, recently launched an association of RIOs to develop best practices to better assist one another (*RRC 11/13, p. 1*).

Suspicious first arose in January 2013 "when one of [Cho's] external collaborators...detected human antibodies in a sample sent by the complainant's lab" and "promptly" notified Cho, according to the Inquiry Report. The name of the collaborator and his or her lab are redacted. In the same month, Cho notified Bronson "that there appeared to be 'an inconsistency in data' between his lab and the lab of an external collaborator." Cho

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told Bronson “he was looking into it and would inform [her] if the inconsistency looked like it might be due to misconduct.”

After notifying Bronson, Cho “asked another of his colleagues [name redacted] to check samples of rabbit sera that [Cho’s] lab had sent him. Those tests turned out to be positive for human antibodies in samples that should have only had rabbit antibodies.”

A few weeks later, Cho told Bronson misconduct might have occurred, providing her with “evidence of the spiking.” Bronson made an assessment that “the discrepancy constituted misconduct,” and she notified ORI that ISU officials were “looking into an allegation of research misconduct.”

In mid-March, Bronson emailed Dahlberg, saying “in response to your request, attached are lists of the proposals sent by and awards received by Dr. Michael Cho while at Iowa State University.” The documents that RRC reviewed indicate the two kept in close contact from that point onward, with Dahlberg offering guidance and assistance and Bronson providing updates. Han is referred to as “the respondent” in the documents.

### Further Confirmation Was Sought

Emails from the spring months indicate Cho and Bronson were waiting on outside labs to provide results of tests on new and old rabbit sera. In April, Bronson received an email from one testing lab confirming the fears. “Although we cannot definitively rule out the presence of other human monoclonal antibodies, I feel rather confident that serum from an HIV-1-infected subject is present in these samples,” wrote the outside researcher, whose name and other identifying details were deleted.

More confirmation came in June, when results arrived from possibly another lab. “As you suspected, many samples are positive,” came the email to Cho and cc’d to Bronson.

In July, Dahlberg asked Bronson for an update, noting, “The folks at NIH are becoming increasingly concerned about letting the scientific community know about the problems with the gp41 peptide issue.”

Bronson and Cho were working out plans, she told Dahlberg, to pinpoint who was responsible and needed a little more time. They ultimately narrowed in on Han.

In an email on Aug. 9 to Dahlberg, Bronson wrote that “yesterday afternoon we met with the respondent and sequestered evidence in the research misconduct case. Thus, the inquiry has officially begun.” She added the news had been shared with NIH officials and Cho’s lab members were “informed...that the neutralization assays involving gp41-54 were unreliable.”

According to the Inquiry Report, Han was permitted no access to the College of Veterinary Medicine from that

point on without Bronson’s OK and “with an approved escort.” In addition, Han’s “keys, ID card and key card were confiscated and his access to ISU email and ISU servers was removed.”

The evidence that was sequestered included 34 notebooks dating back to 1999, other paper files from “both his office and the laboratory,” and “electronic media,” specifically “a USB stick; Macbook laptop; iMac desktop; portable hard drive; and a Dell Instrument Controller,” which was used in Cho’s lab. ISU’s Information Technology Services kept the original drives, and copies were given to Bronson. Han was later given back his “computers and copies of the drives.” Officials also sequestered Han’s “rabbit and mouse serum samples” related to the experiments at issue.

On Aug. 23, Bronson notified Dahlberg and NIH officials that “yesterday we received a verbal confession from the respondent. We have given the respondent guidance on how to prepare a written confession and he indicated that he would do so.” At that point Han was placed on administrative leave.

ISU officials, meanwhile, worked to put all the pieces of the Inquiry Report together, including identification of specific instances of misconduct (ultimately three were cited), the evidence gathered, and details of instances where falsified data were used, including in presentations.

In closing out ISU’s misconduct inquiry, Bronson recommended that Han be:

- ◆ “required to retract and remove from the web, to the extent possible, his published poster and oral presentations reporting the falsified data”;
- ◆ try to “correct the research record” through “removing links” or “adding a disclaimer”;
- ◆ work “with his NIH program officers to assure that [his] collaborators and colleagues are aware of the unreliability of the data.”

It was noted that Han “is to be commended for his already considerable progress in this effort.” The report also mentioned that “at least one instance of spiking occurred while [Han] was at Case Western Reserve University,” and that Case Western’s RIO “should be informed of the outcome of this inquiry and the sequestration of research records.”

In his Sept. 30 confession, which also contained his resignation, Han admitted the “problem starts from the first samples I sent to [redacted] on 8/11/09.” He described, in ungrammatical English, a mistaken “contamination,” writing, “Though I later found some samples were wrong and the date were from the wrong samples, I could not tell Michael Cho.” He acknowledged that “in order to show the neutralizing activity continuously I

added the human sera with a neutralizing activity to the second samples" that he sent to a researcher.

"I have regretted deeply that fact that I did it and did not tell it," Han wrote in part. "I was foolish, coward and not frank. My misconduct was not done in order to hurt someone." Instead, his efforts were designed to make the results "look better," Han wrote.

By Oct. 9, the Inquiry Report was done. ISU accepted the findings on Oct. 15, after which Bronson emailed it to Dahlberg. That set in motion the final steps leading up to the publication of the misconduct finding in the Dec. 23 *Federal Register*, which included Han signing the voluntary settlement agreement.

No papers will be retracted as a result of the misconduct finding, as none were published "describing the research results," according to the Inquiry Report. However, Cho presented results from this research during at least four meetings. His talk at one was titled "AIDS Vaccine Development: A Light at the End of the Tunnel?" False data was also shared with eight collaborators, the report showed.

#### Cho: Misconduct 'Difficult to Endure'

Comments that Cho had emailed to journalists about this case were in the documents ISU shared with RRC. "When it comes to doing science, integrity is the first and foremost important thing. So, as a scientist, it was extremely difficult for me to endure that a member of my laboratory committed this research misconduct," Cho wrote, in part. "What hurts me even more is that we wasted valuable resources and time in following a false lead in our efforts to develop a much needed vaccine against HIV-1, the virus that causes AIDS. During the past three decades of AIDS pandemic, the disease has killed tens of millions of lives globally. So, despite this setback, I and the rest of my laboratory members are fully committed in our quest for developing an effective AIDS vaccine."

Bronson told RRC that Han "worked on a variety of projects in Dr. Cho's lab," and no previous problems had been found with his work "to our knowledge." She noted that Han was neither a principal nor co-principal investigator on any of Cho's grants, but "was a researcher in the lab." All told, the two had worked together for 15 years, she said.

"We don't know why Dr. Han felt he couldn't tell Dr. Cho, except for what he said about lacking courage. What he said in his statement is what he told us verbally," Bronson said in response to a question from RRC.

Asked whether Cho believed he could have done anything differently, Bronson said, "As you might imagine, Dr. Cho feels terrible about what happened. However, there is no evidence that anyone in the lab, in-

cluding Dr. Cho, knew about or even suspected the misconduct as it was happening. One of the students in the lab visited me after we did the sequestration and said, in essence, that falsification of the assay was impossible because they ran so many controls, they collaborated so heavily in the lab, and they collaborated with and shared samples with so many other institutions. That student, at the time of course, did not know that the data was being falsified by spiking."

Regarding what ISU has learned through this process or changes that it has made since this incident, Bronson responded, "We do not know what went wrong. My best advice for preventing misconduct is to get as many researchers as possible, at all levels of the research enterprise, to take (or teach) an in-depth course on the responsible conduct of research."

Emphasizing that the course "should include plenty of small group, face to face discussions," Bronson added, "We are working harder to assure that our researchers receive training in responsible research. Dr. Cho's lab has already received training."

Link: <https://federalregister.gov/a/2013-30424> ↗

#### FY 2014 Budget Calls for Study, Expands Open Access Mandate

In addition to giving NIH and the National Science Foundation (NSF) disappointing funding amounts, Congress inserted a few sleeper provisions in the 1,500+ page fiscal year (FY) 2014 budget passed in January.

Among them is one sure to make research compliance administrators and representatives of research universities groan: Congress wants to see *another study on reducing administrative burdens*.

An unexpected provision in the \$1.1 trillion Consolidated Appropriations Act, 2014, is the mandate for agencies with at least \$100 million per year in research and development spending to require grantees to comply with an open access (OA) requirement similar to that in place for NIH grantees.

The act also requires NIH to apply the controversial review of so-called "well-funded" extramural researchers to the agency's own intramural researchers.

The appropriations bill, which the President signed Jan. 17, funds the government through Sept. 30, the end of this fiscal year. As colleges and universities know, the federal fiscal year began Oct. 1, 2013, but Congress' failure to pass a budget by that time led to a 16-day shutdown (RRC 11/13, p. 1).

The agreement reopening the government in October extended FY 2013 expenditures until Jan. 14. After

passing a short-term extension, Congress approved H.R. 3457, the appropriations act.

When the bill cleared the House, the Association of American Universities (AAU) said it “presented a mixed picture for the federal investment in research. Some agencies fared rather well, while some did poorly.” The act only partially restored funding lost to sequestration, and seemed to favor the physical over the biomedical sciences.

After the bill passed the Senate and was sent to the President for his signature on Jan. 17, AAU expressed its thanks to the House and Senate Appropriations Committee leaders, giving them “particular” thanks for their “continued prioritization of scientific research. We hope that Congress and the President will make such investments in FY 2015 and adopt an approach over the longer run that ends sequestration, achieves long-term savings through entitlement reforms, includes tax reforms to encourage economic growth and raise revenues, and places a high priority on investments in higher education and scientific research to close the innovation deficit and build a better future for coming generations of Americans,” AAU said.

### NIH Told to ‘Track and Measure’ Burdens

In its weekly update to members, AAU noted that the act “does NOT include language restricting NSF funding of political science research that was first inserted in the FY13 continuing resolution last March at the behest of Senator Tom Coburn (R-OK). That language prohibited NSF from funding political science research unless the NSF Director certified that the project promoted ‘national security or the economic interests of the United States.’ Because of the difficulty of implementing the provision, NSF has not been funding new political science studies.”

As of press time, agencies had not yet announced how funding would be distributed to which research programs, although Congress included some specifics.

Funding for HHS is found in Division H, Title II of the appropriations act. The explanatory statement for Division H includes the requirement for the burdens study. It states just the following: “Administrative Burden Reduction Workgroup—The Director of NIH should establish a workgroup that includes coordination and participation of universities, not-for-profits, and institutes receiving support from the NIH to develop a method to track and measure the administrative burden on entities participating in NIH supported activities with the goal of developing a plan to reduce such administrative burden as practicable.”

The requirement of a study on burdens is applicable only to NIH, according to the explanatory statement. In

1999, NIH undertook a very similar report, as required by Congress in its FY 1998 funding actions.

The National Science Board is currently in the throes of one such study (*RRC 1/14, p. 5*). Federal grantees are also underwater right now trying to make sense of the Office of Management and Budget’s 759-page Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards, an effort that began as a result of an interagency taskforce created to reduce compliance costs and administrative burdens, among other aims (see story, p. 1) (*RRC 12/11, p. 1*).

The provision for open access is found in Section 527 of the act, which provides appropriations for the Departments of Labor, Education and HHS. It specifies that “each federal agency, or in the case of an agency with multiple bureaus, each bureau (or operating division) funded under this Act that has research and development expenditures in excess of \$100,000,000 per year shall develop a federal research public access policy that provides for—

“(1) the submission to the agency, agency bureau, or designated entity acting on behalf of the agency, a machine-readable version of the author’s final peer-reviewed manuscripts that have been accepted for publication in peer-reviewed journals describing research supported, in whole or in part, from funding by the federal government;

“(2) free online public access to such final peer reviewed manuscripts or published versions not later than 12 months after the official date of publication; and

“(3) compliance with all relevant copyright laws.”

The requirements match somewhat the open access requirements already in effect for NIH grantees and with similar initiatives already underway government-wide through the Office of Science and Technology Policy (OSTP).

*continued*

### Upcoming Grants Management Webinars from FFMA & AIS

- **Jan. 30** Time and Effort Reporting for Your Federal Awards — The Way Forward
- **Feb. 6** “Robust” Subrecipient Management and Monitoring — OMB’s New Prescription
- **Feb. 13** OMB’s New Consolidated Cost Principles — The Question Remains: Can We Charge This to Our Grant?
- **Feb. 20** Single Audit — Good-Bye Circular A-133 ... Hello Revised Procedures
- **Feb. 27** Indirect Cost Realities — What Changed Under OMB’s Federal Grant Reform?

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NIH's policy, in effect on a mandatory basis since 2008, "requires scientists to submit final peer-reviewed journal manuscripts that arise from NIH funds to the digital archive PubMed Central *immediately upon acceptance for publication*. To help advance science and improve human health, the Policy requires that these papers are accessible to the public on PubMed Central no later than 12 months after publication."

The requirement in the appropriations act also comes on the heels of a bill in Congress, the Fair Access to Science and Technology Research Act (FASTR), introduced in both the House and Senate in February 2013. FASTR would require agencies to "provide the public with free online public access to such final peer-reviewed manuscripts or published versions as soon as practicable, but not later than 6 months after publication in a peer-reviewed journal," and imposes other mandates.

Agencies were given until Nov. 30, 2013, to complete five requirements in creating an "open data infrastructure" (*RRC 9/13, p. 1*). Earlier OSTP had given them a deadline of August 2013 to submit draft open access plans that would "provide the public with online access to research manuscripts stemming from funded research no later than six months after publication in a peer-reviewed journal" (*RRC 4/13, p. 1*).

### Some Prefer OA Bill

Peter Suber, director of the Harvard Open Access Project, said it is "possible" that the act "will be interpreted to apply to all agencies across the federal government." In contrast, the Fair Access to Science and Technology Research Act (FASTR) would require agencies to "provide the public with online access to research manuscripts stemming from funded research no later than six months after publication in a peer-reviewed journal."

Suber told *RRC* he personally "prefers" FASTR to the appropriations act requirements because of its shorter embargo period, "reuse rights," and the fact that, "once adopted, FASTR would not expire and need renewal at the end of the fiscal year," in contrast to the act. He counted himself among people "still working hard to pass FASTR."

The act and FASTR also differ in the criteria for which agencies must comply with the requirements, he noted. "The \$100 million threshold in the appropriations act is for 'research and development' and the \$100 million threshold in FASTR is for 'extramural research.' More agencies spend \$100 million per year on R&D than on extramural research."

And, finally, Congress asked NIH to level the research funding field. The explanatory statement noted, "The NIH has announced plans to impose an additional

level of scrutiny on extramural principal investigators with grants of \$1,500,000 or more. The NIH is directed to ensure that this policy, and any other new measures which are intended to improve oversight and accountability for extramural researchers, should apply equally to intramural researchers as well. The NIH shall include an update on this topic in the fiscal year 2015 budget justifications. In addition, peer reviewers for extramural research would benefit from knowing the scope of intramural activities that are related to the subjects under consideration to reduce the possibility of duplication. Therefore, NIH is directed to make such information available to extramural peer review study sections. The NIH shall include an update in the fiscal year 2015 budget request on this action."

NIH actually instituted this "scrutiny," which it calls a Special Council Review, in September 2012, and the funding amount that triggers this was lowered to \$1 million. (See <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-12-140.html>.)

In the coming weeks, agencies will begin issuing notices related to changes occurring as a result of their FY 2014 funding coming through.

**Link to appropriations act:** [http://docs.house.gov/billsthisweek/20140113/CPRT-113-HPRT-RU00-h3547-hamdt2samdt\\_xml.pdf](http://docs.house.gov/billsthisweek/20140113/CPRT-113-HPRT-RU00-h3547-hamdt2samdt_xml.pdf)

**Link to explanatory statement:** <http://docs.house.gov/billsthisweek/20140113/113-HR3547-JSOM-G-I.pdf> ♡

## The Good, the Bad and the Ugly

*continued from p. 1*

Following this overview story, *RRC* will address in subsequent issues other provisions in the guidance and their impact on colleges and universities, including specifics on allowable costs, subrecipient monitoring and changes to auditing processes. For now, *RRC* has taken inspiration from the 1966 Italian spaghetti western, *The Good, the Bad and the Ugly* in grouping the revisions (albeit somewhat subjectively).

### The Good

◆ **Requirements for Adherence to Paperwork Reduction Act (200.206).** "This is an extremely important component of the new regulation [guidance] because it is emphasizing that federal agencies will only be able to use OMB-approved forms and frequencies for gathering information, both financial and performance related, from recipients," Lloyd said. "And the attempt is to preclude federal agencies from engaging in what's called 'bootleg reporting,' which is to require detail levels that aren't authorized, or frequencies that are more frequent than

what's appropriate and thereby, through the back door, increase[ing] substantially the reporting burden imposed on recipients."

◆ **Content of a Federal Award (200.210).** "Another new innovation is going to be the content of a federal award. OMB is laying out...a listing of the things that need to be present in a standard grant or cooperative agreement," Lloyd said. "This is a move in the direction of standardization. Right now if you get an award from a particular federal agency, it's going to look different from an award from another of your federal sources. Those differences are going to morph away with this particular requirement."

◆ **Cost Sharing or Matching (200.306).** Organizations will be happy to see that this section "clarifies policies on voluntary committed cost sharing to ensure that such cost sharing is only solicited for research proposals when required by regulation and transparent in the notice of funding opportunity. It may never be considered during the merit review," OMB said in the preamble. This has

been a concern, as recently expressed at the 2013 annual meeting of the National Council of University Research Administrators (RRC 9/13, p. 1).

◆ **Revision of Budget and Program Plans (200.308).** "For many years, in both the current A-102 and A-110 circulars, there has been the authority present for federal agencies to waive certain prior approval requirements," Lloyd explained. In the new guidance, OMB "has essentially restated" this authority, and recipients should seize the opportunity and "be prepared to stand up and ask for waivers of these requirements as part of the application process, and to say to agencies, 'You can trust us to handle this kind of thing, particularly if you do a good job on the front end determining if we're a responsible grantee.' So, in a sense, the stronger due diligence requirements on the front end may lead federal agencies to be more comfortable providing waivers to these things on the back end," he said.

◆ **Disputes (200.341).** This is a new section that "implies that [for] any dispute that arises under an award, the

## Inside NIH

*Dates that appear at the end of NIH news briefs indicate the issue of RRC's weekly emails in which a news item first appeared, where links for documents may be included. Go to "Recent Email Issues" at [www.ReportonResearchCompliance.com](http://www.ReportonResearchCompliance.com).*

◆ **Just prior to the end of 2013, the HHS Office of Research Integrity (ORI) announced a finding of misconduct that resulted in a three-year supervisory plan for a former NIH post-doctoral researcher now employed by a Chinese government institution.** ORI said Baoyan Xu, formerly a post-doctoral fellow with the National Heart, Lung, and Blood Institute, made a limited admission of falsification of images of 13 "pairs of Western blot bands which had a common origin yet were labeled as from different subjects." The NIH intramural research involved "a Western blot analysis of IgM and IgG antibodies from Chinese subjects in patients with non-A-E hepatitis and control subjects to test reactivity towards a newly discovered virus." The uniqueness of the images was questioned by readers of a 2013 paper in the *Proceedings of the National Academy of Sciences* for which Xu was a co-author. ORI said Xu agreed, for a three-year period beginning Dec. 6, 2013, that any organization seeking her participation in the Public Health Service-funded research will submit a plan for her supervision and to exclude herself from serving in any advisory capacity to PHS, including on a peer review committee or board. According to ORI, Xu is currently with the Institute of Infectious Diseases in China. (1/9/14)

◆ **Beginning Oct. 1, NIH will "fully implement a new policy prohibiting the procurement of dogs from Class B dealers using NIH grant funds," the agency announced Dec. 17.** Under U.S. Department of Agriculture (USDA) regulations, Class A dealers or licensees "are those individuals who deal only in animals that they breed and raise. Class B licensees may breed and raise some of the animals they sell but typically buy and resell animals from other sources. Class B dealers include brokers, operators of auction sales, and bunchers—those who supply dealers with dogs, cats, and other regulated animals collected from random sources." NIH is making the shift following a successful demonstration program that showed "Class A vendors can provide large, mature, socialized out-bred hounds or mongrels" for use in research. Under its new policy, "All ongoing NIH-supported research in FY [fiscal year] 2014 involving dogs from any legal source may continue. FY 2015 noncompeting and competing awards issued on or after October 1, 2014 are prohibited from using NIH funds to procure or support the use of dogs from Class B dealers. Dogs used in NIH-supported research may only be from USDA Class A dealers or other approved legal sources. Any costs incurred in violation of this policy are unallowable and will be subject to a cost disallowance," NIH said. (12/19/13)



recipient must be given an opportunity to challenge that decision through some form of due process," he said. "Now, it doesn't go to the length of identifying what that due process is, whether there would be the possibility of a hearing, or submission of documents on the record, or something of that sort."

This marks "the first time where there's been a government-wide policy on this subject, [which] I think is a good thing because it provides a safety valve for organizations to challenge what may be arbitrary, capricious or wrong decisions by an awarding agency," Lloyd said.

◆ **Entertainment Costs (200.438).** OMB has "tightened up the discussion about conferences expenses. But that being said, they have loosened up the one related to entertainment. They've basically said entertainment is unallowable unless the purpose of the entertainment is something that is project-related. So they taketh away with one hand and giveth with another," he said.

◆ **Intellectual Property (200.448).** This is a new section that "deals with the kinds of costs that an organization might incur for registering patents and copyrights or defending themselves against patent or copyright infringement. This is obviously a matter that's of interest uniquely to those organizations engaged in research. But, nonetheless, I think it simplifies what has been a couple

of diverse cost principles in the current requirements," Lloyd said.

◆ **Training (200.472).** "The existing requirements for training are quite complex and they relate to the nature of the training, the duration, and so on," Lloyd said. "OMB has cut through all of that and in the new cost principles simply says training for staff development is an allowable cost, making no specific distinctions there."

◆ **Travel (200.474).** Changes indicate that "organizations that operate internationally had an impact here," Lloyd said. "While the sections related to lodging, meals, incidental expenses and air transportation are essentially what exists currently, the requirement for prior approval for foreign travel has been dropped. And that should come as a tremendous relief to organizations who are performing overseas or working in multiple countries, where in the past they would have to even get permission to cross an international border. That is going away."

This section also "provides that temporary dependent care costs that result directly from travel to conferences and meet specified standards are allowable," as the preamble to the guidance states, Lloyd pointed out.

There were also some possible changes that didn't make it into the final guidance that can bring grantees some solace. For example, OMB has abandoned its draft

## Timing Issues, and What to Do Now

Federal agencies are busy writing regulations to implement provisions in the new 759-page final guidance, "Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards," issued by the Office of Management and Budget (OMB) in late December (see story, p. 1).

But it will be a while before any of the provisions go into effect. Agencies must first publish their implementing regulations, which are due to OMB in draft form in June. Following OMB approval, regulations would presumably be offered for public comment, although they could be published as interim final regulations, meaning they would go into effect right away.

OMB is planning for the effective date of the guidance and regulations to be Dec. 26 of this year. They would affect expenditures and funding received in the fiscal year beginning after publication. OMB has pledged that "Federal agencies will implement this guidance in unison, which will provide non-Federal entities with a predictable, transparent, and governmentwide consistent implementation schedule."

To help funding recipients understand and prepare for the changes, the federal Council on Financial As-

sistance Reform (COFAR) held a webinar in December and scheduled a half-day training session for Jan. 27.

An agency spokeswoman told RRC the training was to include "facilitators [who] represent several federal grant-making agencies." She added that OMB was developing a frequently asked questions document, expected to be posted on its website this month, that would address questions such as whether aspects of the guidance are in effect now that grantees and other fund recipients could take advantage of.

Speaking during a recent webinar, "What You Need to Know Now: A Strategic Briefing From the Recipient and Subrecipient Perspective," Bob Lloyd, principal of Federal Fund Management Advisor, offered a few ideas in this regard. He also discussed how to read the guidance and what to keep in mind.

"I think it's important to take a close look at the entire document. Read the commentary as well as the regulation itself. It's going to take a while to absorb everything. But note and heed the clear influences that have been present on OMB's decisions," Lloyd advised. "I think the audit community, on balance, had more impact here than anybody else. That should

provision to reduce to six months the amount of time an entity had to submit its audit to the federal clearing house, Lloyd said.

"Thankfully, I think, from all standpoints," the requirement remains "nine months after the close of the fiscal year that the report is due, or within 30 days from the completion of the audit, whichever comes first. So that's something that hasn't changed," he said.

### The Bad

The following are among the provisions Lloyd, and others, consider significant new requirements or expansions of previous circulars. Some new provisions, including the following, make changes that are not clear but may become more so when agencies issue implementing regulations.

◆ **Pre-Award Risk Assessment (200.205).** This "is something that reinforces some behavior that's been present in federal agencies in the past, related to what's called financial evaluations or pre-award financial responsibility determinations," Lloyd said. "I think from a recipient standpoint this is something you want to look at to see what kinds of questions you're going to be asked going into a grant competition. Now, obviously many organizations...are well-known quantities to the federal agencies that they work with. So the level to which this examination would take place might not be as when you're ap-

plying to a new agency that you haven't done business with before, or you're a new grantee who's never had any federal awards. This is where agencies are [having] due diligence [activities] imposed on them by OMB."

◆ **Specific Conditions (applied to awards based on risk) (200.207).** "This is a derivative, as well, of pre-award risk assessment. The idea that if an organization is an applicant or a recipient that has a history of poor performance, is financially unstable, has a management system that doesn't meet the requirements of the reform package, hasn't complied with terms and conditions of a previous award, or is otherwise not responsible, the awarding agency can impose more stringent requirements on that recipient," Lloyd explained.

"In other words, it's a very surgical kind of approach, as opposed to throwing the book at everybody. Now, the language in 200.207 is largely derived from OMB circular A-102, the current version, and it talks about the kind of steps that can be imposed on a high-risk recipient, so the money continues to flow, but that organization is put on a shorter leash if you will," he said. "And it also makes clear that this sort of action can be taken by the pass-through entity [toward] a lower-tier subrecipient."

◆ **Performance Management (200.301).** This section "is emphasizing some aspects of performance management" and financial information, "particularly...for computa-

### Timing Issues, and What to Do Now (continued)

demonstrate a concern about making sure that going forward, when this is fully implemented, compliance is high on your priority list."

Bill Ferreira, counsel in the Sponsored Research Practice at Hogan Lovells, a Washington, D.C.-based law firm that advises research institutions, echoed Lloyd's call for a careful reading of the guidance, paying particular attention to the definitions. He also recommended sharing the load.

"Various institutions have carved up the [guidance] among their compliance staff [with] each person becoming 'expert' in particular areas and reporting back over the next few months," he told RRC. "That exercise already has generated fruitful internal discussion."

Lloyd added that "there are some things where I think it may be to your advantage to start now." Among them is the authority that agencies have to grant waivers under section 200.308, Revision of Budget and Program Plans.

Focus on areas in the guidance for "where there's been relaxation of cost allowability," such as in the re-

quirements for travel. "In the near term, if there's been a relaxation...holding you to the old version isn't a particularly productive exercise. So, it may make sense for you to suggest to your awarding agencies, relaxation is where OMB is headed," Lloyd said.

Monitoring "OMB and federal agency actions" and the COFAR website is another suggestion. "This is going to be an ongoing exercise," Lloyd noted.

And finally, speak up. "I've already heard from a couple of clients of mine who are going to be writing letters to OMB or to their awarding agency, urging them in certain directions related to the implementation of this," Lloyd said. "And there is certainly nothing to preclude organizations from doing that. The fact that there isn't a further invitation for comment doesn't mean that you can't present important insights into how this is impacting the community."

Lloyd will be offering webinars on various aspects of the guidance in coming weeks.

**Links:** <http://federalfundmanagement.com/webinars/omb-reform>; <https://cfo.gov/cofar>

tion of unit costs and things of that nature. And federal agencies are being told there to expect recipients to meet performance matrix[es]. Now, how that will play out I think remains to be seen, but the fact that it is presented the way it is is a new emphasis," Lloyd said.

◆ **Internal Controls (200.303)** "For decades, the requirement for internal controls has been very cryptic and very general," Lloyd said. "It has said that recipients are supposed to develop internal controls to protect funds, property and other assets and to assure that funds are used only for authorized purposes. The design of those controls was left completely to the recipient community."

This section was not in the proposed guidance. It "introduces some additional language," such as the concept of "reasonable assurance," which has been "present in Circular A-133 for years. But it also makes reference to two other sources of information about internal controls. One of them is a document developed by the Government Accountability Office (GAO) called 'Internal Controls for the Federal Government,' often referred to as the 'Green Book.' Now, that document is currently in revision at GAO. The previous version, or existing version, is relatively short. The new version is fairly voluminous."

Among Lloyd's concerns is that the incorporation of the GAO document could lead to "overly prescriptive" kinds of internal controls that organizations "need to put in place. I think it is going to generate a certain amount of argument within the community about the appropriateness of somebody's controls." The second source of information mentioned in this section is the Internal Control Integrated Framework developed by the Committee on Sponsoring Organizations.

### The Possibly Ugly

◆ **Conflict of Interest (200.112)**. This section states, in its entirety: "The Federal awarding agency must establish conflict of interest policies for Federal awards. The non-Federal entity must disclose in writing any potential conflict of interest [COI] to the Federal awarding agency or pass-through entity in accordance with applicable Federal awarding agency policy."

This section was not in the proposed guidance and, without more specifics, would result in many differing COI policies among agencies. Without definitions, it's also not clear what constitutes a COI, or a "potential" COI.

NIH's policy, for example, revised in 2011 after a two-year process, requires investigators to disclose "significant financial interests...that reasonably appear to be related to the investigator's institutional responsibilities." Institutions then determine if the interest constitutes a conflict, and if so, it is reported to NIH along with its

plan for managing the COI. No requirements exist for reporting "potential" COIs.

The National Science Foundation (NSF) has a different policy, which may already be under revision, following a critical audit by its Office of Inspector General (OIG) (*RRC 12/11, p. 6*).

OMB also said in the preamble that the final guidance expanded COI requirements to "require non-Federal entities to have strong policies preventing organizational conflicts of interest which will be used to protect the integrity of procurements under Federal awards and subawards."

◆ **Close-out and Continuing Accountability (200.343-345)**. OMB has imposed "on federal agencies and pass through entities a requirement that closeout occur within one year after the submission and receipt of final financial and performance reports," Lloyd said. "That's going to be a very interesting one to see play out, because there has been lots of criticism coming out of Congress, out of GAO and out of OMB itself about slow closeouts." These "brand new" provisions and existing procedures "particularly related to reconciliation of indirect costs and things of that nature may collide...going forward."

◆ **Compensation for Personal Services (200.430)**. This section "and the requirements related to documentation of time and effort...are getting the most attention," Lloyd said. "One of the things that OMB wanted to do was...to bring all of the sectors under a single set of requirements for time and effort reporting." But OMB did not entirely succeed at this effort, said Lloyd, as it "sought a bridge too far."

"What you'll find in the revised section is a general discussion about after the fact disclosure, and full disclosure of effort, and credible signatures, and things of that nature. But then carved out of that are some separate requirements applicable to institutions of higher education, which reflect the activities that go on within an academic environment, where academic teaching, research and service are inextricably joined and very difficult to break out in any meaningful way," he said. "Similarly, there are some unique requirements related to state, local and tribal governments, and so those individual sectors are reflected in the time and effort section."

Yet for all that, "I think if you look closely at what's there, you'll conclude that to a large degree, continuing to do what you've done in the past is going to pass muster," Lloyd said.

Writing in her blog *Rock Talk* on Jan. 17, Sally Rockey, NIH's deputy director for extramural research, called attention to some of the provisions in the new guidance. The first item she mentioned was effort reporting. In Rockey's view, the new effort reporting guidelines "give

grantees much more flexibility in how investigators document their time and effort on their award.”

Universities are particularly cautious when it comes to time and effort reporting, a process they generally loathe. Numerous audits by both the HHS and NSF OIGs have flagged this as a problem (*RRC 2/10, p. 9*).

Organizations such as the Federal Demonstration Partnership have tried for years, through pilots and other advocacy, to convince the government to accept the use of other methods.

It was concern over this and other burdens facing colleges and universities that led to the creation of the A-21 Task Force, whose efforts predated the guidance (*RRC 12/11, p. 1*). In its 105-page comments on the proposed guidance, the Council on Governmental Relations

(COGR) and other associations urged OMB to move away from effort reporting requirements.

The new guidance “may suggest that effort reporting is not required, but institutions should proceed with caution prior to making final decisions,” COGR warned members after the guidance was published.

**Link to final guidance, related materials:** [http://www.whitehouse.gov/omb/grants\\_docs](http://www.whitehouse.gov/omb/grants_docs)

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## In This Month's E-News

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

◆ **Embargo periods that prevent publishing for up to two years, disclosure of data used by peer reviewers to make funding recommendations and restricted access to useable research results are among the more problematic provisions in the draft version of the Frontiers in Innovation, Research, Science and Technologies (FIRST) Act,** according to a Jan. 2 letter sent to the chair and ranking member of the House Committee on Science, Space and Technology by the Association of American Universities (AAU) and the Association of Public and Land-grant Universities (APLU). The groups say the public access efforts under way by the White House Office of Science and Technology Policy are sufficient and urge FIRST Act provisions be rewritten to “direct agencies to adopt embargo periods that are as short as possible” and to eliminate the “unjustified” requirement for peer reviewer information. The bill “should specify that agency repositories provide not only access to but full reuse of research results, including text-mining and data-mining,” they said. Other groups have expressed grave concerns about the draft bill. (1/9/14)

◆ **Officials with the HHS Office for Human Research Protections (OHRP) have issued a letter to Washington University in St. Louis (WUSTL) praising its human research program, staff, policies and procedures.** Five OHRP staff members

and two “expert consultants” completed a three-day onsite evaluation of WUSTL in September 2013, during which they reviewed institutional review board “files for over 40 HHS-supported research studies, IRB meeting minutes for the past year, IRB written procedures and observed an IRB meeting.” The OHRP team also met with numerous WUSTL officials and 15 principal investigators. OHRP officials said WUSTL’s staff had an “enthusiastic and sincere concern for, and an exceptional commitment to, the protection of human research subjects.” OHRP had accolades for WUSTL’s “pre-IRB administrative review” of protocols; its useful “regulatory guides and charts”; “impressive training initiatives,” which include videos shown at the start of IRB meetings; and its “buddy system” that pairs new and experienced IRB members. The Dec. 11, 2013, letter to WUSTL’s vice chancellor for research was recently posted on OHRP’s website. (1/9/14)

◆ **OHRP has advertised the position of director of the Division of Education and Development, formerly held by Elyse Summers, now president and CEO of the Association for the Accreditation of Human Research Protection Programs.** Summers, who had been with OHRP since its inception, left the office in October (*RRC 1/14, p. 3*). “For this position, specialized experience is experience developing and implementing educational programs for audiences

**In This Month's E-News (continued)**

which include personnel of research institutions, government agencies, and other organizations conducting scientific research on issues related to the protection of human research subjects," the job posting states. An advanced degree is not listed among the requirements. The salary range is \$124,995 to \$157,100 annually; the deadline for applications is Jan. 31. (1/9/14)

◆ **George Velmahos, Massachusetts General's chief of the division of trauma, emergency surgery and surgical critical care, "violated regulations governing the proper conduct of clinical studies involving investigational new drugs" in one clinical trial that was not identified by name, according to a Nov. 29 warning letter from the Food & Drug Administration, which FDA posted on its website on Dec. 11.** FDA contended that four violations occurred, namely deviations from the approved protocol, such as "incorrect" dosing; drug administration by individuals not under investigators' supervision; lack of "adequate and accurate case histories" and other data; and missing informed consent and use of expired consent forms. The letter indicates Velmahos offered explanations and proposed corrective actions that "are acceptable if they are properly implemented" regarding some of the issues, but that the agency requested further responses to address other concerns, such as why dosages were wrong and ordered before randomization. FDA asked for "written documentation of the actions you will take to correct these violations and prevent the recurrence of similar violations in current and future studies for which you are the clinical investigator," to be provided to FDA within 15 days of receipt of the letter. (12/12/13)

◆ **FDA also posted a Nov. 27 warning letter sent to St. Vincent Health, a hospital-based system headquartered in Bloomington, Ind., stated that "From our review of the FDA establishment inspection report, the documents submitted with that report, and the [institutional review board's] written response, we conclude that the IRB did not adhere to the applicable statutory requirements and FDA regulations governing the protection of human subjects."** Specifically, the IRB allowed non-members to vote on "clinical investigations" on at least several occasions during the past three years and failed to assess whether pediatric research met the subpart D requirements under the Common Rule. FDA said St. Vincent's proposed corrective actions

regarding IRB voting were adequate "if properly implemented and executed," but that outstanding issues remain regarding review of pediatric research. FDA requested responses within 15 days of receipt of the warning letter. (12/12/13)

◆ **James Troy Clark, an information technology specialist for the National Science Foundation (NSF), faces up to 10 years in prison when he is sentenced next year, following his Dec. 6 guilty plea for "theft of government property."** According to an announcement by the Department of Justice, Clark, 51, had government-issued credit cards that he used "to purchase items for his personal use and the personal use of others, including cellular telephones and the attendant monthly service charges for those phones; multiple laptop computers and tablets; [and] thousands of dollars in movies, music, and other content." The goods were valued at \$94,493. *The Washington Post* reported Clark apologized for his actions and agreed "to pay more than \$77,000 in restitution and let the government keep the electronics authorities had seized from him." Sentencing is scheduled for Feb. 21, 2014. (12/12/13)

◆ **All three legal petitions filed in separate New York County courts on Dec. 2 that sought to establish legal "personhood" status for four chimpanzees have been dismissed, but the group seeking their release from "prison" plans to appeal.** Hercules and Leo — two of the four chimpanzees that are the subjects of the petitions — are currently housed at Stony Brook University, according to the petition by the Nonhuman Rights Project (NhRP), and are owned by the New Iberia Research Center, part of the University of Louisiana at Lafayette. The other two chimpanzees in the petitions are privately owned, according to the group. "All three lower court judges denied our petitions," the group said in a Dec. 10 post on its website. "This was not unexpected, however, since this is novel territory and there are no precedents on which lower court judges can rely. Expanding the common law of New York, which is what the NhRP is trying to do, is typically left up to the higher courts, in this case the Intermediate Appellate Court and New York's highest court, the Court of Appeals. It's also, in part, why we filed these first suits in New York State, which has an automatic right of appeal in *habeas corpus* petitions. These cases now move on to the New York Appellate Courts." (12/12/13)



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Bob Lloyd, Principal of Federal Fund Management Advisor, is a respected authority on the policies and practices affecting award, administration and oversight of federal grants, contracts and subgrants. Bob has more than 40 years of experience in federal award implementation. Prior to starting his management consulting practice in Washington, D.C., in 1982, he served as the executive director of the Grants Management Advisory Service and held staff positions in two large federally funded organizations. Since then, he has been a consultant, trainer or advisor to award and audit units in 16 federal award-making departments and agencies, and to recipient and subrecipient organizations and their professional advisors located in all 50 states, the District of Columbia, several U.S. territories and 18 foreign countries. He also is a Charter Life Member of the National Grants Management Association and served on its Board of Directors for five years.

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