Report on
RESEARCH COMPLIANCE

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Contents

Universities Ask OMB for Longer Closeout, Seek Relief From New Procurement Rules

Individually and through membership organizations, institutions are asking the Office of Management and Budget (OMB) to relieve them of having to comply with procurement standards called for under the new uniform guidance governing federal awards that is set to go into effect at the end of this year.

Universities also are seeking a longer award closeout period to make final expenditures and complete reports — 120 versus 90 days — than allowed by the guidance, technically titled the "Uniform Administrative Requirements, Cost Principles and Audit Requirements for Federal Awards" and also referred to as the omnicircular *(RRC 2/14, p. 1)*.

These are among the requests included in a July 9 comment letter the Council on Governmental Relations (COGR) submitted to the National Science Foundation (NSF) and addressed in other correspondence it sent directly to OMB and to the Council on Financial Assistance Reform (COFAR), a federal interagency body advising OMB on the reforms.

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Waiting for OHRP to Act on SACHRP's Recommendations? Just Fugetaboutit!

The HHS Office for Human Research Protections (OHRP), which in recent years has shown itself markedly less interested in formally pursuing allegations of violations of the Common Rule and in issuing determination letters than it had been, also doesn't see the value in publishing guidance, particularly on topics that its own advisory committee has asked it to address.

Instead, the Secretary's Advisory Committee for Human Research Protections should try on its own to publish its recommendations in journals, given that guidance doesn't have the force of law, OHRP Director Jerry Menikoff told SACHRP members at their two-day meeting outside Washington, D.C., July 21-22.

The approach suggested by Menikoff for SACHRP, in which it would develop recommendations meant for HHS and offer them directly to the research community for adoption, seems at odds with its mission as set out in its charter. But perhaps seeing no other options for their work to be acknowledged and disseminated, SACHRP members went on to discuss ways to draw more attention to their recommendations and to have them published.

SACHRP was created in 2001 to "provide expert advice and recommendations to the Secretary, through the Assistant Secretary for Health (ASH), on issues and topics pertaining to or associated with the protection of human research subjects," according to its charter.

Historically, SACHRP has performed its responsibilities by embedding recommendations, often voluminous and the result of years of careful work, in "correspondence" it sends to the HHS secretary. The transmission process itself — to say nothing of

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whether OHRP ever acts on SACHRP's recommendations — can be time-consuming and opaque.

For example, SACHRP's recommendations might not be formally sent to the secretary until months after the meetings during which members approved them, and then many more months might pass before they actually appear on OHRP's website on a page called "secretarial correspondence," found under the tab for SACHRP. These are posted only if the secretary has "signed off" on them, which simply means that OHRP is cleared to consider the contents of the correspondence, not that it is compelled to act on the recommendations.

Menikoff's comments came after SACHRP Chair Jeff Botkin asked OHRP at the start of the meeting to update the panel on the status of a number of recommendations SACHRP has submitted in recent years to the secretary that don't seem to have resulted in any action by OHRP. The number of investigations and other actions taken by OHRP has been steadily falling since Menikoff joined it in 2008 *(RRC 5/14, p. 1)*. For example, in all of 2013, OHRP opened only one investigation; so far this year, that number is three, according to HHS.

Botkin said his question was prompted by "conversations" and "perhaps frustration about 'Are we getting enough feedback about the recommendations that we're making?'" Acknowledging that unaddressed recommendations go back much further, Botkin said he wanted to focus on "issues that we have addressed" since he became chair in October 2012 and to hear from OHRP "as to where we might be with action and consideration of those initiatives."

The recommendations that Botkin drew attention to are as follows:

◆ At its previous meeting in March, SACHRP approved recommendations regarding engagement in research and federalwide assurances, certificates of confidentiality, and cluster randomized trials and informed consent (*RRC 4/14, p. 1*).

◆ At its March 2013 meeting, SACHRP approved recommendations on expedited review applicability and categories and on Internet research (*RRC 4/13, p. 1*).

◆ In October 2012, recommendations approved by SACHRP addressed institutional review board "knowledge of local context" related to the use of a single or central institutional review board (IRB), investigator responsibilities, and informed consent and waiver of consent (*RRC 11/12, p. 1*). SACHRP also submitted comments on joint draft guidance issued by OHRP and the Food and Drug Administration (FDA) on transfer of research between IRBs. Despite the joint nature of the original guidance, on its own FDA recently issued final guidance on this topic, but OHRP still has not (*RRC 7/14, p. 5*).

While OHRP generally meets three times a year, its October 2013 meeting was cancelled due to the government shutdown. SACHRP does not always have recommendations before it at each meeting to approve; it did not, for example, during the most recent meeting in July.

It was largely inaction on the part of OHRP, and longstanding need in the research compliance community, that spurred publication by the Hastings Center of a special issue, "The Intersection of Research Fraud and Human Subjects Research," on July 15. Included is a paper proposing a framework to integrate investigations into misconduct and Common Rule violations that was co-authored by former SACHRP Chair Barbara Bierer and attorney Mark Barnes, who co-chairs SACHRP's Harmonization Subcommittee. The starting point for the paper was a set of recommendations SACHRP approved in February 2012 and submitted to HHS but that has not been acted upon by the department (see story, p. 4).

Responding to Botkin's request for an update on the status of the recommendations, Julia Gorey, SACHRP's

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executive director and a member of OHRP's policy and assurance division, said OHRP can't consider acting on any of the recommendations that SACHRP approved in March, such as those addressing cluster randomized trials, because they have not been formally received back from the secretary.

She added that the "majority" of the other recommendations that Botkin listed "would, in one way or another, impact issues that are currently being considered" by HHS as part of "potential" revisions to the Common Rule that OHRP has been working on for at least the past four years. "Therefore, at this point in time, OHRP is not able to give a more substantive response as to where these particular recommendations are," she said.

Gorey was referring to the July 2011 publication of an advance notice of proposed rule making (ANPRM) modifying the Common Rule *(RRC 9/11, p. 1)* All of the recommendations Botkin ticked off were completed after the ANPRM was published.

Common Rule Revision 'Is Not Dead'

At the start of the meeting, Menikoff said a proposed rule to follow up on the ANPRM was still "actively being worked on" and that it is "definitely not true" that this project is "dead" or "stagnant." He said there is "still a great deal of interest in this on the part of the federal government….Let's be hopeful that something will actually hit the light of day sometime in the relatively near future."

Menikoff made a similar statement about guidance on so-called "standard of care" research, saying he hoped "draft guidance will be released in the relatively near future." This is guidance OHRP has been working on for nearly a year, following a public meeting to address the controversy surrounding informed consent documents used in a multi-center, NIH-funded trial involving saturation levels of oxygen provided to premature infants *(RRC 10/13, p. 1)*.

Menikoff said some of SACHRP's recommendations were outside the "scope" of OHRP's jurisdiction, echoing comments by Gorey. Gorey also said OHRP was "open" and "welcome" to working with SACHRP to develop ways to provide members with "more impactful feedback…regarding the status of their recommendations once they are back to our office having been signed by the secretary."

But beyond these particular specific guidance documents that OHRP is currently working on, per requests by FDA or HHS, Menikoff implied that it was not worth the effort to issue new regulations or guidance that is recommended by SACHRP. He stated that the simple fact that SACHRP had produced some document containing recommendations might go far enough.

As an example, Menikoff noted SACHRP's recommendations from March 2013 on Internet research, which members discussed later in the meeting in light of the recent study conducted by Facebook and researchers at Cornell University (see box, p. 6).

Without mentioning that OHRP has not acted on the recommendations or publicly endorsed them, Menikoff said the mere posting of them on OHRP's website might be "the most significant development that one might want," and could still serve to "change behavior in the Internet field."

SACHRP's recommendations fill a "void," he said, and noted they were contained "in a lengthy document that advised points to consider, best practices, whatever it is, that is, in fact, out there now," Menikoff said.

"Part of the recommendation was that OHRP and OCR [the HHS Office for Civil Rights] should get together and issue some kind of guidance, whatever," Menikoff acknowledged. "But often if we issue guidance it might not be all that different in terms of a legal matter" from a letter SACHRP might send to the secretary spelling out its thoughts on a particular topic, he said.

Menikoff explained that guidance isn't binding — only regulations are — and that guidance is an "interpretation" of the regulation. Guidance becomes "tricky" in terms of enforcement when the word "must" versus "shall" is used, as "must" holds more legal weight but it is still not a regulation, he added.

"There are limits to our ability, basically, to enforce the letter of the words that we put out in terms of guidance," Menikoff said.

Menikoff: A Paper May Be Better Than Guidance

At least one SACHRP member, however, pointed out that official guidance documents from any agency — even when issued in draft form — are viewed as useful and are required reading by regulated entities. Speaking of FDA guidance documents specifically, these "are very closely followed and people pay a lot of attention to them even though we recognize" that often guidance documents may contain more instances of the word "should" rather than "must," said Albert Allen, who is with the Development Center of Excellence of Eli Lilly & Co.

It was Botkin who first raised the notion of SACHRP publishing its recommendations, but this idea was quickly embraced by both Gorey and Menikoff. In particular, Menikoff said "people in our field are used to looking at the major journals" and that getting something published "could have a huge impact" compared to what can be gained when SACHRP's work products are posted on OHRP's website.

Botkin said he has always considered SACHRP's work products "appropriate for publication in the schol-

arly literature," and stated he would "encourage subcommittee members and committee members to think about those as possibilities." He added the caveat, however, that publications wouldn't be "done on behalf of OHRP or HHS" but would "be the work product of the individuals who put them together."

Nevertheless, these would have to be vetted through HHS and approved prior to publication, said Gorey, who offered her assistance to SACHRP in doing so.

"I have never had any sense [that publication] barriers are on the Health and Human Services side," Botkin added. "I think the barriers are simply with folks [not] thinking about and putting that extra time into taking the work products and crafting them into a publishable format, so I think we need to take responsibility on our end for perhaps taking that final step. So, it may be actually worth thinking about approaching journals to see whether there might be a welcoming platform for the work that we do."

What If There's No Guidance or Publication?

David Borasky, deputy director of the Office of Human Research Ethics at the University of North Carolina, Chapel Hill, and a member of SACHRP's Subpart A Subcommittee, added that his institution routinely disseminates some of SACHRP's work products, such as a frequently-asked-questions document on biospecimens. He said he knows about these documents because of his association with SACHRP.

"If they're not all going to make it to publication, and not all going to be reformatted as guidance, I wonder if there is a way internally to give them more prominence," Borasky said. "Because if you're not familiar with SACHRP, you don't know where to start drilling down on websites to find some of these great documents."

Gorey responded that there are some SACHRP documents that she gets more calls about than others and that she considers to be SACHRP's "greatest hits," which could probably be featured in a prominent way on OHRP's website.

Later in the meeting, Menikoff signaled OHRP's hands-off approach regarding other matters. For example, asked to weigh in following a lengthy discussion that involved presentations by three experts on the topic of returning research results to subjects, Menikoff begged off, saying OHRP considers the topic "extra-regulatory."

However, officials from FDA in attendance at the meeting said they, too, are grappling with this issue and would welcome SACHRP's input and engagement.

Link: http://www.hhs.gov/ohrp/sachrp/mtgings/2014%20Jul%20Mtg/july21-22,2014sachrpmeeting.html ✧

Model Proposed to Mesh Human Subjects, Research Integrity Probes

A lead paper and five related commentaries published in a special issue of the *Hastings Center Report* that explore "the intersection of research fraud and human subjects research" may provide assistance to research compliance and integrity officials who face overlapping investigations when allegations of fabrication, falsification and plagiarism may also give rise to violations of the Common Rule governing research subjects.

Published July 15, the special issue is anchored by a paper titled "Research Misconduct Involving Noncompliance in Human Subjects Research Supported by the Public Health Service: Reconciling Separate Regulatory Systems," coauthored by Barbara Bierer, former chair of the HHS Secretary's Advisory Committee for Human Research Protections, and Mark Barnes, currently co-chair of SACHRP's Harmonization Subcommittee, on behalf of a "working group" of stakeholders.

Bierer is also the senior vice president for research at Brigham and Women's Hospital and a professor of medicine at Harvard Medical School.

The paper represents the outcome of a process that was initiated several years ago when SACHRP began to identify "significant disharmonies" between the procedures for addressing research misconduct and Common Rule violations, as contained in two separate sets of regulations, and overseen by two distinct agencies within HHS. Research misconduct falls under the Office of Research Integrity (ORI) while Common Rule violations are the purview of the Office for Human Research Protections (OHRP). Other procedures imposed by the Food and Drug Administration (FDA) also come into play.

Many Have Expressed Their Gratitude

In March 2012, SACHRP sent a letter to the HHS secretary asking that HHS issue "uniform and coordinated guidance" or, "to the extent necessary, regulatory amendments" to address "oversight of research misconduct and regulatory non-compliance."

Nothing happened in response, but the issue got new life again when ORI convened a two-day meeting in January 2013 of approximately 80 individuals, among them research integrity officers (RIOs), institutional officials (IOs) and members of institutional review boards (IRBs), who vowed to produce their own set of best practices for running these sorts of dual investigations *(RRC 2/13, p. 1)*.

In an interview with *RRC*, Barnes said the new paper, which includes a series of frequently-asked-questions and answers, has been met with an overwhelm-

ing display of gratitude from the research compliance community.

"I have gotten a lot of unsolicited emails saying, 'Thank God this is out….We have needed it,'" Barnes said.

Beyond the members of the ad hoc group that helped draft the paper, Barnes said the document reflects the input of government officials at ORI, OHRP, FDA and NIH, as well as the National Science Foundation. Over the course of writing it, he and Bierer received more than 2,000 comments on their draft document and spent "a lot of time" trying to incorporate them.

Barnes told *RRC* he has not "seen a perfectly integrated system" for investigating human subjects noncompliance and research integrity issues, but quickly added, "that's not necessary and not what [the document] recommends."

What's essential is really more basic — a sharing and coordination between IRBs, RIOs and IOs, Barnes said: "a continuing conversation and communication" between these officials and their efforts.

As evidence of the need to improve these relationships, Barnes cited an email he received from an individual who told him that the institution's RIO "didn't know who the IO was" prior to reading the new paper. Barnes said he found himself "amazed but not surprised" by such comments.

While smaller institutions might not deal with many research misconduct or human subject violation investigations each year, so overlap might be minimal, the problem might even be more prevalent at larger organizations because of silos, Barnes said.

In addition to the FAQs, the paper also includes a helpful list of "categories of researcher actions in human subject research that may violate both sets of regulatory standards." This may assist officials to pinpoint the misconduct and human subject rule cases that should trigger more intense cooperation.

These are:

- "falsifying or fabricating medical or clinical tests;
- "inventing subjects;
- "altering research data;
- "eliminating outlier data or selectively reporting data;
- "creating documentation for visits, tests, interactions, and payments that did not occur;
- "altering dates and results from subjects' visits;
- "swapping or substituting biospecimens or records;
- "falsifying consent forms;
- "misrepresenting significant issues, such as serious adverse events or unanticipated risks;
- "altering eligibility screening dates or screening results;
- "not conducting interviews with subjects and creating records of the nonexistent interviews;
- "fabricating data from subject interactions and inserting those data into a medical or clinical chart or research record;
- "recording results of follow-up visits with deceased subjects or with subjects who were lost to follow-up; and
- "fabricating or falsifying information on an IRB protocol to obtain approval."

Now that the paper is out, Barnes isn't expecting that it will somehow become official HHS guidance. "That would be nice, [but] we have no hope that is going to happen," Barnes said. Indeed, OHRP Director Jerry Menikoff recently indicated that there is often little value in issuing guidance (see story, p. 1).

Instead, said Barnes, "We do have hope that [research universities] will look at it and follow it as voluntary guidance."

This may be a safe bet given "there is such a hunger out there in the research community" for help with straddling the two types of investigations. Widespread acceptance and adoption will make the framework something of a "best" or standard practice, Barnes said.

He said he believes if "the industry defines its own practices and follows them, the government will often leave it alone."

Link: http://onlinelibrary.wiley.com/doi/10.1002/hast.2014.44.issue-s3/issuetoc ✧

Audits Find UC-Chapel Hill, NYU Down, UC Santa Barbara Way Up

After a bit of a dry spell, a couple of audit reports were recently issued that continue to show the dangers that lurk for universities — but also a quite impressive reversal for one educational institution that fought back against a multi-million repayment request from the Office of Inspector General (OIG) of the National Science Foundation (NSF).

First, the story of the victor. University audit officials no doubt have been keeping an eye out to learn the conclusion of a near-two-year campaign by University of California, Santa Barbara (UCSB) in opposition to a $6.325 million repayment request by the NSF OIG for what its auditors said were unallowable costs.

In addition to the size of the potential repayment, the audit drew interest when it was issued in September 2012 because it was among the first for which auditors employed "data analytics," a much ballyhooed approach

by NSF that is said to be the wave of the future for its ability to zero in on areas thought to be at high risk for unallowable costs. The audit encompassed a span of time from Jan. 1, 2008, to Dec. 31, 2010, during which UCSB claimed $143.4 million in costs amid more than 266,000 transactions from 604 NSF awards *(RRC 1/13, p. 1)*.

UCSB fought the findings of unallowable costs, citing, among others, problems with the audit process itself, particularly a lack of time to respond. Per policy, OIG auditors make repayment and other recommendations based on their findings, but it is up to NSF to sustain or reject findings and require actions by institutions that were audited.

In a report resolving the audit findings dated June 13, NSF largely concurred with UCSB, rather than OIG auditors, determining that, in the case of $1.9 million in questioned costs for summer salaries, NSF has a different "understanding" of UCSB's policies for these expenditures, all of which NSF allowed.

The largest category of costs the auditors found unallowable was $2.5 million in "unfulfilled cost sharing," but NSF determined that UCSB "was compliant" with both Office of Management and Budget and its own relevant policies, and ruled all the questioned cost-sharing amounts as appropriate.

The $43,551 of costs that NSF did agree were questionable stem primarily from some equipment purchases made "near the end or after [an] award period." NSF thanked UCSB for its "patience, cooperation and timely responses."

After Facebook Study, SACHRP Revisits Internet Recommendations

The document the Secretary's Advisory Committee on Human Subjects Research (SACHRP) forwarded to HHS last year to serve as the basis of guidance on the conduct of research involving the Internet is often "on target." But several issues have emerged following publication of a controversial study conducted by Facebook and two Cornell University researchers that warrants a second look, SACHRP members agreed at their July 21-22 meeting outside Washington, D.C.

During the last discussion of the two-day meeting, SACHRP Chair Jeff Botkin summarized what is known about the research, which was published last month in the *Proceedings of the National Academy of Sciences* (PNAS) (*RRC 7/14/14*). He led the panel through a discussion of whether problematic aspects of the study were addressed in SACHRP's March 2013 set of recommendations *(RRC 4/13, p. 1)* These recommendations are among many that HHS has not acted upon, which was another topic of discussion at the meeting (see story, p. 1).

The PNAS paper, "Experimental evidence of massive-scale emotional contagion through social networks," described how Facebook, for a one-week period in 2012, manipulated the amount of positive and negative information included in the "news feed" for nearly 700,000 users and then studied whether they, in response, posted more positive or negative updates themselves.

At the start of the discussion, Jerry Menikoff, director of the HHS Office for Human Research Protections (OHRP), said he wanted to make it clear that HHS had no plans to take any actions regarding the study, as his agency has no jurisdiction over the research at issue.

This is primarily because the study was not federally funded and according to its current federalwide assurance on file with OHRP, Cornell, which said its researchers helped analyze data and draft the paper, "unchecked the box" and did not extend requirements under the Common Rule to research it conducts that is not federally funded.

However, there have also been discussions about whether the study met the definition of research and research activities of a type to which the Common Rule applies. Menikoff said he thought it would probably take "an act of Congress" to bring this type of research, when conducted by a private company, under the Common Rule.

The consensus among the SACHRP members seemed to be that, given the nature of the manipulation and the size of the test group, they would have wanted the research at least to have been reviewed by their institutional review boards (IRBs).

They felt that should occur even if they ultimately didn't have authority to require changes, which might be the case for various reasons, such as if the study was being done during an investigator's personal time and without institutional resources.

As SACHRP member Pilar Ossorio, associate professor of law and bioethics at the University of Wisconsin Law School, observed, "We do review some things that, under the engagement guidance, probably wouldn't count as research, but we do it."

The goal is to assure that "some IRB reviewed it and that our researcher and our institution [are] not getting involved in something that would be really ugly," Ossorio explained.

"UCSB is pleased that the issue has been resolved, and the concerns raised by the IG's audit were addressed," Robert Tarsia, UCSB director of audit and advisory services, told *RRC* in an email. "This confirms that UC Santa Barbara has high standards and provides the highest caliber research." He declined to comment further, but did say that UCSB had accepted NSF's finding that $43,551 should be repaid.

Link: http://www.nsf.gov/bfa/dias/caar/docs/auditreports/auditrep121005_ucsb.pdf

FDP Defense Didn't Fly

New York University (NYU) also recently found itself tangling with the NSF OIG, but its repayment request is far less — $75,000. The 27-page audit, completed by Cotton & Company, LLP, under a "solicitation" NSF OIG issued in July 2012, covers the period from July 1, 2009, to June 30, 2012, during which time "NYU had 394 active NSF awards, and reported expenditures on those awards of over $72.6 million."

Half of the section in the June 12 audit report titled "Objectives, Scope, and Methodology" is redacted, particularly two paragraphs that begin with "Our work required reliance on," which presumably describes how the auditors selected which costs to review.

The breakdown of the questioned costs is as follows:

◆ $35,054 in "unallowable" indirect costs, which the auditors said resulted from NYU's use of an inappropriate modified indirect cost rate. NYU said it corrected the rate but because this occurred after the audit was issued, "the finding remains in the report," the auditors said. The rates were redacted from the report.

◆ $29,288 in "unreasonable" foreign travel costs, of which $19,018 was "direct" travel cost. These were relat-

Fellow SACHRP member Suzanne Rivera, associate vice president for research at Case Western Reserve University, agreed that IRBs should have the opportunity to give at least a cursory review to similar research.

But she added that, in her view, the risk posed by the study "was less than minimal," and that any IRB reviewing the study would likely have waived consent. Getting consent may have made the study impractical to conduct, she said. Based on "knowing how Facebook works...I think it would have been a slam dunk for most IRBs to say that," Rivera said.

Any review needs to take place "within the context of [understanding] the risks and the privileges that we enjoy in regular, everyday life," she said.

The authors of the paper contended that Facebook users gave their consent to be in the study when they agreed to Facebook's terms of use or service. "I don't think that would pass muster," said Stephen Rosenfeld, chairman of Quorum Review IRB, adding, "the fact that they explicitly make that statement in their paper is a bit disturbing."

Albert Allen, who is with the Development Center of Excellence of Eli Lilly & Co., said he wasn't sure that SACHRP had addressed this issue in its 2013 recommendations and should consider revising them to touch on what is acceptable as a proxy for informed consent.

The members also agreed that it was "disingenuous" for researchers to say they were not engaged in research because they became involved after the data were collected, and that any researcher who contended that obtaining consent would render the research impractical to conduct should have to provide clear evidence for that argument.

SACHRP members said Facebook's claim that consent was already given "through the end user license agreement" was probably not an equivalent proxy for giving actual consent. Other issues that might be of concern include that, based on such a large study population, the opportunity for harm may be increased, even if the actual risk isn't high.

No doubt echoing the sentiments of many in the research compliance community, Ossorio cautioned that this type of study is "something that, as people in universities associated with IRBs, we have to be on the lookout for."

Increasingly, researchers engaged in similar studies using "big data" were educated "through the computational sciences [and] are not like people who came up through medicine and human biology," Ossorio said. "They don't get training in ethics necessarily, the way that people do who are in a Ph.D. program funded by NIH.…They don't work in departments where all of the colleagues know about the Common Rule [or] have submitted IRB applications."

These researchers, she said, also tend to think of "consent" simply in terms of data collection, and may not ponder whether they have consent "to manipulate the data once you got it," necessitating that universities "will have to be interacting with them and educating them."

Link to SACHRP Internet research guidelines: http://www.hhs.gov/ohrp/sachrp/commsec/attachmentbsecletter20.pdf

ed to just one award, "CAREER: Identifying and Measuring the Economic Value of Information on the Internet," according to the audit. NSF's award database identifies this as award #06438347, which ran from Jan. 16, 2007, to an "estimated" expiration date of Jan. 31, 2013. The total award amount was $498,435.

According to the auditors, the award included some redacted amount for travel but only if it was domestic. At issue were expenditures that the principal investigator (PI), who is not named in the report but is identified in an NSF awards database as Anindya Ghose, claimed for five foreign trips that he took.

These were Dec. 24, 2011, to Jan. 11, 2012, to three locations in India; Jan. 19-29, 2012, to Tanzania; March 13-18, 2012, to two of the same three locations in India; April 7-12, 2012, to Seoul, South Korea; and May 12-19, 2012, to Munich.

NYU appears to have disputed OIG's questioning of all of the travel costs, stating they were appropriate, but OIG maintained repayment was required because the trips "partially or wholly benefitted other research projects." NYU was "unable to provide documentation showing that the costs were allocable" to Ghose's award or "were allocated to it in accordance with relative benefits received or another equitable relationship," the auditors said.

◆ $10,027 in "unreasonable equipment purchases made at the end of a grant's period of performance."

Interestingly, the audit contends that NYU claimed because it was a member of the Federal Demonstration Partnership (FDP) it has expanded "authority to make such purchases," regarding its acquisition of a number of workstations (the total was redacted), and a computer with a widescreen monitor (purchase price and brand name redacted).

The auditors countered that "FDP organizations must still adhere to the requirements of their awards, as well as the federal regulations regarding costs claimed on federal awards; participation in the FDP does not relieve NYU of the requirement to only charge reasonable, allocable, and allowable costs to its NSF awards."

◆ $1,125 in "unallocable conference fees." These relate to award #06133893, which NSF identifies as a three-year, $562,243 award for PI Helen Nissenbaum to develop "a software design methodology that takes values into account when designing software systems." OIG flagged expenditures of $194 for meals and $931 for alcoholic beverages, charges that "included 27 bottles of wine and 10 individually ordered alcoholic beverages." All appear to have been consumed during the same meal, on May 6, 2010, at an unidentified restaurant in New York City; the number of conference participants, for whom the dinner was held, was redacted.

NYU agreed to repay the cost of the alcohol but not the meals. Overall OIG recommendations are for NYU to "strengthen the administrative and management controls" but NYU appeared to state, again amid heavy redactions, that its controls were sufficient.

Link to NYU audit report: http://www.nsf.gov/oig/nyu.pdf

UCSD: Our Oversight Is Sufficient

Meanwhile, on another UC campus, auditors from the HHS OIG concluded that UC San Diego (UCSD) should repay just $3,765. That audit, dated June 26, concluded that UCSD "generally claimed administrative and clerical payroll costs charged directly to HHS awards in accordance with Federal regulations" for fiscal years 2010 and 2011. But the auditors found that "a small amount of costs was unallowable."

OIG reviewed "administrative and clerical payroll costs charged as direct costs to grants, contracts, and other agreements between the University and components of HHS, including the National Institutes of Health and the Public Health Service," in particular "a stratified random sample of 200 monthly payroll payment records, totaling $503,863."

Of these, "195 were allowable, and 5 were unallowable. The five unallowable sample items totaled $3,765, consisting of $2,510 of unallowable direct administrative and clerical payroll costs and $1,255 of related F&A [facilities and administrative] costs. The University claimed unallowable costs because it did not always provide adequate oversight of administrative and clerical payroll costs charged directly by departments to HHS awards to ensure compliance with Federal regulations," the audit said.

OIG recommended that HHS seek repayment of $3,765, while the university agreed to refund $1,766. OIG also recommended that the university "enhance oversight of administrative and clerical payroll costs charged directly to HHS awards to ensure compliance with Federal regulations."

According to the auditors, UCSD "stated that it had communicated our findings to the appropriate University officials and would continue to provide education and guidance on appropriate charging of administrative and clerical costs. However, the University stated that because of the small number and dollar value of the errors, it did not believe a change in business practices for charging or supporting effort on sponsored awards was warranted," the audit said.

Link: https://oig.hhs.gov/oas/reports/region9/91201001.asp

OIG Cited Mysterious Transfers

Finally, a June 27 audit also issued by the HHS OIG seeks a repayment of $352,843 from the University of North Carolina at Chapel Hill (UNC-CH) — but in this instance, the finding isn't being disputed. The period covered by the audit is July 1, 2009, through June 30, 2011, during which time UNC-CH "claimed reimbursement for approximately $956.3 million in costs incurred on 1,447 grants, contracts, and other agreements (awards) from HHS," the auditors said.

The auditors' findings are based on a "random sample" of 163 transactions totaling $8.496 million. Of these, the auditors concluded 155 transactions were allowable, but eight were not.

The eight consisted of $298,275 in costs that "were not adequately documented;" $34,557 in costs that "were not reasonable;" and $3,042 in costs that "were not treated consistently." Moreover, UNC-CH "claimed unallowable F&A costs totaling $16,969 that were associated with the unallowable costs," the auditors said.

Among the costs the auditors said were not adequately documented were expenditures attributed to "research related equipment, supplies and services." The auditors cited as an example $265,000 for scientific equipment that UNC-CH "initially charged to a University trust fund account but transferred the amount to an HHS grant 10 months later."

The documentation "was limited to a note that stated that, after review, the University determined that a portion of the equipment should be charged to the grant," and there was no stated "allocation basis for the amount transferred" nor an explanation as to "why it took so long to transfer the costs," the auditors said. Similarly, the auditors said there was a claim of $7,694 "for research animal care" and $1,870 for lab supplies transferred from other university accounts that also lacked adequate documentation concerning "the nature or justification of the transfers."

Among the costs the auditors said were "unreasonable" were $34,557 "in various costs charged to a foreign award that were duplicate[d];" $19,667 "for audit fees to meet accountability status requirements with foreign regulatory bodies" that also include some duplicate amounts, and $5,529 "for foreign housing" that had "already been claimed."

In addition to the repayment, the auditors recommended that UNC-CH "enhance oversight of charges to Federal awards to ensure consistent compliance with federal requirements." UNC-CH concurred with both recommendations.

It listed eight actions it had taken or would take to beef up compliance and oversight, including holding a "full day symposium…that will be offered to Research Administrators and will cover a wide range of compliance topics such as cost transfers, cost accounting standards and roles and responsibilities. An emphasis will be placed on reviewing federal compliance requirements and university policies and procedures." It also deployed a new "audit software package to assist with monitoring certain categories of expenses" and modified and updated several of its policies and procedures.

Link: https://oig.hhs.gov/oas/reports/region4/41301024.pdf ✧

Head of Controversial HHS Office Resigns Amid Hunt for ORI Chief

Howard Koh, head of an HHS office that is the subject of calls for investigations by two members of Congress, was expected to return to Harvard University this fall after "stepping down" at the end of July from the government post he's held since 2009.

New HHS Secretary Sylvia Mathews Burwell, who was sworn in on June 24 following the resignation of Kathleen Sebelius, told some HHS staffers of Koh's pending departure in an email sent two days before the July 4th holiday.

As the assistant secretary for health (ASH), Koh ran the Office of the Assistant Secretary for Health (OASH). Among the agencies under OASH are both the Office of Research Integrity (ORI) and the Office for Human Research Protections (OHRP).

The ASH has to be confirmed by the Senate. Burwell said Koh was to "assume a new position at the Harvard School of Public Health as Professor of the Practice of Public Health Leadership," and she thanked him for his contributions while at HHS. Koh previously held positions at Harvard.

An HHS spokeswoman said Koh's departure was "not related" to criticisms directed at his office, but she did not offer a reason for his resignation. Even with just five years at HHS under his belt, Koh reportedly has said he is HHS's longest serving ASH.

continued

On July 8, just days after Burwell's email, in a speech on the Senate floor, Sen. Chuck Grassley (R-Iowa) repeated his calls for HHS to conduct an investigation into claims made by former ORI Director David Wright in a resignation letter Wright submitted to Koh in February (*RRC 7/10/14*).

In the widely reported letter, Wright had said penny-pinching and politically motivated meddling by staffers in OASH — which he termed "secretive, autocratic and unaccountable" — had made it impossible for him to remain in his position just two years after accepting it.

Wright did not call for Koh to step aside in his resignation letter but he urged HHS to reconsider whether ORI and OHRP belonged within OASH because, he said, that environment was highly politicized. Wright termed Koh's departure "abrupt" and said he did not know what was behind it.

Wright told *RRC* he hoped the choice of his successor as head of ORI would be made by whoever replaces Koh, in consultation with Burwell.

Grassley: HHS, NIH Oversight Is 'Lackluster'

While the position remains vacant, the HHS spokeswoman told *RRC* on July 21 that the process for selecting Wright's replacement was "moving along. We hope to identify the new ORI director soon," she said.

Before Wright was hired in January 2012, the post had been vacant for more than two years *(RRC 8/10, p. 1)*.

Before Wright's resignation, Grassley had been separately probing whether ORI and NIH imposed appropriate sanctions on a researcher at Iowa State University who was barred from government funding for three years after admitting to research misconduct in HIV studies; the researcher has since been indicted on federal fraud charges, and ISU is repaying some of the grant funds (*RRC 7/10/14*).

A spokeswoman for Grassley's office told *RRC* the senator was unaware that Koh planned to leave when he made his speech.

Jill Gerber said Grassley has "made clear, in his recent floor speech, in interaction with Ms. Burwell about Dr. Wright's concerns during her nominations process, and in his communications with HHS and NIH, including staff follow-ups to NIH and HHS, that he expects now-Secretary Burwell to take the lead in making sure ORI functions at a high level and that NIH does much more to oversee federal research dollars and take action when fraud occurs."

Gerber added that "NIH and HHS have been unresponsive to staff follow-ups" to Grassley, and that "agency letters in response to Sen. Grassley have been lacking in detail."

"Sen. Grassley chose to give a floor speech in part to outline his concerns in the face of lackluster interest from the agencies in tackling fraud oversight," Gerber said.

OASH came under fire again in May when Rep. Rosa DeLauro (D-Conn.) and Michael Carome, director of the Health Research Group of Public Citizen and a former OHRP official, called on the HHS Office of Inspector General to "immediately launch a formal investigation" into what happened in 2013 when OHRP sought to bring an enforcement action against the lead university in a $20 million, NIH-funded multicenter trial of varying oxygen saturation levels provided to premature infants.

DeLauro and Public Citizen released 439 pages of emails, among them many written by or CC'd to both Koh and Wanda Jones, who has been named the acting ASH, which they said showed improper meddling by HHS and NIH into OHRP's investigation of the oxygen level study *(RRC 6/14, p. 4)*.

"Dr. Koh obviously failed miserably in insulating OHRP from inappropriate interference by officials at NIH and senior officials in the Office of the Secretary," Carome told *RRC*. "Whether his successor will take a stand to protect OHRP from such interference remains to be seen. At this point, I don't yet have a sense [of] whether the new Secretary will alter the dynamics regarding the performance of OHRP."

DeLauro's office did not respond to *RRC*'s requests for comment on Koh's resignation. ✧

Universities Ask OMB for Fixes

continued from p. 1

COGR's comment letter was submitted in response to NSF's May 9 publication of proposed plans to implement the uniform guidance.

NSF's draft implementation plan took the form of a revised Proposal & Award Policies & Procedures Guide (PAPPG), traditionally the vehicle through which NSF specifies requirements for awards. Unlike other agencies, NSF does not issue regulations.

As of *RRC*'s deadline, NSF remains the only federal agency to reveal how it will put the guidance into practice *(RRC 6/14, p. 1)*. Comments were due by July 8. None are posted on regulations.gov, the federal website where comments typically can be viewed. COGR and the University of Minnesota (UM) are among those that have made their comments public. The Association of American Universities and the Federation of Societies for Experimental Biology did not submit comment letters, representatives told *RRC*.

Hopes are dwindling that others will follow NSF's lead and issue a draft proposal for the research compliance community to review and comment on before the

new guidance goes into effect beginning Dec. 26. Some changes will not be felt until later in 2015 depending on when new grants and contracts are made.

"We took the opportunity to comment on the NSF implementation [and highlight] all the issues we believe need to be addressed by OMB and COFAR," COGR President Tony DeCrappeo told *RRC*.

This was done because, "at least as far as we know right now, we won't see any other implementation [plans] until December. We do not have any other information at this time regarding other agency implementation" strategies, DeCrappeo said.

While the Department of Defense has given parts of its plans to COGR for its feedback, DeCrappeo said these are not public and that he could not share the content of them with *RRC*.

Lots for OMB, COFAR to Consider

The comment letter was the last of three recent documents COGR produced regarding problems with the guidance. On June 17, it sent a letter to OMB and COFAR addressing the new procurement requirements and processes involving the handling of fringe benefits, which it called two "immediate priorities for the research community." COGR promised that "the other priority issues that we have raised in other conversations will be addressed in subsequent correspondences."

On June 26, COGR submitted to OMB and COFAR a proposed, 12-page frequently-asked-questions (FAQ) document. The FAQ does not address procurement or fringe benefits.

COGR supplied answers that it hopes will clarify and modify certain requirements to the benefit of educational institutions. DeCrappeo hasn't yet heard whether OMB and COFAR will embrace the document and issue it in the name of the federal government.

Institutions identified problems with the closeout and procurement requirements (which also apply to subawards) almost immediately.

Under section 200.343, awardees face a deadline of 90 calendar days "after the end date of the period of performance" to both submit all required reports and "liquidate all obligations."

COGR devoted a full page of its seven-page NSF comment letter to the closeout requirements.

"COGR respectfully asks NSF to request a deviation from OMB that the submission date for all financial, performance, and other reports and the liquidation date be set to a new standard of 120-days after the end date of the period of performance. A new 120-day standard would ensure that research performance is not adversely impacted by an artificially short period for closeout. Further, it would enable timely submission of accurate and compliant reports, which do not require revisions and do not jeopardize institutional funds due to hurried reporting," DeCrappeo argued in COGR's comment letter.

"Finally, from the standpoint of lawmakers and other stakeholders who expect timely closeouts, a new 120-day standard can be integrated within the 15 month standard that is established in 2 CFR §200.343 Closeouts, (g), and hence, will not compromise the important expectation of timely and accurate closeouts of federal awards," he added.

Closeouts have become a hot-button issue for agencies. Allison Lerner, NSF's inspector general, recently suggested investigators who continue to miss reporting deadlines should be considered for debarment *(RRC 8/13, p. 1)*.

While closeout worries remain unaddressed, the research compliance community got some good news from NIH in the middle of last month pertaining to subaccounts. Responding to concerns expressed by COGR and the Federal Demonstration Partnership, NIH announced on July 11 that it would begin the transition for continuing awards to HHS's payment management system (PMS) for subaccounts beginning in October 2015, a delay of one year.

This applies to domestic, non-competing continuation awards to PMS subaccounts "that have not yet transitioned," NIH said.

"As of October 1, 2015, NIH will utilize only subaccounts for awarding grant funds. Every grant that is awarded funding in FY 2016 (whether it be in the first, second, third or fourth quarter of FY (fiscal year) 2016) will be in a subaccount," the agency said. (See http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-103.html.)

Procurement Changes Would Be Costly

In its letters to NSF and to OMB and COFAR, COGR addressed problems with the procurement requirements. In the latter, COGR asked that "OMB and the COFAR provide exceptions/corrections for research performers (Higher Education and Nonprofit Research Institutions)."

It stated that "a change from the current standards in Circular A-110 to the more prescriptive and cumbersome standards in the Uniform Guidance will result in expensive process-workflow and IT system changes."

"Implementation of the Procurement Standards will affect research productivity. For example, critical research tools and supplies that normally would be acquired in one-day would now take at least one-week to acquire," COGR said. "Research institutions have developed sophisticated, timely, and responsible procurement pro-

cesses that meet the highest stewardship standards. A shift to the new standards in the Uniform Guidance will compromise the quality of research and add little to the level of accountability."

Instead of this change, COGR asked that current A-110 procurement requirements be "reinstated" for higher education and non-profit research institutions and for "research performers."

COGR expressed other concerns with the PAPPG itself. These include policies addressing computer services, indirect cost services, fixed rates for the life of an award, inclement weather policies and dual use research of concern, among others.

In its comment to NSF, UM agreed with COGR on the closeout issue and added a few of its own concerns.

"We encourage NSF to critically consider the closeout process described in the COGR letter," wrote Pamela Webb, UM associate vice president for research administration. UM is also seeking information from NSF on how awardees are to handle "expiring funds," pointing out the draft PAPPG does not address this issue. She also offered thanks to NSF for using the Award Cash Management $ervice (ACM$) system instead of the federal financial report system.

Webb requested that the NSF correct a statement indicating that foreign subrecipients cannot recover indirect cost rates "unless the subrecipient has a previously negotiated rate agreement." She noted that the guidance calls for subrecipients to receive indirect costs based on a *de minimis* rate of 10% in the absence of a pre-existing rate agreement.

Link to COGR documents: http://cogr.edu

Link to UM comment letter: www.ospa.umn.edu/documents/documents/NSFImplementationPlanComments.pdf ✧

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. Please call 800-521-4323 or email 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.*

◆ **Effective Aug. 24, Cora Marrett, deputy director of the National Science Foundation, will step down from her position, NSF said July 18.** The agency did not give a reason for the departure. Marrett, who was confirmed by the Senate as deputy in 2011, called the decision "difficult" but expressed confidence that "the highly dedicated and capable NSF team…will continue to nurture the discoveries and innovation vital to our nation's future." *(7/24/14)*

◆ **Seeking to update guidance issued in 1998, the Food and Drug Administration (FDA) has announced the publication of *Informed Consent Information Sheet: Guidance for IRBs [Institutional Review Boards], Clinical Investigators, and Sponsors.*** The previous guidance needs revising "in response to numerous questions about informed consent from subjects, subject advocates, and the research community," FDA said in a July 15 *Federal Register* notice. Sept. 15 is the deadline for comments. *(7/17/14)*

◆ **A former technician at an affiliate of the University of Alabama Birmingham accepted a three-year, governmentwide debarment to settle allegations of misconduct in research supported by two contracts from the National Institute of Allergy and Infectious Diseases and a grant from the National Human Genome Research Institute, according to a June 25 notice on the Office of Research Integrity (ORI) website.** While working at the Southern Research Institute, Melanie Cokonis "knowingly falsified data for cytoprotection assays with antiviral compounds and provided the false data for inclusion in reports submitted to NIH" for the contracts and the grant. For a three-year period, beginning May 29, Cokonis agreed to the debarment and to "exclude herself voluntarily from serving in any advisory capacity to PHS [Public Health Service] including, but not limited to, service on any PHS advisory committee, board, and/or peer review committee, or as a consultant." *(6/26/14)*

◆ **The Department of Defense (DoD) is accepting comments until Aug. 25 on a proposed rule that would require contractors conducting research involving live vertebrae animals to make their facilities "available for inspection by appropriate officials."** Other changes to the Defense Federal Acquisition Regulation Supplement (DFARS) affect training using such animals, according to a notice in the June 24 *Federal Register*. *(6/26/14)*