Report on
RESEARCH COMPLIANCE

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News and Analysis for Colleges, Universities, AMCs and Other Non-Federal Entities

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Staff Departures Fuel Fears Vital Research Integrity Enforcement Agency Is 'Dying'

The HHS Office of Research Integrity (ORI) likely will have ended 2016 with just seven findings of research misconduct against federally funded researchers who have committed fabrication, falsification and plagiarism — a low not previously seen in 16 years and half the number in recent years, including in 2015.

A finding of misconduct is an extremely significant action, carrying with it debarment from future federal funding or supervision, retractions of papers, and public notice in the *Federal Register* of the investigator's fraudulent deeds along with the name of his or her institution. In some instances imprisonment may also follow if criminal charges are brought. Serving as a warning to others, ORI's findings are intensely monitored by research integrity officers (RIOs) at institutions around the country, if not the world.

But the drop in findings isn't due to a lessening of the incidence of misconduct, which, when pervasive, can pollute the scientific literature for decades, misleading other scientists as well as patients when clinical studies are involved. Instead, the small number reflects a crippling of ORI investigative muscle, an apparent casualty of the leadership of ORI Director Kathy Partin, who came to ORI just one year ago, multiple sources in and connected with ORI, tell *RRC*. Partin herself is prohibited from commenting on personnel matters, according to HHS.

"ORI truly is dying," lamented a current investigator. Senior staff with unique skills honed through years of experience are fleeing due to "intolerable" working conditions or being pushed out by Partin, according to the investigator, one of several who spoke to *RRC* on the condition of anonymity because they fear for their jobs and are hunting for new employment. "We have stopped closing cases. We have stopped getting voluntary settlements. The staff has been too preoccupied with the survival of our [division] directors and our jobs. ORI has come to a complete standstill."

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Last Minute Cures Act, AICA Sweeten Reg Stocking Already Laden With Coal

Sen. Lamar Alexander (R-Tenn.) termed the 21st Century Cures Act a "Christmas miracle." Also called a "landmark," the new law provides for the creation of a Research Policy Board and a host of other measures that were advocated as ways to relieve burdens associated with federally funded research.

"With two outs in the bottom of the ninth, Congress came through," was the analogy the Association of American Universities (AAU) used following a vote by the House when it was essentially already on holiday recess that enabled the American Innovation and Competitive Act (AICA) to become law. It also contains provisions that strike at paperwork and red tape but importantly also support the National Science Foundation's (NSF) merit review system.

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Editor
Theresa Defino
tdefino@aol.com

While the impact of these remains to be seen, they were a bit of welcome good news at the end of a year that saw new regulations and NIH policies that increase costs and administrative tasks for researchers and their institutions, pointed out Lisa Nichols, director of research and regulatory reform for the Council on Governmental Relations (COGR).

As Nichols noted, these include a revised federal policy expanding reporting to clinicaltrials.gov *(RRC 10/16, p. 1)*. Another related requirement is for investigators and others involved in clinical trials to receive training in good clinical practice, which NIH has not agreed to fundamentally alter despite requests from COGR and others (*RRC 12/1/16*).

Another policy going into effect later in 2017 is a mandate for the use of a single institutional review board in multisite trials, which NIH recently agreed to delay — but only by four months (see story, p. 3).

But the two newest laws have the potential to reduce some burdens. First introduced as H.R. 6, the Cures Act passed the House in 2015, but Sen. Alexander chose not to take up this bill in the Senate where he is the chair of the Health, Education, Labor & Pensions (HELP) Committee. Instead, the committee separately passed more than a dozen bills. Just after Thanksgiving the House and Senate leadership introduced H.R. 34, the repackaged Senate bills, which passed the House a few days later. The Senate approved H.R. 34 on Dec. 13, and it was signed into law by President Obama on Dec. 16. (*RRC 12/15/16*).

The Cures Act is close to 1,000 pages long; a summary released by congressional leaders is 44 pages. Upcoming issues of *RRC* will explore both the Cures Act and the AICA in more detail.

But, as a start, the follow sections in the Cures Act will be of interest to the research community:

◆ Sec. 2012. Privacy Protection for Human Research Subjects.

◆ Sec. 2034. Reducing Administrative Burden for Researchers.

◆ Sec. 2039. Enhancing the Rigor and Reproducibility of Scientific Research.

◆ Sec. 2063. Accessing, Sharing, and Using Health Data for Research Purposes.

◆ Sec. 3023. Protection of Human Research Subjects.

◆ Sec. 3024. Informed Consent Waiver or Alteration for Clinical Investigations.

On Dec. 16, the House passed AICA, S. 3084, which the Senate had approved on Dec. 10. As of press time, President Obama had not signed the legislation but was expected to shortly.

"This bill represents a bicameral, bipartisan agreement between legislation that recently passed the Senate Commerce, Science and Transportation Committee and nine House Science Committee bills that passed the full House over the last two years, including H.R. 1806, the America COMPETES Reauthorization Act of 2015," said Rep. Lamar Smith (R-Texas), chair of the House Science, Space and Technology Committee.

According to a summary released by Smith's office, S. 3084 "improves" NSF's "grant-making process, requiring transparency and affirming research funded through the merit review selection process must be in the national interest by meeting one of seven broader impact goals."

Also the bill "requires NSF to address concerns about waste and abuse by improving oversight of large research facility construction, updating a conflicts of interest policy, and requiring transparency of the use of rotator personnel."

As *Science* magazine explained, "The final text strongly endorses the two criteria NSF now uses to judge its grant applicants — the 'intellectual merit' of the idea, and the 'broader impacts' of the research on society. The 'national interest' categories favored by Rep. Smith remain in the bill — increasing economic competitiveness, advancing the health and welfare of the public, training

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Editor: Theresa Defino

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a globally competitive workforce, strengthening national security, and enhancing partnerships between academia and industry. But they are now listed as examples of how researchers can satisfy NSF's second criterion — broader impacts — rather than as the primary rationale for the proposed research."

Further, it "establishes an interagency working group to reduce administrative burdens on federally-funded researchers by providing recommendations on issues such as micro-purchase approval and grant sub-recipient monitoring." It also "directs the working group to develop a uniform grant format for Federal science agencies and establish a centralized researcher profile database."

Link to Cures Act summary: http://tinyurl.com/zvow9ot.

Link to AICA summary: http://tinyurl.com/jo9yq9f.

Link to *Science* story: http://tinyurl.com/h3up4ea. ✧

NIH Grants Extra Four Months to Relieve sIRB Policy 'Heartburn'

While saying NIH is "obviously anxious" to move ahead with its controversial mandate for the use of single institutional review boards (sIRB) for "all sites participating in multi-site studies involving non-exempt human subjects research" funded by NIH, Director Francis Collins has granted a four-month extension of what he called a "suggested" deadline of May 25, 2017. He also has indicated that NIH will "implement flexibility processes" to make compliance easier.

Collins made the announcement during an early December meeting of his top advisory committee, a change that was confirmed a week later in a brief announcement in the *Federal Register.* The new effective date of the requirement is Sept. 25, 2017, eight months shorter than the deadline requested by all the key organizations representing research universities and institutions.

NIH's policy was issued in June *(RRC 7/16, p. 1)*. A draft version was announced in December 2014 *(RRC 1/15, p. 7)*. The mandate was opposed by some organizations that support the concept of an sIRB; among the concerns is a lack of time to get systems up and running *(RRC 6/16, p. 1)*.

In October, the Association of American Universities, the Association of Public and Land-grant Universities, the Council on Governmental Relations and the Association of American Medical Colleges asked NIH to delay the mandate by a year (*RRC 10/27/16*). Chief among their arguments was that NIH itself had failed to issue promised guidance and FAQs that would provide implementation details — documents that still had not been published as this issue of *RRC* was going to press.

NIH officials told *RRC* on Nov. 16 that the agency was still considering the request but expected to issue a decision soon *(RRC 12/16, p. 7)*. HHS granted three years to comply with such a mandate under its September 2015 proposed rule revising human subject regulations, also known as the Common Rule *(RRC 10/15, p. 1)*.

Collins: 'Model Works Well'

Collins' announcement came on Dec. 9, the first day of a two-day meeting of the Advisory Committee to the Director (ACD), the highest ranking body that counsels Collins, which meets just three or four times each year. His remarks came nearly four hours into the six-and-a-half-hour meeting, prior to a presentation on agency funding.

In the meeting, Collins offered no explanation for how NIH chose four months and did not mention that the requests had been for a year delay. He said NIH "looked hard" at the issue and understood that the policy was leading to "pain" and "anxiety" because of the change it was engendering.

The new policy, he said, is "very much directing institutions that are running multisite clinical trials" to use an sIRB, "as opposed to the current situation where there are often a large number of IRBs and tending to, frankly, slow things down a bit as each one tinkers with the details of the protocol or the consent form."

The sIRB "model actually works quite well," Collins said, noting that that National Cancer Institute, NIH's Clinical and Translational Sciences Award program and the new Precision Medicine Initiative all use sIRBs.

"We think it's time to move that [concept] forward," he said, explaining that "NIH did issue for our grantees this policy back in June suggesting an effective date of May 25th of 2017."

NIH, Collins said, had "certainly been hearing from a number of organizations about this issue," and summarized for the ACD what had transpired so far. Collins also defended the mandate.

NIH is "obviously anxious to proceed with this policy now that it has been clearly documented to be successful," he told the ACD, without providing details. "We think we can speed up research [in] many instances, perhaps carving off many months of the time necessary to get a multisite trial underway. But we are sympathetic with what institutions are facing here considering this is

a change in things they've been doing for a long time, so we are going to extend that date."

Collins said he also wanted to "make it clear that we will implement flexibility processes for fundable projects, [handling] this in the same way that we do with other just-in-time analyses."

'Bundle' of FAQs Is Promised

Specifically, "people submitting applications that involve multisite trials will not be expected to have every detail in place about how their sIRB is going to operate, only that they are planning to use an sIRB," he said. "Then when we get to the point where that application is actually in the fundable range, then we can negotiate about the detail about how that sIRB would work."

NIH recognizes that the mandate "may, in some instances, require resources but we'll work with the applicant to make sure that that happens," Collins said. Given how the "grant review" cycle works, this will give "some additional months…for successful applicants to get the sIRB in place."

Collins reiterated that NIH will issue FAQs, calling them "a bundle." He said he hoped the announcement of the delay and the fact that the just-in-time procedure will be used "will provide some reassurance to institutions that were looking at the May 25th deadline with that sense of anxiety."

To help with compliance, the HHS Secretary's Advisory Committee on Human Research Protections (SACHRP) developed a document with "points to consider" for institutions grappling with the mandate. This was posted on the website of the Office for Human Research Protections on Nov. 2. Written as a set of recommendations, the document discusses issues associated with whether an institution will be the "relying" or the reviewing institution when an sIRB is called for *(RRC 12/16, p. 7)*.

However, in reference to SACHRP's recommendations, OHRP's own website states, generally, "The content of these documents is advisory and does not represent the official views or policies of OHRP or the Department of Health and Human Services." In contrast, NIH guidance, when issued, will have the government's imprimatur.

SACHRP has been regularly churning out recommendations for years that have not been adopted by HHS, which was a source of concern for at least the previous two SACHRP chairs, including Jeff Botkin, who stepped down in October (*RRC 11/3/16*). A new chair and three members were recently appointed (see story, below). One recent exception, however, is joint guidance OHRP has developed with the Food and Drug Administration. On Dec. 15, the agencies released final guidance on obtaining informed consent through electronic systems and processes (see story, p. 6).

Link to *Federal Register* notice extending effective date: http://tinyurl.com/hh4udf7.

Link to webcast of ACD meeting: http://tinyurl.com/jddf7com. ✧

SACHRP Chair Hails from IRB Firm; Rand Corp. Rep Named

Stephen Rosenfeld, M.D., chair of a commercial institutional review board (IRB) firm, has been named to lead the HHS Secretary's Advisory Committee on Human Research Protections, marking the first time in SACHRP's 14-year history that the top position has been granted to an individual who is not affiliated with a university or medical school.

As its name implies, SACHRP, technically speaking, advises the HHS secretary on safeguards for trials involving people, including children. However, it reports directly to the HHS Office for Human Research Protections, whose current director is Jerry Menikoff. SACHRP appointments, agendas and other operational matters are controlled by Menikoff.

OHRP announced the appointment of Rosenfeld, chair of Quorum Review IRB in Olympia, Wash., on Dec. 14. At the same time, OHRP identified four new members; like Rosenfeld, two have backgrounds unusual among previous SACHRP rosters.

Rosenfeld currently serves on SACHRP, a fact that OHRP did not mention in the announcement. An official told *RRC* Rosenfeld's term, due to expire in July, has been extended to July 2020. Rosenfeld is replacing Jeff Botkin, M.D., the associate vice president for research integrity and professor of medical ethics and pediatrics at the University of Utah, who completed a four-year term in October. It was his second time serving on SACHRP.

"I'm excited by the opportunity to continue my participation on SACHRP, particularly in the role of chair. The appointment is a great honor, and I believe it is particularly meaningful in that, as you note, I'm the first non-academic in the position," Rosenfeld wrote in an email in response to questions from *RRC*.

He does not view his selection as "someone from outside the academic community as signaling any shift in SACHRP's positions or priorities." Instead, Rosenfeld said he believes this "reflects an open-minded approach to what individual, regardless of their current affiliation, would best serve the agency and the interests of research participants."

Rosenfeld pointed out that he previously "spent 19 years at NIH and have participated in and served the research community in a number of capacities." His positions at NIH include serving as the chief information officer for the Clinical Center and associate director for Clinical Research Information Systems.

Flurry of Upcoming Activities

The chairmanship was not something that Rosenfeld sought, he said. "I was approached by OHRP about the possibility several months ago," said Rosenfeld.

His appointment coincides with a time of uncertainty at HHS, and not just because of the recent election. President-elect Donald Trump has named Tom Price, M.D., (R-Ga.) as the new HHS secretary, a post that requires Senate confirmation. The research community is also waiting to see whether HHS will issue a final rule revising the human subject regulations, also known as the Common Rule. The proposed rule was published in September 2015 to widespread opposition, based on an analysis of comments received *(RRC 6/16, p. 1)*.

Moreover, a committee empaneled by the National Academy of Sciences recommended in June that HHS scrap the NPRM entirely and that a national commission be appointed to update the oversight and regulatory framework of human subjects research *(RRC 8/16, p. 6)*. Despite its role, SACHRP was not consulted during the government's regulatory drafting process, which began in 2011 with an advance notice of proposed rule making *(RRC 10/11, p. 4)*.

When Botkin came on board as chair, he expressed an interest in having SACHRP make improvements in the informed consent process *(RRC 11/12, p. 10)*. While that did not occur due to various factors, including the NPRM, SACHRP produced 17 "significant" statements and recommendations, Botkin said at his last meeting in October (*RRC 11/3/16*, p. 1). He also expressed "frustration on the lack of feedback on the high quality statements we provide [to OHRP]," which has acted on few, if any, of SACHRP's recommendations, a situation that also bedeviled the previous chair, Barbara Bierer *(RRC 11/12, p. 1)*.

In 2014, under his watch, SACHRP produced "15 significant" statements and recommendations, Botkin said. But Menikoff told SACHRP in 2014 that it should try to publish its recommendations on its own, an action that is not customary for a government advisory committee *(RRC 8/14, p. 1)*.

RRC asked Rosenfeld if he had similar concerns.

"I have great respect for the members of SACHRP, as well as leadership of OHRP," he said in response. "While I understand the frustration that our recommendations have not been explicitly adopted as often as we would have wished, I also recognize that we are one voice in the increasingly complex research community — a voice that needs to be balanced with others in making policy decisions. Our effectiveness should be assessed both by our direct effect on policy and our influence on the conversation."

Botkin said at his final meeting that he hoped that, in the future, SACHRP would address improving researchers' "engagement" with subjects.

Asked if he had formulated any priorities for SACHRP to address, Rosenfeld said "it's too soon to say." He cited the HHS leadership changes, possible NPRM and recent passage of the 21st Century Cures Act, which has a number of research and IRB-related provisions (see story, p. 1). SACHRP's first meeting of 2017 isn't scheduled until March.

Is 'Intellectual Diversity' Lacking?

The new SACHRP members include Sandra Berry, chair of the Human Subjects Protection Committee for RAND Corporation of Santa Monica, Calif. According to information from OHRP, Berry is also a senior behavioral scientist at RAND and "specializes in evaluation of mental health prevention and early interventions programs in California."

Also appointed was James Giordano, chief of the Neuroethics Studies Program at Georgetown University Medical Center's Pellegrino Center for Clinical Bioethics. According to OHRP's announcement, Giordano "was appointed to the Neuroethics, Legal, and Social Issues Advisory Panel of the Defense Advanced Research Projects Agency" (better known as DARPA), and is a "Senior Science Advisory Fellow of the Strategic Multilayer Assessment Group of the Joint Staff of the Pentagon."

The third member is Aviva Katz, M.D., director of the Consortium Ethics Program, assistant professor of surgery and vice chair of the IRB at the University of Pittsburgh. In addition, OHRP appointed Leslie Wolf, professor and director of the Center for Law, Health & Society at Georgia State University College of Law in Atlanta.

Among the departing SACHRP members is Thomas Eissenberg, professor of psychology and director of the Center for the Study of Tobacco Products at Virginia Commonwealth University. Eissenberg "stressed the importance of having someone with sociobehavioral research expertise serve on SACHRP, both on the main committee and on its subcommittees," according to an OHRP summary of the October meeting, which was also his last. Eissenberg "suggested the possibility of a new

subcommittee that focuses specifically on the concerns of sociobehavioral research."

At the time, the summary states, "Dr. Botkin observed that the new Rule may provide opportunities for a stronger voice from the sociobehavioral research community. He suggested that an educational panel focusing on regulatory issues for sociobehavioral researchers might be planned for SACHRP's March meeting."

Zachary Schrag, professor of history at George Mason University and author of *Ethical Imperialism: Institutional Review Boards and the Social Sciences, 1965–2009,* expressed disappointment at the SACHRP membership.

"Once again, HHS has appointed SACHRP members with a narrow range of expertise: bioethics, medicine, mental health, and public health, to the neglect of research fields not directly connected to health research," Schrag told *RRC*. "This lack of intellectual diversity will continue to lead SACHRP to make recommendations that affect scholars in the social sciences without seeking their input. Such was the case in 2015, when SACHRP attacked provisions of the notice of proposed rulemaking that could benefit social scientists."

Schrag added that "the problem is not the individuals who are selected for SACHRP; it's the viewpoints that are excluded. For more than half a century, bodies without representation from the social sciences have been writing rules for the social sciences, and that is both undemocratic and ineffective."

Link to SACHRP membership list (may not be updated): http://tinyurl.com/zwff977. ✧

FDA, OHRP Finalize 2015 FAQs On Electronic Informed Consent

The Food and Drug Administration (FDA) and the HHS Office for Human Research Protections (OHRP) have issued a series of 16 FAQs on using electronic informed consent (eIC) with research subjects. The Dec. 14 guidance finalizes a proposed document published on March 9, 2015 (*RRC 3/12/15*).

"For the purposes of this guidance, electronic informed consent refers to the use of electronic systems and processes that may employ multiple electronic media, including text, graphics, audio, video, podcasts, passive and interactive Web sites, biological recognition devices, and card readers, to convey information related to the study and to obtain and document informed consent," the guidance explains. The agencies clarify that "when implementing an eIC, a variety of approaches may be used to fulfill HHS and FDA regulatory requirements for informed consent and IRB review (45 CFR part 46 and 21 CFR parts 50 and 56) and FDA regulations for electronic records and electronic signatures (21 CFR part 11)."

FAQs Are Broad

The guidance responds to the "interest in using electronic media to supplement or replace paper-based informed consent processes," the guidance states. "An eIC may be used to provide information usually contained within the written informed consent document, evaluate the subject's comprehension of the information presented, and document the consent of the subject or the subject's LAR," or legally authorized representative. "Electronic processes to obtain informed consent may use an interactive interface, which may facilitate the subject's ability to retain and comprehend the information. Furthermore, these electronic processes may allow for rapid notification to the subjects of any amendments pertaining to the informed consent that may affect their willingness to continue to participate. Electronic processes may also promote timely entry of any eIC data into a study database and allow for timely collection of the subject's informed consent data from remote locations."

The agencies remind investigators, sponsors and institutional review boards that "informed consent is often mistakenly viewed as synonymous with obtaining a handwritten signature from the subject" or his or her LAR. In reality, informed consent "involves providing a potential subject with adequate information about the research to allow for an informed decision about the subject's voluntary participation in a research study. Informed consent must include a process that facilitates the subject's comprehension of the information and allows adequate opportunity for the subject to ask questions and consider whether or not to participate (45 CFR 46.116 and 21 CFR 50.20)."

FAQs range from "how and where may the eIC process be conducted" to "what methods may be used to verify the identity of the subject" who is consenting electronically. The guidance points out that sponsors must have a process for answering subjects' questions, and, for HIPAA covered entities (CEs), the eIC system must encrypt the data held electronically, "unless the entity documents why encryption is not reasonable and appropriate." Subjects would also have to be notified of data breaches as required under HIPAA.

For non-HIPAA CEs, "the electronic system that supports the eIC must be secure with restricted access (see 21 CFR 11.10 and 11.30) and should include methods to ensure confidentiality regarding the subject's identity, study participation, and personal information after informed consent has been obtained," according to the guidance.

Link: http://tinyurl.com/jv2msu3. ✧

OLAW Webinar Offers Tips to Foster Trust, 'Self-Reporting'

Failing to report instances of noncompliance with animal research regulations may seem like a good way to avoid getting into trouble and perhaps prevent damage to the institution's reputation. But in the long run, it's against federal regulations, an overall bad idea and can ultimately compound problems.

Institutional officials (IOs) are required to report, among other things, "serious or continuing" noncompliance to the HHS Office of Laboratory Animal Welfare (OLAW). When appropriate, violations of the Animal Welfare Act should be communicated to the U.S. Department of Agriculture (USDA). But first the IO must know about them and be willing to report — more on that shortly.

The University of Cincinnati (UC) created a "comprehensive plan for self-evaluation" to uncover, report, and ultimately to reduce noncompliance. The self-evaluation is conducted as a team but also by various components independently — principal investigators (PIs), veterinarians and veterinary techs, the institutional animal care and use committee (IACUC), and animal care staff.

'Self-Reporting' Is Encouraged

All are encouraged and incentivized to "self-report," explained George Babcock, chair of UC's IRB and professor emeritus in Department of Surgery at its College of Medicine. Babcock described UC's program during a Dec. 15 webinar hosted by OLAW, "Self-Evaluation and Reporting: Always Let the *Guide* (or How to Encourage PIs and Their Staff to Self-Report)."

The use of the word "guide" is a play on words, referring to the related *Guide for the Care and Use of Laboratory Animals*, which programs that have a federalwide assurance agree to follow. The guide implements the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals. Those institutions doing research with USDA covered animals are also required to follow that agency's requirements, or the guide, whichever is more stringent. There are also timelines for reporting noncompliance.

Under the PHS Policy, "The IACUC, through the Institutional Official, shall promptly provide OLAW with a full explanation of the circumstances and actions taken with respect to: any serious or continuing noncompliance with this Policy; any serious deviation from the provisions of the *Guide*; or any suspension of an activity by the IACUC." (See http://tinyurl.com/zo9tj8s.)

The guide may not require self-reporting or evaluation *per se*, but it references "continuing review." According to Babcock, continuing review "includes continuing protocol review, oversight and evaluation of facilities and animal use areas, regular review of the Program, and ongoing assessment of animal care and use."

As Babcock explained, "Program review and facilities inspections should occur at least annually as per the *Guide*, or more often as required by the AWA or the PHS Policy. The PHS Policy requires semiannual program and facilities review. And as we know, when there are two guidelines, PHS assured institutions are expected to meet the more stringent guideline."

But, he notes, "Although continuing review of ongoing animal related activities by the IACUC is a requirement imposed by the PHS Policy and USDA animal welfare regulations, there is lack of uniform understanding and application of these federal requirements. A variety of mechanisms can be used to facilitate ongoing protocol assessment and regulatory compliance, including post-approval monitoring. Thus each institution must devise its own plan for self-evaluation which meets the federal requirements."

Team Approach Is Suggested

UC's program is one such example. During his presentation, Babcock described the elements of UC's self-evaluation program but cautioned, "Self-evaluation is more difficult than most of us realize. We are often too harsh or lenient in our institutions."

What UC has found to be success is to "have many pairs of eyes and ears to get a diverse opinion. People should come from all parts of the animal program including outside members, attending veterinarian, principal investigators, animal care staff, and especially veterinary technicians," he said.

A "major goal" of the program is to "develop a system devoted to continual learning and improvement of animal care, top to bottom and end to end," Babcock said, suggesting that "a positive attitude" is important.

"We are all humans, no one is perfect, and no program is perfect. The vast majority of the PIs and staff wish to do a good job, to reduce animal suffering, and to be proud of their work," he said.

Babcock offered a series of recommendations tailored to each of these groups. For example, for IACUCs, he suggested developing a standard inspection form that is shared with PIs, "making post-approval monitoring (PAM) a friendly, non-confrontational experience," and "try not to act as police," he said.

"Adding vet techs to the PAM program is another suggestion. They have their feet on the ground and often know what's happening behind the scenes," Babcock added.

Similarly, institutions should "encourage lab animal staff to observe procedures being performed in their

work area so that they can understand what the various researchers are actually doing to the animals. They can often be helpful to the researchers, and prevent possible problems," Babcock said.

"One approach that we've had great success with at UC is to have lab members and the PI attend IACUC meetings separately," he continued. "We find that when there is a deviation or noncompliance, by calling them to an IACUC meeting in the absence of the PI, the lab members become very transparent and cooperative with the IACUC."

Gaining PIs' "trust and cooperation" is crucial. "Stress the importance of a compliant animal program to the PI," Babcock said. "It's not about just his or her lab but it's about the whole program. Explain that corrective actions don't necessarily equal punishment. They are just that — to correct the problem."

He also suggested "offering incentives for reporting" as a way to "increase the rate of self-reporting at institutions. As an example, in letters to the IO and OLAW, PIs can be given credit for promptly disclosing and/or correcting a noncompliance."

One PI Paid for a Vet Tech

But, just "because a PI self-reports a noncompliance, it doesn't mean that you can forgive or overlook the problem. Reported noncompliances must have a corrective action attached," he added.

Since UC instituted its program, PIs self-report one to two times per month, and 80% of the noncompliance reports come from PIs, Babcock said. "Prior to introduction of the concept of self-reporting, there were zero self-reports," he said. "At the same time, UC has discovered that PIs who self-report rarely repeat noncompliance."

Without providing specific data, Babcock said that the total numbers of noncompliance reports have increased overall. "And they probably should, because we might have missed many noncompliances if they had not been self-reported. So this doesn't necessarily mean that more noncompliances have occurred, just that more are coming to the surface," he said.

Babcock also described some strategies for dealing with particularly noncompliant PIs. Protocols can be suspended, for example, an action that isn't taken lightly but may be necessary for repeated problems.

"Something we've used in extreme circumstances is to assign a vet tech to the laboratory. We had one particularly noncompliant PI, where we suspended the protocol. In order to get the protocol reactivated, this PI was required to pay a vet technician's salary for one year. The vet tech would then come in every day, help with some of the experiments, and monitor how the laboratory was performing," he said. "In certain cases we have also set conditions for reinstating a protocol, such as appointing a lab manager to oversee the animal work in the PI lab. This is often a person who is already in the lab but may or may not manage other lab members."

He also offered a suggestion for when the problem person is a little higher up on the totem pole. "This may seem like a joke, but at one unnamed institution, which I am very familiar with, it was found that the IO was not reporting violations to OLAW which had been reported to him by the IACUC," Babcock said. "This, of course, put the institution in jeopardy, and eventually produced administration shake-ups at that institution. The IACUC must have the IO on their side."

When asked by a webinar participant what could be done in such a case, Babcock said in the one instance in which he was involved, "We went over the IO's head to the president and it worked out well."

OLAW Director Patricia Brown, also participating in the webinar, said these situations should be discussed with OLAW staff.

"Our advice is if the IACUC has such a concern that there are serious noncompliances that have not been reported because the IO is trying to hold them back, that they have a conversation directly with OLAW's compliance staff about this," Brown said. "We are there to assist and guide and also provide encouragement to the IACUC to take the appropriate actions within the institution to have a cooperative process leading to a corrective action for such a situation."

The webinar marked OLAW's fourth and final for 2016. The others addressed vertebrate animals and grants policy *(RRC 4/16, p. 4)*; balancing risks and ethical considerations in protocol approvals *(RRC 7/16, p. 7)*; and a case study on "implementing guidance on significant changes" to protocols *(RRC 11/16, p. 7)*.

The series of webinars will continue in 2017, and OLAW is seeking suggested topics. Ideas may be emailed to olawdpe@mail.nih.gov.

Link: http://tinyurl.com/z7u74ar. ✧

HHS OIG: Subject Payments Are Not Actionable Kickbacks

According to a new advisory opinion posted by the HHS Office of Inspector General (OIG) on Dec. 20, a university conducting a National Cancer Society-funded study to prevent anal cancer in HIV-infected individuals can use grant funds to waive copayments and pay subjects for their "time and effort" without facing enforcement by OIG relative to the federal anti-kickback statue.

Although binding only on the individuals and organizations that requested them, OIGs post advisory opin-

ions on their websites to serve as informal guidance to others experiencing similar situations. Identifying details are redacted. However, the university at issue in this opinion appears to be the University of California, San Francisco, based on a news release about a study posted on its website in 2013. (See http://tinyurl.com/zxb2el5.)

Federal law "provides for the imposition of civil monetary penalties against any person who offers or transfers remuneration to a Medicare or State health care program (including Medicaid) beneficiary that the benefactor knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of any item or service for which payment may be made, in whole or in part, by Medicare or a State health care program (including Medicaid)," OIG wrote.

'Nominal' Definition Expanded?

However, "nominal" incentives are permitted. OIG "has taken the position that incentives that are only nominal in value are not prohibited by the statute, and currently interprets 'nominal in value' to mean no more than $15 per item, or $75 in the aggregate on an annual basis," OIG said.

The university may have sought an opinion because it will exceed these amounts, and this favorable opinion would appear to permit larger payments, at least in this specific case.

The opinion does not state why the university wanted OIG to weigh in, nor address how common, or uncommon, the practice of using grant funds to offer subjects reimbursement might be.

The study is funded with $89 million under the National Cancer Institute's AIDS Malignancy Consortium, OIG said. "Participants who are enrolled in the Study normally would be liable for applicable out-of-pocket cost-sharing obligations for medically necessary items and services they receive in connection with Study participation," OIG said. "According to Requestor, these out-of-pocket obligations could be significant, particularly for those who are randomized to the treatment arm. Under the Proposed Arrangement, Study participants would be relieved of all out-of-pocket cost-sharing obligations for Study-related health care services."

In addition, the "trial sites would waive any cost-sharing obligations Study participants owe, and then submit an invoice to [the lead site] for reimbursement of the waived amounts."

Concurrently, the "trial sites would continue to bill, and collect reimbursement from, third-party payors, including Federal health care programs, for the services the trial sites render to Study participants, when applicable," OIG said. NCI had already approved allowing NCI funds to be used as "reimbursements for cost-sharing obligations."

"Study participants will be asked to attend Study visits at least every six months for five years or more," under the study. Participants would receive reimbursements of $25 or $100, depending on the services provided at the visits.

Relevant Features Outlined?

OIG concluded that the reimbursement arrangements "implicate" both the "anti-kickback statute and the CMP [provisions]," but because OIG concluded there is a "minimal risk of fraud and abuse," the university would not be subject to enforcement action.

The conclusion is based on three factors:

◆ ***NCI approved the reimbursement plan and will conduct its own oversight.*** In addition, a study monitor, an "independent entity with no financial interest in the outcome," has been hired to "monitor compliance with the Study's protocol, perform site visits, and frequently report data to NCI," among other duties.

◆ ***Without reimbursement, recruitment and retention of research subjects would be difficult if not impossible,*** particularly because the study "aims to enroll a widely diverse group of participants, including under-represented minorities and individuals of varying socioeconomic backgrounds." In addition, because it is a prevention rather than treatment trial, the incentives to remain enrolled are fewer, especially if costs are high. OIG said the reimbursement arrangements "appropriately address these hurdles and therefore are reasonable means of achieving Requestor's goals."

◆ ***The study "is neither a commercial study nor a product-oriented or product-specific study"*** and is "not intended to develop, study, or benefit any specific commercial product or entity."

Link: http://tinyurl.com/hf5jl6k. ✧

Concerns ORI Is 'Dying'

continued from p. 1

John Dahlberg, the former ORI deputy director who recently retired, confirmed the dire state of ORI. "Four of ten investigators in the ORI have left or soon will," he told *RRC*. "It is already largely nonfunctional."

Dahlberg and others first sounded a public alarm about conditions at ORI under Partin this fall, after months of failing to get a response from HHS, despite numerous attempts. As chronicled by *RRC*, *The Washington Post* and *Science* magazine, staffers described an atmosphere of fear and intimidation *(RRC 10/16, p. 1)*.

Now, calls for help are growing more urgent as conditions are further deteriorating, sources tell *RRC*, with

the falling number of closed cases being just one example. They also cite the resignation on Dec. 9 of Zoe Hammatt, who ran ORI's Division of Education and Integrity (DEI) (*RRC 12/8/16*). ORI has two divisions, DEI and the Division of Investigative Oversight (DIO). However, as of Dec. 19, ORI had not acknowledged that Hammatt has, in fact, resigned, and her bio was still listed on ORI's website, along with that of other individuals who no longer work there.

ORI is the only agency in the federal government that holds investigators accountable who commit fabrication, falsification and plagiarism while applying for, conducting or writing about research supported by the billions expended by NIH and other agencies in the Public Health Service.

Hopes Were Dashed Early

Many had high hopes after Partin's arrival, particularly because ORI has suffered long vacancies at the top, following the retirement of then-director Chris Pascal in 2009 *(RRC 8/10, p. 1)*. When she was hired in December 2015, Partin's job had been empty for nearly two years, following the departure of David Wright, who cited dysfunction at HHS and a lack of resources when he resigned *(RRC 4/14, p. 1)*. Wright also struggled through a two-year process to bring Hammatt on board *(RRC 2/13, p. 1)*.

Partin expressed a desire to learn the ropes and collaborate with the ORI workforce and conducted a "listening tour" to gather input *(RRC 1/16, p. 1)*. But ORI sources say her actions have gone in the opposite direction. Without exception, all those who have worked directly with Partin and spoke to *RRC* used the same words to describe her: they say she's a "bully" who doesn't understand the misconduct regulations or how findings are made.

Of special concern are the loss of personnel, and Partin's hiring of individuals criticized as "unqualified," including Deputy Director Scott Moore, who hails from the National Science Foundation Office of Inspector General (OIG). While most of ORI's cases involve image manipulation, OIG's concern plagiarism. The regulations that govern OIG findings differ from ORI's. For example, OIG has subpoena power; ORI does not.

Most recently, workers complain that a new investigator was brought on board who they say has no previous investigative experience and no published papers to support a professed background as a researcher. When the individual met with current investigators during the interview process, five gave a thumbs down, yet Partin made the hire anyway, *RRC* was told.

Many of the workers who remain are unable to focus due to what they describe as a tense, siege-like atmosphere. They say that soon after her arrival, Partin set her sights on removing and replacing Hammatt and Susan Garfinkel, an ORI staffer since 2003 who leads DIO.

Cases Require Years of Shepherding

The departures will have a lasting impact on ORI.

"We desperately need experienced basic science people who can begin the years of long training it will take to learn to conduct oversight reviews, analyze images, examine hard drives with forensic software, run and interpret plagiarism software, and learn from fellow investigators" as well as how to work with the HHS Office of General Counsel, whose attorneys prepare case settlements and court documents, when necessary, an investigator told *RRC*.

The work is painstaking and requires deep knowledge and experience to "accurately interpret and use 42 CFR 93 to make legally sufficient ORI findings," one investigator told *RRC*.

Furthermore, the involvement of an investigator from start to finish who is conversant with the nuances of a case, including all of the evidence gathered, is crucial to a successful misconduct finding, which generally takes years.

Only two ORI staffers are trained in the use of forensic software; were they to leave, ORI would be severely hampered, sources tell *RRC*. "Without looking at hard drives in some cases, we cannot prove intent. If we can't prove intent, we must decline to pursue. ORI will be closing cases left and right because of lack of legal sufficiency," an investigator told *RRC*. Investigators also take phone calls and give advice and suggestions to institutions and others suspecting misconduct has occurred.

Sources also pointed with concern to a recent presentation Partin made at the University of Utah where she twice used the term "sociopath" to refer to investigators facing misconduct allegations, a label that could be seen as at odds with ORI's charge to impartially investigate alleged misconduct.

In her Nov. 14 comments at the university's conference on reproducibility, Partin mentioned that misconduct, by some estimates, may exist in up to 2% of published papers, and stressed the role of mentoring and good recordkeeping that are essential to creating an environment that fosters research integrity, rather than misconduct. Partin mentioned that she hoped ORI would be pursuing a "test case" to make a misconduct finding based on "reckless behavior," allowed under the law but which the agency has not done to date.

Her remarks gave little hint that, back in ORI's Rockville, Md., headquarters, there are virtually no education staff members left, the number of investigators is dwin-

dling, and the agency is on track to tie the 2000 record for the lowest number of findings.

These developments continue to be troubling to many, including former director Wright.

"Because of the short staffing, ORI is not keeping up with the pace of allegations," Wright told *RRC*. He is not optimistic ORI will be able to make appropriate hires to replace staff in order to make more findings and case resolutions, which he believes serve as a deterrent.

Because findings often require investigators to retract or correct the papers containing fraudulent information, cases that are unresolved allow false data to remain available.

"If ORI gets to a smaller percentage of allegations, it would embolden [those facing allegations] at least to not cooperate to reach voluntary settlements, and string the process out," said Wright. The result, he said, is "delayed justice."

Link to ORI's 2016 findings: https://ori.hhs.gov/case_summary.

Link to the University of Utah presentation: http://tinyurl.com/hvv9zhc ✧

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 on your subscriber-only website. Please call 888-580-8373 or email service@hcca-info.org if you require a password to access* RRC*'s subscriber-only website or are not receiving weekly email issues of the newsletter.*

◆ **The HHS Office of Research Integrity (ORI) has posted 11 new videos that "address integrity issues faced by those involved in the research endeavor."** Titles include "Reproducibility or Luck? The Struggle to Get Results" and "You Suspect Research Misconduct. Now What?" Featured in the videos posted on Dec. 9 are a fictitious research professor at a "budding research lab," a postdoctoral fellow and a graduate student, who "are navigating challenges inherent to working in a competitive research environment," ORI explained on its website. "By touching upon topics that affect researchers at all levels of their careers, such as mentoring, authorship and publication practices, data integrity, and possible research misconduct, these scenarios encourage viewers to consider how to make responsible choices at every turn." The videos were created to "serve as a springboard for discussion about conducting research responsibly," the post quotes Zoë Hammatt, described as the director of ORI's Division of Education and Integrity, as saying. Hammatt resigned from ORI on Dec. 10, amid turmoil under Director Kathy Partin, who came on board a year ago (see story, p. 1). *(12/15/16)*

◆ **In the second half of fiscal year (FY) 2016, the National Science Foundation (NSF) Office of Inspector General (OIG) conducted 13 audits and reviews, including "five of which questioned $5.5 million.** "Our investigative staff closed 58 administrative and criminal/civil investigations, referred four cases for criminal and/or civil prosecution, had seven cases result in research misconduct findings by NSF, and recovered over $2 million for the government," OIG said. Also of note in the semiannual report, which covers the six-month period ending Sept. 30, is a section on OIG's view of NSF's management challenges. As in other recent semiannual reports, OIG said NSF needs to step up its efforts to combat research misconduct, stating in this report that "broader proactive measures are needed." OIG is also "completing" a review of "institutional responses" to an NSF requirement to develop training programs on the responsible conduct of research, first begun several years ago; it did not say when this would be issued. In related news, OIG issued a separate report, or "inspection," as it called the document dated Nov. 29, which reviewed NSF's progress toward meeting the requirements in the DATA Act by May. The deadline applies to all federal agencies (*RRC 4/16, p. 1*). While NSF has made progress, ultimately the agency could miss the deadline for the law, which requires reporting of various funding elements, "because of external issues such as changes and delays in implementation guidance." OIG also said it "found that due to project management challenges, NSF may miss or overlook project tasks and milestones when implementing DATA Act requirements because of weaknesses in NSF's project planning tools, progress metrics, and documentation." NSF "generally agreed" with OIG's recommendation to "strengthen its project management over DATA Act implementation." *(12/8/16)*

In This Month's E-News

◆ **Promising to issue new FAQs on the issue, NIH officials have declined a request from the Council on Governmental Relations (COGR) to extend the effective date of a new requirement for training in good clinical practice (GCP) to May 1 from Jan. 1.** But there is some flexibility, the agency said. "We understand that the first of the year is fast approaching, but we continue to believe that meeting the expectations of the policy will be manageable for institutions," Carrie Wolinetz, NIH associate director for science policy, wrote in a Nov. 21 letter to COGR. "Since GCP training can be beneficial at any point in the life cycle of the trial, we did not limit the policy to new awards. However, institutions should not regard the policy's effective date as a deadline by which we would expect all staff involved in the conduct, oversight, and management of clinical trials to be GCP trained. Rather, as long as steps are being taken to meet the expectation, e.g., staff who have not yet been trained have signed up for a course, the training itself can be taken in a timely fashion after the effective date." COGR had cited lack of clarity and increased administrative burden in its request, sent Oct. 6 (*RRC 11/16, p. 3*). In her letter, which was copied to NIH Deputy Director Michael Lauer, Wolinetz added that, "[w]ith regard to the added effort that will be needed to ensure compliance, we hope institutions will be able to ease the burden by adapting systems they already have in place for tracking those who are required to take training in responsible conduct of research and human subjects' protections." Wolinetz also addressed COGR's concerns about the applicability of the requirement, stating, "We hope these points and clarifications will be helpful. We also intend to issue a set of FAQs that we hope will be helpful in clarifying the intent of the policy for the community." *(12/1/16)*

◆ **A University of Michigan investigator and his team did not commit "clear regulatory violations" of federal rules when they "continued to reach out to subjects after they had given a hard refusal to participate, or to continue to participate" in an NIH-funded study of retirement and health, the HHS Office for Human Research Protections (OHRP) wrote to UM in an Oct. 24 determination letter.** But OHRP said the teams' "subject withdrawal practices…were less than ideal." In response to a complainant, OHRP first wrote to UM about the issue in December 2014 and received correspondence back in January 2015 and March of this year. According to OHRP's letter, UM's institutional review board worked with the investigator and study team and operationalized the definition of "hard refusal," including that "[t]hreats of legal action and allegations of harassment should also be considered hard refusals." Subjects expressing such sentiments are assigned a code and would then be "immediately taken from an interviewer's workload for in-depth review by senior staff to confirm the respondent's request to not be contacted again and placed on a do-not-contact list." These and related actions "adequately address the concern" that subjects weren't freely able to join or leave the study, OHRP said. *(12/1/16)*

◆ **The HHS Office for Human Research Protections has concluded an investigator and research team at the University of Louisville conducting three NIH-funded studies involving subjects with spinal cord injuries failed to report unanticipated events; may have "misinformed [subjects] regarding costs of research procedures that they would be responsible for, in violation of HHS regulations"; allowed subjects to be enrolled before required screening was completed; and, in several instances, "did not conduct the study as described" in the protocol approved by the institutional review board.** According to OHRP's Oct. 17 letter, the university's audit uncovered additional instances of noncompliance, including that "adverse events for the study have not been tracked or monitored by the research team." OHRP said four other situations occurring during the trials did not rise to the level of violations. The university took a variety of corrective actions in response to the determinations, including establishing a required data safety monitoring board, implementing an eligibility "checklist," and retraining the "principal investigator, physician, research nurse, and regulatory coordinator," which OHRP said were adequate. Concerns about the studies were brought to OHRP's attention by an unidentified complainant. *(11/17/16)*

Report on Research Compliance's Thursday E-Newsletter will not be issued on Dec. 22 or Dec. 29. Please watch for the next issue in your emailbox on Jan. 5. Happy holidays to all!