Report on
RESEARCH COMPLIANCE
Volume 14, Number 5 • May 2017
News and Analysis for Colleges, Universities, AMCs and Other Non-Federal Entities

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HEALTH CARE COMPLIANCE ASSOCIATION

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NAS Panel Calls for Integrity Advisory Board, Focus on Institutional Inexperience

Exhuming a recommendation advanced 25 years ago by a similar panel studying misconduct in science, a new committee of the National Academy of Sciences (NAS) has proposed the creation of an independent, non-governmental research integrity advisory board.

Fostering Research Integrity, issued April 11, offers a hodgepodge of other ideas for how "researchers, institutions, publishers, funders, scientific societies, and federal agencies…should improve their practices and policies to respond to threats to the integrity of research."

While not having any investigative or enforcement power, the board would assist research institutions that "face significant challenges in ensuring that research misconduct allegations are effectively addressed and investigated."

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In a 'Strange Time,' HHS Secretary Takes Direct Aim at NIH's Indirect Payments

Since the president's controversial budget "blueprint" for fiscal year (FY) 2018 was issued in March, some of the mystery of how the Trump administration plans to shave nearly $6 billion or 18% from NIH's budget come October has been solved: The target is on the backs of universities and other recipients of the agency's research funds.

Meanwhile, the Office of Management and Budget (OMB) has ordered HHS and the other agencies to spend the next two months preparing plans to cut programs and staff to levels equal to the amount in the blueprint—reductions likely to go into effect irrespective of whether Congress appropriates more funding than the administration requests.

Universities, medical schools, researchers and organizations that represent them aren't taking the threats lying down. The Council on Governmental Relations (COGR), for example, has developed talking points about indirect costs, which are "an absolute necessity for a functional and effective research enterprise" in its view (see story, p. 3).

The budget blueprint released on March 16 calls for an increase of $54 billion in defense spending and a corresponding decrease in domestic programs; specific aim is taken at many federal research budgets. Details and an actual budget are expected to be released later this month *(RRC 4/17, p. 1)*. The budget document is being called "skinny" both for its length, just 62 pages, and level of reductions in spending.

But in a hearing before a House subcommittee, HHS Secretary Tom Price described the strategy he and NIH officials are using to make the cuts called for in the blueprint. Price seemed to suggest he had only recently discovered that NIH pays for indirect costs, a global term that encompasses facilities and administrative (F&A) expenditures that Price apparently considers unnecessary. And he received some support from Rep. Andy Harris, R-Md., who was recently in the running to head NIH (see story, p. 7). The blueprint also calls for a "reorganization" within NIH, but little has been revealed about this and it did not consume much of the discussion at the hearing.

continued

At the start of the hearing convened by the House Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies, chair Rep. Tom Cole, R-Okla., told Price he was "extremely concerned about the impact of the 18% cut on NIH." Cole asked Price to "describe how your proposed budget would enable the United States to maintain the biomedical research enterprise and continue progress in developing new treatments and cures within this funding level."

Referring to NIH as a "massive organization that does incredible work," Price defended NIH's proposed budget amount, saying it currently "comprises over a third" of HHS' discretionary budget and would remain so under the blueprint. Price said he also was "struck by the need for efficiencies and in decreasing duplication and the like within our entire department."

The administration's goal is to "fashion a budget that focuses on the things that work, that tries to reduce areas where there are duplications or redundancies, or waste" and officials are working to "get a larger return for the investment" of tax dollars, Price said.

"I was struck by one thing at NIH, that is, about 30% of the grant money that goes out is used for indirect expenses," which he told the committee was "money that goes for something other than research that's being done."

Report on Research Compliance is published monthly by Health Care Compliance Association, 6500 Barrie Road, Suite 250, Minneapolis, MN 55435. 888.580.8373, www.hcca-info.org.

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Rep. Mike Simpson, R-Idaho, who noted that given all that had been released was a blueprint, pressed Price for more details. "This is the difficult part," Simpson said. "We can only talk about the skinny budget and not the full budget [until] that comes out. It's a strange time."

Pointing out that the blueprint also calls for a reorganization at NIH but provides no details, Simpson noted Price spoke of "funding priorities and how we fund things." The subcommittee could "support" efforts to "get more money into the actual research," he said.

Price responded that HHS was pursuing both reorganization and changing funding priorities. He said HHS had not "made a presupposition about what the end point is in all this," again mentioning the indirect costs. "That's an amount that actually would cover much more than that reduction that's being proposed," Price said.

Blend Research, Care?

HHS wants to "save money so that you can actually provide more grants for individuals to be able to study all sorts of…diseases and challenges," Price said.

During his questioning of Price, Harris seemed to embrace cutting indirect costs, declaring, "I have had NIH grants. I know how it's done."

Harris also noted that private research funding organizations, such as the American Heart Association, Alzheimer's Association and Bill and Melinda Gates Foundation, pay a 10% indirect cost rate, while the American Lung Association officials "pay no indirect costs…don't allow them." He called it "very interesting that the private sector doesn't hold these indirect costs to be so valuable as to pay them, but when the taxpayer dollar is involved, somehow we do."

Price also defended the elimination of the Agency for Healthcare Research and Quality (AHRQ), which HHS plans to "fold" in to NIH. He could not yet say whether it would become an institute, center or what form it would have in the future.

"We envision the opportunity for NIH to assume the duties, the important duties, of AHRQ, and then to decrease, or reduce, or eliminate the duplication and redundancies. Some of the kinds of things being done at AHRQ are also being done at NIH," he said. HHS will "make certain we're continuing to fulfill the mission" of AHRQ, he said.

Price also commented on the separation that exists between patient care and research at NIH.

When he had the opportunity to "walk the halls" at NIH, Price "was really struck by the fact…down one hall is where the research, the scientific research is being done" by "clinical scientists," and "then on an adjacent hall is where patients are being seen, inpa-

tients are being seen and cared for. So that's where we believe that there are some significant redundancies within the system itself," Price said.

Rep. Katherine Clark, D-Mass., asked Price why the administration would cut NIH funding so significantly, even if there may be "inefficiencies" at NIH. "We can have a long discussion about how we fund our universities and the research partners that they are," Clark said, "and what indirect costs really go to."

Price responded that FY 2018 is a "tough budget year, there is no doubt about it." HHS, he said, is seizing an "opportunity to focus on those kinds of things that will allow us to accomplish the core mission and to actually get greater dollars, more dollars, to the research that must be done in order for us to remain at the forefront" of biomedical research.

Just three weeks after Price's testimony, OMB Director Mick Mulvaney declared that the federal hiring freeze was terminated as of April 12, but in its place are requirements for agencies to "[b]egin taking immediate actions to achieve near-term workforce reductions and cost savings, including planning for funding levels" that Trump proposed.

In addition, agencies are to develop a "plan to maximize employee performance" by June 30, and a separate "Agency Reform Plan that includes long-term workforce reductions," which will be part of the agency's FY 2019 budget to OMB. A draft of the reform plan is due by June 30, with a final expected by September.

Link to subcommittee hearing: http://tinyurl.com/mensghn

Link to OMB memorandum: http://tinyurl.com/mgyxf3m ✧

Fighting F&A Cuts with Facts

The Trump administration is considering cutting back on indirect costs paid to NIH awardees as a way to reduce HHS' overall budget by 18%, with a $5.8 billion drop at NIH (see story, p. 1).

In response, the Council on Governmental Relations (COGR) posted a trio of documents "to help explain and clarify what F&A [facilities and administrative] costs are and how the system works." These consist of a one-page summary; a three-page "primer" that explains how rates are calculated and includes a chart demonstrating that, at least since 2002, indirect costs as a percentage has remained constant at approximately 25%; and three pages of talking points that respond directly to some of the accusations leveled during the budget hearing.

As universities know, indirect costs are composed of expenditures referred to as F&A costs; these are also called research operating costs. COGR and similar organizations argue that these cannot be separated from direct costs.

In 1991, the Office of Management and Budget (OMB) imposed a cap of 26% on the administrative costs, which is widely agreed to be inadequate. In fact, in 2010, the Government Accountability Office (GAO) surveyed universities and concluded that "83 percent of schools had fiscal year 2007 administrative costs above the administrative cap, with a reported average administrative rate component of 31 percent." Its report was titled *Policies for the Reimbursement of Indirect Costs Need to Be Updated.*

The cap remains in place, and was not addressed when OMB issued its Uniform Administrative Requirements, Cost Principles and Audit Requirements for Federal Awards, also known as the Uniform Guidance (UG). This supersedes OMB Circular A-133 (and other circulars); current requirements are now part of 2 CFR Part 200, which implements the UG *(RRC 2/15, p. 1).*

As COGR explained, indirect cost rates are:

- "Calculated by the university according to rules defined by OMB and based on audited university financial data;
- Submitted to the rate-setting cognizant agency (for research universities and most research institutions, either the Department of Health and Human Services, Cost Allocation Services or the Department of Defense, Office of Naval Research);
- Reviewed and/or audited, rigorously, by the rate-setting cognizant agency;
- Negotiated between the university and the rate-setting cognizant agency and normally effective for a period of two to five years; and
- Charged by multiplying the negotiated F&A rate by a subset of the direct costs of the sponsored research project."

In their documents, COGR officials addressed Harris' remarks about private foundations paying a lesser rate or no indirect costs. COGR suggested such comparisons are not accurate. They noted that "rates charged to industry and other non-

NIH: Inclusion of Preprints Welcome, Use Care When Reporting, Posting

Giving a boost to the movement for online publication of early scientific findings, NIH is accepting inclusion of "preprints" and other interim research products in progress reports and biosketches submitted with funding applications.

Declaring the agency "a little bit late to the party," Michael Lauer, NIH deputy director for extramural research, described the many benefits of the new policy, which goes into effect May 25.

In an interview with *RRC*, Lauer and Neil Thakur, Lauer's special assistant, noted that the agency wants to ensure that investigators follow NIH's guidelines on selecting a "responsible" site to place their early results and that they are careful to use the proper citation format.

They also promised that NIH would be monitoring the implementation of the policy, with a particular focus on its impact on reviewers.

As NIH explained when it issued the new policy on March 24, interim research products are "complete, public research products that are not final." Of these, one common type is a preprint, a "complete and public draft of a scientific document. Preprints are typically unreviewed versions of peer-reviewed journal articles. Scientists issue preprints to speed dissemination, establish priority, obtain feedback, and offset publication bias."

A "preregistered protocol" is another kind of interim research product. With these, "a scientist publicly declares key elements of their research protocol in advance. Preregistration can help scientists enhance the rigor of their work," NIH said. Officials noted that

Fighting F&A Cuts with Facts, continued

federal sponsors are charged to the entire contract amount (versus the lesser 'modified' amount used for federal awards, which excludes costs such as graduate tuition and equipment). These awards may also reimburse for costs not allowed under federal rules. Private foundations and charitable organizations often place limitations on F&A reimbursement. Research institutions accept these awards when such sponsors support mutual research and service aims for which funding opportunities are limited."

COGR also noted that a "number of federal programs, such as NIH career and training awards also place limitations on F&A reimbursement (restricted to 8%) with the rationale that these programs are less F&A intensive than others. When considering how different sponsors structure their F&A reimbursement method, it is important to note that research institutions are never fully reimbursed for their F&A outlays; this is in sharp contrast to private industry that is not subject to the same limitations."

As the organization put it, "fair reimbursement of F&A costs is crucial to a stable and viable research enterprise. Research universities and institutions cannot implement research programs if sponsors do not support the real costs of research infrastructure and compliance activities. Construction and maintenance of state-of-the-art research laboratories and administrative efforts that ensure compliance with federal rules and regulations are necessary investments."

Expenditures for F&A costs, according to COGR, "are often devalued for primarily two reasons: (1) due to the way some agencies provide for F&A, some stakeholders view the F&A budget category as diverting funding from direct costs, and (2) the reimbursement mechanism for F&A costs (i.e., the 'F&A rate') is complex and thus difficult to explain and to understand."

That complexity is one reason the University of California (UC) system created a webpage to help its research administrators and principal investigators "understand this issue with clear descriptions about indirect cost bases and the type of sponsors that use various indirect cost recovery methodologies," said Michael Kusiak, the policy resource coordinator in the office of the president. (See http://tinyurl.com/kkkrtrw.)

"The biggest misconception we encounter is what an F&A rate is and how it is used," said Kusiak. "Outsiders looking in, even many administrators and investigators, don't necessarily appreciate how that rate is part of a formula. For every indirect cost rate, you need to know your indirect cost base."

He pointed out that "the percentage of your total award allocated to indirect costs is much smaller than your published F&A rates."

Link to COGR documents: http://tinyurl.com/k43rbex ✧

"some NIH policies require registration of clinical trial protocols," and that existing policies on clinical trial registration "supersede" the interim research products policy.

Lauer, who rose to the number two spot in NIH in September 2015, has long been a proponent of the use of preprints as a means to speed dissemination of research results, perhaps increase the reproducibility of results given the wide opportunity for feedback for publicly posted documents, and to foster greater publication of findings *(RRC 3/16, p. 1)*. Lauer also addressed the new policy in a blog post.

Papers Must Be 'Truly Public'

But NIH took its time in implementing the new policy, first issuing an official request for information last October. An analysis of those responses, which NIH described in the guide notice about the policy, revealed wide support for the concept, although a few concerns were raised.

Currently, NIH permits investigators to cite products in the "reference section of a research plan" in a funding application.

The new policy expands this use in two ways, before and after funding is received. Researchers can now cite interim products in biosketches in requests for funding, and they may include them in progress reports sent to NIH program officials to demonstrate accomplishments during the life of the award.

Investigators should also pay special attention to the citation format NIH is requesting, Thakur said, and where the preprint or other documents appear.

NIH is "asking applicants to be a bit more formal in how they cite preprints, so we know that they are interim products, that they're not final, they're not peer-reviewed [and] they have a DOI so they are truly public," Thakur said.

A DOI is a digital object identifier. Some universities, such as Washington University in St. Louis, have developed processes to help investigators and others obtain such a number. (For more information, see http://tinyurl.com/lbv3jce.)

NIH is not specifying any particular sites that should be used for posting interim research products.

"There are a lot of new preprint servers coming online and even more will be coming online in the next year or so. And we have some guidance on what we're looking for in a responsible preprint repository," Thakur added. For example, it is important that the early results be "preserved."

In its policy, NIH states that it "strongly encourages interim research products arising from NIH funds to be deposited in repositories that ensure:

◆ Content is findable, accessible, interoperable and reusable.

◆ Interim product metadata, including usage statistics, are open, and easy to access by machines and people (e.g. via application program interfaces).

◆ Content is easy to use by machines and people. This access is both a function of permission (e.g. use of Creative Commons licenses) and technology (e.g. application program interfaces).

◆ Policies about plagiarism, competing interests, misconduct and other hallmarks of reputable scholarly publishing are rigorous and transparent.

◆ Records of changes to the product are maintained, and users have clear ways to cite different versions of the product.

◆ Links to the published version, if available.

◆ A robust archiving strategy that ensures long-term preservation and access."

One reason for clear formatting is so that reviewers are alerted that citations are not from peer-reviewed sources, and they will need to "judge the information on its merits," Thakur said.

NIH is hopeful that preprint publication bias doesn't morph into new a version of publication bias that exists today.

Will Bias Creep into Preprints?

Lauer acknowledged that there is a "serious problem with papers that are published in peer-reviewed settings," where it may be assumed "that a paper which is published in *Science, Nature, Cell* or the *New England Journal of Medicine* is automatically 'better' than a paper that is published in the *Journal of the American College of Cardiology* or *PNAS* [*Proceedings of the National Academies of Sciences*]. And that is something that a number of us are concerned about," he said. "We certainly don't want that to be the case [with preprints]."

Preprints and other interim products have been a feature in non-biomedical science fields, such as physics and engineering, and have been accepted by funders, including the National Science Foundation (NSF), Lauer and Thakur told *RRC*. "This is something which has already been used a lot in other fields. And so we in biomedical research are a little bit late to the party," Lauer said.

"I don't know what [NSF's] full policy is," Thakur said, "but as a matter of practice they've been allowing preprints for years in just the way that most of their

disciplines do." Lauer added that research involving physics "is a big part of their portfolio."

Use of these products can benefit the entire scientific community, which is facing new pressures and problems.

The practice can have a number of benefits, Lauer said, such as establishing "providence."

"In some communities, the posting of preprints is normal behavior. Everybody does it, and everybody does it before they submit papers for peer review and formal publication," Lauer said. "And what this does is it makes it easier to establish who did what first and when."

Changes May Pay Off for New Investigators

Developing and citing interim products may be of special benefit "when one is fairly early on in one's career and has not yet had an opportunity to publish a lot of papers [but] nonetheless does want to demonstrate in some kind of reasonably objective way that he or she has accomplished something," Lauer added.

Lauer pointed out that there is "concern within the scientific community about the speed of communication...that it takes longer to get a scientific paper published now than it did 20 or 30 years ago, substantially longer."

This, he said, "is a particular problem for new investigators who are trying to establish a track record. The existence of preprints and the ability to post scientific progress in this kind of a rapid way is potentially going to help us mitigate the adverse effects of the increasing difficulty that people face getting results published."

Asked if NIH has any concerns about investigators padding their biosketches with preprints, Thakur responded that he is "not worried" about this occurring. "There are a limited number of citations... things you can cite in your biosketch. Any applicant puts in a weak citation at their own risk. They have to be strategic. They have to choose" what to include, Thakur said.

Preprints and other interim products may also help NIH ensure its money is being well-spent, Lauer said.

When included in investigators' reports, interim products can "make things easier for program officials to assess progress, particularly early on in a project. It's not at all unusual that it could take three years or even four years before a grant [recipient] will publish a paper in a peer-reviewed journal," said Lauer. "Let's say some significant work gets done over the first year-to-two years, and that gets posted as a preprint. That might make it easier for a program official to have a better sense of how well a project is progressing and to make a judgement that in fact the researchers are doing reasonable work."

Lauer and Thakur said NIH isn't sure how popular the use of interim research products will prove to be.

"I think we will have to see over several [award] cycles how much of a pickup there will be," Lauer said. The number of papers appearing as preprints is "going way up, so we could very well be at an inflection point or maybe beyond an inflection point. You might start to see a dramatic increase in the number of grant applications and progress reports" that contain interim research products.

Thakur added that NIH will be monitoring implementation of the policy.

"We are interested in what the impact is on reviewer experience," Thakur said. NIH will "assess that in a couple of ways, but we have to work that out."

Link to NIH policy: http://tinyurl.com/mgjayjo

Link to Lauer's blog on interim research products: http://tinyurl.com/kzn8tqj ✧

Understanding of Wildlife Permits Will Help IACUCs Review Protocols

In the newest online webinar for members of institutional animal care and use committees sponsored by NIH's Office of Laboratory Animal Welfare (OLAW), Ellen Paul, director of the Ornithological Council, addressed the different types of wildlife permits, when they should be obtained relative to protocol review and "permit policies that pose challenges for IACUC review."

As director of the Ornithological Council, a consortium of societies of ornithologists, Paul's role "includes assisting individual researchers with permit requirements, obtaining expertise for IACUCs, and working with other scientific societies whose members study other taxa," according to OLAW. Paul also co-authored a model protocol for wildlife, released in 2014, and co-edited *Guidelines to* (sic) *the Use of Wild Birds in Research.*

The primary research permits are those required under the Migratory Bird Treaty Act, the Endangered Species Act, the Bald and Golden Eagle Protection Act and the Marine Mammal Protection Act, Paul explained. The Airborne Hunting Act, which imposes "nonregulatory restrictions," may also be applicable. Permits may take up to a year to obtain and may require publication for comment in the *Federal Register.*

"The purpose of laws that are implemented through permits are primarily to protect wildlife populations by placing a limit on the number of animals that can

be studied," Paul said. "And that limit is based on the population status of that species in that place. Place is a flexible concept because it depends on the species. Some species have very narrow or small ranges; others are nationwide. So when you try to implement these limits, you have to consider each species studied."

According to Paul, "the key point to be made here is that there are multiple layers of protection for wildlife populations. And those limits are based on the knowledge and expertise of the agencies charged with implementing those laws."

The Migratory Bird Treaty Act "includes all native species" but "has nothing to do with actual migration of birds," Paul said. The wording "is a historical reference to the treaty itself, first signed with the United Kingdom, then later Mexico, Japan and what was the Soviet Union." Currently, the law protects 1,026 species, including those that don't migrate.

Under the act, "you need a permit to do anything except to observe, use play back, do surveys or monitoring," Paul explained. "If you need to capture a bird, you need a permit." There are different types, however. They are issued by the U.S. Fish and Wildlife Service (USFWS).

For example, there are permits for scientific collecting, which allow for "permanent removal of an individual from the population."

Such a permit "could be used to keep the bird alive to study it in captivity or it could be the take of a bird through euthanasia for various types of studies. It also includes blood/feather/tissue collection but only if the bird is not also being marked in some manner, such as a bird band," Paul said. "Scientific collecting also includes salvage of dead birds."

When birds will be banded or marked, a different permit is required, which is issued by the band birding lab of the U.S. Geological Survey. A banding permit also permits salvage of dead birds. Different permits are required for the relocation of eggs and for "import and export."

Paul pointed out that, under an exception, an institution (acting in its own name rather than in an investigator's name) "may acquire by gift or purchase birds that are protected under this law or their parts, their nests and their eggs without a permit."

IACUCs also need to be aware of when permits expire. "An important thing to note is that, under this regulation, the activity that is permitted may continue even if

Collins May be More Than 'Temporary' NIH Director

NIH Director Francis Collins apparently can get comfortable, once again, in the role he has held since 2009.

"Obviously nobody who works for the government is assured that this is a permanent position, but I'm assuming right now that, as far as I'm able to see, I'm the NIH director," Collins told CNBC in an appearance in late March.

And on April 14, Michael Lauer, NIH's deputy director for extramural research, told *RRC* it is now assumed that Collins has the post for keeps.

Collins is a political appointee who, like others, was expected to step down when Trump was inaugurated.

A blue-ribbon group that included former NIH directors submitted suggestions to the president on the qualities he should look for in a new director *(RRC 12/16, p. 1).*

Collins made it clear that he hoped to remain director after the election. President Trump met with Collins at least once to chat about NIH's top slot and on another occasion to discuss, along with HHS Secretary Tom Price, the national opioid addiction epidemic.

Several other individuals were under consideration for the post, including Rep. Andy Harris, R-Md. In January, NIH announced that Collins was being "held over," presumably pending the appointment of either an acting or interim director prior to the selection of a new, permanent director being named *(RRC 2/17, p. 1).*

Collins made his comments about his position to CNBC on March 30 as part of a conversation on cuts to NIH's budget proposed by President Trump for fiscal year 2018, which begins Oct. 1 (see related story, p. 1).

RRC interviewed Lauer for a story on NIH's new policy for expanded use of preprints and other interim research products and asked if there was any news on who the director of NIH will be under Trump.

"The NIH director is Francis Collins," Lauer said. "There have not been any official announcements one way or another but we are assuming that he's going to be here long term." Asked whether an announcement would be forthcoming, Lauer indicated that he did not know, stating, "this is new territory."

But, he added, "We are certainly working as if Francis is going to be here long term." ✧

the permit expires, so long as the permittee has applied for renewal at least 30 days prior to the expiration date," Paul said.

She also warned that staff reductions at federal offices have slowed down the permitting process and recommended allowing at least 90 days for a renewal.

Turning to the Endangered Species Act (ESA), Paul said that this law currently covers 81 species categorized as endangered and 18 as "threatened endangered." Permits issued under this act are called "recovery permits," Paul said.

She noted that an ESA permit may be required "even if [investigators] are not studying an endangered species, because the research methods may impact an endangered species."

Two other types of permits are those for research involving bald or golden eagles and for marine mammals.

The first is required "if you want to do any of these things: shoot, shoot at, poison, wound, kill, capture, trap, collect, molest or disturb a bald eagle or a golden eagle," Paul said. "'Disturb' has a fairly broad definition here. It means to 'agitate or bother a bald or golden eagle to a degree that causes, or is likely to cause based on the best scientific information available, injury to an eagle, a decrease in its productivity, by substantially interfering with normal breeding, feeding, or sheltering behavior, or nest abandonment, by substantially interfering with normal breeding, feeding, or sheltering behavior.'"

These permits are issued by the UFWS.

Requests May Require Public Comment

The Marine Mammal Protection Act (MMPA) governs manatees, polar bears, sea otters, walruses, dugongs, whales, porpoises, seals, and sea lions. The USFWS handles permits for all but Cetacea (whales and porpoises) and Pinnipedia other than walruses (seals and sea lions), which fall under the National Oceanic and Atmospheric Administration, Paul said.

Permits issued under the ESA and the Marine Mammal Protection Acts must first be published in the *Federal Register,* accompanied by a mandatory 30-day comment period.

The use of live birds in research fall under the Wild Bird Conservation Act, Paul said, explaining that "the amount of effort and money it takes to import live birds, especially in this time of highly pathogenic avian influenza, is extremely hard. We actually advise people to study birds in their country of origin rather than to import live birds."

Permits issued by the U.S. Department of Agriculture may be required for the importation of live animals for research, although this is an infrequent practice, Paul said. The purpose of these permits is to "prevent the introduction of pathogens that can harm U.S. livestock or agriculture," she added.

IACUCs also will need to be aware of how the various laws and regulations treat euthanasia.

State laws and permitting requirements also must be heeded. Of note is that "they almost always prohibit release of wild birds that have been taken into captivity for research," said Paul. While some are simple, others, such as in California, can be "highly restrictive."

"With state permits, generally one permit covers all activities and they are usually called 'scientific collecting,'" said Paul. She termed this a "mismatch in terminology. Scientists do not use that term so broadly. Therefore, scientists might not realize that they require permits because they are not doing collection in the scientific sense," Paul said.

The Ornithological Council lists state permit regulations on its website at http://tinyurl.com/n7oqwgf.

IACUCs Face Practical Considerations

IACUCs will be faced with the prospect of reviewing a protocol before permits are issued. Although approval is possible, actual work cannot begin until a permit is issued. Paul noted that much research involving migratory species, in particular, is "dictated by the season."

The "best practice to resolve this practical dilemma is for the researcher to submit the protocol, listing the required permits and giving the status for each—whether you have the permit, or have applied, or will apply," Paul said. "If the IACUC finds the protocol to be acceptable, the best practice for the IACUC would be to indicate in writing that the protocol has been approved but that the animal work is not to begin until required permits are obtained."

Such a practice is "acceptable" to OLAW, she added.

Care must be taken to stay within the law. "Depending on the statute, there are civil and criminal penalties, including fines and incarceration, and at the very least, it is likely that the researcher will be ineligible for future permits for some time or even permanently," Paul warned.

In their reviews, some IACUCs may want to address the "impact of the research activities on that population" being studied. However, Paul argued against this, saying it "is likely to have little value."

"Most field research methods involve no removal of individuals from the wild or have any lasting impact on survival and reproduction. Moreover, populationlevel impacts are very difficult to predict," Paul said. "The researcher may not have sufficient knowledge of population sizes and species interactions. There may be no

published information and a census, even if possible or practical, will not yield sufficient information. The bottom line is that the impacts, if any, are far too speculative to warrant a review by the IACUC."

The other speaker in the webinar, Axel Wolff, director of OLAW's Division of Compliance, added that "bycatch or inadvertent capture of other species should be considered by the IACUC, especially in regard to aquatic species."

According to Wolff, "often hundreds of extra fish and other water animals not needed for the research are caught and this needs to be addressed in the protocol. OLAW sometimes receives noncompliance reports on this topic," he said. "The specific problem is either the capture of species not listed on the protocol and/or the capture of many more target species than approved."

Protocols may "need to be amended to account for different species or excess numbers of animals captured," he said.

"Following capture, difficulties may arise with trying to release a large number of animals from traps or nets in a humane and timely fashion to avoid distress or death," Wolff said. "From personal experience, when I was mist netting for bats, I caught owls, large tropical moths, and other species that needed to be carefully removed and released."

At the conclusion of the webinar, Paul offered to respond to questions emailed directly to her at ellen.paul@verizon.net. She can also be reached at 301-986-8568. Questions may also be sent to OLAW's Division of Policy and Education at olawdpe@mail.nih.gov.

Link: http://tinyurl.com/l7arzee ✧

NAS Panel Calls for Advisory Board

continued from p. 1

The report, the product of five years' work, is an update of *Responsible Science: Ensuring the Integrity of the Research Process*, published in 1992.

First proposed in the original report, the board remains a good idea, C. K. Gunsalus told *RRC*. "And we think that things might be in a better situation had it been implemented at the time," said Gunsalus, a NAS committee member and director of the National Center for Professional and Research Ethics at the University of Illinois Urbana-Champaign.

RRC asked where the leadership would come from to establish the board. "We believe and hope that the convening power of the National Academy could bring together organizations to address this. I believe that the chair of our committee and others associated with the academies will be reaching out to AAU, AAMC [and] other organizations to talk about this," she said. AAU is the Association of American Universities. AAMC is the Association of American Medical Colleges.

Among the functions of the board would be to "bring a unified focus to addressing challenges in fostering research integrity across all disciplines and sectors," the report states, and bridge differences between the biomedical focus at the HHS Office of Research Integrity (ORI) and the plagiarism focus of the Office of Inspector General (OIG) within the National Science Foundation. The report also calls for the separate OIG and ORI regulations to be harmonized.

ORI Director Kathryn Partin issued a statement after the report was released, thanking the committee members for their efforts. Officials "look forward to reviewing their report," she said.

While ORI makes findings of misconduct (defined as fabrication, falsification and plagiarism), it acts on investigations conducted by institutions. And the institutions are not doing the best possible job.

According to the 285-page report, a "source of difficulty is the infrequency at most institutions of cases that advance from the inquiry to the investigation stage. This means that institutional officials at a given time and place may lack hands-on experience with necessary tasks such as sequestering evidence, forming investigation committees with the appropriate expertise, orienting the committees to see the larger stakes beyond the institution and investigator, and ensuring that institutional and federal policies are followed."

The report stresses that institutions should monitor and improve the research environment.

"One of the things that happens for a research integrity officer is that it's awfully easy to get focused on what's been often called the 'one bad apple' narrative," Gunsalus explained. This is "simplistic, and so doesn't look enough at the environment in which the work was happening."

Committee members also called for a relabeling of so-called "questionable" research practices as "detrimental"; changes to authorship practices at journals; greater protections for whistleblowers; and funding of research to "quantify conditions in the research environment that may be linked to research misconduct and detrimental research practices, and to develop responses to these conditions."

The report provides a number of specific recommendations for researchers and institutions (see box, p. 10). *RRC* will explore some in more detail in upcoming issues of the publication.

Link: http://tinyurl.com/mbelykm ✧

Specific Recommendations for Researchers and Institutions

BOX 9-1
Best Practices Checklist for Researchers

Research Integrity

- ◆ Maintain high standards in own work.
- ◆ Understand policies.
- ◆ Raise questions and problems promptly and professionally.
- ◆ Strive to be a generous and collegial colleague.

Data Handling

- ◆ Develop data management and sharing plan at the outset of a project.
- ◆ Incorporate appropriate data management expertise in the project team.
- ◆ Understand and follow data collection, management, and sharing standards, policies, and regulations of the discipline, institution, funder, journal, and relevant government agencies.

Authorship and Communication

- ◆ Ensure that general and disciplinary standards are followed for research publications.
- ◆ Acknowledge the roles and contributions of authors.
- ◆ Be transparent when communicating with all audiences.

Mentoring and Supervision

- ◆ Model and instruct on research best practices.
- ◆ Regularly check work of subordinates and ensure adherence to best practices.
- ◆ Clarify expectations.

Peer Review

- ◆ Provide complete and timely review.
- ◆ Maintain confidentiality.
- ◆ Disclose conflicts, and eliminate or manage them as appropriate.

Research Compliance

- ◆ Protect human subjects and laboratory animals.
- ◆ Follow environmental and other safety regulations.
- ◆ Do not engage in misuse.
- ◆ Disclose and manage conflicts of interest.

BOX 9-2
Best Practices Checklist for Research Institutions

Research Integrity and Institutional Management

- ◆ Demonstrate that fostering research integrity is a central priority at all levels, including for faculty and institutional leaders.
- ◆ Provide training to faculty in effective mentoring and include mentoring as a criterion for hiring and promotion.
- ◆ Communicate rights and responsibilities to students, faculty, postdocs, and others engaged in research (e.g., through the use of compacts or other mechanisms).
- ◆ Collect and disseminate data on the career prospects of graduate students and postdocs.
- ◆ Consider implications for research integrity when making larger management decisions—(e.g., the number and proportion of soft-money positions).
- ◆ Do not exaggerate research results in institutional communications.

Climate Assessment

- ◆ Gather data on institutional climate related to research integrity.
- ◆ Share data across graduate departments.
- ◆ Share practices of strong departments and address shortcomings of weak departments.

Performing Research Misconduct Investigations

- ◆ Meet formal compliance responsibilities by ensuring that policies and capabilities for performing fair, thorough, and timely investigations of research misconduct allegations are in place.
- ◆ Have multiple entry points to raise questions about possible misconduct.
- ◆ Use checks and balances to guard against institutional conflicts.
- ◆ Involve legal counsel.
- ◆ Incorporate external perspectives when appropriate.
- ◆ Protect whistleblowers during investigations and mitigate negative consequences on their careers afterwards.
- ◆ Take "after action steps" to ensure that papers are retracted.

RCR Training and Education

- ◆ Engage faculty.
- ◆ Make federal requirements a floor, not a ceiling.

SOURCE: The National Academies of Sciences, Engineering, and Medicine. 2017. *Fostering Integrity in Research.* Washington, DC: The National Academies Press. https://doi.org/10.17226/21896.

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.*

◆ **In a blog post titled "A Reminder of Your Roles as Applicants and Reviewers in Maintaining the Confidentiality of Peer Review," Michael Lauer, NIH deputy director for extramural research, and Richard Nakamura, director of NIH's Center for Scientific Review, urge investigators and others to "immediately report any peer-review integrity issues" to the appropriate NIH official.** Posted April 7, the entry on Lauer's "Open Mike" blog describes four scenarios that would trigger reporting, such as a potential awardee sending a holiday card to a reviewer asking for approval or a reviewer sharing an application with a colleague, ostensibly for help in understanding a statistical analysis. Although these situations are a "rarity," Lauer and Nakamura provide information on why they should be reported to NIH and by what means. "While professional interactions between applicants and reviewers can continue while an application is undergoing peer review, discussions or exchanges that involve the review of that application are not allowed. As an applicant, you should not contact reviewers on the study section evaluating your application to request or provide information about your application or its review, no matter how 'trivial' the piece of information may seem," they explain. "As a reviewer, you should not disclose contents of applications, critiques, or scores. Reviewers should also never reveal review meeting discussions or associate a specific reviewer with an individual review." *(4/13/2017)*

◆ **A House-passed bill now pending in the Senate that places restraints on the Environmental Protection Agency (EPA) could "submerge science beneath politics," a group of associations wrote to House Majority Whip Kevin McCarthy, R-Calif., on March 28.** H.R. 1430, the Honest and Open New EPA Science Treatment (HONEST) Act of 2017, prohibits the EPA "from proposing, finalizing, or disseminating a covered action unless all scientific and technical information relied on to support such action is the best available science, specifically identified, and publicly available in a manner sufficient for independent analysis and substantial reproduction of research results," according to a summary by the Congressional Research Service. "A covered action includes a risk, exposure, or hazard assessment, criteria document, standard, limitation, regulation, regulatory impact analysis, or guidance. Personally identifiable information, trade secrets, or commercial or financial information obtained from a person and privileged or confidential must be redacted prior to public availability." The letter, signed by the American Association for the Advancement of Science, the Association of American Universities, the Association of Public and Land-grant Universities and 20 other associations and universities, said the bill is "virtually identical" to bills introduced in previous sessions of Congress that were also opposed. The groups said that "regulations and agency actions should be informed by the best available science and a rigorous scientific process," but that [u]ndermining the integrity of the scientific process, or the ability of federal agencies to utilize rigorous science in establishing policies, could have long-term negative consequences." They "urge[d] caution in setting laws that submerge science beneath politics. In addition, the research community is concerned that some key terms in the bill could be interpreted or misinterpreted, especially terms such as 'materials,' 'data,' and 'reproducible.' Legislation removing concepts like reproducibility and independent analysis from the hands of scientists and into the hands of legislators could undermine the scientific process and reduce the benefits that science could bring to society." H.R. 1430 passed the House the day the letter was sent; the bill was referred to the Senate Environment and Public Works Committee on March 30. *(4/5/2017)*

◆ **The Office of Inspector General (OIG) of the National Science Foundation has questioned $283,801 in costs claimed by the University of California, San Diego (UCSD) among $197 million for 708 NSF awards from April 1, 2012, through March 31, 2015.** Auditors sampled "286 transactions totaling $2.5 million and utilized a data analytics approach to identify potential risk areas," auditors said. The questioned costs consisted of "$214,177 in equipment, materials, and supplies expenses unreasonably

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purchased near award expiration; $54,472 in unreasonable travel; $8,744 in unreasonable participant support expenditures; $5,178 in unallowable indirect costs; and $1,230 in unallocable visa immigration fees." UCSD disputed all of the questioned costs except $50,748: $31,383 for "two environmental rooms," $6,629 for computers, $1,584 for materials and supplies, $4,744 for travel costs, $5,178 "in indirect costs charged for the purchase of a component used for equipment fabrication" and $1,230 in visa fees. OIG recommended that UCSD "[s]trengthen the administrative and management controls and processes for reviewing and approving participant support transactions charged to NSF awards." UCSD's response was somewhat unusual in that it included explanations from one or more principal investigators. *(4/5/2017)*

◆ **One month after sending Richard Burt, chief of the Division of Immunotherapy at Northwestern University's Feinberg School of Medicine, a warning letter detailing a host of sponsor and investigator "failures," including lack of timely reporting of the deaths of two research subjects, the Food and Drug Administration (FDA) closed out its investigation, saying appropriate corrective actions had been taken.** Although dated Nov. 15 and Dec. 13, 2016, the warning and closeout letters were posted March 27 and 28, respectively. FDA communications do not reveal the number of subjects enrolled, nor the name of the study or protocol under review, although the research appears to have been ongoing at least since 2007 and involves multiple sites. The warning letter describes "objectionable conditions observed during" an FDA "inspection conducted between June 17, 2016, and July 11, 2016." The deaths, which were required to have been reported to FDA within 72 hours, and several instances of serious adverse events were not reported until after the inspection, despite having occurred years earlier. Other violations were failures "to identify, evaluate, and report toxicities" and inadequate oversight of study sites. Burt told FDA that monitoring occurred "through email and attendance at Annual Meetings held in Chicago." FDA also said none of nine "protocol versions" were reported to FDA as required, nor were the additions of study sites. FDA's two paragraph closeout letter stated that Burt "addressed" the violations and that "[f]uture FDA inspections and regulatory activities will further assess the adequacy and sustainability of these corrections." *(3/30/2017)*

◆ **Beginning with funding applications due May 25, NIH is permitting researchers to include "interim research products," which include "preprints" and "preregistered protocols," NIH announced March 24.** A preprint, NIH said, is "a complete and public draft of a scientific document." These "are typically unreviewed manuscripts written in the style of a peer-reviewed journal article." A preregistered protocol is "where a scientist publicly declares key elements of their research protocol in advance. Preregistration can help scientists enhance the rigor of their work," NIH said. The agency "intends to maximize impact of interim research products that are developed with NIH funds. Therefore, NIH expects awardees to ensure a high level of public access to NIH supported interim products," NIH said. "To facilitate text mining and other analysis of these products as data, the NIH expects standardized terms of use. NIH also expects awardees will adhere to other norms of responsible scientific communication." Both types "can be cited anywhere other research products are cited," NIH said. Michael Lauer, NIH deputy director for extramural research, explained the changes in a March 28 blog post. *(3/30/2017)*

◆ **In an unusual audit conducted after receiving a complaint, the National Science Foundation (NSF) Office of Inspector General (OIG) concluded Oregon State University (OSU) should "return unspent funds," also termed a "surplus," of $315,016.** The funds are among $11 million claimed from Jan. 1, 2012, to Dec. 31, 2015, for the operation of Oceanus, a research ship owned by NSF. "OSU generally complied with Federal and university requirements for requesting and managing Federal funding, but based some funding requests on budgeted amounts rather than actual reported expenses. As a result, OSU had a surplus," but it did not let NSF know about this. Oregon State "needs to return the unspent funds to NSF and ensure its annual reports and funding requests reflect unspent funds. Additionally, OSU needs to return $3,050 in salary and benefit expenses. We recommend NSF request that for an employee who did not work on" Oceanus, OIG said. Oregon State officials disputed the finding regarding the unspent funds but agreed that the amount for the worker were unallowable; in fact, they brought the issue to the auditors' attention. *(3/30/2017)*