

RESEARCH COMPLIANCE

News and Analysis for Colleges, Universities and Teaching Hospitals

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Citing Compliance Burdens, Universities Raise Objections to Draft COI Regulation

In issuing proposed regulations for financial conflicts of interest (FCOI) among federal grantees, National Institutes of Health officials repeatedly asked for comments and other feedback. In fact, they even extended the comment period, which now ends Aug. 19.

Judging by the comments that have come in so far, the compliance community isn't happy and is proposing many changes to the draft regulations. While the associations representing institutions and universities themselves all profess their commitment to rooting out and managing FCOI, they say some of NIH's plans just aren't workable and are overkill.

"There are...many elements of the proposed rule that seem unreasonably expensive and/or complex to implement, or which we believe will yield little benefit in terms of preventing bias in the design, conduct, or reporting of Public Health Service-funded research should an investigator have a conflict of interest," wrote Steven Beckwith, vice president of research and graduate studies at the University of California. Beckwith, writing on behalf of UC's 10 research campuses and the Lawrence Berkeley National Laboratory, expressed concerns common among those who have responded to the proposed regulations.

continued on p. 11

Long Vacancy at the Helm of ORI Prompts Concerns; Director to Be Named 'Soon?'

The Office of Research Integrity, charged with safeguarding research against scientific misconduct and investigating cases of falsification, fabrication, and plagiarism among those receiving billions in research funds from the Department of Health and Human Services, has not had a director since 2009, following the retirement of long-time head Chris Pascal.

Pascal officially retired Sept. 12, 2009, but he was actually on leave beginning in March of that year. The vacancy is being criticized as sending troubling signals to the scientific community, at an especially sensitive time. Members of the press and Congress, especially Sen. Charles Grassley, have had a laser-like focus on federal agencies and whether they are doing enough to assure that science is free of outside influences and conducted with integrity.

In response to questions from *RRC*, a spokeswoman for HHS, of which ORI is part, issued a short statement saying "a search is underway to name a new director soon" but would not explain what "soon" meant.

She also would not respond to specific questions about the steps in the process for hiring Pascal's replacement, so it is unclear whether a formal job opening has yet been announced. The appointment does not require Senate confirmation. The ORI director

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reports to the HHS assistant secretary for health, in the Office of Public Health and Science (OPHS).

Until recently, it would not have even been clear that Pascal had, in fact, left ORI; approximately 10 days ago, an OPHS webpage still listed Pascal as the director. After RRC brought the error to HHS's attention, the website was updated to list Donald Wright as acting director.

Wright's HHS bio, however, lists him as the assistant secretary for healthcare quality; it does not mention ORI.

The entirety of HHS's response on the issue consisted of the sentence about an appointment coming soon, and a description of the duties of the ORI director, as follows:

"The director of ORI provides executive leadership, guidance and oversight to research integrity functions of the Public Health Service. The director provides leadership and advocacy for the establishment of strong integrity programs in government and the private sector to improve detection of and prevent research misconduct

and to promote research integrity. Moreover, the director provides oversight and monitors the development of policies and procedures for preventing, detecting, reporting and handling instances of alleged or suspected misconduct in science. The director also oversees the operational activities and procedures of ORI."

Vacancy Decried as 'Inexcusable'

Art Caplan, director of the Center for Bioethics at the University of Pennsylvania, called it "inexcusable that there is still no permanent director."

"This sends the wrong message at a time when concerns over research integrity are paramount in the minds of funders, researchers, and subjects," Caplan told RRC. "Having this position vacant suggests that integrity in research is not a top priority at the federal level when it absolutely must be."

Jim Wells, formerly a consultant to ORI and currently the director of research policy for the University of Wisconsin-Madison, also expressed his dismay at the length of the vacancy.

"It is regrettable that HHS has been so slow to find a new director for ORI," he told RRC. "HHS's failure to find a new director for ORI gives the appearance of a lack of priority for research integrity. ORI is an agency with an important mission to oversee the integrity of federally funded research, and it deserves to have its leadership positions filled in a timely fashion."

Pascal left ORI in good stead, especially with the research compliance community, Wells said.

"Chris Pascal was a capable leader of ORI from 1996–2009, having joined ORI in 1992 at a time when its reputation was at a low point," Wells said. "As a director, he oversaw implementation of the Ryan Commission [on Integrity and Misconduct in Research] recommendations and initiated important new programs in responsible conduct of research education and research on research integrity."

Wells also said he personally "had the pleasure to work with Chris and others at ORI helping to estimate the prevalence of research misconduct."

Current Staff Praised

Mark Frankel, director of the Scientific Freedom, Responsibility and Law Program at the American Association for the Advancement of Science, said he believed the delay was not unusual for this White House, but still, he had expected a replacement would have been named already.

"Frankly, this is true throughout the Obama administration," Frankel said. "So many vacancies, many of them in the science and technology area, have gone vacant or only recently been filled. So I don't view this as an aber-

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ration. That being said, however, I would have hoped that a new director would be in place by now."

Frankel also praised the staff for doing a good job.

"Fortunately, the functioning of ORI has proceeded quite well despite not having a director, in large part because of the two division directors," he said, referring to John Dahlberg, who runs the investigative division, and John Galland, who oversees the education division.

Dahlberg joined ORI in 1992, Galland in May 2009.

"They are first-rate professionals, well-respected for both their ideas and their running of their divisions," Frankel said.

Yet, HHS needs to be cognizant of how the vacancy looks, Frankel said. "[T]he symbolism of not having a full-time director is something that should be considered. Based on the conversations that I have had recently with the current acting director, I believe that he is well aware of this and eager to fill the slot," he said.

ORI's director and staff also play an important role on the international stage, as the global scientific misconduct community increasingly looks to the United States

for leadership, direction, and assistance. ORI staff and consultants, for example, were deeply involved in the pioneering World Conference on Research Integrity, held in Lisbon, Portugal, in 2007. ORI representatives also helped plan and spoke at the second annual conference last month in Singapore.

Link: <http://ori.dhhs.gov>. ✧

Updated Animal Guide Addresses New Issues, Including Ethics

Institutions that conduct research involving animals under a federalwide assurance should be familiarizing themselves with a new edition of the *Guide for the Care and Use of Laboratory Animals*, the first update since 1996.

While the Office of Laboratory Animal Welfare and the U.S. Department of Agriculture do not expect compliance with the guide until it is published in final form, the prepublication version is already available.

Janet Garber, veterinary consultant and chair of the committee that developed the new guide, walked RRC

'The Three Rs' Are Key to Good Animal Research Programs

In June, a new edition of the *Guide for the Use and Care of Laboratory Animals* was released, the first update since 1996 (see story, this page). While some things have changed in 14 years, others have not — including the belief that "the Three Rs" should form the core of any good animal research program.

This edition builds on that foundation, spending more time than in 1996 describing these concepts, which the guide says are a "practical strategy for decision-making."

An excerpt from the guide follows:

"In 1959, W. M. S. Russell and R. L. Burch published a practical strategy, referred to as 'the Three Rs,' — replacement, refinement, and reduction — for researchers to apply when considering experimental design in laboratory animal research.

"Over the years, the Three Rs have evolved into an internationally accepted approach for researchers to employ when deciding to use animals in research and in designing humane animal research studies.

"**Replacement** refers to methods that avoid using animals. The term includes absolute replacements (i.e., replacing animals with inanimate systems such as computer programs) as well as relative replacements (i.e., replacing animals, such as vertebrates, with animals that are lower on the phylogenetic scale).

"**Refinement** refers to modifications of husbandry or experimental procedures to enhance animal well-being and minimize or eliminate pain and distress. While institutions and investigators should take all reasonable measures to eliminate pain and distress through refinement, IACUCs should understand that with some types of studies, there could be either unforeseen or intended experimental outcomes that produce pain. These outcomes may or may not be eliminated based on the goals of the study.

"**Reduction** includes strategies for obtaining comparable levels of information from the use of fewer animals or for maximizing the information obtained from any given number of animals (without increasing pain or distress) so that in the long run, fewer animals are needed to acquire the same scientific information. This approach relies on an analysis of experimental design, applications of newer technologies, the use of appropriate statistical methods, and control of environmentally related variability in animal housing and study areas (see Appendix A of the guide)."

Refinement and reduction goals should be balanced on a case-by-case basis.

Link: http://grants.nih.gov/grants/olaw/Guide-for-the-Care-and-Use-of-Laboratory-Animals_Prepub.pdf.

through the update, highlighting changes from the 1996 edition. She also discussed how the guide was produced and the need to keep the guide current in the future.

The update is the culmination of a multiyear effort, Garber said. The update is issued by the Institute for Laboratory Animal Research, National Research Council, and was sponsored by the National Institutes of Health, USDA, and Association for the Assessment and Accreditation of Laboratory Animal Care, among others.

The committee's task was to "update the 1996 version of the *Guide for the Care and Use of Laboratory Animals* to reflect new scientific information related to the issues already covered in the guide, and to add discussion and guidance on new topics of laboratory animal care and use related to state-of-the-art animal research programs." Its specific charge was to "review the scientific literature published since the release of the 1996 guide and determine whether the information currently in the guide concurs with current scientific evidence."

Meetings Began in 2008

Committee members hailed from Virginia Commonwealth, Memorial Sloan-Kettering, and Johns Hopkins, as well from institutions in the Netherlands, Germany, and Canada, as the guide is used internationally. Members began meeting in September 2008, first holding a series of public meetings around the country before getting down to business.

Garber, who was involved in the drafting of the 1996 guide as well, said that while an update has been needed for some time, the 1996 version has held up over the years.

"The 1996 guide, in actuality, had really served us well over the intervening years. One of the reasons was the basic concepts put forward were fairly new at that time. The concept of performance standards is one example. That certainly made the use of the guide more flexible right from the start," Garber said.

But, she said, "after about 10 to 12 years it did become evident to the community that there were some things that were dated, particularly references to technology, certain aspects of care that were influenced by technology, and that a lot of material had been published that warranted an update."

Surveys showed the need for an update and the areas of the guide that would benefit, she said. In 2005 and 2006, NIH collected new research published up to that point, which served as a starting point for the committee's literature review, Garber said. "That was a tremendous help. We were able to start with that."

In addition to new technologies and other changes in the animal care and research field that have emerged since 1996, the new guide also seeks to clarify confusing or unclear language in the previous version.

The committee also sought to "provide information on how to meet the performance standards," Garber said. "The [1996] guide presented a lot of information on what objectives were to be met but not a lot on how to get there. In the intervening years there have been a lot of different ways to do things — environmental enrichments, sanitation," for example.

One strength is that "we were able to provide much more information on the things that program managers can consider when designing a program, or to respond to changes in their program," compared to the 1996 version, she said.

Topics Run the Gamut

The new guide also "expands on the ethics of animal use, the responsibilities of the animal user, and includes a much more defined section on the Three Rs," Garber said. (For more information on the Three Rs, see box, p. 3.)

But, overall, the new guide "really isn't a rewrite," Garber said. "It is intended to be an update. The content hasn't changed substantially."

The five chapters are as follows:

1. Key concepts
2. Animal care and use program
3. Environment, housing, and management
4. Veterinary care
5. Physical plant

"Probably what has changed the most from the 1996 guide is chapter 1," Garber said. The 1996 introduction contained substantive information that the revision committee felt would be better positioned in an actual chapter, which was then split into Chapters 1 and 2. These chapters, she said, "set the stage for what it means to have an effective animal care and use program."

"Chapter 2 probably looks fairly new," Garber said. "Really it just expands on what was in the 1996 guide. Chapter 2 defines the program in the broadest sense — what needs to be there in order to have an effective program. The 1996 guide implies what is in Chapter 2."

Users will also find entirely new sections as well. These include animal biosecurity, disaster and emergency planning, post-approval monitoring, and "hazardous agent containment."

"The last three chapters are virtually the same as in 1996," Garber said. "The most notable change is the chapter on environment, housing, and management." Now, separate sections address guidance on aquatic versus terrestrial species.

"The 1996 guide had a number of places that implied the importance of ethical considerations about the use

of animals in research. Based on the change in the environment in the last 15 years," guide authors wanted to recognize "the importance of stressing the humane use of animals in research." (For a recap of a recent OLAW presentation on ethics in animal research, see *RRC 7/10, p. 5*.)

More Frequent Updates Planned

Since the prepublication version was released, Garber has been involved in a number of briefings for interested individuals and said the response so far has been "extremely positive, in terms of the amount of information provided to enable institutions to more confidently approach the whole performance standard concept."

While no specific plan for future updates has been developed, committee members felt strongly that the

guide will need to be updated more regularly than in the recent past, Garber said.

"The committee, in the preface, did indicate their opinion that there should be an ongoing process to keep the guide alive, and update it on a more regular basis," she said. "It was recognized that, based on the amount of work we had to do that a way to update at least the appendix and review the literature on a more regular basis would be desirable."

Whether another major update is needed "will depend on how the new guide is accepted and whether technologies change dramatically," she said.

Link: http://grants.nih.gov/grants/olaw/Guide-for-the-Care-and-Use-of-Laboratory-Animals_Prepub.pdf. ↵

Biosecurity Part of Animal Care Programs

Researchers who work with deadly viruses, toxins, or other dangerous materials know well the term "biosecurity," which means keeping themselves, their colleagues, and the environment safe and protecting the material from possible access by those who might have a more nefarious purpose for them.

What about applying the concept of biosecurity to animals? Keeping animals healthy so that they can serve their research purpose is something investigators and animal care staff intrinsically do already, but for the first time, the "bible" for animal research programs has mentioned and defined "animal biosecurity."

According to the recently issued 2010 *Guide to the Care and Use of Laboratory Animals*, which was last updated in 1996, biosecurity "refers to all measures taken to identify, contain, prevent, and eradicate known or unknown infections that may cause clinical disease or alter physiologic and behavioral responses or otherwise make the animals unsuitable for research."

The guide states that while all species would benefit from such practices, they are "most important when housing large numbers of animals in intensive housing conditions," such as rodents.

Limiting animals' exposure to "infectious disease agents" involves

- ◆ consideration of physical plant layout and operational practices;
- ◆ separation of clean and soiled caging and equipment, and sometimes staff;
- ◆ procedures that ensure only animals of a desired, defined health status enter the facility;

- ◆ assurances that personnel and materials, especially consumables, do not serve as fomites that harbor infectious agents;
- ◆ practices that reduce the likelihood of cross contamination if an infectious agent is inadvertently introduced;
- ◆ a comprehensive ongoing program for evaluating animals' health status, including access to all animals; and
- ◆ containment and eradication — if desired — of introduced infectious agents.

The guide also describes a number of "related program components" that pertain to animal biosecurity, including

- ◆ procedures for evaluating and selecting appropriate animal suppliers, and possibly quarantining and confirming the animal's health status if unknown;
- ◆ treatment of animals or their products at facility entry to minimize disease risks, such as surface disinfection of fish eggs;
- ◆ establishment of a comprehensive pest control program that may include evaluation of the health status of feral animals;
- ◆ procedures to ensure that all biologicals administered to animals are free of contamination; and
- ◆ development of appropriate procedures for intra- and inter-facility animal transport.

Link: http://grants.nih.gov/grants/olaw/Guide-for-the-Care-and-Use-of-Laboratory-Animals_Prepub.pdf.

Misconduct Researchers Offer Ways To Intervene When Deemed ‘Safe’

When Gerald Koocher was in graduate school, a senior professor studying de-sensitization techniques for those with snake phobias briefly put the snakes in the refrigerator before the experimental (phobic) group handled them, but not before they were presented to the controls. Although Koocher kept silent about how the chilled snakes would be more docile, and thus bias the study, the experience has bothered him ever since.

Nowadays Koocher “is in a role of authority” and knows this kind of scientific misbehavior “still goes on.” So that others might take action in a similar situation, Koocher and others developed a 60-page, highly detailed “user-friendly guide on how to respond to research wrongdoing.” Koocher is an associate provost and psychology professor at Simmons College in Boston.

Koocher’s co-investigators and co-authors are Patricia Keith-Spiegel, a former professor at Ball State University, and Joan Sieber, psychology professor emerita at California State University in East Bay. Their guide was born of the findings of the team’s survey on misconduct; a paper about the survey was published in a recent issue of *Nature*.

More Folks Should ‘Speak Up’

The team’s work was supported by a grant from the Office of Research Integrity and the National Institute of Neurological Disorders and Stroke. All the materials have been posted online at www.ethicsresearch.com, Koocher’s website.

The survey of some 2,500 federally funded scientists found that 84% had experienced one or more incidents of suspected misconduct during their careers, with 63% taking some form of action to remedy the situation.

Koocher told RRC the paper and guide seem to have touched a nerve, and the response “has been universally positive.”

“There is a lot of invisible stuff happening,” he said, and many want to do more to stop it. While the overall goal is to reduce the incidence of misconduct, this project deals more with what should happen *after* a suspicious incident occurs.

Links in the News

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

As Koocher put it, “if people are going to cheat, three things have to happen. They have to rationalize away their scientific principles. Second, the perceived value of cheating has to be so high, or the pressure so intense, to force them into that rationalization. And, third, they have to feel pretty confident that they are going to get away with it.”

He added, “We can try to alter the culture by getting people to speak up more. That was our goal — encourage people to speak up when it is safe. We don’t want you to put your career at risk, but there are some ways” to speak up without that occurring, or that would minimize the effect on one’s career.

Mark Frankel, writing in a forward to the guide, said it provides needed assistance to investigators. Frankel is director of the Scientific Freedom, Responsibility and Law Program at the American Association for the Advancement of Science.

“Recognition of one’s professional responsibility to act is a necessary step in that direction, but it is not enough,” he writes. “What is also needed is a good compass that points in the right direction, warns of hazardous terrain ahead, locates where support is available, and helps people assess and reason through their choices.”

Unethical Acts Warrant Action

Koocher believes the federal definition of misconduct — fabrication, falsification, and plagiarism — is too narrow and should be broadened. The guide deals with much more than these three activities, calling attention to a host of troubling behaviors that may warrant action when suspected.

The guide describes “seven categories of irresponsible or unethical acts” that fall outside the federal definition of research misconduct and, as such, “may be more amenable to informal resolution.” They are as follows:

- ◆ Failure to follow the regulations of science (problems with informed consent, coercion of subjects, no institutional review board approval).
- ◆ Incompetence (inadequate sampling, lack of skills for the task, use of outdated research tools).
- ◆ Carelessness (poor record keeping and backup, lack of security for confidential material, inadequate financial tracking).
- ◆ Inadequate supervision of research assistants.
- ◆ Dishonesty indirectly related to work as a researcher (failure to report conflicts of interest, falsifying or embellishing credentials on resumes or grant applications, renegeing on promises to others).
- ◆ Difficult or stressful work environments that impact the research process (mentally unbalanced supervisors, conflicts among administrators, dysfunctional mentoring relationships).

◆ Publication and authorship disputes.

One section of the guide helps individuals determine how to complain of possible misconduct once they've decided they can't keep quiet.

Assess Support First

"We aspire to help you select a course of action that reduces risks to you while, at the same time, fosters the conduct of responsible science," the authors write. "Handling the matter informally can lead to a successful resolution. At other times an incident merits involving appropriate others or taking the matter to a more formal level. Sometimes it may not be possible or reasonable to do anything. Sometimes the risks to you will be too great to act, given your personal situation. We will present indicators for all of these options."

If the institutional policy "favors expediency or engages cover ups," submitting a formal complaint "can prove problematic," the guide states. "This is particularly important when intervention is needed."

"Some institutions may not be corrupt, but may fail to deal with a formal report adequately and fairly because of disorganization or lack of knowledge as to how to proceed," the authors say.

The authors suggest that individuals understand the institution's research policies and "try to assess the level of support you can expect from your institution by seeking out general information from others."

"You might discreetly ask colleagues if they know of any outcomes of previous cases of research wrongdoing and how the administration reacted to the individuals who reported it," they say. "No one has to know at this point exactly why you are interested."

Having personal support is also key, although not an "absolute condition for a successful intervention among survey participants," the authors say.

First Steps May Be Informal

The guide says it is important to note that situations in which the person acted alone and produced a good outcome "tended to involve informal interventions with students, assistants, or other subordinates, or dealt with people with whom they already had a respectful relationship, or the possible infraction would not cause serious damage and was perhaps an error, and the evidence was clear-cut."

They conclude that "it is very risky to act without support if the individual you suspect is in the same work setting and senior to you, if your relationship with co-workers is contentious, or if your evidence is weak."

Strong evidence is essential. Evidence "should speak largely for itself before going the formal route to avoid

threats or to prevail in any legal action taken by the accused," according to the guide.

Before intervening, the guide suggests the researcher (or administrator — whoever suspects a problem) needs to first "understand the suspected individual's motives and actions as best [as possible] from his or her perspective. That will go a long way toward understanding what [strategy] stands the best chance of producing the most effective outcome."

'Personal' Intervention Is Important

The authors do not recommend discussing the situation over the phone ("unless geographical barriers preclude a direct meeting"), or by e-mail or letters. "Contact the individual privately and ask if you can meet at the earliest mutual convenience," they write. "An office setting would normally be more appropriate than a home or restaurant, even if the colleague is a friend. Try not to be overbearing or mysterious. If the person asks why, try something like 'I need to discuss a project with you' or, 'There is something I'd like to go over with you.'"

The guide also discusses the pros and cons of bringing someone to the meeting for support, what to say, and a range of possible responses by the accused person. When a questionable act has occurred, the authors write, "sometimes, the appropriate action involves simply encouraging the individual to cease what he or she is doing, even if no harm has yet occurred."

What might be needed, if the individual "lacks certain competencies resulting in poor quality work," is suggesting or providing additional education or supervision, or "adding needed expertise to the project. Often the solution will require that the offender (or potential offender) do something differently, coupled with an attempt to redress any damage to the research record, participants, or someone's reputation," the authors write.

So what can go wrong as a result of an "informal" intervention? Lots, though bad outcomes are likely "not the norm," as reported by survey respondents.

"Sometimes things are not handled equitably, competently, or in a timely manner by the institution, which can cause the accuser considerable grief," the authors say. "This is why we advise you to make sure your institution has a sound operation in place before formally reporting a colleague. Sometimes the accused, who now may have a lot to lose, attempts to retaliate or cause some form of trouble for the accuser. Being sued becomes a concern, although our research did not reveal any instance in which threats actually materialized."

continued

Depending on whether the informal response addressed the issue, the next step might be to move on to a formal misconduct complaint process, particularly if the infraction is serious.

Some Issues Demand Formal Process

As the guide states, "At times informal intervention is not the right place to start or even a reasonable option."

Investigators and others "should not attempt handling situations on your own if they seem likely to break down or carry considerable personal risk," the authors say. "If the suspected offense is extremely serious with the potential for significant consequences, such as data fabrication in a federally-funded project, an informal intervention [is] not recommended."

The guide also offers a "general overview of what you would be getting yourself into if you take formal action as well as some resources to consult for further information" but notes, "The details of reporting policies change from time to time, so it is important to access the most recent version of the procedures at your institution and, if relevant, the policies of the funder of the project about which you have concerns."

Another question the guide poses, particularly relevant when a formal complaint is made, is, "Will I be protected by the institution?" The answer, according to the guide, is a qualified...yes, you should be, but expect some fallout.

"Institutions are obligated to protect good faith allegations," the authors write. "To the extent possible, your identity, as well as that of the respondent, will be limited to those who have a right to know while con-

ducting a complete and competent review. Evidence and records must also be held as confidential for the same reasons, except as prescribed by applicable law."

The guide authors "strongly suggest" that individuals who make a formal complaint "identify sources of support...before acting."

"Although there are formal restraints on retaliation, these cannot always protect you from some of the ways you might be treated if you become regarded as a 'snitch' — among your colleagues," they say. The person making the complaint is now opening himself or herself up to scrutiny as well, as a result of the investigation into the accused individual, who "will be accorded due process."

The guide also addresses why, when, and how to approach the issue of going outside an institution to make a claim of misconduct, circumstances that would make the individual a whistleblower. Support is available from www.whistleblowers.org and other sites, they write.

Institutions Must Play a Role

While the guide focuses mostly on what individuals can do, there is a vital role for institutions to play that it also addresses. Institutions must "take a strong public stand on integrity and express that academic dishonesty is not something we will tolerate," Koocher told RRC.

Formal educational programs on the responsible conduct of science are essential (and required under some grants) and should be augmented with more informal discussions that lab directors and others have with their staff, colleagues, and students, Koocher said.

Conversations can simply take the form of discussions about "paying attention to the environment, giving the benefit of the doubt but speaking out" when something seems wrong and "how to avoid problems." As an example, he cited harried research leaders who may forgo seeing or reviewing original data, a mistake that can make falsification undetectable.

An important point: researchers should know "who to talk to if it looks like something serious is happening," Koocher said. Sometimes incidents go unreported, and thus unaddressed, because researchers simply don't know where to turn.

In fact, there should probably be several choices, or, as he put it, a "cluster of people" who could hash out the situation, in confidence, before anything is done. For example, a compliance official should probably not be the person who is designated for this purpose, because the conversation would be at a preliminary stage, Koocher said.

Link: www.ethicsresearch.com. ✧

Other Resources From NCURA and AIS

✓ *A Guide to Managing Federal Grants for Colleges and Universities*, co-published by NCURA and NACUBO, in conjunction with AIS, is a four-part information service: a comprehensive content-rich Web site, daily Web postings of agency actions and weekly e-mail summaries, printed reference documents and a monthly newsletter.

✓ *Sponsored Research Administration: A Guide to Effective Strategies and Recommended Practices* provides research administrators with a "living textbook" on the wide range of research management challenges they face each day. The publication includes quarterly updates and a CD.

Visit www.AISEducation.com

ARRA Requirements Dominate 2010 Audit Compliance Supplement

The 2010 Circular A-133 Compliance Supplement, posted by the Office of Management and Budget, implements changes to further the administration's use of single audits as the primary oversight mechanism for the vast amount of ARRA funds being expended in fiscal years 2009–2011.

Updated each year, the compliance supplement to OMB Circular A-133, *Audits of States, Local Governments and Nonprofit Organizations*, identifies requirements of major federal assistance programs that are expected to be examined during A-133 audits and provides audit guidance regarding those programs. It also provides more general guidance for testing compliance of programs that are not enumerated in the supplement.

OMB previously issued a draft of the supplement to the American Institute of Certified Public Accountants and other stakeholders to help auditors and grantees plan for single audits (*RRC 7/29/10*). The 2010 update also integrates Addendum #1 of the 2009 Compliance Supplement, released in August 2009.

A list of changes to the supplement is included in Appendix V, including any changes made to the draft. The 2010 Compliance Supplement applies to audits of fiscal years beginning after June 30, 2009, and supersedes the 2009 Compliance Supplement.

The new compliance supplement, dated June 2010 but only released recently, differs only slightly from the draft.

Instructions for Evaluating ARRA Reporting

The supplement includes guidance for auditors to follow when evaluating a grantee's ARRA reporting, but audits of the reporting of the number of jobs created will not be part of the audit. The supplement clarifies that, "While the 'number of jobs' is a required data element on the Section 1512 reports, the auditor is not required to test the 'number of jobs' as part of the compliance work performed on the 1512 ARRA reporting."

Auditors must test compliance only with the following data elements required by Section 1512: award number and amount; total amount of ARRA funds received (from federal grants and cooperative agreements) or invoiced (for federal contracts); and cumulative total amount of ARRA funds that have been expended.

ARRA allows prime recipients to delegate some of the reporting responsibilities to subrecipients if they wish. Auditors are told to determine whether prime recipients have methods in place to monitor their subrecipients' reports for accuracy, regardless of whether they have been delegated some Section 1512 reporting

responsibility. However, the audit procedures in Section L of the supplement apply only to primary awards, not to subawards.

Audit procedures for the ARRA reporting data require auditors to test only the Section 1512 report for the calendar quarter preceding the recipient's year end. When testing major programs with multiple awards, such as research and development programs (considered a cluster for audit purposes), auditors should select a sample of ARRA reports for the calendar quarter preceding year-end.

A change from the draft Part 3 materials relates to determining whether prime recipients have reviewed the status of their subrecipients' registration with the Central Contractor Registration. The draft version of Audit Objective 7 in Section M, Subrecipient Monitoring, called for checking that pass-through entities had checked the CCR status "before making subawards," but that phrase was deleted in the final version because there is no actual requirement for them to do so prior to making a subaward.

Further Guidance on ARRA

The ARRA section of Appendix VII was extensively revised in the draft to expand the instructions on determining major programs that must be tested in the single audit and on categorizing the auditee as high- or low-risk. The appendix also prescribes a method of calculating which large loan and loan guarantee programs should be excluded from the Type A program determination.

In the Matrix of Compliance Requirements (Part 2 of the supplement), under Special Tests and Provisions, all ARRA programs show a Y (meaning "yes," the requirement is applicable), due to the special tests for ARRA programs that were added to Part 3 (Compliance Requirements) by Addendum #1.

In Part 3 (Compliance Requirements), a new "ARRA Reporting" section has been added to L. Reporting, as well as to each program supplement/cluster in Part 4, to indicate whether ARRA reporting is "Applicable" or "Not Applicable."

The R&D cluster updates Davis-Bacon Act references for ARRA purposes.

A section titled General Guidance – Internal Control over Compliance for Major Programs with Expenditures of ARRA Awards was added to Part 6, Internal Control. The section, which had been added to Part 6 in Addendum #1 of the 2009 Supplement but did not appear in the draft 2010 version, addresses specific concerns related to internal controls associated with ARRA funds, such as the entity's ability to "ramp up" due to dramatically increased federal funding as a result of ARRA, and the

need to alert management to deficiencies found during the audit process as quickly as possible.

Changes Incorporate New Forms

Changes also have been made in the supplement to reflect federal agencies' transition from the SF 269, Financial Status Report, and SF 272, Federal Cash Transactions Report, to use of the SF 425, Federal Financial

Report. The transition was to have been completed by Oct. 1, 2009. However, as "particular agencies, programs, or awards may transition on varied dates, for the 2010 Supplement," references to the SF 269 and SF 272 are being retained in many cases "to inform the auditor that for some part of the audit period the prior form may have been submitted," according to OMB.

Inside NIH

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

◆ **A summary of inspections of nine chimpanzee facilities by federal officials in the last year reveals that "overall the institutions were found to be in compliance with the Public Health Service Policy and the quality of care and commitment to the psychological well-being of the chimpanzees and other nonhuman primates was high."** The inspections began after the NIH Office of Laboratory Animal Welfare received a list of allegations concerning potential non-compliance at the University of Louisiana–Lafayette, New Iberia Research Center (*RRC 5/09*, p. 7). As a result of those complaints, New Iberia made improvements and paid an \$18,000 fine (*RRC 5/13/10*). According to the recently released summary, "In order to investigate the allegations made against NIRC and to conduct a cross sectional evaluation of all assured institutions housing chimpanzees, OLAW began a year long series of site visits, many of them conducted in conjunction with the USDA inspections [staff]. The objectives of the visits were to determine whether these institutions' programs and facilities for the care and use of chimpanzees were consistent with their animal welfare assurance with OLAW and to evaluate the current state of social housing, husbandry, enrichment, veterinary care, and training practices for chimpanzees." While overall compliance was noted, OLAW recommended more training of nonhuman primates through positive reinforcement "to perform desired cooperative activities" and said that "greater effort must be made to co-house animals." (*8/12/10*)

◆ **NIH recently beefed up the staff overseeing grantees' compliance with federal regulations and has undertaken "site visit initiatives," according to an article by Sally Rockey, acting director of the Office of Extramural Research.** Writing in this month's issue of *Extramural Nexus*, Rockey said staff were added to the Division of Grants Compliance and Oversight. Compliance oversight is a responsibility "shared" between

NIH and grantees, Rockey said, and NIH is "looking forward to strengthening this partnership to ensure efficient and effective management of federal funds." Site initiatives include "proactive site visits, which were designed to promote open communication of policy issues between NIH and grantee institutions. These were not audits or investigations, but, rather, a dialogue during which we provided oral feedback and guidance to the institution. We have also performed proactive assessments and targeted site reviews of institutional compliance with the financial conflicts of interest regulations," Rockey said. (*8/12/10*)

◆ **The August 2010 issue of *Extramural Nexus* also contains a discussion of the "importance of communicating research value."** Investigators and others should "take every opportunity to tell people what you do, why you do it, and why they should care," wrote OER's Sally Rockey. "Knowing that your title, abstract and public health relevance statements will be public if your grant application is funded means that you should consider more than just reviewers when writing them....So I encourage you to use language that best expresses the importance of your research for the portions of your application that will reach the wider community." (*8/12/10*)

◆ **The Centers for Disease Control and Prevention's Office of Health and Safety and NIH have released the fifth edition of *Biosafety in Microbiological and Biomedical Laboratories*.** The fifth edition of these national guidelines for workers in biological and medical laboratories, issued last December, is now available online at www.cdc.gov/biosafety. NIH's Office of Laboratory Animal Welfare notes that the online version of the guidelines "contains a number of updated websites...and as a living, online reference resource, may continue to be updated as websites continue to change." (*7/29/10*)

Appendix VII of the compliance supplement also reiterates OMB's policies that (1) agencies will not grant extensions for submission of the audit report, even for auditees that have no ARRA funding, and (2) recipients with late submissions in either of the two prior reporting periods may not be classified as a low-risk auditee.

Appendix VII: Other OMB Circular A-133 Advisories of the 2010 Compliance Supplement includes an advisory addressing the findings of poor single audit quality in the June 2007 *Report on the National Single Audit Sampling Project*. The appendix encourages auditors to review the report and related updates issued by the American Institute of Certified Public Accountants to ensure audit compliance with Circular A-133.

Link: www.whitehouse.gov/omb/grants_circulars. ✧

Universities Oppose COI Draft

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Universities also say they simply can't stretch their dollars any further. As Beckwith put it, "We believe that these significant expenses cannot be accommodated under the current 26% cap on administrative costs for federal research awards. UC's analysis (and a perspective shared by national associations of institutions of research and higher education) is that the current 26% cap provides inadequate reimbursement for the current, true costs of research administration, which we calculate to be at least 32%."

UC asked that NIH put off an effective date of any final regulations until October 2013, stating it would take that long to put compliance plans in place, given their "scope and complexity." NIH will issue a final regulation at some point in the future.

Organizations submitting comments also requested clear definitions of significant financial interest and asked that this be narrowed to apply to an investigator's research duties only, not all institutional duties generally, as specified in the proposed regulations (*RRC 6/10, p. 1*).

In addition, the Secretary's Advisory Committee on Human Research Protections submitted a comment letter, taking NIH to task for not harmonizing the proposed requirements with those imposed by the Food and Drug Administration, the National Science Foundation, and other federal agencies. SACHRP urged NIH to seize the "opportune moment" to develop consistent regulations.

Other specific objections raised by UC and its peers address the following proposed requirements in the draft:

◆ *Lowering the reportable income to \$5,000 from \$10,000.* In addition to retaining the higher level, suggestions were

made to retain exemptions from reporting for travel, advisory committee, and review panel payments.

◆ *Monitoring conflicts of interest among subrecipients,* which UC termed "impossible to implement, particularly with regard to sub-recipient health and research centers in the developing world."

◆ *Requiring the development of a mitigation plan* in instances when disclosures were not made or reviewed in a timely manner. Mayo Clinic, in its comment letter, deemed this "unnecessary and punitive."

◆ *Creation of a public database by each university to list questioned payments.* This should be NIH's job, commenters said, especially since a similar website is now required under the health reform law (*RRC 4/10, p. 4*).

◆ *Shifting the job of deciding whether significant financial interests are related to the PHS-funded research to the institution from the investigator.* In fact, this provision has prompted a research compliance official in Texas to threaten to drop some of his duties if it's adopted.

"How, as an institutional official (IO), can I read through a 770-page SPORE grant and be aware of all research involved in that grant and be responsible to determine if any involved investigator has any FCOI related to any of this research. It is not possible," wrote Wesley Harrot, executive director of research administration and operations for the University of Texas M.D. Anderson Cancer Center. "The only individuals in a position to make that determination are the investigators. Moving this responsibility from the investigator to the institution is inappropriate and completely unmanageable with the hundreds of annual NIH submissions from our institution. I do not believe in all good conscience that [I] could serve as an IO for COI under this rule."

PIs Are Also Concerned

Some investigators have also registered displeasure.

"I believe that the current rules are operating quite well and that keeping disclosure at the local level rather than reporting the specifics of the conflict to NIH will be burdensome, conflict with individual rights, and lead to gross inefficiencies," wrote Richard Catalano, a professor and director of the Social Development Research Group at the University of Washington in Seattle. "If NIH desires to understand the system it has created, auditing should occur, as it does for other regulation compliance activities. Taking all this information to NIH will create an inefficient and unmanageable system. Finally, making the information public is irresponsible, could lead to misinterpretation, and potential defamation of those involved.... This regulation appears punitive not protective."

Link: www.regulations.gov/search/Regs/home.html#docketDetail?R=NIH-2010-0001. ✧

In This Month's E-News

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

◆ **The FDA has published a compendium of guidance documents "currently in use at the agency" and also identified those it has withdrawn and added in the previous five years.** The document titles, published in the Aug. 9 *Federal Register*, are listed by center and include those from the Center for Biologics Evaluation and Research, Center for Drug Evaluation and Research, Center for Devices and Radiological Health, and others. (8/12/10)

◆ **Sens. Maria Cantwell, Susan Collins, and Bernard Sanders introduced S. 3694, the Great Ape Protection Act, on Aug. 4.** The bill is the Senate companion to H.R. 1326, introduced in March 2009. "The chimpanzee is a poor model for illness research, and the vast majority of the 500 federally-owned chimpanzees are just wasting away in research laboratories resulting in millions of dollars of wasteful government spending," Sen. Cantwell said in a statement. "This bill would require these chimpanzees be permanently retired to sanctuaries, where it is far cheaper to care for them — not to mention a better environment for these great apes." The bill defines great apes as chimpanzees, bonobos, gorillas, orangutans, and gibbons and would ban invasive research on them — regardless of funding source — and specifically prohibit the federal funding of such research. The Humane Society of the United States praised the action, while the National Association for Biomedical Research launched a campaign in opposition to it. (8/5/10)

◆ **The Association of American Universities, the Council on Governmental Relations, and others submitted comments to the U.S. Citizenship and Immigration Service on July 29 "reiterating their opposition to the agency's adding a question about deemed export control licenses to its Form I-129."** The comments, in response to the agency's June 30 *Federal Register* notice proposing to add such a question, echoed concerns first raised in April about the agency's plan to put a question on the form filled out by H-1B visa petitioners that asks them "to state whether or not they will be required to have a deemed export license." The new comment letter repeats the groups' contention that the agency still has not said what it plans to do with the information it would collect. (8/5/10)

◆ **Effective Aug. 23, NSF will institute two changes to its application submission process through Grants.gov.** NSF application packages will include the latest versions of the R&R Project/Performance Site Location and Research & Related Other Project Information forms for funding submissions through Grants.gov. On April 24, NSF initiated automated compliance checking of applications that request funding to support postdoctoral researchers. Such applications must include a postdoc mentoring plan. As of Aug. 23, applications that do not comply with this requirement will not be inserted into NSF's FastLane system and therefore cannot be reviewed. (8/12/10)

◆ **HHS is pondering adoption of a "tiered" select agents and toxins list, according to a July 21 advance notice of proposed rulemaking published by the CDC.** The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 "requires the biennial review and republication of the HHS list of select agents and toxins," the notice states. While reviewing the list, HHS is also considering a tiered procedure in which biosecurity requirements would be "stratified" and based on the bioterrorism risk of each item, a recommendation of several government boards and panels (*RRC 2/10, p. 3*). HHS is weighing "whether the security requirements for agents in the highest tier should be further stratified based on type of use or other factors." (7/22/10)

◆ **The dean of Harvard Medical School has agreed to revise FCOI policies as recommended by a subcommittee of a campuswide team headed by David Korn, Harvard University's vice provost for research.** The new policies, announced July 21 and set to go into effect beginning in January, would limit faculty payment from private corporations that produce items investigators are studying in clinical research and prohibit them from participating in "industry speakers bureaus." The policies also prohibit "all personal gifts, travel or meals from industry, other than travel and meals in the course of allowed activities." Payments from certain outside organizations and corporations would be posted on a public website. (7/22/10)

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