

# RESEARCH COMPLIANCE

News and Analysis for Colleges, Universities and Teaching Hospitals

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## Top Panel Urges Federalwide Consistency With Common Rule, Regs for Investigators

The top advisory panel to the U.S. government on ethics in biomedical research is recommending that all federal agencies conducting or supporting such studies "adopt human subjects regulations that are consistent with the ethical requirements of the Common Rule," which now applies to only HHS and 17 other federal departments and offices.

In "Moral Science: Protecting Participants in Human Subjects Research," its second and final report on the topic, the Presidential Commission for the Study of Bioethical Issues also called for the government to "revise" the Common Rule to address the specific obligations of investigators.

In addition, it urged greater public disclosure of human subjects research, recommending that "each department or agency that supports human subjects research make publicly available a core set of data elements for their research programs — title, investigator, location, and funding — through their own systems or a trans-agency system." Commissioners also said the government should study and pilot a system of compensation for persons injured during research.

These are among the 14 recommendations the panel submitted to the president last month, concluding nine months of study and deliberation. A standing commission, the panel was charged by President Obama in late 2010 with investigating research that occurred in Guatemala in the 1940s, and with assessing the adequacy of current regulations governing studies involving humans.

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## With Pledge of 'Partnerships,' ORI's New Chief Takes Helm After Multi-Year Vacancy

This month David Wright, a veteran research integrity officer who developed the first training programs for officials overseeing investigations into fabrication, falsification and plagiarism, assumes the reins of the HHS Office of Research Integrity, which has been without a permanent director since March 2009.

"I think very, very highly of the people at ORI who I have worked with for a long time," Wright told *RRC*. "There are some really world-class scientists and researchers there. And the work is very important."

ORI is the federal office that oversees institutional handling of research misconduct in work supported by Public Health Service funding. It has the authority to debar investigators and impose other restrictions on them after a finding of misconduct has been made. It has two divisions — investigative oversight and education and integrity. ORI said Wright had been a consultant to the agency since 2001. HHS was criticized for leaving the post vacant for so long, which some said sent troubling signals about the government's interest in assuring the integrity of scientific research (*RRC 8/11, p. 1*).

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### Editor

Theresa Defino

### Managing Editor

Angela Maas

### Executive Editor

Jill Brown



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Wright was scheduled to join ORI Jan. 3, after stepping down as chair of the Department of Community, Agriculture, Recreation and Resource Studies at Michigan State University, where his duties included teaching and writing “on the history of science and technology and the responsible conduct of research,” ORI said in the hiring announcement.

Wright previously served as MSU’s assistant vice president for research ethics and standards as well as its intellectual integrity officer. His duties in that position included “overseeing most of MSU’s research regulatory compliance activity. He has also chaired the university’s Committee on Research Involving Human Subjects for 11 years,” ORI said.

He was responsible for developing and presenting research integrity officer “boot camps,” which the office considers “a major ORI initiative to support and to professionalize the role of research integrity officers.” The first RIO boot camp was held in 2007 at the University

of Michigan; a shortened version will be offered at ORI’s conference in March (see box, p. 3). The meeting will also likely give the research compliance community its first chance to meet Wright in his new post.

Chris Pascal, ORI’s previous director, retired in September 2009. He had joined ORI in 1992 and had been its director since 1996. Pascal had not been in the office since March 2009. The protracted process for hiring his replacement included two job searches (*RRC 4/11, p. 1*).

In August 2010, *RRC* wrote about the vacancy and the fact that Pascal was still listed on ORI’s website as the director. After *RRC*’s inquiries, the website was changed to list Donald Wright (no relation to David Wright), assistant HHS secretary for healthcare quality, as the acting director. HHS did not post the open position on [usajobs.gov](http://usajobs.gov) until the following month — September 2010, a year after Pascal’s retirement began.

### Second Time Was the Charm

Wright likely could have been hired much earlier. But he was not eligible for the position until HHS rewrote the job description, he said.

Although Wright initially was “pretty ambivalent” about whether he wanted to apply, he was encouraged to do so. But he discovered he was ineligible because candidates had to have a degree in a health science field. Wright’s Ph.D. is in the humanities, he said.

HHS was unsatisfied with the applicants from the September 2010 job posting, and in April 2011 told *RRC* the search was beginning again. That’s when Wright came under consideration. HHS rewrote the job description to eliminate the health science degree requirement, he said.

ORI spokeswoman Ann Bradley acknowledged that two job searches were conducted. “HHS realized that the initial requirement for an academic degree in the health or allied sciences had the potential to prevent other highly qualified candidates with deep expertise in the field from applying. Therefore, we recrafted the job description in order to attract a broader pool of candidates,” she told *RRC*.

The position does not require Senate confirmation.

Wright said in December that he was “eager to get started.” He said that, under HHS rules, he will serve a one-year probationary period before his position is considered permanent. MSU allows an unpaid one-year leave of absence, after which Wright plans to retire.

Wright is not moving to the Washington, D.C., area, he said, but plans to “commute.” Wright’s wife, Rebecca Henry, will continue as a professor at MSU’s College of Human Medicine, he said.

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On the one hand, the new job will be an easy transition. "I have worked with everybody in ORI," Wright said. But he added, "I have been very comfortable as an academic at MSU."

In 2010, Mark Frankel, director of the Scientific Freedom, Responsibility and Law Program at the American Association for the Advancement of Science, decried the delay in hiring a replacement for Pascal. He praised Wright's selection.

"I have known David Wright for almost two decades," he told *RRC*. "He's been a university leader in promoting responsible research conduct, at MSU and beyond. He has been involved in a number of AAAS events over the years. He's wise, deliberative and well-informed. He will provide stable and pragmatic leadership at ORI. I think it's an excellent choice."

James Wells, director of research policy at the University of Wisconsin-Madison, said he was "pleased" the post was no longer vacant. In 2010 Wells called the delay in hiring "regrettable," adding, "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."

"I am pleased that ORI has filled the position of director," Wells told *RRC*. "This is definitely a step in the right direction. David Wright has considerable experience with both sides of ORI — education and investigation — as well as many years in the field at Michigan State. I wish him well."

Wright told *RRC* education and outreach are among his priorities in his new post. "Doing whatever one can do to prevent misconduct is really important," Wright said, because when it happens "the pain is devastating for everyone involved in a misconduct case," from the accused to the complainant as well as university officials.

To this end, "Part of my over-arching interest and goals for the agency [are] to build productive partnerships between the research institutions and ORI," Wright said, so that the institutions don't "fear [ORI] as an over-sight agency."

*continued*

### ***ORI March Conference to Feature 'Mini Boot Camp'***

The Office of Research Integrity will hold "Quest for Research Excellence 2012 Conference" March 15-16 in Washington, D.C. The conference, originally planned for last August but waylaid by Hurricane Irene, will include training sessions for research integrity officers designed and presented by David Wright, ORI's new director.

Under a contract from ORI, Wright developed "boot camps" for RIOs, which ORI has offered nine times since 2007. These generally run for several days and provide intensive training. Wright will be joined by other ORI staff, including John Dahlberg, director of ORI's Division of Investigative Oversight.

The March conference will feature a condensed version or "mini" boot camp; although not mentioned on a preliminary agenda, the boot camp is expected to occur during time designated for concurrent sessions.

"A RIO, who may have a variety of institutional titles, is the person who administers his or her institution's policies and procedures for handling allegations of misconduct in research," ORI's website explains. "The boot camps bring together RIOs from major institutions to participate in discussions and training on all the critical aspects of a RIO's responsibilities, including: interviewing respondents and complainants, sequestering data, forensic analysis of questioned data and documents; training inquiry/investigation panels;

and negotiating the regulatory matrix within research institutions and with federal oversight agencies."

At the boot camps, "Veteran RIOs, ORI scientist-investigators and legal counsel experienced in misconduct cases facilitate the discussions, but all the participants are teachers as well as students and help draft best practices and standard operating procedures for critical aspects of the RIO's role," the website states. "The boot camps employ an active-learning model where RIOs practice investigative techniques in realistic simulations drawn from actual cases. Video-taped simulations of RIOs performing aspects of their duties enhance this training."

According to the preliminary agenda, the meeting will also include discussions on "work-life balance;" "parental factors and research misconduct;" "scientists as activists;" and a panel on "the role of the scientist in society."

Among the announced speakers are Sally Rockey, NIH director of extramural research, and Susan Silk, director of NIH's Office of Laboratory Animal Welfare. Representatives from universities are also scheduled to speak.

**Link to boot camp information:** <http://www.regonline.com/builder/site/Default.aspx?EventID=972393>

**Link to meeting information:** [http://ori.hhs.gov/rio/rio\\_bootcamp.shtml](http://ori.hhs.gov/rio/rio_bootcamp.shtml)

He intends to help foster the development of a “network of RIOs,” building on work begun with those who have attended the boot camps.

Until the boot camps began, “very few of them knew anyone at ORI until they got a call from ORI saying something was going on,” he said. Wright added that ORI now receives more calls for guidance and advice from RIOs, which can be helpful in heading off misconduct. He would also like to see continued development of “advanced forensic techniques for analyzing fabrication and falsification.”

Last summer, ORI made its first misconduct finding stemming primarily from sabotage that had occurred in a lab, expanding misconduct beyond a strict interpretation of misconduct (*RRC 6/11, p. 1*). Asked if he foresaw further expansion, such as to include ghost-writing, Wright demurred.

“It would be presumptuous [of him] and speaking from ignorance,” as he hasn’t started the job yet and has not been an RIO himself for several years, Wright said.

But he noted that “It is the case that half or even more of the institutions that have assurances have a more expansive definition [of misconduct] than ORI, such as failure to abide by human subjects regulations.”

He said he had no complaints with ORI in this area. “On the issue of seriousness of cases, they are extraordinarily thorough and careful. They need to stay away from *de minimis* kinds of issues” or minor concerns. ♦

## Associations, Agencies Alike Balk At Reporting Under ‘GRANT’ Act

A bill that recently passed a key committee in the U.S. House of Representatives purportedly designed to increase transparency and accountability in how the government allocates grant funds appears to be more of a vehicle to ensure that small entities get as fair a shot at winning a grant as “big” universities that “pay grant writers.”

Also under the banner of transparency, the bill calls for agencies to disclose the names of peer reviewers who judged successful grants. This provision, along with the requirement that agencies post full copies of funded grant applications, has raised the alarm of universities and federal agencies alike.

The bill in question is H.R. 3433, the Grant Reform and New Transparency Act of 2011, which the Committee on Oversight and Government Reform approved by a voice vote on Nov. 17, a day after its introduction by Rep. James Lankford (R-Okla.). The committee is chaired by Rep. Darrell Issa (R-Calif.). But at least two Democrats on the committee have taken their concerns beyond the

oversight panel and are seeking changes before the bill goes to the House floor.

“The bill focuses primarily on discretionary and competitive grants. In other words, grants through which agencies quite literally transfer tax dollars at their discretion to the projects that the agency deems deserving,” Lankford said during a vote on the bill.

In his opening statement during the markup, Issa claimed that “From 1990 to 2010, federal outlays for grants increased from \$135 billion to more than \$600 billion” and that “grants now consume nearly one-fifth [of] the entire federal budget,” a number that *RRC* was unable to verify and which appears to include programs such as Medicaid.

Issa also took aim at grant-making agencies, claiming that “grants are often executive earmarks.” Democratic members of the committee, saying they supported the intention of the bill, complained that it had been rushed to a vote and that they could not support the naming of peer reviewers or the posting of full grants. Their amendments to change those provisions were defeated, however.

When debate at the meeting turned to a discussion about the danger of posting a full grant award, Issa again made damning comments aimed at universities. The bill would allow the posting of an abstract of a winning grant only if the agency or recipient requested this based on proprietary or sensitive information being revealed. Otherwise, by default, the full application would be posted.

### Accusations Levelled Against Universities

Rep. Gerry Connolly (D-Va.) argued that agencies reported that “most applications, in fact, include sensitive material.”

Issa was dismissive and disdainful of the concerns.

“The universities who prevail [in winning grants], who are generally the ones who have told us, ‘let’s not change this,’ do have a form of proprietary information that will not be exempt,” he contended. “And that will be writing a really good grant, something that you pay grant writers to do. It is not the intention of this committee to have how you write a good grant remain a secret. Whether the grant’s substance has merit is what we want to make sure that grantees [learn], but the style and the capability of what makes a good one should be a lesson that they want all...that universities want all of us to have as a gift to society.”

On Dec. 12, Connolly and Rep. Elijah Cummings (D-Md.) wrote to the chair and ranking members of the House Science, Space and Technology Committee, asking them to address the issue of posting of full grants “should the GRANT Act be considered on the House floor.” The bill was not referred to this committee, but its

leaders could weigh in on the proposed legislation if they choose to do so.

The letter noted that “representatives from the Defense Advanced Research Project Agency, the National Institutes of Health, the National Science Foundation, and major research universities all have recommended that abstracts of grant proposals, rather than full applications, be posted online.” This follows their Nov. 28 “dear colleague” letter to all members of the House, expressing their opposition to the bill because of the posting requirement.

The bill, which currently has no Senate companion, is opposed by the Council on Governmental Relations, the Association of American Universities, and the Association of Public and Land-grant Universities, among others.

In a Nov. 28 letter, the three associations recommended changes to the bill, but added that “Let us be clear that we offer these concerns and our recommendations for improvements despite our strong doubt about the need for this legislation as it pertains to competitively awarded federal research grants.”

**Link to associations’ letter of opposition:** <http://www.cogr.edu/viewDoc.cfm?DocID=151876>

**Link to congressmen’s letter:** <http://www.aau.edu/WorkArea/DownloadAsset.aspx?id=12914> ↵

## After Pulling Back, OLAW Requires Guide Implementation by Year’s End

With just two sentences, the NIH Office of Laboratory Animal Welfare put to rest a controversy that began 18 months ago over what it wanted research institutions to do about the eighth edition of the *Guide for the Care and Use of Laboratory Animals*, and its position can be summed up in two words:

Use it.

OLAW announced last month it will require all assured institutions — those that use federal funds to conduct research using animals — to “base their program of animal care and use” on the eighth edition of the *Guide* as of Jan. 1.

And institutions had better get cracking to meet OLAW’s schedule.

By the end of this year, “assured institutions must complete at least one semiannual program review and facility evaluation using the eighth edition of the *Guide* as the basis for evaluation by Dec. 31, 2012,” OLAW announced Dec. 1. “It is not required that all necessary changes be completed by [that date], but rather that an evaluation must be conducted and a plan and schedule

for implementation...must be developed by Dec. 31, 2012.”

In an email to RRC, OLAW officials clarified that “OLAW adopted the *Guide* in its entirety. Just as with previous editions of the *Guide*, the Public Health Service Policy allows institutions the flexibility to depart from the standards in the *Guide* if the following conditions are met: (1) there is a scientific justification for the departure [and] (2) the departure has been reviewed and approved by the institutional animal care and use committee.”

The policy also provides that IACUCs “identify specifically any departures from the provisions of the *Guide* and state the reasons for each departure.”

### IACUCs Should Focus on ‘Musts’

Such departures would relate to activities in the *Guide* that are described as a “must.” As OLAW’s website states, the agency “considers a ‘must’ statement in the *Guide* to be a minimum standard required of assured institutions.” The IACUC’s report is sent to the organization’s institutional official.

Although the implementation requirements are final, before the end of this month institutions will have something of an opportunity to weigh in on OLAW’s decision. OLAW is accepting comments on “position statements” the agency released to explain its thinking on some of the major themes and provisions in the new *Guide*. The statements also clarify “how OLAW expects assured institutions to implement the eighth edition of the *Guide*.”

OLAW said in a statement that the *Guide* would lead to needed improvements in the field of animal research.

“In OLAW’s judgment, the eighth edition of the *Guide* empowers continued advancement in the humane care and use of vertebrate animals in research, research training, and biological testing,” the statement said.

In moving ahead, OLAW is bucking the 60% of commenters who, when responding to OLAW’s request for feedback on how it should proceed, said OLAW should either scrap the guide entirely or make major revisions (or give institutions lots of latitude).

But its decision has the full support of the Association of the Assessment and Accreditation of Laboratory Animal Care, which embraced the *Guide* when it was published and has been using it as the basis for site visits since September (RRC 12/11, p. 1).

The guide, published by the National Research Council of the National Academy of Sciences, is “a result of a lengthy study by the Institute for Laboratory Animal Research,” OLAW explained. “Since 1985, PHS Policy has required that all institutions receiving PHS support for animal activities base their programs of animal care and use on the current edition of the *Guide*.”

*continued*

The eighth edition — the first update since the seventh was published in 1996 — was initially embraced by OLAW, which posted news in June 2010 that a pre-publication version was available. “Until the eighth edition of the *Guide* is published in its final form, the 1996 edition will remain the official *Guide* for the purposes of implementation of the PHS Policy. OLAW will issue guidance on implementation of the eighth edition of the *Guide* after it is published,” the 2010 statement said.

The final version was published in December 2010.

So it came as something of a shock when OLAW announced in February 2011 that it was opening a 30-day comment period focusing on whether it should adopt the new *Guide*, and what folks thought about possible imple-

mentation by March 2012. OLAW twice extended the comment period, which ultimately spanned 90 days.

OLAW was silent on the *Guide* and did not post any of the comments until Dec. 1. But officials told RRC in November they had received 806 comments. With the new announcement, OLAW posted most of the comments, as well as an overview of what they said. OLAW also explained that it was addressing seven areas that had generated the most responses, such as cost and housing issues, and, as noted, was seeking comment on those statements.

“A majority of respondents opposed the adoption of the eighth edition of the *Guide*. Many of the organizations and individuals that opposed the adoption of the *Guide*

## In This Month's E-News

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

◆ **A proposed rule purporting to reorganize regulations governing select agents and toxins issued by HHS and the U.S. Department of Agriculture fails to live up to the expectation that changes would require biosecurity protections based on the risk posed by the materials, as divided into tiers, according to a Dec. 2 comment letter by the Council on Governmental Relations.** The HHS Center for Disease Control and Prevention and USDA's Animal Plant Health and Inspection Service issued the proposed rule Oct. 3; revisions to select agent and toxin rules have been under consideration since at least 2009 (*RRC 2/10, p. 3*). “We are not confident that the proposed regulations meet the crucial balance between increasing the nation's security and reducing the hurdles faced by scientists as they pursue research on potentially dangerous SATs.... What is proposed is heightened security for identified Tier 1 SAT and increased security requirements for those SAT remaining on the principal or non-tiered list,” COGR said in its letter to the agencies. (*12/8/11*)

◆ **In its semiannual report to Congress covering the period ending Sept. 30, the Office of Inspector General in the National Science Foundation states that the agency has “closed 50 investigations, had five research misconduct cases result in findings by NSF, and recovered \$12,903,449 for the government.** In addition, eleven audit reports and reviews were issued which identified \$201,756 in

questioned costs and nearly \$76 million in funds put to better use.” OIG also reports that “a joint investigation of false claims made under NSF grants led to a settlement agreement requiring a Georgia college to reimburse the government \$1.2 million and enter into a five-year compliance plan. Expenses charged to the NSF grant included personal purchases and travel. Four ongoing investigations of fraud and duplicate funding involving NSF awards resulted in \$875,000 being either recovered from awardees or retained by the government.” (*12/1/11*)

◆ **The Council on Governmental Relations has submitted a paper to an inter-governmental task force that documents its problems with and alternatives to the current effort reporting system.** The A-21 Task Force, so named for the Office of Management and Budget Circular A-21 that governs allowable award and administrative costs, is developing strategies for possible adoption that alleviate regulatory compliance burdens on research universities. In response to a request from the task force, the organization “further elaborated on its position to discontinue the effort reporting requirement,” COGR said on its website. In the paper, COGR described a “compliance-based solution” that “represents a model framework that institutors could adopt immediately” and that “no longer requires an effort reporting system to be layered on top of the institution's existing payroll distribution system.” (*11/17/11*)

supported many sections. Their objections were confined to specific topics and issues; these are the subjects of OLAW's position statements," OLAW said. "Many of those opposed to adoption of the entire *Guide* applauded the new reference section as *excellent, valuable and needed*, liked the section on aquatics, and commended the effort put forth to compile the new edition. A minority of respondents fully supported the adoption of the eighth edition of the *Guide*. The consensus among these respondents was that the new material in the *Guide* was overdue and necessary."

Janet Garber, veterinary consultant and chair of the committee that developed the new *Guide*, earlier said that the updating process had begun in 2008, and that the latest version focuses on "performance standards." New material on ethical considerations and biosecurity were also added (*RRC 8/10, p. 3*).

OLAW pointed out that it had received feedback from the new *Guide* authors, who said "All decisions made by the committee were determined by consensus... The process for selecting members of the committee was intensive and unprecedented for any previous version of the *Guide*. The qualifications of the 13 members were intensely scrutinized over several months, followed by a 20-day public comment period before the committee roster was finalized."

However, commenters echoed the concerns of the Council on Governmental Relations, the Association of American Universities and the Association of American Medical Colleges, which said in a joint letter that the *Guide* actually seems instead to "move away from performance-based standards toward more rigid engineering standards in the new edition of the *Guide* without adequate scientific rationale."

OLAW issued position statements on:

- (1) *Cost;*
- (2) *Housing (including non-primate, environmental enrichment and rabbits);*
- (3) *Non-pharmaceutical grade substances;*
- (4) *Food and fluid restrictions;*
- (5) *Multiple surgical procedures; and*
- (6) *Agricultural animals;*

Christian Newcomer, AAALAC's executive director, told *RRC* OLAW's decision was a win-win.

"I am certain that AAALAC's accredited U.S. institutions were very pleased to note that [the government's] independent critique of [the *Guide*] resulted in its adoption with positions that are highly concordant with those of AAALAC International," he said. "This outcome should allay many of the concerns associated with changing regulatory standards in institutions and permit organizations to proceed with revisions or new develop-

ments in their animal care and use programs with confidence and clarity. It's a dual win for animal welfare and the support of scientific inquiry with animal models."

OLAW recently held a webinar to help explain the new *Guide*. Slides from the presentation are available online; a transcript will be posted. Given record participation in the webinar and interest in the new *Guide*, the agency said it may have a second webinar on the topic, likely in March. It also updated its frequently-asked-questions page to accommodate references to the eighth edition.

**Link to implementation information:** <http://grants.nih.gov/grants/olaw/2011guideadoption.htm>

**Link to updated FAQs:** <http://grants.nih.gov/grants/olaw/faqs.htm>

**Link to webinar:** <http://grants.nih.gov/grants/olaw/faqs.htm> ✦

## **COI Webinar Provides Some Help, But Shows Great Need for More**

In a nearly 90-minute webinar designed to explain NIH's new financial conflict of interest regulation, officials provided an overview that hewed closely to what the agency already has on its website.

What was striking was the apparent hunger for information and assistance that the research community is experiencing as the clock is ticking toward the August compliance deadline. The regulation makes significant changes to COI requirements, first issued in 1995 (*RRC 10/11, p. 1*).

At least three problem areas have cropped up as institutions are trying to develop new policies: handling the travel requirements, determining what is truly a conflict of interest, and overseeing COI compliance by subrecipients.

And for those first two items, NIH was admittedly less than helpful in the Nov. 30 webinar, "What NIH Grantees Need to Know About the 2011 Revised Financial Conflict of Interest Regulations."

The agency will probably have another COI webinar, perhaps in May, said Sally Rockey, NIH director of extramural research. NIH officials also offered to entertain specific questions by phone or email.

Moderating the seminar was Joe Ellis, director of the Office of Policy for Extramural Research Administration. Participants were Diane Dean, director of the Division of Grants Compliance and Oversight; Dorit Zuk, Rockey's science policy advisor; and Kathy Hancock, an assistant grant compliance officer.

Under the new regulation, significant financial interests that must be disclosed include payment for certain

types of travel (with exclusions for some sources). Investigators are required to disclose to their institutions any “reimbursed or sponsored travel” of any amount that is for travel “related to their institutional responsibilities.” Then the institution reviews it to determine whether a financial COI exists.

Excluded is reimbursement by “a federal, state, or local government agency; an institution of higher education as defined at 20 U.S.C. 1001(a); an academic teaching hospital; a medical center; or a research institute that is affiliated with an institution of higher education.” This provision has been controversial because it does not exempt non-profit organizations, such as the American Cancer Society.

Ellis described the travel provisions as “a fairly challenging area of the regulation.”

The question was, “External travel and consultant fees paid directly by a third party to an employee are not currently tracked by most institutions. What are the best methods to follow?”

His response was that he didn’t think “we have established best practices yet,” before turning over the question to Rockey, who agreed with Ellis.

“The travel section is a very complicated section and we know this is a new requirement. We have put out some frequently asked questions but we are still working toward getting further guidance on how to manage the travel component of the regulation,” she said.

Officials did clarify one aspect of the travel reporting requirements, namely that if an institution itself receives money from an outside source, such as a pharmaceutical company, and uses those funds to cover an investigator’s travel, the investigator isn’t required to disclose that money to the institution “for a review of potential COI.”

But Rockey added something of a warning, saying, “The way by which the institution receives that funding is not covered directly under this regulation. But I think that the institution should be cognizant of the fact of where they’re receiving their funds.”

### **Agreements With Subs Must State Timelines**

As noted, one new area of concentration and of possible problems for institutions is subawardees. As Zuk pointed out, “in 1995, there was a very short description of what needs to be done about subrecipients, and said institutions must take reasonable steps to ensure that investigators working for subrecipients comply with the regulation.”

But in rewriting the regulation, officials chose to spell out what this meant in more detail. Rockey said a written agreement was not a new requirement, but what it must contain is new.

“Since [the 1995 regulation] seemed a little vague, the 2011 revised regulation clarifies this by requiring the institution to incorporate language as part of a written agreement with the subrecipient, terms that establish whether the FCOI policy of the awardee institution or that of the subrecipient will apply to the subrecipients’ investigators,” Zuk said, “and also include a time period to meet disclosure requirements and FCOI reporting requirements to the awarding institution.”

Dean noted that the regulation requires investigators to disclose SFI “at the time of application” when a grant proposal is reviewed by an institution. This also includes subrecipients, meaning those that submit grant applications with named subrecipients will need to poll them ahead of time to be able to report any SFIs, if they exist. Dean also clarified that “annually, each investigator, and, of course, this does also include subrecipient investigators, must submit an updated disclosure of those SFI” and any new SFI within 30 days of discovery.

“Subrecipient institutions who rely on their own COI policy, as clarified in the written agreement with the prime institution, have to be mindful that they have to complete these processes in time to report to the prime institution so that the prime institution can submit their reports to NIH and be in compliance with those reporting deadlines,” Dean added.

If an institution determines that the subawardee’s SFI is a conflict of interest, it will have to develop a management plan and report this to NIH, unless the subrecipient is following the home institution’s policy, in which case those responsibilities fall to that institution. In either case, Dean made it clear that the disclosure, management, review and mitigation processes and all other provisions in the regulation “flow down” to subrecipients.

### **Help Requested in Determining Bias, FCOI**

The new regulation requires institutions to determine if an investigator’s SFI are “related to institutional responsibilities” and “related to NIH-funded research,” and then whether they pose a conflict.

Institutions must also make other judgments, such as when an SFI is not reported appropriately and is found to be an FCOI; in this case, the institution must conduct a “retrospective review.” This looks at “all the investigator’s activities and the project to determine whether or not there is bias in the design, conduct or reporting of the NIH funded research,” Hancock explained.

On this point there was a specific plea for help, and again NIH officials could not provide an answer. The questioner asked if NIH could “provide examples of bias in each of the following activities: design, conduct, or reporting.”

Ellis said he could give an “off-the-cuff answer” but that to address this in detail “is probably more than we can handle in this session.”

He said that “the gold standard for bias would be if someone conducted misconduct in research.” However, bias itself is not a form of misconduct. Federal law defines misconduct as fabrication, falsification and plagiarism. Institutions can use this definition or change it on their own. In the past, investigators have run into trouble for receiving NIH funding for studying a medication and failing to disclose simultaneous receipt of financial support from the manufacturer of the medication (*RRC 6/10, p. 11*).

Ellis went on to say that determinations of bias are “very case-specific, and situation-specific.”

“So it’s not something you can define absolutely. That’s why the regulation leaves a lot of latitude for the institutions and responsibilities in defining that area,” Ellis said.

Another question addressed the subtleties of determining whether a conflict exists, asking if NIH would “provide assistance [with] how to evaluate an SFI when the [investigator] has a relationship to the financial disclosure but it is not direct or easily measurable.” Again, Ellis said he couldn’t provide an answer.

“I think this comes down to the institution’s responsibility to, ultimately, take those disclosures and consider whether this constitutes a financial conflict of interest,” he said.

### **Rockey: Institutions Have ‘Experience’**

Institutions can surely come to NIH for help, Rocky said. “I would certainly say, particularly in this next year when institutions are trying to put their new policies in place, that we’re here to help,” Rocky said. “If there is a particular issue you want to talk with us about, we would be happy to talk with you about it.”

Rockey also noted that NIH is “collecting best practices and other things that are situations and scenarios that institutions are going through, to help the community provide resources for the community.” She did not elaborate on what she was referring to, but she did not say that NIH planned to release any of the information it had been gathering.

Then she added that institutions have already had more than a decade of experience managing FCOIs.

“Ultimately...I think this a very case-specific type of activity that the institutions are going to be working through,” Rocky said. “They have been doing it now for 15 years, [determining] when a significant financial interest constitutes a conflict of interest, so there is a lot of great experience out there. And I’m certain that the community can learn from each other, as well, when

determining what significant financial interests generate a conflict of interest.”

In answering another question, officials clarified that web-based courses are allowed as a way to meet the new requirement that investigators receive training on the COI regulation. An archive of the webinar and related slides are available online.

**Link:** <http://videocast.nih.gov/Summary.asp?file=16994> ✦

## **Panel Calls for Consistency**

*continued from p. 1*

The commission’s report on the Guatemalan studies, issued in September, documented in graphic detail research on sexually transmitted diseases involving more than 5,500 Guatemalan prisoners, sex workers, children in orphanages and mental hospital patients. It found that none of the individuals gave consent, fewer than half of those infected were likely treated, and that no published research resulted from any of the work, which U.S. government researchers knew was unethical and sought to keep confidential (*RRC 10/11, p. 1*).

The new report, issued Dec. 15, takes the phrase “moral science” from an essay by Benjamin Franklin, who wrote, “O that moral science were in as fair a way of improvement, that men would cease to be wolves to one another, and that human beings would at length learn what they now improperly call humanity!”

“What Franklin called ‘moral science’ is what we would today call ‘ethics,’” wrote the 13-member commission, chaired by University of Pennsylvania President Amy Gutmann.

### **Improvements Are Needed**

While the commission concluded that “Existing evidence suggests...that the rules governing federal research today adequately guard against abuses analogous to those perpetrated in Guatemala,” it could not say with certainty that today’s regulations go far enough. Part of the reason is a lack of basic information.

“The commission concludes that current regulations, which apply to a diverse and wide-ranging portfolio of research, generally appear to protect people from avoidable harm or unethical treatment. However, because of the currently limited ability of some governmental agencies to identify basic information about all of their human subjects research, the commission cannot say that all federally funded research provides optimal protections against avoidable harms and unethical treatment,” the commission said.

Commissioners sought information only from Common Rule agencies, while acknowledging others also

conduct or support human research. Within the Common Rule agencies, the commission determined that “the federal government supported approximately 55,386 human subjects research projects in fiscal year 2010,” with the Department of Health and Human Services the biggest funder.

“The commission also learned that many federal departments and agencies have no ready means to identify basic information about the research they support (e.g., location of study sites) or link funding information with study-level data,” the commissioners wrote.

To address this gap, the commission recommended the mandatory posting of data, and said the Office for Human Research Protections “or another designated central organizing agency should support and administer a central web-based portal linking to each departmental or agency system. This should not preclude the prospective development of a unified federal database that may ultimately be more cost-effective and efficient.”

### **ANPRM Provisions Supported**

The commission’s work was ongoing at the same time HHS, OHRP and the Office of Science and Technology Policy in July issued an advance notice of proposed rulemaking proposing significant changes to the Common Rule (*RRC 8/11, p. 1*).

In their report, the commissioners listed a number of “current federal reform efforts” stemming from the ANPRM that they support, including to “harmonize the Common Rule and existing regulations of the Food and Drug Administration, and require that all federal agencies conducting human subjects research adopt human subjects regulations that are consistent with the ethical requirements of the Common Rule.”

The idea of holding all federal funders of human subjects research to ethical tenets in the Common Rule is not specifically mentioned in the ANPRM. Rather, it suggests “requiring domestic institutions that receive some federal funding from a Common Rule agency for research with human subjects to extend the Common Rule protections to all research studies conducted at their institution.” It also proposes harmonizing the various guidance documents issued by Common Rule agencies.

Although not presented as a major recommendation, the commission also made it clear that non-federally funded research should offer protections to research subjects, stating it “believes that the ethical principles for human subjects research should not — indeed *must* not — vary depending on the source of funding or location of the research. While the specific methods of implementing the ethical principles of human subjects research are likely to differ, the principles should not. Ethical principles provide the foundation for the rules and regulations

that govern human subjects research as well as lay the groundwork upon which everyone who conducts human subjects research must stand.”

The commission stated that it particularly supports efforts in the ANPRM to:

◆ *“Restructure research oversight to appropriately calibrate the level and intensity of the review activities with the level of risk to human subjects;”*

◆ *“Eliminate continuing review for certain lower-risk studies and regularly update the list of research categories that may undergo expedited review;”*

◆ *“Make available standardized consent form templates with clear language understandable to subjects;” and*

◆ *“Work toward developing an interoperable or compatible data collection system for adverse event reporting across the federal government.”*

The commission also noted that its recommendation on amending the rule to outline “specific regulatory directions for investigators” could be part of this “reform” effort. The commission said it “urges the government to consider doing so.”

### **Single IRB of Record Proposed**

The commission also joined the chorus of commenters who said that although the ANPRM’s proposal to mandate the use of a single institutional review board of record for multisite studies was well-intentioned, such use should be voluntary.

However, commissioners also indicated that such a body should be used when possible.

“Regardless of the process used to review and approve studies, institutions should retain responsibility for ensuring that human subjects are protected at their location as protection of human subjects includes much more than IRB review. The use of a single IRB of record should be made the regulatory default unless institutions or investigators have sufficient justification to act otherwise,” they said.

The commission did not provide much detail on its recommendation to spell out investigator duties in the regulations.

The report stated simply: “The Common Rule should be revised to include a section directly addressing the responsibilities of investigators. Doing so would bring it into harmony with the FDA regulations for clinical research and international standards that make the obligations of individual researchers more explicit, and contribute to building a stronger culture of responsibility among investigators.”

In a related recommendation, the panel said more emphasis needed to be placed on “ethics discourse and

education,” but it stopped short of mandating training in ethics.

“To ensure the ethical design and conduct of human subjects research, universities, professional societies, licensing bodies, and journals should adopt more effective ways of integrating a lively understanding of personal responsibility into professional research practice,” the commissioners said. “Rigorous courses in bioethics and human subjects research at the undergraduate as well as graduate and professional levels should be developed and expanded to include ongoing engagement and case reviews for investigators at all levels of experience.”

### Sample of Projects Should Be Assessed

The commission also recommended research be conducted to determine the efficacy of current regulations, and specifically noted that determination letters issued by OHRP typically describe finding minimal issues related mostly to processes rather than serious noncompliance.

Such letters are sent to institutions following investigations into possible noncompliance with the Common Rule and other regulations. They have been dropping off in recent years, with just 15 issued in 2011. Since 2007, the office has averaged 35 letters a year, down from a peak of 146 in 2002 and another high of 86 in 2006 (*RRC 3/11, p. 1*). Going forward, the panel “encourages future reviewers and policy makers” to pursue real means of assessing compliance.

“Once a database of federally sponsored human subjects research is readily available, there are various methods that could be useful to assess investigators’ specific understanding of ethical requirements and practices on the ground,” the commission said. “For example, a project-by-project assessment could be undertaken using a sample of recent federally supported projects in order to determine how individuals and organizations conducting human subjects research currently apply federal regulations and international standards. Such an assessment could identify the practical ethical challenges facing researchers and the organizations that oversee them. Document review of agency IRB records, structured interviews with research team members and other stakeholders, as well as site visits, could bring far more specific information than is now readily available.”

The commission said it simply didn’t have the time or resources to conduct such a study itself.

HHS and other funders of research should take additional measures to strengthen protections for research subjects, including determining that “researchers and the sites that they propose to select for their research have the capacity — or can achieve the capacity contempora-

neously with the conduct of the research — to support protection of all human subjects,” the commission said.

Another recommendation addresses the government’s ethical responsibility to those who may suffer injuries or otherwise be damaged by their involvement in research. “Because subjects harmed in the course of human research should not individually bear the costs of care required to treat harms resulting directly from that research, the federal government, through the OSTP or HHS should move expeditiously to study the issue of research-related injuries to determine if there is a need for a national system of compensation or treatment for research-related injuries,” the commission said. “If so, HHS, as the primary funder of biomedical research, should conduct a pilot study to evaluate possible program mechanisms.”

Turning to another issue under study, the commission said, “The federal government, through OHRP and federal funding agencies, should develop and evaluate justifications and operational criteria for ethical site selection, taking into consideration the extent to which site selection can and should respond to the needs of a broader community or communities. OHRP should produce, and other agencies should consider developing, guidance for investigators.”

Seeking to make it clear that many of the report’s recommendations were not new and should be acted upon — finally — the commission wrote a recommendation termed “responding to recommendations,” for which a public explanation is asked if no changes are envisioned.

And it developed a chart listing the 14 recommendations and the agency responsible for implementing each one.

“The commission recommends that OSTP or another appropriate entity or entities within the government respond with changes to the status quo or, if no changes are proposed, reasons for maintaining the status quo with regard to the recommendations [included],” the report stated.

**Link:** <http://bioethics.gov/cms/node/558> ✧

### Links in the News

Links to documents referred to in this issue are posted at [www.ReportonResearchCompliance.com](http://www.ReportonResearchCompliance.com) under “Links in the News.” Back issues of newsletters also are posted at the website.

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## Inside NIH

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◆ **Most research using chimpanzees is "unnecessary," and upon renewal of these programs and going forward with proposed research, NIH should approve such research only if it meets certain strict criteria, a panel of the Institute of Medicine concluded in a report released today.**

The 12-member Committee on the Use of Chimpanzees in Biomedical and Behavioral Research was created at the request of Congress and NIH (*RRC 7/11, p. 4*). In its report, *Chimpanzees in Biomedical and Behavioral Research: Assessing the Necessity*, the committee "concludes that while the chimpanzee has been a valuable animal model in the past, most current biomedical research use of chimpanzees is not necessary. Notable exceptions include prophylactic HCV vaccine development, short-term continued use for monoclonal antibody research, comparative genomics research, and behavioral research." The committee also recommended that NIH establish "an independent oversight committee that builds on the [HHS] Interagency Animal Model Committee and uses the recommended criteria." (12/15/11)

◆ **In a response after the report on chimpanzee research was issued, NIH Director Francis Collins said he had "considered the report carefully and [had] decided to accept the IOM committee recommendations.** NIH is in the process of developing a complete plan for implementation of the IOM's guiding principles and criteria" and would be "assembling a working group within the NIH Council of Councils to provide advice on the implementation of the recommendations, and to consider the size and placement of the active and inactive populations of NIH-owned or -supported chimpanzees. We will not issue any new awards for research involving chimpanzees until processes for implementing the recommendations are in place." Collins said NIH has approximately 37 projects that would be reviewed, and he estimated about 50% would probably not meet the criteria and would be phased out. (12/15/11)

◆ **NIH and the National Science Foundation have each recently issued notices warning recipients of Recovery Act funding that previously automatic no-cost extensions will not be granted and that projects need to end by Sept. 30, 2013, unless the agency has given prior approval.** This is neces-

sary because the Office of Management and Budget has said projects funded with Recovery Act money should be completed by this date, or agencies will have to take steps to "reclaim funds that remain unspent." In its Dec. 13 notice, NIH noted that for projects that already have end dates beyond Sept. 30, 2013, "NIH staff administering these grants will also reach out to recipients to discuss possible strategies for accelerating progress and expenditures. Revised award terms will vary depending on the award terms provided in the current notice of award." In a nearly identical notice also issued on Dec. 13, NSF outlined the requirements for expenditures by Sept. 30, 2013, but also indicated that it may seek a waiver from OMB's mandates. Other government agencies are expected to issue similar notices to grantees who received Recovery Act funding. (12/15/11)

◆ **In its semiannual report to Congress, HHS's OIG recounted findings that NIH had "mixed compliance with appropriations laws" in some contracts administered by the National Institute of Allergy and Infectious Diseases.** "Our reviews of the NIH contracts assess compliance with the purpose, time, and amounts requirements specified in appropriations statutes. For four of the contracts we completed in this semiannual period, NIH had a bona fide need for the items and appropriately funded the contracts and their modifications from the pertinent appropriations years," OIG said. "We found time and amount issues in four other contracts in which NIH's National Institute of Allergy and Infectious Diseases (NIAID) potentially violated" the Antideficiency Act (*RRC 5/5/11*). (12/1/11)

◆ **NIH has created a website that will give researchers and others greater access to unpatented materials developed by government-funded investigators and provide "faster turn-around time...for companies to find research materials available from NIH labs."** The site, <http://www.ott.nih.gov/erma>, holds NIH's electronic research materials catalogue, NIH said in a Nov. 29 announcement. "For non-profit research organizations interested in obtaining NIH materials through a material transfer agreement, the NIH will launch the Transfer Agreement Dashboard in December," NIH said. (12/1/11)

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