Report on
Research Compliance

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

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Hope Expressed for Congressional Action To Create Research Board, Rein in OIGs

Although a National Academy of Sciences (NAS) committee is still hammering out part two of its report on reducing administrative burdens for research institutions and investigators, members are optimistic that Congress might actually act on the recommendations in part one — and soon.

In September, the NAS Committee on Federal Research Regulations and Reporting Requirements issued *Optimizing the Nation's Investment in Academic Research: A New Regulatory Framework for the 21st Century.*

Among other things, the report called for the creation of a quasi-governmental advisory board and provided separate sets of recommendations for Congress, federal agencies and institutions (*RRC 9/24/15*). Special note to auditors and financial managers: among the recommendations are a series that would redirect the efforts of agencies' Offices of Inspector General in ways the committee hopes will tamp down the sometimes adversarial OIG-institution relationship (see box, p. 8).

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Feds Combing Through 2,000 Comments On NPRM Revising the Common Rule

The federal government has begun analyzing the more than 2,000 comments received on its controversial notice of proposed rule making (NPRM) revising the U.S. policy for oversight of human research studies found at 45 CFR part 46, also known as the Common Rule.

But even if more commenters reject than support certain provisions — such as those requiring consent for the use of unidentified biospecimens and mandating a single institutional review board (IRB) — these may still end up in a final rule.

That was the word from Jerry Menikoff, director of the HHS Office for Human Research Protections (OHRP), which oversees compliance with the Common Rule in research funded by agencies within the Public Health Service, most notably NIH. Speaking at a recent meeting in Washington, D.C., Menikoff also made it clear that OHRP isn't "in charge" and won't have the final say on a rule, a situation he indicated wasn't exactly how he expected things would turn out.

The government's first attempt at revising the common rule was published in the form of an advance notice of proposed rule making (ANPRM) published in July 2011 *(RRC 8/11, p. 1)*. The purpose of an ANPRM is to help the government flesh out details and solicit ideas later incorporated into an NPRM. The ANPRM posed 74 questions, which generated about 1,000 comments *(RRC 8/12, p. 3)*.

Many were stunned by the fact that the NPRM, published four years after the ANPRM, also posed a lot of questions — 88, in fact.

Issued in September, the NPRM had an initial comment period of 90 days; that was ultimately extended to Jan. 6 (*RRC 12/3/15*). According to regulations.gov, where

the government posts comments received during the rule-making process, 2,185 comments were submitted to HHS, although some are also posted under other departments that apply the Common Rule to applicable studies they fund. That's more than double the number received on the ANPRM.

Some of the commenters attempted to answer the questions, but others urged the government to start over, dispensing with contentious provisions first opposed in the ANPRM *(RRC 12/1, p. 1; 1/16, p. 1).*

No Predictions on Timing, Content

What is particularly problematic about the NPRM is that many of the provisions and features are not fleshed out. For example, the NPRM calls for the government to develop at least one tool, if not more, that would be used by investigators to determine if research is exempt from the Common Rule.

Similarly, HHS is tasked with developing a set of privacy and security safeguards that would be applied to research that does not need to undergo full IRB review.

Menikoff addressed the major provisions in the NPRM during a session at the Federal Demonstration Partnership meeting Jan. 11-12. At the meeting, officials from federal agencies also gave updates on their activities (see story, p. 3).

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The comments "are being reviewed as we speak," Menikoff said, adding that he did not know how long this process would take or when a final rule would be published.

"I shy away from making predictions" about the rule-making process, he said. "Certainly a lot of people are making guesses…in terms of where things are at and what will happen in terms of changes. But this is a complicated rule" and 18 agencies are involved, Menikoff said.

"HHS is obviously playing a major role" as is the "executive office of the president," Menikoff continued. "I must admit I take some of this personally because I was involved" in the process with former White House advisor Zeke Emanuel that led to the drafting of the ANPRM, Menikoff said. But, he said, "you sometimes discover you can't control where things go."

He added that "I am not making the decisions on what happens here. OHRP is not making the decisions…. There are a lot of players higher up on the food chain." He noted that "a lot of major decisions have to be made; clearly a lot of issues were raised [in] the comments."

Disputes over whether NIH or OHRP would be in the lead on writing the NPRM became public in 2014 when emails between the agencies were leaked *(RRC 11/20/14).*

Another meeting participant noted that the NPRM embraces many provisions that were already roundly opposed by the research community; that attendee questioned whether they could still be adopted.

Menikoff responded that he was not going to comment on any specific provisions.

"This is a complicated thing that I'm not an expert on in terms of how notice and comment works, and this is getting into fundamental issues relating to how democracy works and it's not always that a particular group or even a majority of a particular group says something" that later becomes part of regulations, he said.

"Ultimately, decisions are made by the people who are entrusted with running certain aspects of the government. They are going to evaluate the relevant issue[s]," he said.

No 'Computer Algorithm'

Regarding the biospecimen provisions, "part of the premise here was that a significant enough chunk of the public feels so, so strongly about wanting their consent to be obtained," he said.

Menikoff also contended that OHRP was "hearing this from the research community and from the government that you need to impose this sort of rule like this

because if you don't, the public will lose" their trust in researchers.

A decision won't be based on the volume of comments advocating one position or another, he said. There's "not a computer algorithm that you just plug these in…how many said this and how many said that," Menikoff said. "The bottom line: this is a broader issue relating to how the government functions and if you end up seeing a resulting rule that you don't like, you're still within a political process in terms of trying to change that as it goes forward. I'm not the one who is going to make this decision. There are people fairly high up that have certain desires.…That's about all I can tell you."

A member of the audience asked Menikoff whether OHRP would work with universities and others to develop the exemption decision tools before they are issued, stating that her organization was using one already. The answer is no, according to Menikoff.

He assured the audience that the exemption tools and other "big ticket" items that the government is developing will be "put out for public comment" before being finalized, just as with the NPRM.

But working directly with the government before anything is published for comment "gets more complicated," Menikoff said, adding that this is something that government lawyers probably wouldn't allow.

The "standard way that the government operates" is by soliciting comments on ANPRMs and NPRMs as it develops regulations, he added.

Tool Provides a Safe Harbor

Once a tool is developed it should prove useful, Menikoff said. "The benefit of the federal decision tool… is this is a safe harbor. So unless the investigator blatantly deceives or lies about [a protocol], the federal government cannot go after you. So, it is as good as you're going to get, in terms of, in a binding way, for you not to be troubled about what's going on."

In response to a question about how existing depositories of biospecimens would be affected, Menikoff said the NPRM provides "what I think are fairly generous grandfathering provisions" applicable to biospecimens collected prior to the effective date of the provisions for biospecimens.

He pointed out that "we're not even talking about the date that the new rule goes out there in the *Federal Register*, but three years after that" for when a requirement would go into effect. Waivers of consent would also be available.

"The goal was certainly to grandfather a lot of stuff," Menikoff said. ✧

NIH, NSF Leaders Promise Final Research Terms, Revisions to Forms

NIH is hoping to implement new research grants terms and conditions within the next two months, following an analysis of the 100 or so comments received after draft RTC were published in the *Federal Register* last October.

The new RTC, which spell out requirements associated with funding, will replace those in effect since 2008 and are being updated to comply with the Office of Management and Budget's (OMB) uniform guidance (UG) *(RRC 2/15, p. 1)*. The deadline for comments on draft RTC was Dec. 14 *(RRC 10/15/15).*

The RTC and associated materials are being developed by a working group reporting to the Research Business Models (RBM) interagency panel under the National Science and Technology Council *(RRC 2/15, p. 1)*.

Michelle Bulls, NIH director of the Office of Policy for Extramural Research, and Jean Feldman, head of policy for the National Science Foundation (NSF), have been leading the working group. Both provided updates on this process as well as information about other initiatives at their respective agencies during the Jan. 11-12 meeting in Washington, D.C., of the Federal Demonstration Partnership.

Now the agencies are analyzing the comments and "resolving" them as they write the final RTC, Feldman and Bulls said at the meeting. Neither gave any hints as to whether the final RTC would differ much from the draft version.

Bulls said NIH is hoping to implement the RTC within the first half of fiscal year 2016, which began Oct. 1, 2015. But that timetable comes with a "fingers crossed" qualifier. The RTC must ultimately be cleared by OMB, as was the draft version, before it can be published.

COGR: We Need Matrices

The Council on Governmental Relations (COGR) was among those to comment on the draft RTC.

Although COGR officials noted "many positive developments," they requested a number of revisions, clarifications and other changes to the draft RTC. Among the issues COGR would like to see addressed are how conflict of interest requirements apply to subrecipients under procurement requirements, when prior written approvals are required, and procedures for requests and approvals of one-time extensions.

COGR also pointed out in its Dec. 9 comment letter that its review of the draft RTC was "only partial at this time until the appendices (Prior Approval Matrix (Appendix A), Subaward Requirements Matrix (Appendix B) and National Policy Requirements Matrix (Appendix

C) have been made available for comment" (see http://tinyurl.com/zr6hylr).

Officials had promised a year ago that these documents would be issued but they are still in development. The UG has been in effect since Dec. 26, 2014, although a few of the requirements, such as those affecting procurement, have later implementation dates.

"We believe that in order to avoid additional concerns from the research community, successful implementation will be most effective if all appendices and Agency-Specific Requirements can be made available for comment prior to any finalization of the Research Terms and Conditions," the organization said.

"COGR anticipates providing a follow up comment letter once all appendices have been released," the letter states.

When finalized, the RTC will be utilized by the following agencies, in addition to NIH and NSF:

◆ National Institute of Food and Agriculture, part of the U.S. Department of Agriculture;

◆ National Institute of Standards and Technology and the National Oceanic and Atmospheric Administration, both part of the Department of Commerce;

◆ Department of Energy;

◆ Department of Homeland Security;

◆ Federal Aviation Administration;

◆ Environmental Protection Agency; and

◆ NASA.

COGR also urged the government to rally other agencies.

"We encourage the RBM and participating agencies to continue efforts to require or encourage participation of remaining agencies and their components funding research at our member organizations to adopt the RTCs as well as remind participating agencies that implementation deviations from the RTC's will complicate and add burden to institutions," COGR said.

"We recommend as a further commitment to consistent application of the Uniform Guidance and these RTCs, that participating agencies identify a high ranking official within the agency as a contact for confidential inquiries from recipients when agency actions appear to deviate from requirements of the Uniform Guidance and these RTCs without the proper exception approvals," it continued.

In other agency activities, Bulls said NIH is working through responses received to an August 2015 request for information (RFI) on ways it could improve instructions for completing applications.

Researchers and compliance officials should "stay tuned" for "updates to the instructions derived from the RFI," she said *(RRC 8/13/15)*. Bulls reminded the FDP members that NIH's online application process, Application Submission System & Interface for Submission Tracking, is available for use.

In addition, Bulls listed areas where NIH would be implementing changes to policies, instructions and forms for grant applications that she said had already been approved by OMB. NIH expects "to have system support and guidance for these updates in place by March 25, 2016," she added.

Without providing details, Bulls said changes will focus on:

◆ ***Rigor and transparency in research,***

◆ ***Vertebrate animals,***

◆ ***Inclusion reporting,***

◆ ***Data safety monitoring,***

◆ ***Research training and training tables,***

◆ ***Assignment request forms,***

◆ ***Font requirements,*** and

◆ ***Biosketch clarifications.***

"The main takeaway here is that we plan to do so in phases…trying to pace ourselves and pace you all in terms of the changes that are being made," Bulls said.

Report Revisions Underway

NSF and NIH are also working on revisions to the Research Performance Progress Report to highlight the "rigor and transparency" of non-competing awards.

NIH is expecting to implement a revised Final Research Performance Progress Report to include new requirements.

The outcomes section of the final report "will be publicly available, allowing recipients the opportunity to provide the general public with a concise summary of

the cumulative outcome or findings of the project," Bulls said. NIH hopes to implement the revisions by October.

Across the government, agencies will be utilizing OMB's Federal Awardee Performance and Integrity Information System (FAPIIS). Federal award recipients (both grantees and contactors) will be required to report "poor performance" to the database, and agencies themselves must submit similar data.

Agencies will check FAPIIS before making an award. Bulls said NIH is awaiting guidance from HHS about FAPIIS but is targeting Feb. 1 as the "internal" implementation date.

NSF Clarifies Submitter Time Zone

Feldman also reviewed some of the changes in the Proposals & Awards Policies and Procedures Guide (PAPPG). Among the changes is strict enforcement of the 5 p.m. deadline (submitter's time) for proposals to be accepted *(RRC 12/16, p. 1)*.

Feldman said she anticipates that someone will try to submit a proposal at 5:01, which will be rejected. "And they're going to say, 'NSF has changed its policy; we haven't been notified of this and we are going to the Office of the Director.' Well, the Office of the Director already knows about this," she said amid laughter, "and the Office of the Director has reminded us that this has been in place *forever*. So they're prepared to get those requests. And it's not going to be a happy response. I'm telling you folks…don't wait till the last minute to be submitting those proposals."

In response to a question, Feldman said the location of the submitter's institution as listed in its NSF profile forms the basis for determining the applicable time zone — so if the authorized organizational representative is on vacation and in a different time zone from his or her institution, that vacation time zone does not matter.

Feldman also called attention to the fact that collaborator and other information "has been removed from the biographical sketch and will now be submitted as a single copy document." This addresses a "very bad situation when it came to the two-page limitation" that had been imposed on sketches.

Similarly, Feldman highlighted clarifications to the portion of the proposal where PIs list results from prior NSF support, "always a delightful section to talk about."

Specifically, NSF has clarified "when the start date of that five-year period [of support] begins" and that among the items that can be reported in this section is receipt of graduate research fellowships, Feldman said.

NSF recently signed a memorandum of understanding with the NIH Office of Laboratory Animal Welfare and is now using the same format as NIH for these kinds of proposals *(RRC 8/20/15)*. Feldman said OLAW and NSF were developing a set of FAQs "that both agencies will use to ensure there is a common understanding between all parties" as to how research involving wildlife is affected.

Feldman reminded attendees that the date of submission for the final project report and the project outcomes report is now 120 days, from 90, "for consistency with financial reporting information."

This is applicable to new awards and funding increments on existing awards, so institutions and PIs "are going to have to take a look…at the terms and conditions" of the award to determine the applicable deadlines, she said.

NSF is continuing to test its public access system and has contacted PIs to ask them to voluntarily submit documents. The requirements vary for different grants, she pointed out.

Link to NIH FDP presentation: http://tinyurl.com/z4wsogr

Link to NSF FDP presentation: http://tinyurl.com/gqva6df ✧

OHRP Ends Year With Record Low Of Five Letters, Faces OIG Review

Although the HHS Office for Human Research Protections (OHRP) received more than 700 "incident reports" last year, it opened five and completed three investigations into allegations of violations of federal laws safeguarding study participants.

Organizations submit incident reports to OHRP when there are:

◆ Unanticipated problems involving risks to subjects or others;

◆ Serious or continuing noncompliance with the Common Rule or with IRB requirements or determinations; or

◆ Suspension or termination of IRB approval.

OHRP has said, however, that these rarely present circumstances that warrant opening an investigation. In 2014 it received approximately 600 incident reports.

Last year, OHRP also conducted just two not-for-cause investigations, according to data OHRP provided to *RRC*. Typically the agency has conducted four of these per year.

The numbers indicate OHRP has continued the pattern of decreasing enforcement actions that has characterized the agency under Director Jerry Menikoff, who arrived in late 2008. The agency has jurisdiction over more than 10,000 institutions that have a federalwide assurance with HHS, required when research is funded by the U.S. government.

continued

This year, OHRP will be receiving extra scrutiny of its operations. The HHS Office of Inspector General (OIG) will be conducting a review of how OHRP has conducted "compliance evaluations" from 2000 to 2014.

Last year OHRP received 135 complaints alleging violations of the Common Rule, the agency told *RRC*. "The vast majority of those OHRP does not have authority over" such as research that falls within the Food and Drug Administration's purview, or are "are complaints regarding the government controlling their thoughts and the like." In 2014, it received 142 complaints and opened seven investigations.

In addition, OHRP issued just five determination letters in 2015, which represent resolutions of investigations and typically involve corrective actions by research institutions. This number represents a record low.

Letters Serve Educational Purposes

The previous low was eight letters, set in 2014. In 2012 and 2011 there were 23 letters each. This contrasts with 34 letters issued in 2008. The peak was 146 in 2002; there was another high of 86 letters in 2006 *(RRC 3/11, p. 1)*.

Such letters served as the basis for papers and research by OHRP itself and individuals who study institutional review boards *(RRC 4/10, p. 6)*. They are also scrutinized by regulated organizations and investigators to gain insight into OHRP's thinking on acceptable and unacceptable practices.

OHRP's virtual discontinuation of the letters has occurred in tandem with a decline in issuing guidance and in adopting recommendations put forth by the Secretary's Advisory Committee on Human Research Protections (SACHRP). These have spurred criticism from a presidential bioethics commission and two authors, among others *(RRC 5/15, p. 1)*.

When questioned by *RRC*, the agency used wording to explain the drop that was identical to that provided to *RRC* in 2011 and in 2014 *(RRC 4/14, p. 1)*.

"In recent years, OHRP has attempted, when possible, to address relatively straightforward allegations (for example, a complaint from an uncompensated research subject) informally (for example, by conversation with the delinquent payer institution)," OHRP said in the new statement and in 2011 and 2014.

Congress Sought Investigation

The OHRP review by OIG is one of several noteworthy activities OIG described in its fiscal year (FY) 2016 Work Plan, which went into effect Oct. 1, 2015. It stems from a requirement Congress included in its FY 2015 funding legislation, H.R. 83, the Consolidated and Further Continuing Appropriations Act.

Brief details about the review, which builds on a previous OIG report on OHRP, were included in appropriations committees' explanatory statements. However, what Congress asked OIG to do doesn't line up exactly with the wording OIG used in the new Work Plan.

"Recent reviews by the OIG raise questions about the independence of the OHRP during the process to make determinations," the committees' report said at the time.

"The [budget] agreement requests the OIG conduct a formal review of OHRP procedures and make appropriate recommendations to ensure and strengthen human subjects protections in future research and ensure the independence of OHRP," it said *(RRC 1/15, p. 5)*.

Congress' reference to independence refers to OHRP's actions following its February 2013 determination that some informed consent forms used in the Surfactant Positive Airway Pressure and Pulse Oximetry Trial (SUPPORT) study violated the Common Rule because they did not disclose all foreseeable risks, such as death.

Big Drop After SUPPORT Controversy

OHRP asked the SUPPORT coordinating center for a corrective action plan to address similar research in the future, a move that advocates, such as the watchdog group Public Citizen, found insufficient, but which outraged NIH *(RRC 7/13, p. 1)*. In that year, OHRP's enforcement actions took their biggest dive yet — the agency opened only one investigation in all of 2013 *(RRC 4/11, p. 1)*.

Public Citizen later released 439 pages of emails between NIH, OHRP and other federal agencies that it said showed NIH improperly interfered with OHRP's decisions regarding the study, prompting members of Congress to call for an investigation into the issue *(RRC 8/14, p. 4)*.

OHRP ultimately backed off its action and instead held a day-long meeting on "standard of care research" and published proposed guidance on the topic *(RRC 12/14, p. 1)*.

But no final guidance has been issued, and the new notice of proposed rule making specifically does *not* apply to standard of care research *(RRC 10/15, p. 8)*.

The 2016 Work Plan states that Section 492 of the Public Health Service Act authorizes OHRP "to establish a compliance oversight process to review violations of HHS regulations protecting human research subjects."

OIG officials said the new review "will describe the extent and scope of OHRP's compliance evaluations from 2000 to 2014. We will also describe how OHRP works with relevant government entities and institutional review boards during its compliance evaluations, and how OHRP's working with these entities enhances or constrains its capacity to conduct compliance evaluations."

OIG Has Other Plans of Interest

Under the new Work Plan, OIG also will launch a new initiative to examine "colleges' and universities' controls over the subcontracting of NIH grant and contract work."

OIG said it would "determine whether colleges and universities effectively monitor the services subcontracted to other organizations and ensure that Federal funds are spent on allowable goods and services in compliance with selected cost principles and the terms and conditions of the grants and subcontracts."

As background, OIG noted that "Cost principles for Educational Institutions at 2 CFR 220, are used in determining the allowable costs of work performed by colleges and universities under sponsored agreements. The principles shall also be used in determining the costs of work performed by such institutions under subgrants, cost-reimbursement subcontracts, and other awards made to them under sponsored agreements."

Briefly addressed in the Work Plan are reviews to be done of grantees. "We will conduct reviews at selected organizations based on the dollar value of Federal grants received and on input from NIH."

OIG will also continue a number of reviews and activities begun in previous years. For example, it will continue to "coordinate efforts" with FBI, the Centers for Disease Control and Prevention and the U.S. Department of Agriculture "to investigate violations of Federal requirements for the registration, storage, and transfer of select agents and toxins."

As OIG noted, "HHS issued a final regulation on possession, use, and transfer of select (biological) agents and toxins that applies to academic institutions; commercial manufacturing facilities; and Federal, State, and local laboratories" in 2015.

Enforcement actions for violations have been rare but they do occur. In May 2014, for example, OIG issued a brief announcement that it had entered into a settlement agreement with an unidentified Arizona university for $165,000 to resolve allegations it had failed to:

"(1) maintain current and accurate inventory records regarding certain select agents;

"(2) implement biosafety and containment procedures commensurate with the risks associated with the select agents and toxins in its possession; and

"(3) failed to ensure compliance with the requirement of 42 C.F.R. Part 73" *(RRC 7/14, p. 2)*.

Link: http://oig.hhs.gov/reports-and-publications/workplan/index.asp#current ✧

Reports Examine Gender Bias, Use of 'Other Transactions'

In separate reports released recently, the Government Accountability Office (GAO) undertook a review of gender bias in six federal funding agencies' STEM (science, technology, engineering, and mathematics) research and eleven agencies' use of "other transaction agreements" when awarding funds.

In reviewing data from fiscal years 2009 through 2013, GAO determined that "no disparities in success rates [existed] between women and men at three agencies selected for review, but data limitations provided limited insight into success rates at three other agencies."

GAO found the following:

◆ ***No evidence of disparities in success rates:*** NIH, the National Science Foundation, National Institute of Food and Agriculture (part of the U.S. Department of Agriculture).

◆ ***Evidence of disparities varied or insufficient data to analyze success rates:*** NASA, the Departments of Defense and Energy.

Two of the agencies — HHS and Department of Defense — are not conducting required Title IX compliance reviews, GAO found. Title IX addresses nondiscrimination on the basis of sex in federally funded programs.

"Since HHS oversees Title IX compliance" by recipients of funding from NIH, the agency that awards the bulk of STEM research grants, "billions of federal research dollars may not be subject to potential Title IX oversight," GAO said.

Further, although the Department of Justice has the responsibility to coordinate Title IX compliance across federal agencies, GAO said that "it has no formal information sharing process among STEM agencies."

The report, *GAO-16-14: Women in Stem Research: Better Data and Information Sharing Could Improve Oversight of Federal Grant-making and Title IX Compliance,* includes 13 recommendations for improving the representation of women in STEM research.

They cover improvements in four general areas:

(1) Agency leadership and collaboration,

(2) Family-friendly policies for grantees,

(3) Research proposal review, and

(4) Funding and assisting institutions.

Link: www.gao.gov/products/GAO-16-14

In its second report, GAO looked at federal agencies' use of so-called "other transaction agreements," defined as "agreements that generally do not follow a standard format or include terms and conditions required in traditional mechanisms, such as contracts or grants."

Most agencies that use these agreements do so for the flexibility they offer.

Nine of the 11 agencies reviewed used these agreements for research and development activities and pilot projects — everything from medical research to research on energy development.

Such agreements, however, continue to account for only a small percentage of any agency's funding portfolio, although two agencies that used them for funding other than R&D and prototypes — the Transportation Safety Administration and NASA — had larger numbers of agreements, GAO said.

The report is *GAO-16-209: Federal Acquisitions: Use of 'Other Transaction' Agreements Limited and Mostly for Research and Development Activities.*

Link: www.gao.gov/products/GAO-16-20 ✧

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Congress May Act on 'Burdens'

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The NAS report is getting renewed attention now because of the expectation that many of its provisions will find their way into the Senate version of the 21st Century Cures Act currently being drafted by the Health, Education, Labor & Pensions (HELP) Committee. Sen. Lamar Alexander (R-Tenn.), who chairs the HELP committee, was among those requesting the report. A version of the bill has already passed the House.

Congress required the report in its fiscal year (FY) 2014 appropriations legislation to address administrative burdens faced by university investigators *(RRC 3/15, p. 6)*. The committee was empaneled last year and has held six meetings so far, the most recent of which was Jan. 14-15.

NAS committee members Joseph Haywood, assistant vice president for regulatory affairs at Michigan State University and former president of the Federation of American Societies for Experimental Biology, and David Robinson, executive vice provost of Oregon Health & Science University, described the report at the January meeting of the Federal Demonstration Partnership (FDP).

Once the committee began meeting, Alexander requested that the report be completed by the end of the summer last year, six months earlier than expected. Alexander believed fall 2015 and "early winter" of this year represented a "unique opportunity" to move forward legislation that would "reconsider, in a bipartisan

NAS Committee Takes Aim at OIGs

In September, the National Academy of Sciences Committee on Federal Research Regulations and Reporting Requirements issued *Optimizing the Nation's Investment in Academic Research: New Regulatory Framework for the 21st Century.*

The recommendations in the report commissioned by Congress may soon see action if included in a new bill being drafted by the Senate Health, Education, Labor and Pensions Committee (see story, p. 1).

While the report proposes a new oversight "framework," it also is a near total repudiation of the process of auditee selection and findings by OIGs. The report cites the National Science Foundation (NSF) Office of Inspector General (OIG) in particular.

The NSF OIG has issued nine audit reports containing findings questioning salary costs, but NSF dismissed such findings. Addressing these dismissals, OIG told *RRC* its auditors made the correct findings at the time, and when appropriate will now consider the salaries allowable if they comply with NSF's "revised" policies and if they occurred in 2015 *(RRC 12/15, p. 4)*.

Also highlighted as a problem is NSF OIG's use of a process called "data analytics" to assign a risk score to awardees that it does not share with institutions. To some degree, analytics are also used by the HHS OIG *(RRC 10/12, p. 5)*.

Additionally, the report takes OIGs to the woodshed for always bringing bad news to Congress in their semiannual reports and for not developing or sharing what in effect would be best practices for financial management of research dollars, despite this task being part of their duties as spelled out in the law establishing OIGs.

Committee members want Congress to require OIGs to:

manner, the regulatory environment governing federally funded research," Robinson said.

The thinking was that if the committee "could strike early enough," the proposals could then be included in legislation before the end of President Obama's second term and the conclusion of the 114th Congress, Robinson explained.

Robinson said Alexander asked for recommendations to be phrased as specific steps that Congress could take or tasks it could require of agencies. The committee made 12 recommendations to Congress, six to the White House and Office of Management and Budget, three to federal research agencies and two to universities.

In its report, the committee proposed four overarching recommendations:

◆ "The regulatory regime (comprising laws, regulations, rules, policies, guidances, and requirements) governing federally funded academic research should be critically reexamined and recalibrated."

◆ "The committee recommends the creation of a new mechanism, the Research Policy Board, to include an active public-private forum and a designated official within government, to foster a more effective conception, development, and harmonization of research policies."

◆ "To advance the government-academic research partnership, research institutions must demand the highest standards in institutional and individual behavior."

◆ "Inspectors General responsibilities should be rebalanced so that appropriate consideration is given both to uncovering waste, fraud, and abuse and to advising on economy, efficiency and effectiveness. The relationship between Inspectors General and research institutions should be based on a shared commitment to advancing the nation's interest through a dynamic and productive research enterprise."

"We approached this in terms of cradle to the grave" as far as looking for improvements in the process for acquiring grants as well as the management required when funds are expended, Haywood explained. The report includes a chart showing the growth of regulations (see box, p. 11).

Time and again, investigators complain about spending hours writing applications that don't get funded. To address this, the report recommends that the government develop a "uniform [application] format to be used by all research funding agencies," Haywood said.

That recommendation was greeted with applause, prompting Haywood to quip: "This isn't the State of the Union. I'm just talking about a simple report here."

continued

NAS Committee Takes Aim at OIGs, continued

◆ "Resolve issues regarding their interpretation of agency policies and priorities with the agency before conducting formal audits of research institutions; this should not apply in those situations in which the audit itself is directed toward inconsistent agency policy interpretations."

◆ "Include in their semiannual reports, publish on their websites, and highlight in their presentations to Congress examples of effective, innovative, and cost-saving initiatives undertaken by research institutions and federal research agencies that both advance and protect the research enterprise."

◆ "Provide to Congress and make publicly available information generated each year on the total costs (agency and institutional) of Inspectors General audits of research institutions, the total amounts of initial findings, the total amounts paid by institutions after audit resolution, and any significant management, technology, personnel, and accountability steps taken by research institutions as the result of a completed audit."

◆ "Reexamine the risk-based methodology in identifying institutions as candidates for agency audits to take into account the existing compliance environment and oversight on campuses, recognizing that many research institutions have clean single audits, are well managed, and have had long-standing relationships with the federal government."

◆ "Encourage all federal agencies to report only final audit resolution findings on their websites and in their semiannual reports to Congress."

Addressing this last recommendation, David Robinson, executive vice provost of Oregon Health & Science University and a member of the NAS committee, said that "what usually happens is…[OIGs] announce their initial audit findings, which can possibly be in the millions of dollars, and then the institution works with the agency through the audit resolution process and sometimes the amount of audit findings are reduced by an order of magnitude or more."

News headlines "usually focus on the bigger number and not the smaller number," Robinson said. He discussed the report at a recent meeting of the Federal Demonstration Partnership.

Link: http://tinyurl.com/p4kq45l

Among the other recommendations is a call for a federalwide conflict of interest policy. As mentioned earlier, also proposed is a sort of advisory body to be called the Research Policy Board (see box, p. 11). The board "fits between Congress, the executive branch and the research community," Haywood explained. This "private sector" board would be funded "by mandatory assessments of research institutions," according to the report.

Board members would work with professional associations. "Its mission would be to improve and maintain a regulatory environment that is conducive to optimal performance of the research partnership" and would "become the primary policy forum relating to the regulation of federal research programs in academic institutions," Haywood said. In addition, its general role would be to offer recommendations "regarding conception, development, and harmonization of regulations," according to the report. The board would be made up of six-to-nine individuals from academic research institutions as well as six-to-eight "liaisons from federal agencies, all designated through formal processes."

Robinson and Haywood expressed optimism that their report won't be just another in a series that sounds good but goes nowhere. But they said it is incumbent upon institutions, investigators, associations and other stakeholders to advocate for congressional adoption of the recommendations.

Haywood is "hopeful of Congressional action in the next few months and the [research] community really needs to start this conversation.…There's a role for everybody in shaping what the outcome is going to be."

Stating that events had brought the issue of relieving burdens to a fork in the road, Haywood said, "If Yogi Berra were still with us, he'd tell us to take the fork in the road. And I think that's exactly what we're going to have to do in the coming months."

He urged the audience members to read the whole report and to not just focus on recommendations of interest. "There are a lot of gems in the report, a lot of nuances, things that maybe we couldn't actually come out and say in English," Haywood said.

It's also important, he said, to "acknowledge that agencies are moving on this topic" of reducing burdens for researchers and institutions.

"Everybody at this point is taking this report seriously," said Haywood.

Stay Tuned for Part Two

The second half of the report is due out sometime early this year. It is being developed in near secrecy. Both Jackson and Haywood said they could not reveal the topics to be addressed, only that issues in the first part will not be revisited in part two — with the possible exception of human research subject regulations.

At the time the report was released, the government had not yet issued the notice of proposed rule making revising the Common Rule so this subject needs to be reviewed.

According to a statement by NAS announcing part one of the report, topics that will be explored in part two are export controls and dual-use research of concern. So far, though, it's not been possible to glean much about the committee's current deliberations.

The agenda for the January meeting was posted online. But only two hours of the two-day meeting were listed as open. (One of the committee's five 2015 meetings was entirely closed.)

During those January sessions, the committee discussed the idea of the policy board with Howard Shelanski, administrator of the White House Office of Information and Regulatory Affairs, and held a video conference with Jeff Botkin, M.D., chairman of the HHS Secretary's Advisory Committee on Human Research Protections and the associate vice president for research and professor of pediatrics at the University of Utah, according to the agenda.

Link to report: http://www8.nationalacademies.org/onpinews/newsitem.aspx?RecordID=21803

Link to FDP presentation: http://sites.nationalacademies.org/cs/groups/pgasite/documents/webpage/pga_170265.pdf ✧

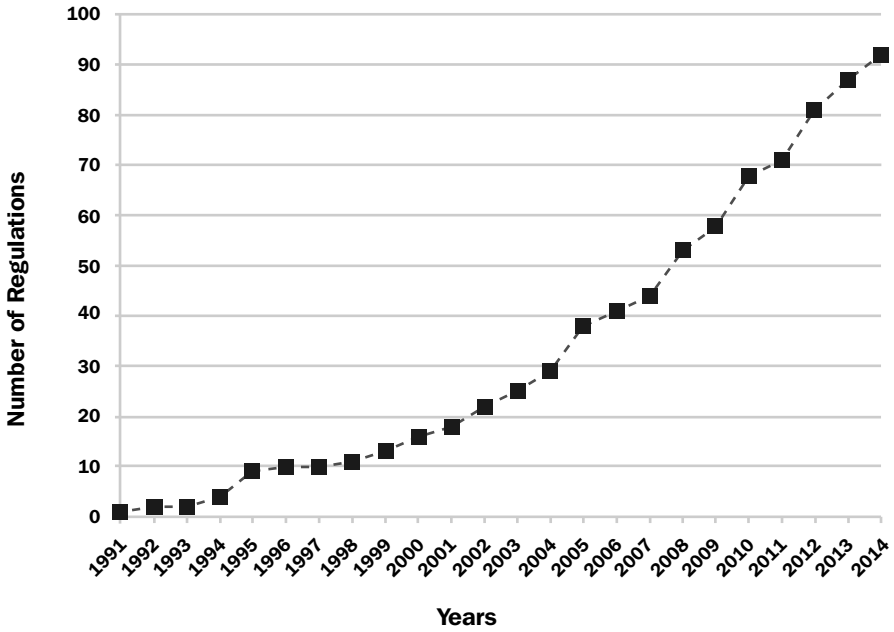
Inside NIH

Dates that appear at the end of NIH news briefs indicate the issue of RRC's *weekly emails in which a news item first appeared, where links for documents may be included. Go to "Recent Email Issues" at www.aishealth.com/newsletters/reportonresearchcompliance.*

◆ **NIH will have to hammer out details of a new mandate in the fiscal year 2016 budget law signed by President Obama that the agency require certificates of confidentiality for some research.** "In order to strengthen privacy protections for human research participants, NIH shall require investigators receiving NIH funding for new and competing research projects designed to generate and analyze large volumes of data derived from human research participants to obtain a certificate of confidentiality," the provision states. "NIH is developing a plan for implementation of the requirement," a spokeswoman told *RRC. (1/7/16)*

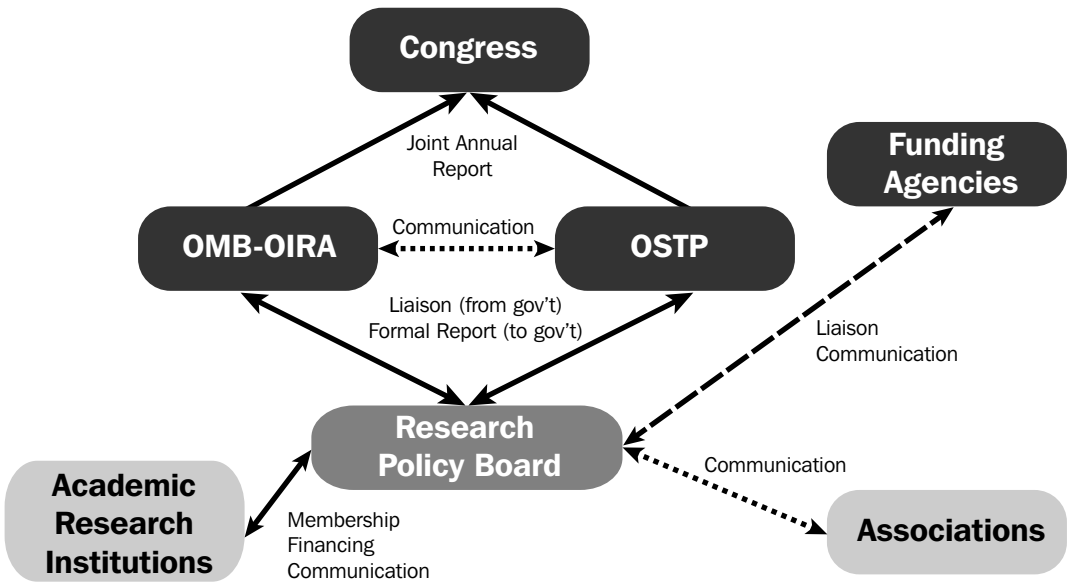
National Academies of Sciences Report Scrutinizes Regulatory Burden

Cumulative Number of Regulatory Changes Applicable to Research Institutions (since 1991*)



* The year of the implementation of the 26 percent cap on administrative costs in the F&A Cost stipulated under OMB Circular A-21 (Cost Principles for Educational Institutions). This graf should not be read as implying that there were zero regulations prior to 1991. Compilation of this data began in response to the implementation of the cap. It would be difficult to collect a complete list for years prior to 1991, as some regulatory changes might have affected only a small segment of research and, therefore, may easily be overlooked.

Schematic Representation of Relationships in a New Regulatory Framework



SOURCE: Reprinted with permission from *Optimizing the Nation's Investment in Academic Research: A New Regulatory Framework for the 21st Century: Part 1,* 2015, by the National Academy of Sciences, Courtesy of the National Academies Press, Washington, D.C.

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.aishealth.com/newsletters/reportonresearchcompliance. Please call 800-521-4323 or email customerserv@aishealth.com if you require a password to access* RRC*'s subscriber-only website or are not receiving weekly email issues of the newsletter.*

◆ **A firm founded by Homayoun Karimabadi, then a former research professor at the University of California, San Diego, did not disclose that he was "employed full-time at UCSD both at the time of the award submission and during the performance,"** failures that resulted in charges of wire fraud and criminal forfeiture related to grants awarded through his firm, ScriberQuest, Inc., the U.S. Attorney's Office for the Southern District of California announced earlier this month. Karimabadi, according to Retraction Watch, pled not guilty to the charges but the firm pled guilty and agreed to make restitution of $180,000. Karimabadi agreed to a deferral of prosecution for a three-year period, at which time the charges against him could be dismissed, Retraction Watch reported. *(1/21/16)*

◆ **With grant support from the HHS Office of Research Integrity, Indiana University (IU) is holding a conference, Sequestration Analysis: Collaborative Institutional Approaches & White Collar Concerns, from March 30-April 1.** In this context, sequestration refers to the collection and preservation of evidence that is used to investigate allegations of misconduct, which federal law defines as fabrication, falsification and plagiarism. "Individual presenters include IT forensic specialists, general counsel and legal representatives, research integrity officers and staff, compliance and safety personnel, campus security and counseling services," according to IU. "The goal is to provide practical tools and resources to successfully implement what is learned from this innovative and interactive conference. Registration for the event, to be held at IU's Indianapolis campus, is free. One session on what IT officials "need to know and do during the sequestration process to ensure a successful sequestration of electronic data" will be webcast. *(1/14/16)*

◆ **Writing in brief that a 57-month sentence was "not substantially unreasonable," the U.S. Court of Appeals for the Eight Circuit upheld the prison term imposed on Dong-Pyou Han, Ph.D., the former director of an HIV research lab at Iowa State University (ISU) who confessed in 2013 to fabricating results of NIH-funded animal research.** It does not appear that Han appealed a repayment of $7.2 million to NIH that was part of his February 2015 plea agreement prior to his sentencing in July. Han admitted to spiking rabbit blood with human HIV antibodies during research designed to produce an HIV vaccine. The payment was meant to cover some of the $13 million in grants awarded to ISU and to Case Western University, where Han also worked (*RRC 8/15, p. 1*). The misconduct went on for nearly four years before it was detected; suspicions were first raised by an investigator collaborating with ISU (*RRC 2/14, p. 1*). The denial of the appeal was reported by Retraction Watch. *(1/14/16)*

◆ **The Association of American Universities and three other organizations representing educational institutions have told the Environmental Protection Agency that its proposed rule on hazardous waste could impose undue burdens on universities** because the institutions "generate a large and ever-changing variety of hazardous wastes mostly in small quantities, from multiple facilities." At issue are provisions addressing "determinations of hazard[ous] waste, container labelling, recordkeeping, and shipping." *(1/14/16)*

◆ **Research universities and others that conduct studies covered by HIPAA will want to make note of new guidance issued today by the HHS Office for Civil Rights, "Individuals' Right under HIPAA to Access their Health Information."** Applicable to all HIPAA covered entities (CEs) generally, the guidance discusses the provisions of 45 CFR § 164.524. "With limited exceptions, the HIPAA Privacy Rule… provides individuals with a legal, enforceable right to see and receive copies upon request of the information in their medical and other health records maintained by their health care providers and health plans," OCR states in the introduction. The guidance reiterates that CEs may deny patient access if the protected health information (PHI) requested "is part of a research study that includes treatment (e.g., clinical trial) and is still in progress, provided the individual agreed to the temporary suspension of access when consenting to participate in the research. The individual's right of access is reinstated upon completion of the research." *(1/7/16)*

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