After Request From Grassley, OMB Warns On Management Fees, Seeks Agency Data

The Office of Management and Budget has asked federal agencies to keep a close eye on when they allow certain fees and income on awards and to provide OMB with data on their oversight of these items by the end of this month. So, word to the wise, awardees: make double certain that neither you nor your subawardees are tucking any verboten expenditures, such as for alcohol, under the management fee category.

Such an inappropriate claim isn’t as outlandish as it would seem; the alert was prompted by a 2014 National Science Foundation Office of Inspector General (OIG) audit that found, under the cover of “management fees,” the National Ecological Observatory Network (NEON) “billed NSF for such normally unallowable costs as $25,000 for a Christmas party, $11,000 for coffee services for employees,” and others.

Sometime in April OMB quietly posted a one-and-a-half page “CONTROLLER ALERT: Management Fees or Profit under Federal Assistance Awards” to a website for chief financial officers (CFOs) in the government agencies. OMB provided a copy of the alert to Sen. Chuck Grassley’s (R-Iowa) office on April 15, a spokeswoman for his office told RRC.

Grassley’s office issued a statement about the alert the following day, under the headline “OMB Reins in Federal Grant Recipient Spending on Parties, Alcohol, Lobbying After Push.” However, that significantly overstates what OMB actually did and gives the false impression that a widespread problem has been identified. To date, the
only awardee with such costs flagged is NEON, although a half-dozen others that have received NSF management fees are under review.

The alert, OMB said, “reminds Federal awarding agencies to exercise due diligence when considering whether to allow grant and cooperative agreement recipients to earn management fees or profit under Federal awards” and “also requests data from Federal awarding agencies regarding the prevalence of this practice.”

The purpose of alerts, posted at https://cfo.gov/document-library, is to “highlight emerging financial management issues that may require agency attention or action.” But they are also a good source of information for awardees who want to stay abreast of the concerns on OMB and agencies’ radar so they can focus their own compliance efforts in these areas.

Unfortunately, while the cfo.gov website is public, the alert makes reference to another page that requires a log-in where OMB said are posted “examples of agency best practices regarding management fees or profit.”

OMB referred to this site as the Council on Financial Assistance Reform (COFAR) OMB MAX site, which is at https://community.max.gov/x/0AcdJg.

This is the same page where agencies go to enter data in response to OMB’s request.

In the alert, OMB told agencies they should “carefully consider whether there is an appropriate justification for allowing management fees or profit in the terms and conditions of the Federal award.”

**Agencies Should Ask Purpose of Fee**

OMB suggested that agencies should develop “controls, policy or guidance for Federal award officials to consult when determining whether management fees or profit are appropriate. For instance, Federal awarding agencies should review and receive a reasonable justification and explanation from the potential recipient that provides the intended use of the management fees or profits.”

Further, such policies and guidance “should include examples of inappropriate uses of management fees or profit such as purchase of alcoholic beverages, entertainment, meals for non-business purposes, membership dues for social or sporting clubs, and lobbying.”

OMB also restated that “[m]anagement fees should not be used to circumvent statutory or other limitations included in the terms and conditions of the award on otherwise allowable costs.”

NSF’s $443 million, five-year contract with NEON was the focus of congressional hearings in December and February. The former featured testimony by Allison Lerner, NSF’s inspector general (IG), who described a timeline related to NEON audit findings that indicated it was OIG itself that caught problems with NEON’s spending and with an audit completed by its audit contractor, the Defense Contract Audit Agency (DCAA).

**Draft Audit Omitted Fee Issue**

Lerner said per its usual practice, OIG had kept in touch with DCAA officials as they were conducting an OIG-requested audit of NEON’s “accounting system” and knew of draft findings of unallowable costs expended as management fees among eight “conditions constituting non-compliance.” But just one — related to “time-keeping” — made it into DCAA’s final audit.

According to the opening statement of Rep. Lamar Smith (R-Texas) at the December hearing before the House Science, Space, and Technology Committee, an auditor within OIG invoked the Whistleblower Protection Act and brought the draft findings to the attention of Grassley and Sen. Rand Paul (R-Ky.), resulting in their correspondence with NEON and NSF officials over the issue.
Anita Bales, DCAA director, also testified at that hearing, stating that the audit did not raise the issue of the management fee because NSF policies allow for this “if approved by the grants/agreement officer, which it was.” However, DCAA provided “supplemental” information to Lerner’s office when asked.

Bales also testified that DCAA “can find no regulation that prohibits the payment of a management fee under a cooperative agreement to a non-profit entity” nor any NSF policy “for determining when a fee should be awarded or how a negotiated fee should be used by a non-profit entity.”


The November documents state that NEON’s cooperative agreement with NSF “shows the initial management fees were established at amounts needed to cover expenses that were not reimbursable as costs under the cooperative agreements but were incurred in the operation of the non-profit entity. Subsequent awards were made without consideration of the need to reimburse specific unallowable costs.” In addition a cap was established of $2,168,950 for management fee[s] for the life of the cooperative agreement.”

It also states that “DCAA reviewed NEON’s use of management fee from 9/20/12 to mid April 2013 and found that NEON billed NSF for such normally unallowable costs as $25,000 for a Christmas party, $11,000 for coffee services for employees, $3,000 for Board of Director dinners (which included alcohol), $3,000 for t-shirts and other apparel for Contractor employees,” $83,000 for “business development,” and $112,000 for lobbying, which are unallowable under OMB Circular A-122.

However, the DCAA Oct. 23 letter itself makes no mention of these costs. It recommended that the OIG “consider requiring the NSF to strengthen the NSF Grant Policy to specify requirements for determining and monitoring the award of [the] management fee. We also recommend you benchmark with other federal agencies to determine their use of [a] management fee and how other agencies allow the use of that fee.”

**NSF: NEON Showed ‘Poor Judgment’**

During his testimony before a House committee in February, NSF COO Richard Buckius said “although NEON Inc.’s use of the management fee is technically permissible under NSF’s award, NSF shares the Committee’s concerns that NEON could have shown better judgment in the use of their management fee. We are following up with NEON on those findings. In addition, we have used this situation to clarify our policies and procedures in the awarding, and oversight, of those fees.”

He added that NEON’s management fee to date had totaled $1.7 million.

Buckius also described NSF’s recently published proposed policy on management fees. In a Dec. 30, 2014, Federal Register notice with a Feb. 13 deadline for comments, NSF noted it has a “long standing practice” of paying “a small but appropriate management fee...in limited circumstances related to the construction and operation of major facility projects. NSF is strengthening both the criteria used to establish such management fees and the controls that may be necessary to ensure that uses of fees are consistent with those established criteria.”

According to the Federal Register notice, NSF proposes to “recognize” just three criteria for “negotiation and award of management fee,” namely when it is for “Working capital necessary to fund operations under an award, Facilities capital necessary to acquire assets for performance,” or when it is for “other expenses that are ordinary and necessary for business operations but that are not otherwise reimbursable under the governing cost principles.”

“These new policy requirements address the fact that a management fee is not to be used to provide organizations a means to cover expenses such as alcoholic beverages, personal or luxury items for employees, non-business related travel, or any activities that would contravene federal restrictions on lobbying. The new policy will also require that organizations requesting [a] management fee provide information on actual uses of any management fee previously awarded by NSF in the preceding five-year period,” Buckius testified.

**OIG Critiques Proposed Policy**

NSF itself has not posted any of the comments it has received in response to the proposed policy. However, OIG did issue its response to the proposed policy, which was written by Brett Baker, the assistant IG for audit.

In his Jan. 29 comment letter, Baker described the federalwide paucity of guidance on management fees, and reviewed policies currently in place at specific agencies, including NASA and the Department of Defense. This information serves as a useful reminder to awardees, who are currently managing awards under the old OMB circulars and new uniform guidance.

“Until December 26, 2014, guidance as to the treatment of costs under federal grants and cooperative agreements with educational institutions and non-profit organizations is set forth in OMB Circulars A-21 (educational institutions) and A-122 (non-profit institutions). Neither OMB Circular specifically addresses the allow-
ability of the type of management fees discussed in this memorandum,” Baker wrote.

“Likewise, the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (Uniform Guidance), which replaces the circulars, and which becomes effective January 1, 2015, does not specifically address ‘management fees.’ It does address the concept of ‘profit’ in broad terms as follows: Section 200.400(g) The non-Federal entity may not earn or keep any profit resulting from Federal financial assistance, unless expressly authorized by the terms and conditions of the Federal award,” Baker continued.

He also offered a handful of “observations” about the proposed policy, which, in general, indicated NSF needed to add details for how various provisions would work in practice.

Link to OMB CFO alert: http://tinyurl.com/k0387e2

Link to Grassley statement: http://tinyurl.com/05sspft

Link to December House hearing: http://tinyurl.com/ol643d7

Link to Buckius testimony: http://tinyurl.com/q6ekv3a

Link to NEON audit report: http://tinyurl.com/mffurje

Link to NSF OIG proposed management fee policy: https://federalregister.gov/a/2014-30244

Link to NSF OIG comments on proposed policy: http://tinyurl.com/l9j8jg8

Universities Dispute Questioned Costs in Three NSF OIG Audits

Three new audits by the National Science Foundation Office of Inspector General have questioned more than a million dollars that three universities in total claimed for salaries OIG said exceeded NSF’s two-month limit, and for other expenditures.

But the University of California, Berkeley (UCB), Michigan State University (MSU) and the University of Florida (UF) disputed many of the questioned costs. All the universities said their salary expenditures were grounded in an NSF FAQ document the auditors, which were the same for the three audits, said wasn’t a valid justification.

And while some audit reports make for dry reading, UF’s featured an account of a post-doc’s unlucky driving decision — or as OIG put it, “imprudent actions” in unsuccessfully driving across a river bed in a “remote area of Kenya” where the waters later rose, causing more than $16,000 in damages to his or her disabled vehicle. OIG disallowed the repair costs, a decision UF opposed.

The UCB audit marks the second time in recent years the NSF OIG has questioned salaries at a UC campus as above the two-month threshold. OIG’s previous interpretation of the allowability of summer salaries proved controversial. In June 2014, NSF sided with the University of California, Santa Barbara, which disputed an OIG finding that UCSB had inappropriately claimed $1.9 million in summer salaries (RRC 8/14, p. 5).

Salaries Were for 97 Awards

The period of the review in the UCB audit was January 2010 through the end of 2012. “This provided an audit universe of approximately $379 million, in more than 318,000 transactions, across 1,033 individual NSF awards. Of the $379 million in the universe, our audit questioned $1,863,351 of costs claimed on 97 NSF awards,” the auditors said.

Among these were “$1,608,944 in senior personnel salary, fringe benefits, and applicable overhead that exceeded NSF’s two month limit,” $15,451 “in unallowable meal expenditures; $9,904 in unreasonable travel; $6,997 in unsupportable and unallocable immigration fees; and $3,891 in purchases before the award effective date.”

OIG redacted the amounts in two other categories of questioned costs: “unreasonable equipment charges” and “unallowable transactions.”

Auditors also stated the questioned costs “resulted in seven areas identified where UC Berkeley controls could be improved to ensure compliance with laws and regulations.” According to the auditors, “UC Berkeley relied on an informal November 2010 Frequently Asked Questions (FAQ) document on Proposal Preparation and Award Administration which states, ‘NSF has not changed the terms and conditions or any of our post-award prior approval requirements. Therefore, under the normal rebudgeting authority, an awardee can internally approve an increase of salary after an award is made.’ However, the FAQ document is non-authoritative and contradicts the NSF requirement per the AAG [NSF Award & Administrative Guide] which was in effect during the audit period. Therefore, we question the $1,608,944 in overcharges that NSF did not approve.”

In a nine-page letter, UCB disputed all of the questioned costs except $23,673. Officials also quoted correspondence with Jean Feldman, NSF policy head, which they said supported their position.

Link to UCB audit: http://www.nsf.gov/oig/reports/15-1-012-UCB.pdf

The MSU audit reviewed $235 million claimed from Jan. 1, 2010, through Dec. 31, 2012. Auditors questioned $913,210 in senior personnel salary that they said exceed-
ed NSF’s two-month limit. The amount was claimed on 63 NSF awards and was composed of $490,751 in senior personnel salary, applicable fringe benefits of $122,685 and indirect costs of $299,774, according to the auditors.

Auditors recommended that NSF require MSU to resolve the questioned costs and strengthen administrative and management processes and controls.

MSU disputed the lone finding and recommendation, and, in its accompanying response, said “the questioned costs in this finding are related to post-award, specifically effort that was not anticipated in the proposal phase, but necessary after the award was issued.”

The university said it “relied on an informal [NSF] November 2010 Frequently Asked Questions (FAQ) document on Proposal Preparation and Award Administration,” which it maintained said that, “under the normal rebudgeting authority, an awardee could internally approve an increase of salary after an award is made.”

MSU further argued that “the NSF Proposal & Award Policies & Procedures Guide (PAPPG) that went into effect December 26, 2014 should be viewed as a major subsequent event with direct relevance to this audit.... NSF’s incorporation of the Frequently Asked Questions (FAQ) information into the latest PAPPG suggests that MSU accurately interpreted the intent of the FAQ. Given MSU’s compliance with the intent of NSF’s two month salary policy, as evidenced by the small proportion of salaries questioned (approximately 1%), with no indication these changes resulted in any change of scope, and the clear written language regarding budget revisions in the PAPPG and in the NSF FAQ’s, the finding is not warranted and should be removed.”

The auditors contended that the FAQ “made no mention of the ability to disregard or violate the NSF Award & Administrative Guide,” where the NSF two-month salary policy is set down, and “rebudget authority does not apply.”


The UF audit report covered 91 awards that spanned from April 1, 2010, to March 31, 2013. In the UF report, auditors questioned $992,462, as follows:

- $867,188 in senior personnel salary that exceeded NSF’s two-month limit;
- $42,958 for travel expenses and services performed after award expiration;
- $32,822 in unsupportable or unallocable expenses;
- $27,331 in unreasonable equipment;
- $7,880 in student stipend advances;
- $7,160 in unallowable travel expenses and associated services;
- $5,495 in unreasonable meals;
- $1,628 in a foreign currency conversion error.

As for the vehicle mishap...OIG reported that it “questioned $16,223 charged in major car repairs to one NSF award. The vehicle was purchased for $55,000 on a previous NSF award, and was being used in Kenya. A post-doc tried to cross a river during heavy rains resulting in the need for major bodywork, as well as a complete engine overhaul and rebuild. There was insurance on the vehicle, but a mechanic had already substantially started the repairs before the insurance company could assess the damages, leading to a breach of the insurance contract.”

The auditors said UF “settled with the insurance company for $3,994, which UF states has been returned to the grant. We are questioning the total cost of repairs of $16,223 due to the imprudent actions of the post-doc when operating the NSF-purchased vehicle and the breach of the insurance contract.”

The questioned costs resulted in eight areas that auditors identified where UF controls could be improved.

According to the audit report, “UF reviewed and agreed with the facts via email for $100,326 in questioned costs” but it “did not agree with $892,136: 1) $839,118 for senior salaries exceeding NSF limit; 2) $25,000 for services performed after award expiration; 3) $21,865 for unreasonable equipment; and 4) $6,153 for unallowable meals.”

UF made, and the auditors dismissed, the same argument as MSU: it relied on the November 2010 FAQ, which it interpreted as granting it rebudgeting authority without consulting NSF and the ability to approve “an increase in person months devoted to the project after an award is made, even if doing so results in salary support for senior personnel exceeding the 2 month salary rule.”

In 2014, both the University of Illinois at Urbana-Champaign and Virginia Tech had questioned costs (of $52,584 and $1.456 million, respectively) in payments to...
investigators they said exceeded NSF’s two-month senior salary limitation (RRC 10/2/14; RRC 9/14, p. 3). Both made the same argument about rebudgeting and the FAQ and also got no sympathy from the auditors.


This story was excerpted from the April 2015 issue of RRC sister publication Federal Grants News. For more information or to order, visit http://AISEducation.com.

AAMC FCOI Compliance Study Questions Impact of Costly Effort

As could be expected, the number of significant financial interests (SFIs) that investigators disclosed increased at a majority of institutions after NIH’s expanded financial conflict of interest (FCOI) regulation went into effect.

But according to a new study by the Association of American Medical Colleges of the costs and outcomes of the FCOI 2011, there wasn’t a corresponding, proportional boost in the incidence of FCOIs that institutions ultimately reported to NIH.

“When we just take the raw numbers, we can see that SFIs went up 45% and FCOIs went up 13% but that doesn’t even come close to saying what happened,” Heather Pierce, AAMC senior director for science policy and regulatory counsel for scientific affairs, told RRC. “In some institutions, the FCOIs and SFIs actually even decreased over time.”

The findings are part of an “analysis in brief” AAMC released during its Forum on Conflict of Interest in Academic meeting April 15-17 in Atlanta.

The previous FCOI regulation, in effect since 1995, required investigators to disclose SFIs of $10,000 or more to their institutions. The new regulation, which went into effect in August 2012, lowered that to $5,000 and required mandatory FCOI training for investigators, disclosure of any payments investigators receive for travel and for equity investments, and reporting by institutions to funding agencies of specific plans to manage identified conflicts (RRC 8/12, p. 1).

In addition to halving the threshold, the regulation expanded the definition of an SFI to include one “that reasonably appears to be related to the investigator’s institutional responsibilities” (RRC 8/12, p. 8).

Called the “Metrics Project,” AAMC launched its study to collect data on implementation costs and outcomes in October 2012.

At the time, Pierce told RRC the study was “part of a bigger discussion around evidence based regulation” (RRC 12/12, p. 6).

AAMC wanted to learn the costs of compliance and whether the revised regulation would result in more FCOIs being reported, she said. Another possible outcome could be that, over time, FCOIs are reduced, and the integrity of research is presumably better assured.

Although 74 institutions were included in the study, not all were able to provide data on the elements AAMC studied. For example, 66 were able to say how many FCOIs they reported to NIH under the old regulation as well as the new version, while 56 calculated the number of SFIs.

Findings Are ‘Complicated’

Pierce, who said collection was difficult for some to conduct, called the data that emerged “more complicated than some people thought it might be.”

One finding that doesn’t require much interpretation, Pierce said, is that, judging by the level of resources expended, institutions took compliance with the FCOI regulation seriously. She called the reported expenditures “eye-opening” — particularly in light of HHS’s estimate of compliance costs reported in the final rule.

HHS estimated an annual cost of $23,236 among “3,000 applicant institutions” and “2,000 awardee institutions” to comply with the regulation. AAMC’s data showed just how far off that estimate was, and documented the enormous cost of complying, as Pierce put it, with “a single regulation.”

Highlights of the study are as follows:

◆ 71 institutions expended a total of $22,557,744, approximately $318,000 each and a median investment of $126,000, related to the regulation.

◆ Of the expenditures, $11.6 million was for “one-time personnel costs.” Another $9.7 million in capital expenditures was for “primarily financial interest-tracking software.” Training and other costs came in at $1.2 million.

◆ Regarding timing, 61% or $14 million of the expenditures were made before the rule went into effect, with the balance — 39% or $9 million — booked the year after.

◆ The 56 institutions received an overall total of 54,354 SFI disclosures in the year before the revised regulation, compared to 79,035 the following year, an increase of 45%.

◆ The 66 institutions reporting FCOIs to NIH said they grew from 880 to 997, an increase of 13%.

◆ As noted earlier, however, the group of 56 saw a decrease in the percentage of SFIs that were determined to be FCOIs in first year they were complying with the revised regulation. Specifically, the percentage dropped from 4.8% to 1.4%.

“Institutions indicated that the increases in disclosed SFIs likely were the result of both the decreased...
Disclosure threshold,” the brief said of the results, “and the requirement to disclose financial interests related to all institutional responsibilities, not just those related to federally funded research.”

But these institutions “were largely unable to determine the contribution of each factor in the increase,” AAMC said.

In sum, “When the cost of implementation is considered, there is a question as to whether the rule accomplished its intended goals in a manner that appropriately balanced the benefits and burdens of the requirements,” according to the brief. AAMC made no recommendations in the report.

Portions of AAMC’s findings were released in February to the Committee on Federal Research Regulations and Reporting Requirements: A New Framework for Research Universities in the 21st Century (RRC 3/15, p. 6).

Pierce said they have also been shared with NIH officials, and that data collection on the project is continuing.

Link to study: http://tinyurl.com/m9w8v26

Link to COI regulation: https://federalregister.gov/a/2011-21633

**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.ReportonResearchCompliance.com.

- **A notice issued by NIH on April 15 warned grant hopefuls of “serious consequences” for submitting applications with errors.** “Be mindful that non-compliance can have serious consequences. NIH may withdraw any application identified during the receipt, referral and review process that is not compliant with the instructions” in NIH’s application guide, “Funding Opportunity Announcement, and relevant NIH Guide Notices,” the announcement said. NIH gave examples of non-compliance, which included improperly completed biosketches. (4/16/15)

- **It has been four years since the HHS Office of Inspector General (OIG) recommended that NIH “promulgate regulations that address institutional conflicts of interest (COIs),” but the agency has failed to do so.** This situation is among the top 25 recommendations that haven’t been followed that are cited in OIG’s 2015 edition of the Compendium of Unimplemented Recommendations. “NIH lacks information on the number of institutional conflicts at its grantees and the impact these conflicts may have on NIH-sponsored research,” OIG said. (4/2/15)

- **Penny-pinchers take note: NIH wants your best ideas on how to “maximize the productivity and creativity of the biomedical research workforce it funds” and “ensure funding for a broad and diverse group of investigators studying a wide range of important questions.”** In issuing a request for information (RFI) on April 2 with a comment deadline of May 17, NIH said it is seeking strategies that “should enhance the stability of individual research teams and the sustainability of the overall research enterprise.” The RFI was also discussed on Rock Talk, the blog of Sally Rockey, NIH deputy director for extramural research. (4/9/15)

- **As promised, NIH has issued a revised Grants Policy Statement to conform with the new Office of Management and Budget Uniform Guidance.** The new policy statement, published March 31, includes a final set of research grant terms and conditions, superseding NIH’s interim terms issued on Feb. 5 (RRC 2/15, p. 1). NIH also published a document summarizing the significant changes it has made since the policy was last modified in 2013. (4/2/15)

**SACHRP Joins Chorus of ‘Nos’ On Single IRBs Mandate Idea**

The highest ranking federal advisory committee on clinical research has added its voice to those roundly rejecting a proposal NIH floated in December that requires, with some exceptions, the use of a single institutional review board (IRB) in multisite trials. The concept is also referred to as a “central” IRB structure.

But the criticism offered by the Secretary’s Advisory Committee on Human Research Protections (SACHRP) that NIH has no data to show such a move would be beneficial may do little to derail the mandate train that seems to be steam-rolling through the federal government under NIH’s lead.

NIH may simply have lifted a requirement that may very well be contained in an upcoming expansive rewrite of 45 CFR Part 46, also known as the Common Rule, now undergoing approval by the Office of Management and Budget (see box, p. 8). Once approved, any final rule would likely be adopted by more than a dozen agencies that today follow the Common Rule. But while a formal
regulation will take years to go into effect, NIH can impose a new policy when it so chooses.

In leading the discussion on the topic, SACHRP Chair Jeff Botkin remarked that “we all see the advantages of single IRBs in the context of certain types of multicenter studies…[and] have a positive sense of moving forward with this general idea, but I think our bottom line is that it’s premature and we need to work through a variety of details before any uniform mandatory approach would be acceptable.” SACHRP, he added, was not being “obstructionist or circling the wagons” in opposition to the proposed mandate.

The comment letter states, in part: “SACHRP strongly maintains at this time that a uniform mandate of single IRB review for all domestic multi-site studies is premature. SACHRP instead takes the position that a more measured and careful process of encouraging single IRB use, accompanied in a step-wise way by issuing guidance on critical issues involved in the use of single IRB review would result in less disruption of the research enterprise, and eventual improvements in a single IRB process that is anchored in deep collective experience,” the letter said, in part. This is the same position taken by the Association of American Medical Colleges, the Council on Governmental Relations and others.

SACHRP stood its ground despite comments from an NIH official who contended the proposed policy already has a lot of support, albeit from investigators, not institutions or institutional review boards. Valery Gordon, NIH acting director for clinical research, told SACHRP that NIH is advancing the idea to meet a “demand,” and not “just to keep you busy.”

Gordon told SACHRP members that it would “be more helpful if you could provide evidence why you don’t think it’s a good idea…provide citations [for] why, or even if it wouldn’t be a good idea.”

But Botkin countered that if NIH wanted to “make a fundamental change in the system,” the “onus is on NIH to present the data to say why this is going to work” and that the “benefits are greater than burdens.”

Now that the Office of Management and Budget (OMB) is coordinating review of a notice of proposed rule making that would revise the Common Rule, which governs human subjects research, speculation has turned from wondering about timing to questions about what the NPRM may contain.

On Feb. 24, an item appeared on www.reginfo.gov indicating that OMB had received the NPRM (RRC 3/19/15). At this website, OMB notes only that it has received a draft or final regulation; the regulation itself is not posted. The clearance process can take months to years. OMB may be consulting with all of the agencies currently following the Common Rule before giving the NPRM its stamp of approval.

It will be many years before any changes in the Common Rule ultimately go into effect. As with the advance notice of proposed rule making, published in July 2011, the NPRM will have a comment period, which may be up to 120 days. After that, officials would repeat the same process that accompanied the drafting of the ANPRM, although hopefully with a truncated timeframe.

Once published, final rules often do not go into effect for a year or longer, as the regulated entities are given time to revise their policies and procedures and otherwise bring their activities into compliance.

A refresher on the major provisions seems timely. RRC will also review how the 1,100 comments stacked up, relying on a February 2012 summary provided to the Secretary’s Advisory Committee on Human Research Protections (SACHRP) by an official with the Office for Human Research Protections (OHRP), the lead HHS agency for the ANPRM.

It is difficult to predict which of the many proposals in the ANPRM will make it into the NPRM, but one seems likely — a mandate that multisite trials use a single, or central, institutional review board (IRB). NIH recently issued a proposed policy on just such a mandate, which OHRP officials told RRC they supported, calling it a “positive development” (RRC 1/15, p. 7).

According to the summary SACHRP heard, however, commenters were split on the issue. According to that analysis, the comments received on the issues were “nearly evenly divided,” for and against. “Researchers and disease advocacy groups tended to favor the single IRB review requirement,” while “IRB and institutional representatives tended to be opposed to the possible requirement, although many indicated single IRB review should be encouraged.”

SACHRP itself weighed in on NIH’s plan during its March meeting, sending HHS comments opposing a mandate (see story, p. 7).

Here is an overview of some of the other ANPRM provisions and the responses they generated.

A Refresher on the 2011 Common Rule ANPRM

Call Bailey Sterrett at AIS (202-775-9008, ext. 3034) to find out about our very reasonable rates for bulk subscriptions and site licenses for your entire campus.
Addressing assumptions that a single IRB may save money, SACHRP’s letter also calls for a greater level of funding when a single IRB is involved. “Budgets for grants should increase where single IRB review is an integral part of the proposal and take into consideration the additional costs to both the reviewing and relying institutions,” the recommendations state.

SACHRP also laid out considerations for how NIH could “qualify” an IRB serving “in a central capacity,” should the policy be implemented. SACHRP’s “points to consider” might also prove useful to IRBs today.

As they vet others with which they work in a coordinating, collaborating or oversight role, IRBs may want to ensure that partner IRBs have:
◆ “Written SOPs describing how local cultural and resource context information will be gathered, both at initial and continuing review;
◆ “Adequate record keeping systems and written standard operating procedures [SOPs] for tracking each site independently, including the ability to manage site-specific emergency care, conflicts of interest, sub-studies, unique consent forms, subject complaints, compliance issues, and unanticipated problems;
◆ “Process[es] to adequately obtain knowledge of state laws where the single IRB reviews sites in other states in order to assure compliance;
◆ The “[c]apacity to conduct site visits, as necessary;
◆ “Written SOPs describing how the single IRB and institutions will coordinate issues such as review by other committees (IBC [institutional biosafety committee], Radiation, etc.) and unique institutional policies;
◆ “Accreditation of its human research protection program; and
◆ “Appropriate oversight” by the HHS Office for Human Research Protections and the Food and Drug Administration.

Also at the meeting, SACHRP approved a host of other recommendations, including on electronic informed consent and the use of “big data” in research.

**Link to recommendations:** http://tinyurl.com/m3xgbn3

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**Broadening the applicability of the Common Rule to encompass all human subjects research regardless of funding source when conducted by a U.S. institution receiving any federal research funding from a Common Rule agency.** Commenters were “nearly evenly divided” on the merits of the proposal. Institutions today have the option of applying the Common Rule in this manner, but increasingly numbers no longer do so by virtue of “unchecking the box” on their federalwide assurance. “Emphatic language” was used by a “number of commenters” opposed to this idea.

**Expanding the exempt research categories.** A “strong majority” of commenters said history, ethnography/observation, linguistics, internet/virtual reality/online research and quality assurance and quality improvement studies be exempt from the Common Rule.

**Requiring consent for secondary use of biospecimens, even when deidentified.** A “strong majority” expressed opposition to this idea, which would reflect a change from current practices.

**Eliminating continuing review for research approved under expedited procedures.** This suggested change got a thumbs up from a “strong majority.”

**Requiring investigators to disclose, during the informed consent process, “financial relationships they have with study sponsors.”** A “very strong majority” of commenters supported this suggestion. While financial conflicts of interest (FCOIs) must be either reported on a public website or provided to individuals upon request, such information is not required to be disclosed to research participants.

**Requiring, for some studies, investigators to assess how well subjects understood the trial before signing a consent form.** Responses indicated that the “strong majority” favored guidance or regulations that would “encourage assessment of subject comprehension.”

**Applying HIPAA standards for de-identification and limited data sets.** Support was offered by some that already comply with HIPAA but “a strong majority” of commenters were opposed to the application, particularly for social and behavioral research.

**Requiring adverse events and unanticipated problems to be reported to a single government-wide database available to all federal agencies.** While garnering “agreement in principle” by a “strong majority,” this proposal elicited “practical concerns,” including about costs, access to and uses of the data and harmonization of “definitional differences” among the agencies.

**Harmonizing regulations and agency guidance.** As might be expected, a “very strong majority” favored efforts to promote harmonized guidance.” among HIPAA, the Common Rule and Food and Drug Administration, but commenters also urged regulatory harmonization, including with rules in place in Europe and elsewhere.

**Link:** http://tinyurl.com/oqjvcr3
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continued from p. 1

Dreger cites RRC’s documentation that the agency’s investigations have dwindled in recent years, with just one opened in all of 2013 (RRC 5/14, p. 1).

Klitzman’s book, based on interviews with IRB members and chairs at three dozen institutions nationwide, also showed that some OK non-federally supported studies “without much social benefit” because federal money has dried up. But ultimately, much still remained hidden even to Klitzman, prompting him to urge more transparency and research into IRBs as well as the development of “protocols” and areas of “consensus” to remove some of the inconsistencies among IRBs.

He also calls for the creation of an “appeals process” for investigators who are unhappy with decisions by their IRBs and for IRBs to ensure they have one or more truly unaffiliated community representatives as members. Klitzman described his findings in an April 14 webinar sponsored by the WIRB-Copernicus Group and also talked to RRC.

“I think OHRP can, and should, be doing a better job, a different job,” he told RRC. Klitzman also said OHRP needs to act on the recommendations that the Secretary’s Advisory Committee on Human Research Protections (SACHRP) has submitted to it.

The fact that it hasn’t is contributing to the variations among IRBs both operationally and in their oversight of research and is partly the reason why some have been pushing for central, or single, IRBs, he said. “Working in this interpretive vacuum without guidance can generate stress and discrepancies” among IRBs, he wrote.

IRBs often find themselves “caught in the middle between feds and researchers,” and some suffer from insufficient resources, he said during the webinar. “The amount [of support] varies immensely” and some IRBs are helpless to improve their lots. One IRB chair, when asked about his relationship with the institution, said simply, “Our office is in a trailer in the parking lot.”

‘Mouth of God’ Now Closed

But when they reach out to OHRP for support, IRB officials reported getting nowhere. In the chapter titled, “Federal Agencies vs. Local IRBs,” Klitzman wrote that one chair told him, “Many times when you call for advice, they essentially just read back the regulations.”

One recounted waiting two years to hear from OHRP on changes it had made. When federal officials respond, “they often refrain from doing so in writing, or say that the clarification does not apply more generally,” Klitzman was told.

“Joe,” an IRB chair, told Klitzman that OHRP officials “have not been very forthcoming. In fact, it has been very difficult to get any kind of opinion from them, which is very disturbing.”

Joe also told Klitzman that IRBs “want to hear it from the mouth of God, and we don’t get that.” In the book, Klitzman assigns first names only to his interviewees and does not identify where they are employed.

The IRB officials Klitzman interviewed also seem to believe that OHRP is understaffed. Regarding SACHRP recommendations, Klitzman wrote that “OHRP may read and reflect some of this input, but still hasn’t formally made major changes as a result.”

An IRB administrator referred to as “Liza” told Klitzman, “If they [OHRP] would just show some effort to say, ‘We’re listening. Advisory committees are important to us….We’re doing this, or changing that as a result,’ it would make IRBs feel easier,” she said.

Variations Abound

Perhaps the most disturbing information Klitzman obtained concerns the seemingly random and arbitrary way IRBs make decisions to approve — or disallow — protocols. Under a “big topic” he called “causes of variation,” Klitzman described aspects that may or may not come into play in IRB decisions.

Variations can occur among different IRBs, internally within a single IRB and even among separate IRBs operating in the same institution. Some IRB members also reported being regretful about decisions they had made, saying they later regretted approving a particular protocol. His interviews also found that these variations do not so much concern “research ethics” or “community values” but IRBs’ “procedural definitions” and the personal whims of IRB officials themselves.

IRB chairs and members, according to Klitzman, “relied on gut feelings, intuition, the sniff test. People wanted to feel comfortable….They wanted peace of mind” about the studies they approved. Decisions were influenced by “pet peeves” and the “prudishness” of IRB members and chairs. Some IRBs are “user-friendly” or “pro-research,” he said.

When seeking to justify their actions, some told Klitzman they were “simply interpreting the regulations differently. Some said these were just minor differences, they were just fine-tuning. But often the differences reflected a bit more than that,” he wrote.

Klitzman also documented varying approaches that IRBs have toward investigators, with some “actively” inviting them into meetings while others insisted they cannot even contact anyone at the IRB office except through a generic email address.
Relationships with institutional compliance offices also vary, with some sharing space while others have little interaction.

One chair remarked that he instructs members not to discuss what happens during meetings so as not to anger investigators whose protocols might have been criticized.

Falling NIH grants have increased pressure on IRBs to approve industry or pharmaceutical-sponsored studies because an investigator’s career may be on the line if some research, even if it’s a study of “me-too” drugs without much social benefit, doesn’t go forward under his or her name, according to Klitzman.

Regarding operational issues, some IRB members’ identities are not disclosed while others may directly engage with researchers whose plans they are reviewing. IRBs also differ in the tone — friendly versus bureaucratic — and type of correspondence they provide to investigators, Klitzman’s research showed. Some said they try to “help researchers” by pointing out issues that can be corrected.

His research also found “support for local IRBs” and a “general wariness” of central ones. Local IRBs bring direct knowledge of subjects to their tasks and are able to conduct “curbside consults with researchers,” to discuss, for example, study design, he said.

Klitzman said he heard other complaints about central IRBs, including concerns about a lack of autonomy, for-profit status, incompetence and conflicts of interest. In his view, however, “conflicts of interest are ubiquitous” and that “the key thing is how we manage them.”

**Commission: Research Is Suffering**

But Klitzman and Dreger are hardly alone in their criticisms of OHRP’s inaction. To the nation’s top bioethics advisors, the agency has thwarted promising brain research because it has failed, despite SACHRP’s efforts, to issue guidance related to the inclusion in research of “individuals with impaired decision making.”

On March 26, the Presidential Commission for the Study of Bioethical Issues released *Gray Matters: Topics at the Intersection of Neuroscience, Ethics, and Society*, which called for the adoption of uniform federal standards, among other actions (RRC 3/26/15).

In remarks to reporters about the report, Amy Gutmann, president of the University of Pennsylvania and chair of the commission, said that without clear requirements on who can serve as a legally authorized representative (LAR), “often researchers feel like they can’t engage in this research.” Family members and individuals, for their parts, “in almost all cases, [also] want to be involved in this research but not having uniform federal guidelines is a serious obstacle,” she said.

As the report states, “SACHRP provided 10 recommendations on several topics, including consent capacity, IRB membership and procedures, participant selection, and LARs. In addition, it proposed a regulatory solution for defining who can serve as an LAR. This guidance reached beyond mental health or psychiatric conditions to address the wide array of conditions that can lead to impairments in consent capacity. Similar to the proposals that preceded it, SACHRP’s recommendations were not incorporated as official guidance or regulations for researchers. Yet SACHRP’s recommendations are widely cited in current discourse on appropriate additional protections.” SACHRP “recommended a list of persons (in order of priority) who can serve as LARs, to be relied upon in the absence of applicable state law. Federal regulatory bodies could endorse SACHRP’s recommendation and explicitly permit researchers and IRBs to rely on SACHRP’s priority list of potential LARs.”

**Help May Not Be On the Way**

OHRP Director Jerry Menikoff recently said there was virtually no benefit to HHS acting on SACHRP’s recommendations and suggested members publish them independently (RRC 8/14, p. 1). He also contended that some topics SACHRP has addressed may be clarified when HHS issues a notice of proposed rule making (NPRM) revising the Common Rule (see box, p. 8).

But other areas of concern to IRBs and researchers that SACHRP has addressed are unlikely to be in an NPRM and are inappropriate for inclusion in such a document. These include guidelines for research on the Internet and studies involving children (RRC 4/12, p. 1).

Other areas, such as compensation for injured research subjects and harmonization of U.S. regulations with international requirements, were deemed by past SACHRP members to be worthy of their study.

But Menikoff prevented SACHRP from taking them on, so these issues remain unaddressed (RRC 11/12, p. 1).

In a statement to RRC in response to the concerns raised in *Ethics Police*, OHRP said the agency “recognizes the growing challenges IRBs face, arising from multiple sources and pressures in the modern research context, and is striving to address concerns within its regulatory scope. To that end, OHRP seeks to respond appropriately and helpfully when it receives questions from the public.” Regarding why OHRP had not endorsed SACHRP’s six-year-old recommendations on subjects with impaired decision making and others, OHRP said it is “carefully considering these recommendations in assessing future possible policy development and regulatory action in which the office may be engaged.”

Link to Klitzman’s webinar: http://tinyurl.com/qqafvcv
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. Please call 800-521-4323 or email customerserv@aispub.com if you require a password to access RRC’s subscriber-only Web site or are not receiving weekly email issues of the newsletter.

◆ The Food and Drug Administration has issued final guidance on “how FDA considers the role of postmarket information in determining the appropriate type and amount of data that should be collected in the premarket setting to support premarket approval, while still meeting the statutory standard of safety and effectiveness,” the agency announced in an April 13 Federal Register notice. The guidance, Balancing Premarket and Postmarket Data Collection for Devices Subject to Premarket Approval, updates a proposed rule issued April 23, 2014. (4/16/15)

◆ The HHS Office of Research Integrity (ORI) entered into a three-year exclusionary agreement with a researcher who committed misconduct at Columbia University (CU). In a notice published in the April 7 Federal Register, ORI said Ryousuke Fujita, a former postdoctoral scientist at CU’s Taub Institute for the Aging Brain, “inflated sample numbers and data, fabricated numbers for data sets, manipulated enzyme-linked immunosorbent assay (ELISA) analysis, mislabelled immunofluorescent confocal images, and manipulated and reused Western blot images” that were later contained in two published and one unpublished papers. Fujita agreed not to advise the Public Health Service and to exclude himself “from any contracting or subcontracting with any agency of the United States Government and from eligibility or involvement in nonprocurement programs” for a three-year period beginning March 18. (4/8/15)

◆ In a separate April 7 Federal Register notice, ORI also said it entered into an unrelated three-year exclusionary agreement with a researcher who committed misconduct at Wayne State University (WSU). Teresita Briones, formerly an associate professor in WSU’s College of Nursing, “intentionally, knowingly, and recklessly engaged in research misconduct by falsifying and/or fabricating data that were included in five (5) publications and three (3) grant applications submitted” to the National Institute of Nursing Research. Briones also agreed not to advise the Public Health Service and to exclude herself “from any contracting or subcontracting with any agency of the United States Government and from eligibility or involvement in nonprocurement programs” for a three-year period beginning March 12; Briones also will seek retractions of the five published papers. (4/9/15)

◆ A group of more than 700 relatives of Guatemalan individuals who were unknowingly included in studies in the 1940s of sexually transmitted diseases (STDs) funded by the U.S. government are seeking $1 billion in punitive damages. The suit, filed April 1 in the Circuit Court for Baltimore City, names Johns Hopkins University, its medical center and medical school as well as the Rockefeller Foundation and Bristol-Myers Squibb Co. for their roles in the research, which was the subject of two damning reports by the Presidential Commission for the Study of Bioethical Issues (RRC 1/12, p. 1). According to press reports, the named organizations said they would fight the suit. (4/2/15)

◆ HHS has re-advertised the top job at the Office of Research Integrity, as well as posted a new listing for a position in ORI’s Division of Education and Integrity. Former director David Wright resigned from the position in February 2014 after two years on the job, amid a flurry of complaints about micromanagement by HHS (RRC 4/14, p. 1). May 15 is the deadline for applications. The other listing is for a “health science administrator”; April 6 is the deadline for applying for this position. (3/26/15)

◆ A year after falling victim to publishing 18 “fake” papers, the Springer publishing firm has made available SciDetect, a free software program that purportedly can determine “whether an entire document or its parts are genuine or not.” This “open source software discovers text that has been generated with the SCIgen computer program and other fake-paper generators like Mathgen and Physgen,” the publisher announced March 23. “Springer uses the software in its production workflow to provide additional, fail-safe checking.” Springer publishes “more than 2.500 English-language and close to 200 German-language journals” and “the largest portfolio of open access journals, including the journals from BioMed Central.” (3/26/15)
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