Report on
Research Compliance

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In Columbia's 2nd False Claims Case Since 2014, Site of Research Was Key

While employed by Columbia University, Matthew Chisholm worked as an "internal administrative consultant" assisting different units and "putting out brush fires," as his attorney Timothy McInnis described it.

But during his tenure, Chisholm discovered something akin to a raging wildfire that ended up turning him into a whistleblower and costing Columbia nearly $10 million to extinguish. The incident holds lessons for recipients of federal dollars who must apply indirect cost rates to their projects.

On July 14, the U.S. Attorney for the Southern District of New York announced that Columbia would pay $9.5 million to settle a False Claims Act (FCA) suit first brought by Chisholm as an unnamed *qui tam* litigant. As part of the settlement, Columbia "acknowledges and accepts responsibility" for charging a higher on-campus indirect cost (also called facilities and administrative, or F&A) rate on more than 400 NIH grants for psychiatry and neuroscience research that was actually performed rent-free in state-owned facilities.

The resolution agreement echoes an FCA settlement from just two years earlier. In 2014, Columbia and affiliated entities agreed to a $9.02 million settlement for effort reporting issues with grants for an HIV/AIDS program *(RRC 12/14, p. 4)*. That case was also initiated by a whistleblower but is unrelated to the new one.

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NAS Committee Recommendations Include Call for Institutions to Heal Themselves

Rein in overzealous Inspectors General (IGs). Abandon the contentious proposed revision of the Common Rule. Streamline export controls and conflict of interest requirements. And put a new Research Policy Board (RPB) at the helm of designing a new "regulatory framework" dedicated to ensuring rules don't squelch valuable research.

New recommendations by a National Academy of Sciences (NAS) committee examining how the government could ease administrative burdens read like a virtual wish list drummed up by research compliance officials and investigators alike.

And in many ways they were, as the committee that wrote *Optimizing the Nation's Investment in Academic Research: A New Regulatory Framework for the 21st Century* hailed largely from academia, including former members of the government's highest ranking advisory board on human subjects protections. But in their report, committee members also advised institutions to look inward to see what they could do to reduce self-imposed burdens.

And that may be the only way changes will come, at least in the near term. Time is short for the slew of promising reforms proposed in the report to make it into law before the end of this year. Following a seven-week recess, Congress is not due back on Capitol Hill until after Labor Day.

continued

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After meeting during the month of September, the House and Senate will adjourn again, taking off all of October. Some members will be running for office, while others will be trying to ensure their candidate is elected president.

The report was issued in two parts; the first appeared last year (*RRC 9/24/15*; *RRC 2/16, p. 1)*. The second was published June 29. The biggest news from the concluding part was the recommendation that the federal government abandon its current effort to finalize the September 2015 notice of proposed rule making (NPRM) that would make significant revisions to 45 CFR part 46, the human subjects regulations that are followed by NIH and nearly two dozen other federal agencies (*RRC 6/30/16*). Whether the government will heed this recommendation regarding the Common Rule is an open question (see story, p. 6).

Also included in the second half of the report are suggestions for revising government regulations and oversight of export controls, select agents and toxins, and intellectual property (see box, p. 4).

Overall, the full report stresses that the foundation of the research enterprise is a partnership between the federal government and research universities, with the latter playing a crucial role, committee Chair Larry Faulkner, former president of the University of Texas at Austin, and committee member Barbara Bierer, professor of medicine at Harvard Medical School and Brigham and Women's Hospital (BWH) and faculty co-chair of the Multi-Regional Clinical Trials Center, noted in interviews with *RRC*.

The report is couched in a series of nine "findings" about the academic research enterprise. The seventh is aimed squarely at universities, stating, "Some academic research institutions have failed to respond appropriately to investigators' transgressions or failed to use effectively the range of tools available to create an environment that strongly discourages, at both the institutional and the individual level, behaviors in conflict with the standards and norms of the scientific community."

While the report makes numerous specific recommendations, it contains just four overarching ones. The report divides specific recommendations by the entity that should take the action, for example, Congress, the Office of Management and Budget (OMB), etc.

The first recommendation calls for "the regulatory regime (comprising laws, regulations, rules, policies, guidances, and requirements) governing federally funded academic research" to be "critically reexamined and recalibrated."

Imperative for 'Highest Standards'

To put this recommendation into effect, the report calls for Congress to take 13 specific actions. It also assigns six tasks to OMB and three to Congress and the administration to undertake jointly.

The third recommendation is that IG duties "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."

The call for the RPB comes in part four, in which the report recommends the creation of "a new mechanism, 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."

In a recommendation to universities, the committee stressed the need for a commitment to integrity.

"To advance the government-academic research partnership, research institutions must demand the highest standards in institutional and individual behavior. This can only be achieved if universities foster a culture of integrity among academic leaders, faculty, postdoctoral trainees, students, and staff, and institutional administrators, and mete out appropriate sanctions in

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instances where behavior deviates from the ethical and professional norms of the institution and of the academic research community," the report states.

"Universities that deviate from or fail to enforce the norms of behavior should be sanctioned. The committee recommends that a newly established Research Policy Board should collaborate with research institutions on the development of a policy to hold institutions accountable for such transgressions."

RRC asked Faulkner to discuss this issue, as the report says nothing more about it. "We believe institutions need to adhere to the highest standard no matter what," he said. "It is in their own interests to do so…because it is our view or finding that regulation grows because of isolated cases."

"Transgressions," as the report calls them, can prompt a disproportional response, he said, compared to what the committee believes is a small number of problems. "There are highly publicized cases, and those cases produce a reaction in the regulatory world that in the end often seems to apply…to the entire community when one institution or investigator is at fault," Faulkner said.

Asked if NIH's financial conflict of interest policy, which is widely perceived to be overkill, was one such example, he said, "I think it could be interpreted that way."

'Conduct a Review'

In terms of reducing burdens on their own, the committee recommends that universities:

◆ "Assess their own regulatory processes to determine where their compliance activities can be streamlined to ensure effective use of indirect research recovery costs, while still meeting the requirements of federal regulations."

◆ "Conduct a review of institutional policies developed to comply with federal regulations of research to determine whether the institution itself has created excessive or unnecessary self-imposed burden."

◆ "Revise self-imposed burdensome institutional policies that go beyond those *necessary and sufficient* to comply with federal, state, and local requirements."

"One of the things that we did was to balance our recommendations between those that the government could do, that Congress could take action on and that institutions could do," said Bierer, who served as senior vice president for research at BWH from 2003-2014.

The report is "not all about the government," she stressed.

In light of this report and others that have made similar recommendations, the Council on Governmental Relations has developed a "checklist" to help institutions review policies and procedures with an eye toward eliminating unnecessary ones.

"I was delighted to hear that COGR and others are taking this approach seriously, to see what they can do to stratify the administrative requirements between those that are required and those that are not, and making sure the administrative requirements conform to the regulations," Bierer told *RRC*.

IGs Object to Recommendations

But one thing is certain: At least two IGs are not exactly keen on the suggestions that refer to them, which were included in part one of the report *(RRC 2/16, p. 8)*.

The HHS and NSF IGs are batting back recommendations in the report, including the idea that they should abandon the use of data analytics and "cease conducting formal audits of research universities when the [IG] and the agency cannot agree on the interpretation of agency policies and priorities beforehand."

In their 14-page letter posted May 12, Brett Baker, then NSF's assistant inspector general for audit, and Gloria Jarmon, HHS deputy inspector general for audit, defended their practices and said some of the suggested changes would compromise the IGs' independence and requirements under the Inspector General Act of 1978.

They also offered a number of "clarifications or corrections" to the report.

One recommendation is that IGs "[re]examine 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."

In their defense, the IG officials said their "innovative use of constantly-changing data analytics in audit risk assessments has the potential to discover institutional risks that annual single audits do not detect, and even the institutions with the very best management may not uncover. [IGs] are continuously reexamining their 'risk based methodology in identifying institutions as candidates for...audits....' as they refine their analytical methodologies based on prior experience."

They added that "it would be inappropriate for [IGs] to rely only (or even primarily) on institutions' past performance as evidence of reduced risk given the potential to uncover new risks with the use of the powerful tools currently available in data analysis."

According to NAS staff, the letter marks the only formal, written response to the report from federal agencies.

continued

But Faulkner said there is reason to hope Congress, in particular, will be open to enacting some of the recommendations, many of which have been made in previous reports.

"What might be different this time," said Faulkner, is "the report was requested by congressional leaders" and the findings have been "listened to."

The report "has met with high interest from those leaders. To me, that's a feature of this [situation] that might lead to more follow-through" than in the past, he said.

Two bills have been introduced in Congress that call for the creation of the RPB and other provisions designed to relieve some administrative burdens, but neither has seen any action. (See http://tinyurl.com/jr62efw.)

Reforms Also Proposed for Export Controls, IP

Much of the recent attention garnered by the National Academy of Science's concluding report on reducing administrative burdens in research centered on what's been called its "bold" recommendation that the government abandon its rewrite of the Common Rule (see story, p. 1).

But that's not all that's noteworthy in part two of the report, *Optimizing the Nation's Investment in Academic Research: A New Regulatory Framework for the 21st Century.*

Part one of the report was issued in 2015 *(RRC 9/24/15; RRC 2/16, p. 1).* It recommended, among other actions, the creation of a Research Policy Board (RPB) and changes to how Offices of Inspector General perform their work *(RRC 2/16, p. 8)*.

Part one contained seven chapters; part two adds six more. Chapter 8 is an introduction; nine addresses the Common Rule. In the final chapter, "the committee illustrates how future regulations might be developed as part of its proposed regulatory framework and elaborates on the roles that the proposed RPB, the White House Office of Science and Technology Policy, and the Office of Management and Budget might play."

In between are chapters on intellectual property (IP) and tech transfer, select agents and toxins, and export controls.

IP and Tech Transfer

The governing law for intellectual property is the Bayh-Dole Act, which "requires institutions to provide data to agency sponsors of research on inventions that result from the funded research. This reporting is accomplished through the Interagency Edison (iEdison) invention reporting system." Developed by NIH, "the system is cumbersome to use, is not used by all agencies funding research" and also is "inadequately staffed and maintained, making it difficult for universities to comply with agency requirements."

The committee said it is "particularly burdensome" for universities to have to report annually for 20 years the life of the patent, for all patents even though "less than half of U.S. patents issued by U.S. higher education institutions are successfully licensed, and of that, less than half generate income."

To rectify these problems, the committee suggests:

- "Congress should transfer responsibility for the operation of the invention report system…to the Department of Commerce and allocate appropriate resources to the department for upgrading the invention reporting system so as to create a user-friendly interface for the input of data on inventions."
- Commerce, working with the RPB, "should develop a uniform set of requirements regarding the frequency and type of data to be submitted to federal agencies regarding invention reporting, ensuring that these do not exceed what is required by the Bayh-Dole Act."
- "[I]nvention data reporting obligations imposed on recipients of federal funding by all agencies" should be "aligned with agreed-upon reporting requirements," the report says.

Select Agents, Toxins

As with the IP provisions, the committee is recommending streamlined oversight and harmonization of regulations governing select agents and toxins research. These are regulated by both the Centers for Disease Control and Prevention and the Department of Agriculture.

As the report notes, "Research on select agents is heavily regulated, and those who are not authorized to possess, use, or transfer select agents but do so are subject to criminal and civil penalties."

The regulatory environment is complex and evolving, with related requirements for dual use research of concern coming into being in just the past few years. New requirements for oversight of "gain-of-function"

There's no doubt that relief is necessary; Faulkner said he saw the changes throughout his long academic career, which ended in 2006 when he stepped down as UT-Austin president after eight years. Previously, he spent 25 years at the University of Illinois at Urbana-Champaign in a variety of positions including provost.

"The job of VP for research changed from that of a person whose job was to foster research and the development of teams for opportunities mainly to a person focused on regulatory activity and how the institution was going to cope with it," Faulkner said. "That trend just continued after I left office."

He termed the job of regulatory compliance on campuses today "massive and difficult."

Link to NAS report: http://www.nap.edu/catalog/21824/optimizing-the-nations-investment-in-academic-research-a-new-regulatory

Link to IGs' letter: http://tinyurl.com/hp7aps3 ✧

research are still in development and have been controversial *(RRC 11/14, p. 1)*.

"As a result of select agent regulations, the cost of research involving select agents and toxins has increased significantly," the report said.

To ease these concerns, the committee recommended that:

◆ "[T]he President assign the responsibility for regulating all microbes and toxins on the Select Agents and Toxins List to a single agency."

◆ The program "develop and promulgate a reasonable inventory management system for biological select agents and toxins that takes account of the living, self-replicating nature of biological agents."

◆ Select agent regulations be amended to allow "researchers to more readily access relevant select agents in times of public health emergencies; [i]ncrease the number of lower-virulence strains of select biological agents available to researchers; and [m]ake more transparent the process by which materials are added to and removed from the Select Agents and Toxins List."

Export Controls

As the report explains and universities know well, both the Departments of Commerce and State are involved in regulating the export of "certain manufactured items, software, biological agents, and technical information (technology) that could be of military use to an adversary." In 2009, President Obama launched an export control reform initiative, with the goal of better meshing Commerce's Export Administration Regulations known as the EAR and State's International Traffic in Arms Regulations, known as the ITAR *(RRC 11/13, p. 6)*.

But the effort has fallen short, and the "current export control regime is broken," the report states, and "is unnecessarily burdensome and even counterproductive to national security objectives. Export controls have impeded university research in areas such as integrated circuits, material sciences, advanced optics, encryption, earth observation, infectious disease, and space research. Deemed export regulations have been particularly difficult for universities, which strive to provide fully open campuses and typically have large numbers of international students and visitors."

An allowable exemption for "fundamental research" isn't uniformly honored and "does not encompass either the tools and instrumentation used to conduct the research or the components used to construct an advanced research apparatus," according to the report.

The committee recommended the following:

◆ The government and Congress should "support a robust continuation and renewal of the Export Control Reform Initiative," as it "has the potential to make further, marked improvements (e.g., to the regulations, oversight process, and ease of compliance) that would bring significant benefits to national security, to commerce, and to the economy, as well as to federally funded university research."

◆ University input should be sought "at all stages of the process" of export control reform. The RPB "would be an ideal vehicle for providing such input."

◆ Additionally, the "deemed export provision" should be addressed with the help of "universities and other stakeholders." The reform initiative should "vigorously support the spirit and letter of the fundamental research exclusion."

"The lessons learned in the [Export Control Reform] initiative over the past 5 years could help participants in the process accelerate the rate at which needed regulatory revisions are proposed and adopted," the committee said.

Link: http://www.nap.edu/catalog/21824/optimizing-the-nations-investment-in-academic-research-a-new-regulatory

Will Administration Heed Call For Commission, NPRM Reboot?

In a surprise move, a committee empaneled by Congress to propose ways to reduce regulatory burdens for research universities is calling on the government to withdraw the notice of proposed rule making (NPRM) issued in September revising the Common Rule governing human subjects research (*RRC 6/30/16*).

The big question of the day: How will the government respond?

First, a look at the origins of the recommendation, which really has two parts, as the committee is also calling for the creation of a national commission to develop a new oversight framework for human subjects research.

The recommendation is contained in part two of a report, released June 29, *Optimizing the Nation's Investment in Academic Research: A New Regulatory Framework for the 21st Century.*

The National Academy of Sciences (NAS) committee contains several individuals who formerly served on the HHS Secretary's Advisory Committee on Human Research Protections (SACHRP). Current SACHRP members urged the Office for Human Research Protections (OHRP), the lead agency on the revisions, to commit to a "comprehensive rewrite" of the major provisions in the NPRM, which it labeled "impenetrable."

Timing Is Apt for New Look

The NAS committee recommends that the new commission be charged with "examining and updating as necessary the ethical, legal, and institutional frameworks governing human subjects research."

The commission would "make recommendations to the President, Congress, and relevant federal agencies regarding how the basic ethical principles governing human subjects research should be applied to unresolved human research questions and novel human research contexts," the committee said, and offered a list of subjects to be studied.

The committee agreed with the premise behind the NPRM, which proposed the first revisions to 45 CFR part 46 in 20 years, but not its execution.

The regulations need to be updated, as they are grounded in principles first articulated in the 1978 Belmont Report, and don't address a number of pressing issues, the members said.

Among these are quality assessment and comparative effectiveness research, cluster randomized trials, and the use of genomic data and biospecimens. With the exception of biospecimens, the new NPRM doesn't address these items.

"Given these formidable questions about the application and scope of the Belmont principles, it is necessary to broadly reconsider the legal and regulatory frameworks governing human subjects research, including the optimal locus of regulatory authority within the executive branch," the committee said.

"The current regulatory atmosphere indicates that our nation would benefit from a standing independent national advisory commission tasked with regularly examining and updating regulations governing all federally funded human subjects research and charged with addressing difficult and precedent-setting cases as well as matters of general policy," the committee members maintain.

Should Oversight Be Consolidated?

They questioned whether the "oversight" of trials should "reside within each executive branch agency that funds human research, as is currently the case, or within a single independent federal agency that oversees and regulates all federally funded human research."

The work of such a commission would necessarily derail finalization of the NPRM; the committee said the government shouldn't propose anything further at this time.

The report recommends that the "regulatory structure protecting human research subjects not be revised until the national commission has issued its report and the research community, patient groups, the public, and others have had an opportunity to consider and respond to the commission's recommendations."

Negative Comments Steeled Resolve

NAS committee member Barbara Bierer told *RRC* that the committee took care to ensure that the recommendation for the commission and a new NPRM was "supported by evidence," with much drawn from analyses of comments on the NPRM that were conducted by OHRP and by the Council on Governmental Relations. These analyses were coincidentally issued in the same week *(RRC 6/16, p. 1)*.

The committee felt more confident when the breadth of the opposition to the NPRM was revealed, coming not just from research universities and investigators but from patient advocates as well, said Bierer, who served as chair of SACHRP from 2008-2012.

The advance notice of proposed rule making (ANPRM) came out during Bierer's term. Despite its charge and expertise, OHRP and other agencies did not consult with SACHRP in drafting either the ANPRM or the NPRM.

Asked whether the recommendation to throw out the NPRM grew out of Bierer's experiences with SACHRP, she responded that "there were a whole group of individuals [on the committee] who were very attuned and aware of the human subject environment."

Bierer presided over a remarkably productive period for SACHRP, which produced dozens of recommendations. In a situation that frustrated not only Bierer but also current chair Jeff Botkin, who succeeded her, few if any of SACHRP's recommendations have ever been acted upon *(RRC 8/14, p. 1)*.

Many of the suggested areas for study by the commission have already been the subject of recommendations by SACHRP, but the committee did not specifically endorse them, Bierer said.

However, work by SACHRP and others can inform the new commission, should it be created, she said.

"A commission should go back to the work that's been done [by] SACHRP and elsewhere," she said. "There's been real scholarship brought to bear on these issues."

However, Bierer quickly added that she hopes a commission would be "balanced" and "represent all stakeholders," including patients and their advocates as well as pharmaceutical firms.

'Regulatory Vagueness' Could Be Crippling

The idea for urging the outright abandonment of the NPRM came as a result of a regional meeting Oct. 29-30 at Rice University that the NAS committee held shortly after the release of the NPRM.

In addition to concerns over the NPRM's proposed changes to the use of biospecimens, the report cited numerous other examples of problems with the NPRM.

"The omission of specifics on key tools and guidelines like the exemption determination tool, consent templates, and list of privacy safeguards is problematic; because the items are undefined at present, it is impossible to comment on their merit or utility prior to the issuance of the final rule," it states. "Furthermore, it is not possible to provide an accurate estimation of regulatory impact without a clear understanding of what compliance will involve."

Committee members also raised the specter of more negative effects due to "regulatory vagueness" in the NPRM.

"Uncertainty may also lead to an increased regulatory burden as institutions, in an effort to comply with vague or fragmentary regulations, implement speculative procedures which may ultimately be unwarranted," according to the report. "Institutions may also elect to reject, delay, or halt research in areas of regulatory vagueness," it said.

SACHRP submitted a 50-page comment letter that contained 23 recommendations on one provision alone — the call for consent for the use of biospecimens, even when deidentified and unidentifiable *(RRC 1/16, p. 1)*.

HHS: Rule Still in Development

At least outside of the government, the committee's recommendations for a commission and a new NPRM have generated support, including from the Association of American Medical Colleges (AAMC).

"The Academies' bold recommendations to suspend revisions to the Common Rule and create a commission to examine a comprehensive way forward could ensure the rule more effectively meets the needs of research participants, researchers, and ultimately the patients who will benefit from research advances," AAMC President and CEO Darrell G. Kirch, M.D., said.

Similarly, the Council on Governmental Relations, the Association of American Universities and the Association of Public and Land-grant Universities said in a joint statement that they are "concerned about the rush to issue a final rule and believe there is no urgency to do so."

The organizations "agree with the committee's assessment that 'the NPRM does not adequately or effectively address the breadth, depth, and import of unanswered questions' and that the current complexity of issues requires thorough and thoughtful consideration from a broad range of disciplines and stakeholders," they said.

Federal officials may be under pressure to get a final rule out before the end of President Obama's term in office. Some sources have suggested to *RRC* that the administration will go ahead with a final rule despite the NAS report, albeit in a scaled-down version, while others speculate a final rule could be abandoned. Faulkner noted at the press conference announcing the report that its findings had not been shared with HHS in advance.

For its part, the agency has given few hints as to its reaction to the recommendation, but doesn't seem ready to throw in the towel.

A few weeks after the NAS report was released, HHS provided this response to *RRC*'s request for comment on the recommendations for a commission and for the rule making process to stop:

continued

"The Notice of Proposed Rulemaking on regulations governing research using human participants (also known as the 'Common Rule') received more than 2,100 public comments. The U.S. Department of Health and Human Services — and the 18 other federal agencies involved in this effort — have spent the past few months reviewing all of these comments. We take all public comments seriously and are considering them as we develop the final rule. We look forward to reviewing the report."

Bierer remains upbeat that the report will have an impact.

"I am hopeful that the government will take it seriously and not issue a final rule," she said, but instead, "take a step back" and create a national commission, which she noted could be impaneled by the President or created by Congress.

"I think it would be a huge mistake to come out with a final rule along the lines of the NPRM and *then* create a national commission," she added.

Link to report, press conference and related materials: http://sites.nationalacademies.org/PGA/stl/researchregs/index.htm#meetings

Link to COGR/AAU/APLU statement: http://www.aau.edu/WorkArea/DownloadAsset.aspx?id=17871

Link to AAMC statement: https://www.aamc.org/newsroom/newsreleases/462770/national_academies_common_rule_06292016.html ✧

Awaiting Single IRB Guidance, Institutions Pack Webinars

With less than a year before NIH's single institutional review board (sIRB) policy goes into effect, organizations are nervously awaiting promised guidance from the agency and soaking up any information they can find.

Generally speaking, the policy is mandatory for any NIH funded "studies where the same research protocol is being conducted at more than one site" domestically *(RRC 7/16, p. 1)*. It applies to "all competing grant applications (new, renewal, revision, or resubmission) with receipt dates on or after May 25, 2017."

Since the policy was announced on June 21, NIH has issued a two-page, 10-question FAQ document. Mostly basics are addressed that were already expressed in the policy itself, but the document does clarify a few issues.

For example, it notes that "[p]articipating sites are also responsible for meeting other regulatory obligations, such as obtaining informed consent, overseeing the implementation of the approved protocol, and reporting unanticipated problems and study progress to the sIRB."

In addition, agency officials have authored various posts about the policy.

However, NIH has not yet published promised guidance that will address a number of issues, including "considerations" in choosing an IRB, IRBs' roles and responsibilities, and sample authorization agreements.

Two Webinars Offered So Far

Organizations have stepped in to help prepare compliance officials and investigators, and they are seeing a huge response.

On July 11, the Association of American Medical Colleges (AAMC) held a webinar on the sIRB policy; the speaker was Heather Pierce, senior director for science policy and regulatory counsel. The webinar drew some 350 participants.

Pierce told *RRC* the "magnitude" of the change the policy will bring isn't yet clear, and AAMC wants to hear from member organizations about the resources they will need to comply.

A day later, the organization Public Responsibility in Medicine and Research (PRIM&R) held its own 90-minute webinar, Navigating the New Reliance Agreement Landscape, which attracted approximately 800 participants. The webinar had "the highest turnout we've seen for a paid webinar on a human subjects protections topic in recent years, and the second-highest registration since we began doing webinars in 2005," a PRIM&R spokeswoman told *RRC*.

A poll conducted at the start of the webinar indicates organizations have some familiarity with single IRBs.

Sixty-seven percent said their institution had served as either a relying or as a single IRB site, while just 7% said that they had been neither. About twice as many (16%) has been the sIRB, while 10% said they had been the relying site.

Featured speakers in the PRIM&R webinar were Tracy Ziolek, executive director of human research protections at the University of Pennsylvania, and Emily Chi Fogler, counsel with the law firm of Verill Dana LLP.

Both webinars are archived and available online. There is a cost to access PRIM&R's.

Link to AAMC webinar: https://www.aamc.org/initiatives/research/462768/nihpolicyonsingleirb.html

Link to PRIM&R webinar: http://www.primr.org/webinars/july2016

Link to NIH sIBR page, including FAQ document: http://osp.od.nih.gov/office-clinical-research-and-bioethics-policy/clinical-research-policy/models-irb-review ✧

Columbia Settles for $9.5 Million

continued from p. 1

However, the new case does share a connection with a different previous FCA settlement. McInnis is the same attorney who successfully represented a whistleblower in a 2003 lawsuit against Columbia. In that case, the university paid $5.1 million to settle FCA charges that it had billed Medicaid for services performed by midwives but claimed the care was rendered by obstetrician-gynecologists.

Other recent FCA settlements involving universities include $3 million paid by Northwestern University and $1.5 million paid by Emory University *(RRC 10/13, p. 1)*.

According to the government's documents, Columbia's "collaborative relationship" with the New York State Psychiatric Institute (NYSPI), run by New York state, calls for the two to share "certain staff, facilities and equipment" and "participate in joint research projects."

Under the terms of Columbia's F&A agreements with HHS, the university was required to apply the off-campus rate for "all activities within a 50 mile radius of campus and performed in facilities not owned and operated by the institution and to which rent is directly allocated to the project." It also specified that if "more than 50% of a project is performed off-campus, the appropriate off-campus rate will apply to the entire project."

Three Sites Were Involved

The university did not pay rent on the NYSPI research spaces, but in 2009 and again in 2011 made some adjustments in the arrangement. "During fiscal years 2009 and 2012, in lieu of rental payments, Columbia shared with NYSPI the indirect cost recoveries it received from NIH for certain sponsored research projects performed in the Kolb building, [for] which recoveries were calculated using the on-campus F&A rate." Two other NYSPI sites were also involved, known as the Pardes Building and the City Building.

The government reported that, in 2011, the New York State Comptroller "issued a report recommending… fair consideration from Columbia" for the NYSPI, after which time "Columbia began reimbursing New York State for the operating expenses, utilities, and telephone costs associated with space" at the Kolb and Pardes buildings.

McInnis, who declined to make Chisholm available for an interview, said his client knew the on-campus cost rate was being inappropriately applied and brought it to Columbia's attention, to no avail. The FCA suit was filed on July 19, 2013, and amended on Dec. 13, 2013.

In his suit, McInnis alleged the higher rate was inappropriately applied to several dozen grants, a number the government later found to be 432, including some subawards. The U.S. court documents indicate the research was "primarily performed in space not owned or operated by Columbia."

"Columbia periodically submitted to NIH certified Federal Financial Reports that used the on-campus F&A rate to calculate the indirect cost rate amounts claimed by the university for the Covered Grants," the suit adds.

The university should have disclosed that the research would be conducted off-campus when it was applying for the funds, the U.S. documents indicate. "Furthermore, Columbia did not state on the applications for the NIH Grants that the research would be primarily perfonned (sic) off-campus. HHS' guide for preparing these applications states that 'the Primary Location should be that of the applicant organization or identified as off-site in accordance with the conditions of the applicant organization's negotiated Facilities and Administrative (F&A) agreement.' SF424 (R&R) Application Guide for NIH and Other PHS Agencies, Section 4.3."

"However, Columbia did not designate the NIH Grants as offsite and instead frequently included the main address for the College of Physicians & Surgeons in the section of the application that was supposed to list the primary performance location. Even where the NYSPI Buildings or the City Building were listed in that section of the grant application, or mentioned elsewhere in the application, Columbia failed to disclose that these buildings were not owned and operated by the university," the suit says.

The Department of Justice did not respond to *RRC*'s request for information about the settlement, including whether it intends to pursue action against any individuals associated with the over-billing. The settlement leaves this possibility open, and requires Columbia to cooperate if this does occur.

Chisholm no longer works at Columbia and did not face any retaliatory actions by the university, said McInnis, who was unable to provide the dates of his client's employment.

continued

Of the $9.5 million, Chisholm will receive $1.995 million, equal to 21% of the settlement amount, with a portion of Chisholm's share going to McInnis' firm.

The university did not respond to specific questions from *RRC* about the settlement, but provided a statement indicating it believed its actions were allowable.

"Columbia is committed to compliance with all requirements for federal grants. In this case, Columbia believed in good faith that it was appropriate to apply an 'on campus' indirect cost rate to research performed by Columbia faculty in certain buildings owned by the state or city that are located on our medical center campus, and Columbia openly and consistently disclosed the rate applied to these buildings in its grant applications," the statement said.

"The government disagreed with the University's approach and took the position that a lower 'off campus' indirect cost rate was appropriate. We are pleased to put this dispute behind us and resolve the matter. Columbia looks forward to continuing to work cooperatively with its valued research partners in government," it said.

COFAR Posts UG Training Seminars

The Council on Federal Assistance Reform (COFAR), an intergovernmental agency, has posted a series of training videos on complying with the Office of Management and Budget's Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards, also called the Uniform Guidance (UG).

The purpose of the videos is to share what COFAR calls "promising practices" in meeting the requirements of the UG, which was published in the *Federal Register* in December 2014; most provisions went into effect a year later. Universities and others are hopeful that requirements for procurement will be delayed further *(RRC 7/16, p. 5)*.

Panels were held on risk assessment; contract versus subaward; subrecipient monitoring; personnel practices; indirect cost rates; and single audits and the Cooperative Audit Resolution and Oversight Initiative.

Videos of each panel are posted, along with documents referred to during the discussions.

Link: https://cfo.gov/2016/07/05/july-2016-uniform-guidance-promising-practices-in-implementation.

What If Attorneys Are Wrong?

The settlement shows that universities and others need to assure they are accurately applying the correct indirect cost rate, particularly when space is shared. McInnis told *RRC* he was not sure how frequently similar arrangements might be occurring with other universities, but suggested it could be "more rare than commonplace." For him, what was notable about this case was that the government was not deterred by Columbia's explanation of why it had chosen the higher F&A rate.

McInnis said he was "very heartened" that the government "aggressively pursued this case" despite the fact that Columbia "had received a legal opinion that could be interpreted to mean what they were doing was OK."

"People are getting these legal opinions and putting them in their files, then pulling them out" years later when actions are questioned, claiming the "reliance on advice of counsel" defense, McInnis said.

He called this situation "something that needs to be addressed on a policy basis, a contracting level" with NIH. In his view, funding terms and conditions should require grantees to alert NIH "that they may not be compliant" and that they have sought an "outside opinion."

Of course, one option for an organization on the losing side of an FCA case is to turn, itself, to the judicial system for relief if it believes it got bad legal advice. That's exactly what happened just days before the Columbia settlement was announced.

Advisers May Be Subject to Lawsuits

In 2013, Tuomey Healthcare System in Sumter, S.C., refused to settle when it was accused in a whistleblower suit of violating physician referral laws. With the help of a law firm, it continued to defend its practices and the case went all the way to a jury trial — reportedly the first FCA case to do so — and Tuomey lost.

A jury found the system had submitted $39 million in false claims based on illegal physician contracts.

The verdict was upheld on appeal and the hospital faced a payment of $237 million for the violations. On July 12, it sued the law firm of Nexsen Pruet for providing what it called "misleading and reckless" legal advice that reportedly had sanctioned the referral contracts Tuomey had established more than 10 years earlier.

The health system is seeking $117 million in damages from the law firm.

Link: https://www.justice.gov/usao-sdny/pr/manhattan-us-attorney-announces-95-million-settlement-columbia-university-improperly ✧

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.*

◆ **The HHS Office of Research Integrity (ORI) has debarred Zhiyu Li, a former postdoctoral fellow at Mount Sinai School of Medicine, for having "intentionally, knowingly, and recklessly engaged in research misconduct."** Li's actions include "falsifying histopathological data reported in fifty-seven (57) images in two (2) published papers, one (1) submitted manuscript, two (2) poster presentations, and seven (7) of Respondent's supervisor's grant applications and fabricating the corresponding nineteen (19) summary bar graphs that were based on those false images," ORI announced on July 20. The agency said the false data and images were used to "depict the effects of recombinant [Clostridium perfringens] Cp strains on their ability to destroy cancer cells in a murine model, when these bacterial strains were not produced nor the data derived from them." Under the terms of the five-year debarment, which began July 3, Li is also prohibited from advising the government. The case is related to ORI's misconduct action against Li Chen, a post-doc in the same lab as Li, who was debarred for three years beginning April 11, 2014 (*RRC 5/1/14*). Two papers for which they were coauthors have been retracted, according to the notice. *(7/21/16)*

◆ **In a notice in the *Federal Register* seeking comment on a fairly routine request to extend a series of information collections related to human research studies, the Food and Drug Administration (FDA) revealed it disqualified one institutional review board this year and expects to issue notices of non-compliance to seven IRBs during a one-year period.** No information was provided about the disqualified IRB. According to federal regulations, an IRB can be disqualified under several conditions, including when it "has refused or repeatedly failed to comply" with applicable regulations; notice of a disqualification may be published in the Federal Register. "To date, no IRB or institution has been reinstated or applied for reinstatement," FDA added. The agency is seeking comments on the information collections by Sept. 19. *(7/21/16)*

◆ **Oregon Health and Sciences University agreed to pay the HHS Office for Civil Rights (OCR) $2.7 million following two separate incidents in 2013, OHSU announced July 13.** It did not release an accompanying, "rigorous," three-year corrective action plan, and OCR had not issued the expected announcement as of *RRC*'s deadline. "The first incident involved a stolen laptop and the second resulted from the use of an internet-based information storage service, or 'cloud storage' service, without a business associate agreement," OHSU said in a statement, adding there is no evidence of misuse of the data for the 7,066 affected patients. "We made significant data security enhancements at the time of the incidents and now are investing at an unprecedented level in proactive measures to further safeguard patient information," the statement said. In related news, OCR issued a new warning alerting all HIPAA covered entities of the threats posed by ransomware, and how to respond following an attack, including factors to consider when there is a demand made for payment. OCR sent notice of the guidance in an email to list servs, and it was also the subject of blog post on July 11. The post notes that a ransomware attack "usually" results in a reportable breach. The guidance includes a separate FAQ document and a letter from HHS Secretary Sylvia Burwell to chief information officers, dated June 20. *(7/14/16)*

◆ **The Animal and Plant Health Inspection Service (APHIS), part of the U.S. Department of Agriculture, recently posted a May 26 letter to the University of Texas-El Paso, warning that it violated provisions in the Animal Welfare Act related to the deaths from dehydration of two male prairie voles in 2015.** "At the time of the inspection, there were no documents indicating that an investigation had been initiated" by the institutional animal care and use committee regarding the deaths, a July 1, 2015, related inspection report states. The report stated that UT lacked "a mechanism of direct and frequent communication…at this research facility to assure that timely and accurate information regarding animal health issues is conveyed to the attending veterinarian." APHIS said these two issues were to be corrected by July 10, 2015. UT was also cited for violating requirements related to providing adequate water for animals. *(7/14/16)*

In This Month's E-News (continued)

◆ **Alexander Neumeister, M.D., former head of the molecular imaging program at New York University (NYU) School of Medicine, conducted psychiatric research without providing appropriate oversight, states a Feb. 6 warning letter issued by the Food and Drug Administration (FDA),** which cited a host of problems uncovered in two protocols during an inspection from July 16-Aug. 5 of last year. Among the issues were falsification of records and failure to confirm "the accuracy of a diagnosis for 13 of the 14 enrolled subjects." The industry-sponsored research involved subjects with post-traumatic stress disorder, according to an investigation by *The New York Times (NYT),* which quoted Charles Marmar, chairman of the psychiatry department, who confirmed that Neumeister had resigned as a result of the issues and that a total of eight psychiatric trials were terminated. Neumeister's attorney told the *NYT* there was a difference of opinion as to the seriousness of the problems. Both Marmar and Neumeister's attorney said no subjects were harmed, according to the *NYT*. The publication also interviewed a female participant who blogged about her experiences, including having to stop her medications five times due to "false starts" of the research. View the *NYT* article at http://www.nytimes.com/2016/06/28/health/nyu-cannabis-ptsd-psychiatry.html. View the warning letter at http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2016/ucm493086.htm. *(6/30/16)*

◆ **The single institutional review board model used by NIH's National Center for Advancing Translational Sciences (NCATS) is an example of a "flexible and user-friendly toolkit"** that may be considered now that NIH has mandated the use of a sIRB for NIH-funded multisite trials (*RRC 7/16, p. 1*). Michael Lauer, NIH deputy director for extramural research, and Carrie Wolinetz, associate director for science policy, said in a June 21 post on Lauer's blog, Open Mike, that the mandate, effective May 25, 2017, "presents a unique opportunity to harmonize the standards and agreements used in clinical research." NCATS calls the model the Streamlined, Multisite, Accelerated Resources for Trials IRB Reliance Platform. It already is used by "several" centers for translational science awards, and the goal is for all to adopt this model, they wrote. *(6/23/16)*

◆ **The actions of a mass spectrometer operator working at the U.S. Geological Survey's (USGS) Energy Geochemistry Lab in Lakewood, Colo., may have led to false readings used by scientists engaged in $108 million in funded research from 2008 to 2014,** according to a report by Department of Interior Office of Inspector General (OIG). "In the long run, we determined the scientific misconduct and data manipulation also impacted USGS organizational integrity in ways that are still unfolding and difficult to quantify," the report said. "Although USGS closed its Inorganic Laboratory on February 25, 2016, it still has not informed its many stakeholders about the scientific integrity incident and how it may potentially have impacted them. Our one recommendation to USGS was to complete this notification process." *(6/23/16)*

◆ **Following the controversy over a 2014 audit that was missing findings including that a contractor had used management fees for items such as alcohol, the National Science Foundation (NSF) OIG has issued audits of NSF and two contractors, the National Ecological Observatory Network (NEON) and the Association of Universities for Research in Astronomy (AURA) *(RRC 5/15, p. 1)*.** Both dated June 13, one audit of NSF's "negotiation, award and management fees" concluded the agency "did not have policies and procedures on negotiating reasonable management fee rates at the time NSF awarded AURA's and NEON's cooperative agreements." NSF agreed with four of OIG's recommendations for changes, saying some were already implemented, the auditors said. The second report is a "performance audit" covering October 2011 to September 2014 that concluded "NEON's use of management fees was not in accordance with its NSF proposals, and that a significant portion of the fees were not used for ordinary and necessary expenses to facilitate basic business operations." According to the audit, funds "provided as management fees were used to pay for lobbying, alcohol, and entertainment, among other things." OIG made five recommendations, including that NEON "[d]evelop policies and procedures for reporting to NSF annually regarding its actual use of management fees" to NSF. In response to OIG's findings and recommendations, NEON officials said that while they "do not dispute the audit or the facts contained therein," NSF guidance on the use of management fees was not in effect so the firm was "not in violation of any existing guidance at the time." *(6/23/16)*

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