Report on
RESEARCH COMPLIANCE

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

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HHS OIG, UC Riverside at Odds in Final Audit of FDP Payroll Certification Pilot

Buried in the voluminous documents the University of California Riverside (UCR) submitted to the HHS Office of Inspector General (OIG) in response to draft findings saying its experimental payroll certification system "did not provide accountability" was a piece of good news. "Thank you for confirming that HHS OIG is not seeking remuneration, repayment, financial penalties, debarment from federal grants, or disgorgement related to the results of the audit," wrote Chancellor Kim Wilcox.

Were this a typical audit, HHS OIG conceivably could have requested NIH, UCR's funding agency, to claw back *$17.6 million*. But, fortunately for UCR, it was not a typical audit, and OIG called $17.6 million in claimed costs "at risk" rather than "questioned." For its part, UCR is writing a "rebuttal" to the final report, a spokesman told *RRC*. He declined further comment.

Released Feb. 13, the UCR report joins three previous pilot payroll certification audits that likewise had puzzling and mostly negative findings. The four-university pilot was conceived by the Federal Demonstration Partnership (FDP) as an alternative to effort reporting, a burdensome method that has led to cost sanctions (*RRC 1/9, p. 6)*.

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Jailed Researcher Cited Family, Funding Woes for $3.3 Million Device Fabrication

For the second time since 2015, a government-funded scientist's acknowledged deceit has unraveled, leading to his incarceration and a multi-million dollar repayment. On Feb. 1, S. Darion Kinion, Ph.D., began serving 18 months after pleading guilty to one count of mail fraud. This followed an admission that he shipped what the government termed "bogus" parts that were supposed to represent evidence of his advances in the Axion Dark Matter Experiment to colleagues at another research lab.

Kinion, who was 44 at the time of his guilty plea last June, also is required to make restitution of $3.3 million, of which approximately $750,000 is supposed to go back to Lawrence Livermore National Lab (LLNL), his former employer. Funding came from the Intelligence Advanced Research Projects Activity (IARPA) of the Office of the Director of National Intelligence, which is supported by the Department of Energy.

While it has garnered far less attention than that of an Iowa State University (ISU) lab manager serving time for doctoring HIV vaccine tests, Kinion's case shares much in common and is worthy of examination for the circumstances that led to the fraud, as well as the red flags and missed cues that characterize both cases. Of note: in both situations, criminal charges followed findings of misconduct made by the investiga-

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tor's home institution. In addition, the investigators either admitted or were described as feeling isolated and trapped and engaged in the fraud to avoid the shame of failure, rather than personal enrichment.

The ISU case involved Dong-Pyou Han, Ph.D., who confessed in 2013 that he'd spiked rabbit sera with human HIV antibodies, an admission that led to the imposition in 2015 of a 57-month prison sentence *(RRC 8/15, p. 1)*. Han also is required to pay back $7.2 million, while ISU kicked back $2.5 million to NIH, which included the cost of Han's salary *(RRC 8/15, p. 3)*.

Comparatively more is known about what went wrong in Han's situation than in Kinion's, thanks to a trove of documents ISU released under state open records laws. ISU officials also made comments to *RRC*.

LLNL, in Livermore, Calif., did not answer questions *RRC* posed about its investigation and offered minimal responses to other queries, citing "personnel" issues. And although Kinion's attorney, James Vaughns, said his client was preparing replies to questions from *RRC*, he later stopped responding to e-mails and no responses were received by the end of the week *RRC* had given to meet the deadline for this issue.

Basic information about Kinion's situation can be gleaned from a government press release announcing the sentence, while more telling details are revealed in the sentencing memorandums and their responses submitted by government prosecutors and Vaughns. The memorandums frequently refer to a pre-sentence report conducted for the court; the report itself is not public. Other specifics can be found in the transcript of Kinion's plea hearing.

Particularly telling is a statement Kinion made during that hearing. "I was part of a research project that was going bad towards the end, so in an attempt to buy more time for the projects, I mailed a package through FedEx that contained parts that were not as I represented them," Kinion said. The package was sent to the Lincoln Laboratory at the Massachusetts Institute of Technology (MIT).

Vaughns argued for probation, contending a confluence of "internal" and "external" factors led to the fraud, which he said was confined to the period from January of 2012 to sometime later that year. Vaughns also noted that Kinion was a first-time offender, and said any repayment amount should be limited and reflect the value of equipment that can still be used. But the federal prosecutors pushed for a sentence of 57 months and called all of the government's $3.5 million investment, which ran from 2009 to 2012, a loss. While the government did not prevail on the jail term, it won on the restitution amount.

LLNL Found Misconduct in 2012

None of the court documents mention LLNL's role in this situation, but apparently it began four years before Kinion was sentenced. Lynda Seaver, LLNL spokeswoman, told *RRC* it conducted a misconduct investigation "in summer 2012" and that "Kinion was cooperative. He was placed on leave pending the outcome of the investigation; following the investigation his employment was terminated."

At the time Kinion's misconduct was uncovered, he had been with LLNL in some capacity for a dozen years. Kinion earned a B.S. in physics and electrical engineering from MIT and a Ph.D. in applied science from the University of California (UC) Davis. He was engaged in post-doctoral studies at both LLNL and UC Berkeley from 2001 to 2004. According to the sentencing recommendations submitted by Vaughns on Kinion's behalf, he became a "staff scientist" at LLNL in 2004.

LLNL confirmed Kinion had committed misconduct, but Seaver did not respond to *RRC*'s question about what type nor how the investigation was conducted.

"This is a personnel issue and so there are few details on Mr. (sic) Kinion that I will share on this matter. Scientific integrity is a hallmark of Lawrence Livermore's research and development. When the Lab discov-

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ered some inconsistencies in what he was reporting, it began an investigation into his work," said Seaver.

After LLNL's investigation in 2012, the findings "were turned over to the Department of Energy, which then turned its information over to the Department of Justice, who determined what Kinion would be charged with and how the case would be prosecuted," Seaver told *RRC*.

Equipment Reportedly Never Used

It is not clear what happened from 2012 to 2016, but the case moved quickly last year. Kinion was charged on March 8, pled guilty on June 14 and was sentenced on Dec. 20. He reported to prison a month-and-a-half later. The case was handled by Judge Jeffrey S. White of the U.S. District Court for the Northern District of California.

The restitution amount is based on the government's "total loss amount" calculation of $3,584,893 minus the $267,000 cost of a fabrication system that IARPA "was able to redesignate…to another research team in furtherance of IARPA's research program interests." The government also said, "IARPA received a negotiated settlement from LLNL of $756,533."

The government's sentencing memorandum for the case states that, from 2008 to 2012, IARPA awarded Kinion "millions of dollars…to design, build, and test experimental components in the field of quantum mechanics" at LLNL, but that he "never setup and/or operated the equipment that he purchased with $539,000 of IARPA funds for his research project."

Testifying during the plea hearing, Jeffrey Shih, the assistant U.S. attorney assigned to the case, said that Kinion "repeatedly falsely reported and represented to IARPA and to IARPA's testing and validation team that he had successfully built components at Lawrence Livermore using a fabrication system purchased with IARPA funds, that he had successfully tested and obtained results from components at Lawrence Livermore at low temperatures, specifically less than 4 Kelvin, using a dilution refrigerator purchased with IARPA funds, and that he had successfully tested and obtained results from components in Lawrence Livermore at high frequencies, specifically, more than 2 gigahertz."

But Kinion, said Shih, "knew that all of these reports and representations were false because he never used the fabrication system that he purchased with IARPA funds to build any components. He never operated the dilution refrigerator that he purchased with IARPA funds to test the components, and he never conducted the high-frequency test at Lawrence Livermore or any other location for IARPA."

The government maintained in its sentencing memorandum that when IARPA officials tried to "validate" Kinion's "purported results," he "resorted to more deceptive measures to conceal his fraud, including mailing `bogus' components that other scientists wasted time testing, altering Federal Express mailing labels for packages that other scientists wasted time looking for, and conducting a 3-day charade experiment in an effort to fool another scientist. As a result of the defendant's fraud, IARPA lost not only the approximately $3.5 million it invested in the defendant's research, but also the time it allocated to the defendant in its research program for the intelligence community."

In his sentencing memorandum, Kinion admitted he "began missing the milestones" required of his awards as early as 2010, following the death of his mother and the birth of a "severely developmentally disabled" son. At the same time, he was struggling to acquire helium gas needed for his work, which was in short supply nationally.

Kinion also alleged a number of financial improprieties at LLNL, stating that he was "pressured to falsely attribute costs to other projects…and to pad his expenses and encouraged to choose expensive line items over less expensive ones. He disclosed some of the overhead issues to IARPA and was chastised by LLNL because of it." The environment at LLNL, he said, was one of "big waste and a musical chairs system of financial accounting."

Kinion Paints Bleak Portrait of 'Culture'

Winning funds from IARPA, Kinion claimed, thrust him into an "on-going fiscal culture of 'spend it or lose it' at the upper academic echelons of scientific research." According to his sentencing memorandum, Kinion "found himself in the highly competitive arena of universities vs. LLNL as each sought to be the first to make scientific discoveries. Unfortunately, he also discovered a penny pinching process at the lower—application—echelons where he was. His funding would continually run out in March of each year. He would have to make do with what was left over in terms of materials and supplies until more funds were allocated in October. The deficits were mostly occasioned due to a disconnect between LLNL and IARPA in that LLNL had nothing needed to dive into quantum computing on the scale anticipated by IARPA at the inception of the project."

But, in the words of the government, "external factors were not the causes of his fraud." In his response to Kinion's sentencing memorandum, Shih said Kinion alone had acted to defraud the government so that his funding would not be cut off for "non-performance," as he had seen IARPA do with other research teams.

Kinion also maintained that he "understood that MIT-LL was tasked with fabricating the components. It is true that he was the primary scientific investigator on the project. As such, though, his 'work' was cerebral. He had hoped to delegate the relatively mundane task of building to others. MIT-LL had dedicated groups—already up and running—that could have fabricated any components far easier and more efficiently that he could," Vaughns wrote. "There was nothing novel about the equipment—what was novel was the idea."

Again, the government rejected this position, calling it simply "not true" and noted that multiple teams had been funded, independent validation was required, and that, under the terms of his award, Kinion had "promised that he would build, test, and provide experimental components and fraudulently represented repeatedly that he was doing so."

Prosecutors, quoting the presentence report in their memorandum, delved somewhat into the psychological aspect of Kinion's misdeeds.

Kinion "has had a history of social and interpersonal difficulties in relating to others, which includes the fact that he has been unable to admit or discuss his conviction with anyone in his personal life," they said. "These difficulties may have played a part in the defendant's egregious criminal conduct in the instant offense, where he was similarly unable to tell any of his peers earlier that he was not doing the work IARPA funded him to do. As such, these difficulties may provide some insight into why the defendant defrauded IARPA—primarily to maintain his job and to earn peer accolades, instead of primarily for personal financial gain."

Such statements echo descriptions of Han, the imprisoned former ISU HIV researcher. In his case, Han, a South Korean immigrant, had worked for 15 years at two institutions with Michael Cho, Ph.D., professor and Lloyd Chair in Biomedical Sciences at ISU's College of Veterinary Medicine. Cho is co-director of its Center for Advanced Host Defenses, Immunobiotics, and Translational Comparative Medicine. Han was the manager for Cho's lab that was conducting HIV research.

In a signed confession, Han said an accidental cross-contamination had led to false positive results and that he "deeply regretted" not being able to tell Cho what had happened. Han reused the falsified samples and created others, keeping up the ruse for nearly five years before being caught.

But unlike Kinion, Han was only prosecuted following an outcry over his penalty for his admitted misconduct. He had agreed not to receive federal funds for three years under a voluntary settlement with the HHS Office of Research Integrity, which investigates misconduct in Public Health Service funding. His imprisonment was one of only a handful of such sentences meted out and was based on a plea to charges of making false statements.

After Han's case, some said settlement agreements are not sufficient and that the government should pursue criminal charges and repayment more aggressively. And it may have done just that with Kinion, who does not appear to have faced any punishment for the misconduct itself. These penalties range from supervision when engaged in research to lifetime debarment from receipt of federal funds.

Link: http://tinyurl.com/hu8gbod. ✧

Common Rule May Save Tasks But Heavy Lifting Comes First

After years of reviewing draft proposals, submitting comments and waiting, waiting and more waiting, universities that conduct human subjects research are eager to implement provisions in the new final Common Rule, as the regulation implementing 45 CFR part 46 is known.

Published in the Jan. 19 *Federal Register* five years after the first draft was released, the rule contains provisions that should reduce regulatory burdens for universities and institutional review boards (IRB) *(RRC 2/17, p. 1)*.

Discontinuation of IRB continuing review for some already approved research is one such provision. Another is the ability to use "limited" IRB review for studies. But understanding the nuances of the rule and implementing provisions without creating more work is challenging. Arizona State University (ASU) is among those now plotting how to proceed.

Common Rule provisions, Debra Murphy, senior compliance advisor at ASU's Knowledge Enterprise Development, pointed out, include "enhancements to the informed consent process," and others that are "adding to and modifying the exemption categories, eliminating the need for continuing review for many covered studies, and mandating the use of single IRB for cooperative research."

Many of the provisions are interwoven with, and dependent on, others. In terms of possible efficiencies, institutions may want to zero in on the limited review and continuing review.

At ASU, "the first action item for us will be to consider all the changes and dive deeply into institutional policy and procedures to begin making the necessary adjustments and revisions and gaining institutional approval," Murphy told *RRC*.

Added Murphy, "Like others, we are [at] the very infant stages of determining how we will proceed. Conceptually, we agree that changes to the continuing review requirements will reduce the administrative burden to both investigator and IRB staff. However, we believe the jury is still out on how beneficial it will be to implement this change."

'Expedited' Trials May Qualify

The final Common Rule, as the preamble summarizes, "removes the requirement to conduct continuing review of ongoing research for studies that undergo expedited review and for studies that have completed study interventions and are merely analyzing study data or involve only observational follow up in conjunction with standard clinical care."

This is a change from current requirements, or what the final rule calls the "pre-2018 rule," which mandated that "IRBs conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year. Except when an expedited review procedure was used, continuing review of research was to occur at convened meetings at which a majority of the IRB members are present, including at least one member whose primary concerns are in nonscientific areas."

Continuing review is no longer required for protocols that meet the following specifications (the blank refers to the specific numbers for the government agency):

- the research was "eligible for expedited review in accordance with §__.110," unless the IRB determines otherwise;
- the research was reviewed under convened IRB procedures (not expedited) that has "progressed" to consist of "data analysis, including analysis of identifiable private information or identifiable biospecimens" and/or "accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care (at §__.109(f)); and"
- the research was "reviewed in accordance with the limited IRB review procedure described in §__.104(d)(2)(iii)."

"We estimate that 108,873 expedited continuing reviews of protocols occur annually," government officials wrote in the preamble to the final rule. Of these, approximately 25% may automatically qualify to skip continuing review (because of the expedited categories and other provisions). But the rule implies continuing review may still occur for up to half of those that are not automatically free of this requirement.

As the rule notes, "if an IRB chooses to conduct continuing review even when these conditions are met, the rationale for doing so must be documented according to a new provision at §__.115(a)(3). We estimate that 40,773 reviews will require documentation of the rationale for doing so."

To take advantage of this change, institutions will need to know which studies in their portfolio qualify to skip continuing review. They'll also need to determine—and document—instances when they believe continuing review should be maintained.

This may prove to be a big task, at least initially.

"We have right at 1,350 active protocols that currently require annual review," said ASU's Murphy. "To pick through them individually would be a cumbersome process that would require looking individually at each study to determine if annual review is warranted moving forward."

To implement the continuing review provisions will require a reconfiguration of ASU's "system of record" to "manage and document the process," said Murphy. "This will ensure a consistent review of each protocol in a stepwise fashion and bring the project to closure in a timely manner."

Final decisions haven't yet been made, Murphy said, but the limited review provisions are among the "likely candidates for a phased implementation schedule."

"Policies and procedures for making determinations for when continuing review is required and the process of performing limited review will be required" at ASU, Murphy said. "In addition, it will be necessary to develop and provide continuing education opportunities for investigators, the IRB and staff who provide initial vetting and processing. Policy changes should be straight forward when implementation occurs."

But, as with complicated changes, "procedures that provide guidance on implementing the changes will be quite a bit more cumbersome and time consuming to develop and will take an institutional commitment to educating the IRB users, staff and committee," Murphy said.

RRC asked Murphy if ASU was planning to select studies that no longer need a review, and if so, whether this would be a complicated process. Murphy said ASU had not decided how best to tackle this task, and it will need to ensure changes don't add more work.

Among the strategies ASU is "considering is to make that determination at the next regularly scheduled annual review to make efficient use of faculty time, staff time and computing resources," Murphy said. "We use our system of record to send out annual reviews so we will also need to reprogram that process and update the programming as well."

After the continuing review provisions, the next to be implemented at ASU may be "the allowances for review under the exemption criteria, and finally the single IRB provisions," according to Murphy.

Limited Review for Privacy Safeguards

The limited review provisions may be especially confusing. These come into play with exemptions under the final rule.

In a recent webinar on the Common Rule, Pearl O`Rourke, director of human research affairs at Partners HealthCare Systems in Boston, pointed out that it is important to "understand that limited IRB review is a descriptor," and is "really not a new category of review." During the webinar, sponsored by Public Responsibility in Medicine and Research (PRIM&R), she noted that there are "different types of limited review." (For more information, see http://www.primr.org/webinars/commonrule.)

Under the final rule, "the provision at §__.109(a) has been modified to clarify that IRBs have the authority needed to conduct limited IRB review."

As the rule states, the limited IRB review will focus on privacy safeguards for some of the exemption categories.

"To accommodate the fact that the final rule does not include the privacy safeguards, exemption categories in the final rule that are predicated on the need for some type of privacy safeguards will instead require that an IRB conduct a limited review to ensure that adequate provisions are in place to protect the privacy of subjects and to maintain the confidentiality of data," the rule states.

These are as follows:

◆ "The exemption for research that includes only interactions involving educational tests, survey procedures, interview procedures, or observations of public behavior regardless of the identifiability or sensitivity of the information collected/recorded (§__.104(d)(2)(iii));"

◆ "The exemption for research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses or video recording (regardless of the identifiability or sensitivity of the information collected/recorded (§__.104(d)(3)(i)(C));"

◆ "The exemption for the storage or maintenance of identifiable private information or identifiable biospecimens for which broad consent is required, when there is a change specific to the research activity in how the identifiable private information or identifiable biospecimens are stored and maintained (§__.104(d)(7)); and"

◆ "The exemption for the secondary research use of identifiable private information or identified biospecimens for which broad consent is required (§__.104(d)(8))."

In addition, under exemption 7 (biospecimens), the IRB limited review "must determine that broad consent for storage, maintenance, and secondary research use of identifiable biospecimens or identifiable private information is obtained in accordance with the requirements of §__.116(a)(1)-(4), (a)(6), and (d)."

Further, "the IRB would review the appropriateness of the process proposed for obtaining broad consent, and ensure that the required elements of broad consent were appropriately included in the broad consent form (or process, if broad consent is to be obtained orally). Additionally, the IRB must determine that consent is appropriately documented, or that a waiver of documentation is appropriate, in accordance with §__.117."

The Secretary of HHS will develop guidance on "protecting the privacy of subjects and maintaining the confidentiality of data" that will be considered as part of limited review.

Link to final Common Rule:

https://www.federalregister.gov/d/2017-01058. ✧

New NIH FAQs for Single IRB Mandate Address Related Costs

With just seven months to go before the effective date of its mandate for the use of single institutional review boards (sIRBs) in multisite trials, NIH has issued a dozen FAQs addressing how associated costs may be paid for with federal awards.

Under a policy announced last June, the mandate was scheduled to go into effect May 25 of this year *(RRC 7/16, p. 1)*. The research compliance community asked for a year extension but NIH granted only four months; the new effective date is September 25 *(RRC 1/17, p. 3)*. Among the reasons for the delay request was the lack of guidance from NIH on a number of related issues, particularly financial.

In the new FAQs, NIH has declined to offer specifics that some grantees were hoping would be addressed. For example, one question was whether there is a "ceiling" and a "standard formula for calculating sIRB costs."

Nope to both, NIH said in the document. The agency "has not established a prescribed ceiling or formula for sIRB costs. It is the recipient's institutional responsibility to determine and calculate sIRB costs. As with all charges to NIH grants, costs must be reasonable and necessary, allocable, consistently treated, and conform to

the limitations and exclusions as contained in the terms and conditions of award," NIH said.

However, expenses for an "independent" or "commercial" IRB are allowable as a direct cost, provided the IRB is "not affiliated with a research institution," "costs are not part of an institution's facilities and administrative rate" and the IRB does not have its own negotiated indirect cost rate.

Direct Costs Must Meet Requirements

According to the FAQs, institutions may charge IRB-related fees as direct costs "when material…to applicable awards based on actual usage of the services on the basis of a schedule of rates or established methodology."

The methodology must meet the requirements in 45 CFR 75.468, namely that it:

◆ "does not discriminate between activities under Federal awards and other activities of the non-Federal entity, including usage by the non-Federal entity for internal purposes" and

◆ "is designed to recover only the aggregate costs of the services. The costs of each service must consist normally of both its direct costs and its allocable share of all indirect (F&A) costs. Rates must be adjusted at least biennially, and must take into consideration over/under applied costs of the previous period(s)."

NIH also will not provide separate payments to help defray the "infrastructure" costs required to establish a system for sIRB oversight. "Infrastructure costs are typically allowable as F&A costs under NIH grants. NIH does not currently have a mechanism for providing additional funding to support sIRB infrastructure development," the FAQ states.

The new FAQs are posted on a dedicated sIRB page of NIH's Office of Science Policy, which includes other resources. See http://tinyurl.com/zvdgrka.

Link to FAQs: http://tinyurl.com/ztnhb8d. ✧

Another Teaching Hospital Pays Millions for HIPAA Breaches

The lack of encryption and inattention to previous security recommendations has led to a $3.2 million fine imposed on a teaching hospital in Texas, just one of four enforcement actions taken so far this year by the HHS Office for Civil Rights (OCR) for HIPAA violations.

The payment by Children's Medical Center of Dallas on Feb. 1, which was followed two weeks later by OCR's announcement of a $5.5 million settlement with a hospital system in South Florida, demonstrates how OCR is extending its 2016 enforcement spree. Indeed, OCR is on a pace to outdo itself. In just the first two-and-a-half months of this year, OCR has collected $11.375 million, compared to $24.5 million in all of 2016.

Last year's actions included the first settlement with a research organization. Feinstein Institute for Medical Research paid $3.9 million and agreed to follow a three-year corrective action plan (CAP) triggered by the theft of an unencrypted laptop *(RRC 5/16, p. 1)*. Also notable in 2016 were a $2.7 million settlement with Oregon Health and Science University and $2.75 million with the University of Mississippi Medical Center *(RRC 9/16, p. 7)*. As with Children's, these organizations say there's never been any evidence of misuse of the lost data.

OCR fined Children's Medical Center $1,000 a day for a series of breaches that OCR said were caused by failures to comply with the requirements for access controls ($923,000), device and media controls ($772,000) and for impermissible disclosures ($1.522 million). The amounts would have been higher but fines are capped at $1.5 million per year for "identical" violations. OCR identified six thefts or losses of devices containing unencrypted protected health information that occurred from 2008 to 2013: three laptops, one Blackberry, and an iPod. The total number of affected patients, according to OCR's data, was just 6,284.

Research institutions will also want to make note of the fact that OCR singled one specific failure to inventory all sources of electronic protected health information (ePHI).

"Prior to November 2012, Children's information technology (IT) assets were inventoried and managed separately from the inventory of devices used within its

Biomedical Department," OCR said. "Children's IT asset policies did not apply to devices that accessed or stored ePHI that were managed by the Biomedical Department. As Children's did not conduct a complete inventory to identify all devices to which its IT asset policies apply to ensure that all devices were covered by its device and media control policies, Children's was out of compliance with the Security Rule at 45 C.F.R. § 164.310(d)(l)."

The $1,000-per day fine is based on the category of fine called "reasonable cause," which ranges from $1,000 to $50,000 per violation. OCR can impose greater fines if it believes the organization is guilty of "willful neglect." OCR said it chose not to go higher "in consideration of Children's assertion…the alleged encryption noncompliance did not result in any known physical, financial or reputational harm to any individuals nor did it hinder any individual's ability to obtain health care."

Don't Ignore Recommendations

But what seemed to infuriate OCR the most during the six-year investigation was what it saw as Children's disregard for, or slow adoption of, safeguards identified by various consultants and even the HHS Office of Inspector General, which OCR revealed had conducted an audit of Children's in 2012. Children's was advised as early as 2007 that it should "implement encryption to avoid loss of PHI on stolen or lost laptops."

Still, according to OCR, "Children's issued unencrypted BlackBerry devices to nurses beginning in 2007 and allowed its workforce members to continue using unencrypted laptops and other mobile devices until at least April 9, 2013."

Another issue was rather low tech in comparison and emphasized the need for adequate physical safeguards. A laptop stolen in 2013 might have been taken by a "member of the janitorial staff," who had been given "unrestricted access to the area where the laptop was stored," according to OCR. Children's, the agency said, "did not provide encryption to protect the ePHI of this laptop from access by such unauthorized persons."

Children's payment to OCR came not as part of a voluntary settlement agreement, which is the usual way OCR resolves enforcement cases. OCR has made such agreements with 44 of the 47 organizations that it has taken enforcement action against since its start in 2008. With such agreements, organizations typically also pledge to follow a multi-year corrective action plan (CAP), which can be costly.

But in this case, Children's decided not to settle nor challenge the imposition of the $3.2 million fine, choosing instead to accept the penalty. In a statement, a Children's spokesman told *Report on Patient Privacy*, a sister HCCA publication, the following:

"For the past six years, the Office of Civil Rights has been investigating the loss of three electronic devices. Two of the devices contained patient information. We have fully cooperated with the investigation, and we have no reason to believe that any patient or their families were affected by the loss of these devices. We have decided to pay the imposed fine because the efforts to formally contest the claims would be a long and costly distraction from our mission to make life better for children. We remain committed to protecting the privacy of our patients."

The spokesman confirmed that Children's is not following a CAP but declined to answer any other questions.

Link: http://tinyurl.com/j4sq63y. ✧

UCR, OIG at Odds Over Audit

continued from p. 1

OIG took a remarkably dim view of both UCR's pilot method *and* the system it previously used, making a dozen sweeping recommendations. Using equally forceful language, UCR rejected nearly all of the findings and agreed with just one of OIG's 12 recommendations. "UCR was extremely disappointed with the opinions expressed in the draft report," Wilcox wrote.

As the UCR audit explains, the pilot payroll certification system "is a project-based process that relies on the Principal Investigator's (PI's) certification of a predetermined percentage of salary for each employee who is assigned to the PI's awards. The percentage of salary is determined by a finance or budget department in consultation with the [PI] of an award, and the PI receives this information when certifying that all salary and wage charges are reasonable in relation to the work performed."

Effort reporting, in contrast, "is a person-based methodology that allocates each employee's reasonable estimate of time worked on all awards and other activities. Historically, effort reports have been used as the main support for salary and wage charges to Federal grants and contracts, or other agreements (awards). Effort reporting reasonable estimate of time worked on all awards and other activities."

The pilot was proposed at a time when universities had less freedom to implement systems to verify salaries and was done to provide an alternative system that might be palatable to both the OIG community and the Office of Management and Budget (OMB). But since 2014, when OMB published "Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards," known as the uniform guidance

(UG), recipients of federal funds have been allowed to pay for salaries using systems that meet reasonableness and other required specifications under Section 200.430, Compensation-personal services *(RRC 2/14, p. 1)*.

So while the results of the pilot may have diminished in importance, the audits, this one in particular, lay out operational details that could prove useful to other universities considering a payroll certification system. Reviewing audit results may be especially useful because, despite initial plans, there is not going to be a final "roll-up" report on the four pilot sites, HHS OIG told *RRC*.

In the new audit, OIG said FDP believes the certification method "is preferable because (1) effort is difficult to measure, (2) effort reports provide limited internal control, and (3) effort-reporting systems may be expensive to implement and maintain."

Universities and others may want to give up effort reporting for another reason: it has been the target for multimillion-dollar settlements with the government over allegations of False Claim Act violations. For example, in 2014, Columbia University and affiliated institutions paid $9.08 million to settle allegations related to its International Center for AIDS Care and Treatment Programs for issues concerning effort reporting *(RRC 12/14, p. 4)*. Four years earlier, Yale University paid $7.6 million for problems related in part to effort reporting *(RRC 1/9, p. 6)*.

Old System Commanded More Attention

The UCR report comes two years after audits of the three other sites were issued: UC Irvine, George Mason University (GMU) and Michigan Technological (Michigan Tech) University. The HHS OIG conducted the audit of the UC campuses, while the OIG for the National Science Foundation (NSF) audited GMU and Michigan Tech. HHS OIG's audit of UC Irvine, based on data issues, officially had a "no-opinion" opinion *(RRC 2/15, p. 3)*.

NSF OIG concluded in its July 2015 audit that GMU "did not always comply with its documentation policies" *(RRC 9/15, p. 4)*. The question of adequacy of payroll certification itself was not specifically addressed in the audit, which focused heavily on alleged IT lapses. NSF OIG concluded that Michigan Tech's pilot certification system "generally provided accountability over federal funds" but that it "did not always comply" with its documentation policies for payroll transactions under the effort reporting process, as well as the payroll certification pilot (*RRC 10/8/15*).

UCR's audit covered 40 months, from Jan. 2, 2010, through March 31, 2012. For the first 15 months of this period UCR used an effort reporting system to manage salaries; it began the pilot certification program April 1, 2011. "From Jan. 2, 2010, through March 31, 2013, the University claimed $17,204,282 in reimbursement for salary costs applicable to 221 HHS awards," OIG said.

Auditors determined that 129 of 180 sampled salary transactions were "at risk." It put the "value" of the at-risk transactions at $254,497 and the associated facilities and administrative costs at $124,838. NSF OIG's data analytics team was involved in the audit, which the HHS auditors said included interviews with "nine PIs and other employees whose salaries or wages were charged to federal awards from which we selected our sample."

'Appropriateness of Adjustments' Questioned

One criticism was that 83 of the 129 transactions occurred under the prior effort reporting system (not the pilot). These transactions, which totaled $171,157, "were supported by personnel activity reports that did not separately identify nonsponsored activities," according to the audit.

In addition, of the 46 remaining transactions, 12 "totaling $30,187 under the pilot PCS had Payroll Certification forms certified by PIs, but the Payroll Certification forms showed that the PIs had not charged any of their own salary to the awards. The University did not provide any other evidence that these PIs had worked on these awards or had the requisite knowledge of the work performed on these awards," OIG said.

OIG also took issue with 12 different salary transactions totaling $12,436 that it said UCR charged for "administrative and clerical salaries as direct costs under the pilot PCS." OIG charged that UCR "provided no evidence that the awards required an extensive amount of administrative support."

Moreover, auditors singled out nine transactions in the pilot, totaling $15,542, that were "identified in its accounting records as adjustments" but that "did not match the Payroll Certification forms or any other documents that the University provided." OIG also contended that the pilot system "did not ensure the appropriateness of adjustments made after grant expenditures were reported to the Federal Government. PIs adjusted the amounts charged to Federal awards after Payroll Certification forms had been certified without (1) prior supervisory approval, (2) documented justification, or (3) amending the Payroll Certification forms."

Regarding the 83 at-risk transactions under the old system, OIG said its "concern was about having enough information to verify that salaries are reasonable in relation to the work performed."

"Summarizing nonsponsored activities into a single category on the University's personnel activity form does not provide the transparency needed to verify the

percentage of effort spent on nonsponsored activities such as instruction, departmental administration, and departmental research," OIG said. "Therefore, we do not agree that the University's former effort-reporting system complied with OMB Circular A-21 requirements or that the number of at-risk transactions we identified are overstated."

Turning to the pilot, auditors expressed "serious concerns." At the time of the audit, "there were inadequate controls in place, especially those controls enabling the PIs to verify that salary and wage charges made to a Federal grant were reasonable in relation to the work performed. Although the University's pilot PCS relieves administrative burden by requiring only one certification per award each year, the characteristics of the system limit its usefulness in providing accountability over the use of Federal funds and therefore put Federal funds at risk," OIG said.

PIs Faced 'Extraordinary Responsibility?'

OIG contended that the pilot system placed "extraordinary responsibility" on PIs "with little to no oversight, resulting in a system that fails to properly monitor payroll costs charged to HHS awards. The University's monthly reports and the annual certifications did not provide the necessary information for a PI to certify to the reasonableness of salary charges. These reports also failed to provide the University or Federal auditors with the necessary information to verify the reasonableness of salary costs charged to HHS awards. Without the necessary information, the University could neither ensure nor affirm that charges to Federal awards were reasonable in relation to work performed."

Based on its sample, OIG "estimated that the University put at risk $11.7 million in salaries and $5.9 million in associated facilities and administrative costs" for the NIH grants.

The agency contended that UCR's "prior effort-reporting system did not always provide the information needed to confirm that payroll costs had been appropriately allocated to Federal awards, and its current pilot PCS provided less accountability over payroll charges to Federal awards than its prior effort-reporting system."

The 12 recommendations OIG made were both broad and narrow; eight are to help "increase accountability over payroll charges." OIG said, for example, that UCR should be "requiring and documenting prior approval and justification for charging administrative and clerical salaries as direct costs; requiring and documenting prior approval and justification for cost transfers;" and "developing payroll procedures to ensure that salaries are properly allocated and that salaries charged to all activities do not exceed 100 percent."

The balance of the recommendations was directed at UCR's IT system, many of which were simple. These include that UCR should "strengthen" its IT system by "improving restrictions for remote access, implementing a password setting that requires password changes periodically, implementing a patch management system for its desktop computers," and "following Federal requirements for supporting payroll costs claimed."

Forty-eight of the 83-page audit consists of UCR's response and apparently it submitted more documents that OIG did not include. As noted earlier, UCR rebutted nearly every finding and all but one of the recommendations. UCR disagreed with the basis for suggestions, said changes weren't needed or that it had a better way to address an issue than OIG offered. For instance, UCR said it was instituting two-factor authentication to provide for more secure log-ins to its system, calling frequent password changes, which OIG suggestion, a controversial practice that can lead to poor security because users may resort to writing them down or sharing them.

UCR Chancellor Wilcox chalked some of the dispute up to lack of an appropriate exchange of information.

"UCR disagrees with many of the samples identified as at-risk," Wilcox's response said. "UCR believes if discussions of issues occurred during the audit and prior to issuance of the draft report, a more balanced draft report would have been issued. UCR attempted to initiate dialog on the effort-reporting system preliminary findings, but there was no response."

UCR's Response was Expansive

He also wrote that "UCR became aware of HHS OIG's internal control issues for the first time during a May 2016 conference call. Many of the at-risk items could have been resolved prior to the issuance of the draft audit report had HHS OIG initiated communications contemporaneous with the audit field work process."

For example, UCR explained that, for one set of 12 at-risk salary transactions, the PIs "did not have payroll charges, as each of their effort dedicated to their respective project was accomplished with voluntary uncommitted cost sharing that was not quantified in the submitted proposal nor resulting award."

The lone recommendation UCR said it agreed with was that it require and document "prior approval and justification for adjustments made after grant expenditures have been reported to the Federal Government."

In its remarks on the draft audit, UCR said that a high-level committee and leadership team "is actively working on expanding and enhancing training regarding the administration of contracts and grants for implementation" in fiscal year 2017. In addition, UCR said it was "in the process of designing a shared services model

that will serve the entire campus population using common standards for communicating, documenting, and processing human resource, academic personnel and payroll changes."

From UCR's perspective, the pilot was a success. It "improved [PIs'] accountability over their awards while reducing administrative burden," allowing for them "to spend more time on research by simplifying the salary confirmation process for salaries/wages charged to federal funds," its response states. "UCR strongly disagrees with HHS OIG's assessment of our PRC system. The pilot outcomes clearly demonstrate that the payroll certification methodology is an effective method to confirm salaries/wages charged to sponsored awards are reasonable and allocable."

UCR noted that, "As with any pilot program, there are opportunities to make improvements," and it detailed some it had already made and others it plans to have in place by this summer. It added that it had been holding back on "implementing major enhancements" until the audit produced some "feedback," which wasn't forthcoming until April 2016, three years after the audit began.

These improvements include:

◆ "Incorporating all funding sources associated with a PI, such as gifts, department allocations and sales and service activities, not just contract and grant funds. These enhancements will allow the PI to easily access payroll details across all of their funding sources including funds where they are designated as the Co-PI."

◆ Making changes that allow PIs to "drill down and access an individual's full payroll distribution for the certification period; view payroll details including the payroll distribution percentage for each funding source used to pay the employee's salary; add the option to request a sub-certification from a Co-PI and/or employee supervisor; and consolidate all (salary and non-salary) mandatory, committed cost share reporting into the" payroll certification report.

◆ Granting automatic access to all faculty "based upon characteristics of their payroll appointment," while restricting their ability to "view and take action on proposals and awards where they are specifically identified as the Pl." Such an approach "provides departments with the ability to easily adjust access based on department needs while ensuring accountability for access controls exist with those most familiar with staff training and job responsibilities. Based on a user's system access, automated e-mail notifications of required actions throughout the award life cycle are generated."

Link to UCR audit: https://oig.hhs.gov/oas/reports/region4/41301026.asp. ✧

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 on your subscriber-only website. Please call 888-580-8373 or email service@hcca-info.org if you require a password to access* RRC*'s subscriber-only website or are not receiving weekly email issues of the newsletter.*

◆ **Agencies required to comply with President Trump's Jan. 30 executive order (EO) may be able to identify regulations from other agencies to help comply with the requirement that any new, "significant" regulation be accompanied by the possible repeal of two existing rules,** according to a recent memorandum issued by the Office of Information and Regulatory Affairs (OIRA) within the Office of Management and Budget. The EO also sets a "regulatory cap" for fiscal year 2017 (*RRC 2/3/17*). The memorandum, labeled interim guidance, indicates the EO requirements may also apply to guidance documents that are considered significant and instructs agencies to check with OIRA before publishing guidance. Some agencies, including the Food and Drug Administration, routinely publish more guidance than regulations.

Meanwhile, a group of watchdog organizations has asked a court to impose an injunction on the EO on the grounds that it is unconstitutional. "The Executive Order will block or force the repeal of regulations needed to protect health, safety, and the environment, across a broad range of topics — from automobile safety, to occupational health, to air pollution, to endangered species," the groups said in announcing the suit, filed on Feb. 8 in the U.S. District Court for the District of Columbia by Public Citizen, the Natural Resources Defense Council and the Communications Workers of America. Citing OMB's interim guidance, the suit also calls the one-for-two approach "irrational" and notes that "the netting out of costs is divorced from any consideration of the benefits" of the targeted regulations. The EO appears to be having the desired effect: the website, reginfo.gov, that lists

In This Month's E-News (continued)

regulations under OMB review currently shows only two (see https://www.reginfo.gov/public). *(2/15/17)*

◆ **Research and methods to edit genes for purposes of enhancing attributes such as physical strength should not be permitted,** according to a new report by a committee of the National Academy of Sciences (NAS) and the National Academy of Medicine. Human subjects research involving "genome editing of the human germline—adding, removing, or replacing DNA base pairs in gametes or early embryos—could be permitted in the future, but only for serious conditions under stringent oversight," members said in the Feb. 14 report, Human Genome Editing: Science, Ethics, and Governance. If permitted in the future, research on heritable germline genome editing, currently banned in the United States, should first meet a host of requirements. These include that there is an "absence of reasonable alternatives" and that the research is accompanied by "comprehensive plans for long-term multigenerational follow-up" and "continued reassessment of both health and societal benefits and risks, with wide-ranging, ongoing input from the public," according to the report. *(2/15/17)*

◆ **Two heirs of Henrietta Lacks, whose cervical cancer cells have been used in research for decades, say they plan to sue Johns Hopkins University, where she had been a patient, for compensation.** In an article published by the Baltimore Sun, Lacks' son and grandson also said they were not party to an agreement some family members reached with NIH about control of the cells. NIH officials did not respond to a request for comment from RRC. Johns Hopkins issued a statement to the Sun indicating that it "never patented HeLa cells, and therefore does not own the rights to the HeLa cell line" and "did not sell or profit from the discovery or distribution of HeLa cells," as Lacks' cells are called. Controversy over the cells came to light several years ago following publication of The Immortal Life of Henrietta Lacks, which is set to premiere as a movie starring Oprah Winfrey in the title role in April on HBO. *(2/15/17)*

◆ **An organization calling itself Academics Against Immigration Executive Order has gathered some 40,000 signatures in opposition to President Trump's three-month ban on entry into the United States of individuals from Iran, Iraq, Syria, Sudan, Libya, Yemen and Somalia and a halt to admission of all refugees for four months (*RRC 2/3/17*).** "This Executive Order would significantly damage the United States' reputation for academic excellence in higher education. United States research institutions directly benefit from the work of thousands of researchers from the nations affected by this Executive Order," the petition states. "The United States academic community relies on these talented and creative individuals for their contributions to the cutting-edge research." Since the ban was imposed Jan. 27, various courts have temporarily halted implementation of some parts, such as restrictions on individuals with valid visas, but the government has appealed. On Feb. 7, the U.S. Court of Appeals for the Ninth Circuit heard the appeal; it is expected to rule later this week. The group of academics has also posted links to press coverage of institutions' responses to the ban. *(2/9/17)*

◆ **The Food and Drug Administration (FDA) found numerous "objectionable conditions" during an inspection last summer of research conducted by Kang Zhang, professor of ophthalmology and chief of ophthalmic genetics at University of California San Diego,** the agency said in a Jan. 5 "warning letter" recently posted online. "[W]e conclude that you did not adhere to the applicable statutory requirements and FDA regulations governing the conduct of clinical investigations," FDA said, a finding that references both the inspection and Zhang's response to it in a subsequent letter to the agency. "FDA is particularly concerned that you enrolled six of the twelve subjects enrolled into this study without ensuring their subject eligibility," the agency said, in part. "Your inability to account for the disposition of 25 units of unused supplies of study drug raises significant concerns regarding the adequacy of your oversight and control of investigational drug. In addition, your failure to maintain adequate and accurate drug accountability records raises concerns about the validity and integrity of the data collected at your site." The agency requested that Zhang "notify this office in writing of the actions you have taken to prevent similar violations in the future," and that, in the event "you believe you have complied with FDA regulations, include your reasoning and any supporting information for our consideration." According to the letter, "failure to address the violations noted above adequately and promptly may result in regulatory action without further notice." The letter does not describe the research in any detail but notes that Zhang is "both the sponsor and a clinical investigator" of the drug under study. *(2/2/17)*