News and Analysis for Colleges, Universities and Teaching Hospitals

Contents

While OCR Guidance Offers Some Help, OHRP Has Yet to Tackle De-Identification

While the HHS Office for Civil Rights has still not released the long-awaited suite of HITECH Act regulations, expected to contain provisions regarding consent and others of benefit to researchers, the agency did end the pre-election regulations logjam with a post-election guidance document on methods to de-identify protected health information.

However, the guidance breaks no new ground and could not, by its nature, address some of the more pressing concerns that compliance officials and investigators have about the application of HIPAA to research, particularly regarding de-identification and re-identification. They are still waiting for the Office for Human Research Protections to issue a follow-up to its 2011 advance notice of proposed rulemaking, which received overwhelming opposition to its idea of applying HIPAA de-identification standards to nearly all types of research *(RRC 11/11, p. 1)*.

Arguing that "all evidence suggests that HIPAA standards [for de-identification] are gravely inadequate," Latanya Sweeney, founder and director of Harvard University's Data Privacy Lab, and nearly four dozen investigators, scientists, privacy advocates and other experts condemned the idea in their comment letter on the ANPRM.

'Data Analytics' Takes Center Stage in OIG Work Plan, Amid Contentious Audit Report

The University of California-Santa Barbara has joined the list of those rejecting a repayment request from U.S. auditors who disallowed costs claimed on federal awards. UCSB, which faces a possible give-back of $6.3 million, may have the distinction of being among the first to fall victim to "data analytics," a controversial audit method used by the Office of Inspector General at the National Science Foundation, which, while not new, seems on track to becoming the agency's preferred method.

The Council on Governmental Relations, which represents nearly 200 research universities and their medical centers and research institutes, said OIG's increasing use of data analytics in 2012 "marks a significant shift" from more traditional audit techniques, and has expressed its reservations about this method to OIG staff.

Signs that the shift is more than temporary abound in OIG's new work plan for this fiscal year. Not only was the title of one of six directors in OIG's Office of Audit changed to director, compliance analytics, from her former title of a regional external audit director, but the section in the 2012 work plan titled "Risk Analysis: Audit of NSF Awardees" is re-titled in the 2013 version as "Data Analytics: Audit of NSF Awardees."

OIG's new work plan also deletes this sentence in the 2012 document: "OA identifies risk at NSF awardees by analyzing information in NSF's awards database, search-

ing for selected factors known to indicate high risk, such as a new NSF awardee, or a particularly high-dollar or complex award." The document states instead that "OA uses data analytics to identify institutions that may not be spending funds properly."

COGR members "have raised concerns…both in terms of substance (e.g., relevance of the issues raised by the auditors) and process (e.g., unclear protocols for providing responses to findings)," David Kennedy, COGR's director of cost policy, wrote in a recent meeting report to members. Some also fear that "over-reliance on data analytics can lead to false conclusions if the appropriate follow-up is not included in the audit plan," he wrote.

Furthermore, he noted that "data analytics is not necessarily accepted as the 'gold standard' by the audit community." Kennedy declined to comment further to *RRC*.

Said to be in some degree of use by the Department of Defense, data analytics does not appear to have been adopted wholesale by any other federal agency or with NSF's zeal. That could change, however, if it results in

significant recoveries by NSF or catches the interest of Capitol Hill. All OIGs report twice yearly to Congress and are always in something of a competition against one another to show impressive results. (For strategies on getting through all kinds of audits, see story, p. 3.)

Under data analytics, "NSF asks institutions for an electronic version of the general ledger, specifically, NSF funds and accounts. Based on various analytical techniques, auditors look for indicators that suggest audit risk or need for additional information," Kennedy said in his report. But the 2013 work plan indicates OIG is using data analytics across the lifecycle of an award.

In "Phase I," OIG identifies "high-risk institutions" by applying data analytics to agency award data, including proposals, quarterly expense reports, cash drawdowns, A-133 audits, and data reported to the Recovery Board, usaspending.gov and others.

In "Phase II," which appears to relate to institutions selected under Phase I as "high risk," OIG will combine awarding agency data with "awardee transaction data," to come from their general ledger, subsidiary ledger, subaward data and externally reported information and then "refer questionable transactions for review."

UCSB Faced 'Hundreds' of Requests

The 2013 work plan touts that "This methodology enables a review of 100% of applicable data, and reveals anomalies, such as unusual expenditure rates, for further investigation" and "is useful in identifying risks at all stages of awards."

"For example, at the preaward stage, risks would include inflated budgets and conflicts of interest among proposal reviewers. At the active award stage, risks would include unusual burn rates (e.g., expenditures for equipment at the end of an award), excess cash on hand, and no, late, or inadequate project reports. Red flags at the end of an award include multiple post-closeout financial adjustments," the work plan says.

In UCSB's case, auditors spent two years reviewing $144 million in costs claimed on 604 NSF awards from January 2008 to January 2011, before disallowing $6.3 million and recommending NSF seek return of those funds.

In addition to vehemently disputing the findings, which NSF must resolve within six months, the university took issue with the audit process itself, contending in its eight-page response that the auditors "submitted hundreds of data requests to many different personnel," relied on erroneous information supplied by unnamed university personnel, refused requests to provide the communications for the university to review, did not give the university enough time to respond to findings submitted to it in draft form, and omitted material facts.

UCSB was chosen for the audit because the overall UC system had "an A-133 audit report finding for untimely cost transfers [that] remained unresolved for several years and specifically referenced NSF, and because UCSB is one of the largest recipients of NSF award dollars," the auditors said.

Cost-Sharing Amounts Disputed

The audit report includes some details on how data analytics was used, and notes that the period of review "provided an audit universe [of] more than 266,000 transactions" involving award funds.

"Our work required reliance on computer-processed data obtained from UCSB and NSF. At our request, UCSB provided detailed transaction data for all costs charged to NSF awards during the audit period," the auditors said. "We obtained NSF data by directly accessing NSF's various data systems. To select transactions for further review, we designed and performed automated tests of UCSB and NSF data to identify areas of risk and conducted detailed reviews of transactions in those areas."

Their conclusion was that UCSB "had a practice of charging untimely and unrelated costs into its federal awards" throughout the time period covered by the audit.

The university "did not comply with federal and NSF award requirements," the auditors contended. "Specifically, we found $1,913,474 of overcharged summer salaries; $2,821,676 of excess federal cash disbursements resulting from UCSB not fulfilling its grant cost share requirements; $496,466 of inappropriate cost transfers into NSF awards; $473,465 of indirect cost overcharges to NSF grants; $440,148 of unallowable costs charged to NSF grants; and the utilization of $180,255 of remaining fellowship funds for non-award purposes."

Lack of documentation was cited as the reason for the biggest chunk of costs that were disallowed — $2.8 million that UCSB allocated for its cost share requirements.

"As a result of our audit work, we determined that UCSB lacked an adequate system to identify, account for, monitor and track the cost share it contributed to its NSF awards," the auditors said. "Additionally, despite the existence of University of California System policies and procedures requiring centralized tracking and documentation of cost share, these requirements were not followed by UCSB personnel. These deficiencies prohibited us from verifying and validating that UCSB met the majority of its required cost share commitment for the four NSF awards we audited."

Link to work plan: http://www.nsf.gov/oig/FY-13auditworkplan.pdf

Link to UCSB audit: http://www.nsf.gov/oig/UCSB_12-1-005.pdf ✧

Research Administrators, Expert Offer Strategies to 'Survive' Audits

Compliance officials whose institution is undergoing an audit may sometimes feel alone and under siege. Michele Codd, Michelle Vazin and Kimberly Ginn feel their pain.

Codd was assistant director of the Institute for Software Integration Systems at Vanderbilt University for 10 years, during which time she was involved in four federal audits before she was named associate director for sponsored research administration at George Washington University in June 2011.

Vazin worked with Codd at Vanderbilt, where she has been employed for 28 years, most recently as director of contract and grant accounting. Ginn, a principal with accounting and advisory firm Baker Tilly Virchow Krause, LLP, was previously an auditor for the Department of Defense Office of Inspector General; she has conducted or assisted university clients in more than 100 audits during her career.

At the recent annual meeting of the National Council of University Research Administrators, the three presented "How to Survive an Audit," offering some of their hard-learned tips, which are especially timely given new and controversial audit techniques being used by some inspectors general (see story, p. 1).

In addition to discussing the "lifecycle" of a typical audit, the speakers described strategies to help audits proceed more smoothly. They also recommended actions and "best practices" to put in place to reduce the chances of being the target of an audit and to prepare for one should it happen.

As most compliance officials know, any institution that receives federal funds is subject to audits addressing a number of activities and documents, such as pre-awards; financial statements; specific programs; facilities

---

Grants Management Webinars from FFMA & AIS

Listen On-Demand or get CDs of webinars from the *Federal Fund Management Training Library*:

- Orientation to Federal Grants Administration — A Quick Immersion for Program Personnel
- Cost Allowability 101
- Indirect Cost Recovery on Federal Awards — The Essentials
- Time and Effort Reporting for Federal Grants: Requirements and Best Practices

Visit www.FederalFundManagement.com

---

and administrative cost proposals; disclosure statements; business systems, such as accounting, procurement and property; and "special reviews."

Audits may be conducted by sponsors, by an OIG (or its contracted audit firm) for an agency such as HHS and the National Science Foundation, by independent audit firms hired by an institution to conduct annual audits required by law, and by internal auditors working for the institution itself, the speakers said.

Audit May Follow a Pattern

A number of individuals on campus may be involved in an audit, including officials from various offices such as the provost, dean's office, human resources, internal audit and information technology, as well as pre- and post-award.

Even if they are not involved on a daily basis in the audit, senior leadership need to be updated, "especially if you feel like there might be something of concern" that could result in a finding once the audit report is issued, Vazin said.

Whistleblower-initiated audits are a special concern. "If you've got the Department of Justice, the FBI, potentially showing up on campus, you're probably going to have someone with your general counsel's office working with you on that type of audit," Vazin said.

Vazin noted that regardless of the type of audit, "we are audited initially about whether [or not] we are following our own internal policies and procedures." Secondarily, "those need to be compliant with the external rules and regulations that govern federal projects," she said. So for institutions that have made their policies more restrictive than regulations, "you better be abiding by them, or you are going to have issues in an audit," Vazin said.

Notification, definition of scope, preparation and entrance conference are the first four parts of what the speakers called the "lifecycle of an audit," although they tend to overlap a bit.

An entrance conference is conducted when the auditors actually arrive. The notification letter, and later this conference, should be used to identify what is being audited so institutions can take steps to get ready and to respond to the auditors. The institution's officials should also try to determine how long the auditors plan to be onsite.

"After the letter arrives," Codd said, "do your homework. We can't stress that enough. What are they auditing? If they are coming in and they are auditing a single contract, you focus on that. Are they doing an effort report? Whatever it is, make sure you can identify any area that is impacted" and notify individuals in those areas.

Other parts in the lifecycle are field work, exit conference and management response.

Keeping the auditors to the stated scope of an audit is paramount, the speakers said. One strategy is to be sure to "identify an escort" for the auditors once they arrive, Codd said.

"You do not want the auditors wandering around. If they wander down the hall and just pop into a lab and ask people some questions, they might get answers that don't support what you'd like them to say. We are always going to be honest and straightforward but we really need to manage the process," Codd said.

Vazin added that at Vanderbilt, her staff "stick to the auditors like glue. They don't talk to [anyone] or look at any data unless we are part of it. We may not, in an interview process…be an active talker in that interview but we're there so that we have the opportunity to hear what is said."

Field work, Vazin explained, is the "meat" of an audit, "where they're looking at the data that's been provided. That's where the interviews may happen if they feel the need for those."

Draft Findings May Be Shared

The auditors' visit will conclude with an exit conference. Ideally, auditors will "be forthright in what their preliminary observations are" during the meeting, Ginn said.

Auditors may then send a written draft summarizing possible findings, an actual draft final report, or both. (In some types of audits, however, nothing is shared in advance of a final report.)

The institution then can address the draft findings and provide a written "management response," which gets published with the final report. The institution gets just this one chance to comment while the report is still being written, a particular point of contention in the recent audit of the University of California-Santa Barbara.

Institutions may disagree with the findings in the draft report and "it is absolutely, 100%" within officials' "rights to object," Ginn said. "Auditors are people, too, and they make mistakes," she said, and will "want to know whether they have accidentally included something erroneous or not gotten something correct…within a report."

Ginn added that findings are not always "black and white" and they are subject to an auditor's judgment and interpretation of a regulation or other requirement. Audit reports may recommend changes in policies and procedures and require a corrective action plan and repayment of questioned costs.

Leadership will have to determine what to contest, if anything, and be prepared to explain why, the speakers said.

Study OIG Work Plans

The speakers urged their colleagues to be "proactive" in taking steps to ensure compliance and possibly prevent audits. This involves being "aware of the audit environment around you," which comes from reviewing the work plans issued by the OIGs. These work plans describe priorities and areas of focus.

In the work plans, OIGs will say, "'We're looking at subaward monitoring, we're looking at service centers, we're looking more carefully at effort reporting.' It could be a whole host of things," Codd said.

OIGs themselves may have different areas of focus within regional offices, Vazin said. Sometimes the sources of such information are the auditees who put the word out through membership organizations such as the Council on Governmental Relations.

Vazin noted that "HHS OIGs in the Southeastern region" have been focusing on clerical and administrative audits.

Networking with peers can also identify "red flags" to be aware of. For example, "Most people know purchasing computers or hiring clerical [staff] on federal grants is an area that is fraught with problems," Codd said. "So you want to make sure that any of your information at your institution covers these."

Administrators should also regularly review findings from audits that OIGs make publicly available, the speakers said, and share them with appropriate individuals on campus. Further, they should ensure that their training programs "hit the red flags" and areas identified in the work plans, Vazin said.

Imagine Future Audits

Compliance officials also need to understand their accountability — and keep their own houses in order.

"Are you expected to simply process paperwork, [or] are you expected to be a subject-matter expert and advise the PI on things?" Codd asked. "Are you guiding other people? Know what your role and your responsibility is."

"We emphasize and encourage our departmental administrators to be the liaison at the local level, translate the things they know about to their lab managers, to their PIs, to their graduate students, to make sure they're informed, [that] they understand what the policies are calling for, understand what the processes are," Vazin added.

Understanding the technical phrasing for various activities can also be important in the event of an audit. For instance, all PIs need to understand that when they are, more casually speaking, "verifying their time," they are actually engaged in "effort reporting certification," Vazin said. If the PI did not understand an auditor's question, he or she could give an incorrect answer.

Her advice was to always consider how an action might look if reviewed during an audit sometime in the future. If there is a sense that something could be questioned later on, take extra steps to justify it. "We got really good at documenting to prevent problems in the future," Codd said. "This really helped us because this research institute I managed did a lot of unusual things. That documentation helped us to preserve some of the [claimed] costs when they were challenged."

Vazin agreed. "Everything you do could be potentially used against you," she said. "Keep in mind what you put in emails, what you put in writing, in memos, things like that....Make sure it's always just what needs to be there to support the activity but nothing more, nothing less. In the event that you have a whistleblower, you could have documents subpoenaed. Every email, every post-it note, every lab notebook, any dialogue that was captured there that may sound inappropriate" could end up in the hands of auditors or government officials.

Make Use of Internal Auditors

Codd recalled an incident in which a PI emailed her to say that his salary could be allocated to any project that still had funds. She advised him that his "effort" would be properly applied to the project he was working on.

"I had to show that I knew what was right and that I responded [with the] right information," Codd said. "I never want to appear to be a partner in crime because if something happens, unfortunately, usually the person whose job is eliminated is not the faculty member."

Both Vazin and Codd said internal audits also help prevent, and prepare, organizations for external audits. It is worth noting, however, that external auditors can request internal audits, so institutions would be well-served to act on any findings they receive. "It is worse to have known and done nothing then to not know that you had a problem," Vazin added.

Staff auditors themselves can be helpful. Codd said she and Vazin have "found over the years it behooves us to have a very good working relationship with this group of people. You do not want it to be an adversarial relationship on campus. They can actually be a really important partner in sponsored programs….When we write new policies, we get internal audit to vet them with us."

Another tip to stay out of trouble: ensure the institution has "consistent policies" across campus, Codd said, and not ones that apply, for example, to the engineering school but not to arts and sciences.

The speakers also offered the following suggestions regarding audits:

◆ *Ensure knowledgeable staff are involved, especially if communications are with auditors directly.* Said Vazin, "Make sure they know what they're talking about, that

they're comfortable with the subject matter and that they understand the rules of engagement when you have an audit going on. They need to be very knowledgeable about what your own internal policies and procedures are. The last thing you want someone to do is sit down with an auditor and it become glaringly apparent" that they are missing information auditors need.

◆ *Spread the word that only designated staff may speak to auditors and others should decline requests.* "You should not respond to an auditor unless you've been directed to do so," Codd said. "Auditors can call you and they can ask for information. It is absolutely appropriate to let them know that you are not the right person. PIs need to know that, the graduate students need to know that. You don't want somebody getting on the phone" and telling an auditor he or she doesn't have "time for this."

Vazin added that while federal auditors generally know not to approach PIs or program officials without first going to central administrative staff, state auditors may be a different matter and sometimes do go directly to departments and by-pass the central pre- and post-award offices.

◆ *Keep your cool.* "It's important to keep your composure," Codd said. "Audits are challenging but it's going to be OK, so keep a professional demeanor. Don't be rude

or frightened. Don't act like you have something to hide; that gives them energy."

Link to HHS OIG work plan: https://oig.hhs.gov/reports-and-publications/workplan/index.asp#current

Link to NSF OIG work plan: www.nsf.gov/oig/FY13auditworkplan.pdf ✧

Innovative 'Repair' Program Aims To Reduce Repeats of Misconduct

This month the first class of researchers who have committed outright misconduct as defined under federal law or some form of ethical misdeed will complete a novel program involving a three-day workshop and online courses designed to give them the tools to resist engaging in such actions in the future.

Called RePAIR, short for Restoring Professionalism and Integrity in Research, the program is based at St. Louis University and is the brainchild of Jim DuBois, director of an ethics center and social sciences research group at SLU.

For this group of a half-dozen participants, the program may be their last chance to save their careers: most have been told to either attend or face termination from their institutions, program director DuBois told *RRC*.

Inside NSF

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

◆ **The University of Wisconsin-Madison has objected to audit findings by an organization under contract to the National Science Foundation Office of Inspector General that questioned $1,788,036 of $203 million in costs claimed on a cooperative agreement for its IceCube project.** Auditors found no financial discrepancies with two other related cooperative agreements of $12,840,000 and $2,722,722, respectively. No total funding amount is listed in the audit, which was heavily but inconsistently redacted. Funding supported "the design, development, and construction of an 86-string array of mirrors in Antarctica, designed to capture and record neutrinos falling and embedded in the Antarctic ice," the audit said. OIG said it would be completing a "non-compliance report in the near future" and that "additional questioned costs" may emerge. The university said the questioned costs were properly categorized. *(12/6/12)*

◆ **Rather than interviewing by video conferencing up to 500 individuals at 100 NSF-funded institutions about their responsible conduct of research programs and asking extensive questions, OIG should simply "request a copy of the institutional plan for appropriate training and oversight" and "seek verification through an institutional certification" to ensure that appropriate students and postdoctoral fellows have received training, the Council on Governmental Relations wrote in a Nov. 13 letter to the NSF OIG.** COGR was responding to OIG's announcement in the Sept. 14 *Federal Register* that it is seeking the approval of the Office of Management and Budget to conduct the interviews and request detailed information. COGR called OIG's interview plan "burdensome" and argued that it has neither the expertise nor authority to judge the effectiveness of such programs. OIG could recommend that NSF fund a research project to develop assessment tools, COGR suggested. *(11/29/12)*

DuBois also directs an ethics center at Washington University School of Medicine's Institute for Clinical and Translational Science. DuBois used an NIH grant the institute received to develop the RePAIR curriculum and train instructors. "Long-term, the program will be sustained by tuition and institutional partnership fees," DuBois said. The next session will be offered in March.

Although no federal agencies have specifically sanctioned use of the program for errant investigators, John Dahlberg, director of the division of investigative oversight in the HHS Office of Research Integrity, serves as a "project consultant," and ORI blogged that the initiative "provides a solution to redeem researchers."

Aim Is to Reduce Recidivism

Incidents that bring researchers to the program "tend" to fall into three categories, DuBois said: violations of human subject protections and animal welfare regulations or research integrity issues.

"We are prepared to provide training for people who have engaged in fabrication, falsification or plagiarism," he said. "But I would say that would be one of about 10" reasons a person could come. The program could be helpful for individuals who repeatedly violate conflict of interest regulations, for instance.

Confidentiality of participants is paramount (all sign appropriate agreements), but DuBois agreed to share some background on them. Among the group of six there were allegations of data fabrication, animal mistreatment, conducting research without an approved protocol, and inappropriate research subject recruitment.

DuBois developed the program to fill a gap he saw in how institutions respond to reported wrongdoing. "Current options are often extreme, ranging from letters of reprimand to termination," he said.

"For a good number of people," actions short of termination "might be enough to change behavior" and prevent a recurrence, DuBois said. But, he added, data suggest such individuals who remain on an institution's faculty are at the "highest risk" of engaging in wrongdoing again.

"I hope RePAIR will offer an alternative that will enable continued employment while reducing rates of recidivism," he said, adding that the curriculum is patterned on remediation strategies employed by programs that serve physicians who have been reported to their state medical boards.

These programs have produced "spectacular outcomes" in terms of reducing recidivism, and the research field has "nothing" similar to offer, according to DuBois.

So far, all of the participants have been referred by their institutions. RePAIR staff interview institutional officials as well as potential participants to understand their situations, but they promise both that nothing participants disclose during the program will be communicated back to the employer.

"When someone has been investigated and the institution has told them 'You have got to change,' that's a prime time to intervene" with a program such as his, DuBois said.

"My own background is in social psychology and philosophy," DuBois told *RRC*, "and I have worked in research ethics for about 15 years." An analysis of 100 cases of "professional wrongdoing" he completed showed an important pattern, he said.

"Most of the cases of wrongdoing had persisted for more than two years. Their collaborators had to be aware, their supervisors had to be aware, yet they were not intervening in a timely manner," DuBois said. He surmised that these behaviors may not have been reported because individuals feared the only outcome would be termination and possibly the closure of an entire lab.

'Root Causes' to Be Examined

But, he hastened to add, "This is not an ethics course, and we don't believe the root cause is a lack of knowledge. When someone makes up data, we believe they know the rule" forbidding such action.

"The root causes, we think, are very much the same across different kinds of wrongdoing. People are under a lot of stress. They rationalize; they blame others. Many of them are not great at forecasting the consequences of their actions," he said. The program, according to DuBois, will "teach good ways of dealing with stress and address the ways we rationalize our behavior."

Stress management techniques will consist of those that can be used "on the spot, not like yoga," DuBois added.

Two instructors will lead each session during the three days; at least one will be a licensed clinical psychologist with a background in research ethics, he said. "All of them have served on institutional review boards," DuBois said.

Much like group therapy, participants will share their stories and get feedback on how they could respond differently in the future, he said. To address the participants who might be facing deportation or loss of a work visa if they lose employment, instructors will lead a discussion focusing on other triggers for misconduct.

"One exercise we are doing that I picked up from the [physician] remediation programs and modified is to ask, 'What are the three unspoken rules that guided your life growing up and your lab of training?' We will hear different responses and it will be a great opening to

explore" some of the cultural norms that may be factors in misconduct.

Among the responses he expects are "failure is not an option" and "negative findings are useless." Particularly for the latter, discussions can hopefully disabuse participants of some erroneous notions that might be used to justify bad behavior, DuBois told *RRC*.

A strength of the program, which costs $3,000 per participant, is that the sessions are limited to 10 participants, and the curriculum is customized to them, DuBois said. For example, through an arrangement with the University of Miami's online training program CITI, participants will complete "learning modules reviewing the basic values and norms of science, and addressing areas relevant to [their] particular needs."

Participants will also emerge from the program with a written "professional development plan," DuBois said. The program website describes these as "personalized management plans to support professionalism," and adds that "Participants will be asked to identify a mentor or peer support at their home institutions."

Paul Braunschweiger, founder of CITI and a professor of radiation oncology at UM's Miller School of Medicine, told *RRC* the program "will provide institutions a way to give a valued scientist or student who has made a serious error in professionalism a second chance, a way to begin regaining the trust of their institution and colleagues and, finally, a way for the individuals and institutions to escape the public embarrassment that an ORI determination letter would likely bring."

He agreed with DuBois about the lack of remedial programs for investigators akin to those for physicians and attorneys, and said RePAIR would "fill an important void in the research integrity program for [clinical and translational science centers] for the research community in general."

Link to RePAIR: http://repairprogram.org

Link to ORI blog: http://ori.hhs.gov/blog/why-remediate-researchers-response-concerns ✧

OLAW Addresses Annual Report Following Adoption of New *Guide*

The Office of Laboratory Animal Welfare will accept only those annual reports that have been submitted by email, and for most assured institutions, the reports are due by the end of this month.

OLAW Director Patricia Brown addressed the submission requirement and answered questions about other nuances of annual reports during OLAW's last online webinar of the year, held Dec. 13.

Perhaps the biggest change for the 2012 annual reports, of course, is that they must reflect that institutions conducted at least one semi-annual inspection during the past year based on the *Eighth Edition of the Guide for the Care and Use of Laboratory Animals (RRC 1/12, p. 5)*.

The report also must signal whether the program is in compliance with the new *Guide* requirements or contain "a reasonable plan and schedule" for meeting them. Importantly, Brown pointed out that "most changes to programs as a result of implementation of the new *Guide*" are unlikely to trigger requirements for inclusion in the 2012 annual report.

The format and basic content of the reports has not changed, however. Generally speaking, annual reports are the vehicles through which assured institutions report changes in their facilities or programs, including occupational health and training programs, that occurred during the year. Changes in "buildings, species or approximate number of animals housed" must also be reported.

Report Only Certain Changes

For example, "If an institution formerly used only mice and rats and now they've begun research with guinea pigs, then that's a program change to be attached to the annual report," Brown said.

If an institutional animal care and use committee "created a policy to use designated member review, subsequent to full committee review in our IACUC review process," this constitutes a reportable program change, she said in response to a question.

Brown clarified that institutions need to report the name of the institutional official, the animal care program's veterinarian and the IACUC chair, if any have changed. Changes in the veterinarian's qualifications, in the percentage of time assigned to the animal care program, and in his or her authority or responsibilities should also be reported.

Also required in the annual report is the IO and IACUC office's "mailing address, the telephone number, the fax number, and the e-mail address," she said, noting that an email address for the chair was not necessary if one was provided for the IACUC office. These should also have been reported to OLAW at the time of change, she said.

It is also not necessary to report the names of the actual IACUC members, or their contact information Brown said. Changes in the IACUC roster will be reported without this information included.

"We verify that the appropriate roles are being held by the appropriate person," she said. "If you complete [the relevant portions of the report], you've given us the background and the position title of the individuals

named as members and you've also given us their PHS required role."

Reports should also contain the dates of semiannual reviews and of facility inspections, with separate notations for each inspected building. "For each of the dates provided, you should check the box to indicate whether the seventh or eighth edition of the *Guide* was used for the inspections," Brown said.

"OLAW is looking for an up to a seven-month interval between inspections and evaluations, so if you're within that window of time, then we would consider that acceptable," she said. "We would like an explanation if you have not used the eighth edition of the *Guide* for…at least one of your evaluations in 2012, however."

In response to the question, "What does OLAW consider a reasonable plan and schedule" for implementing the new *Guide* requirements, Brown said the agency "expects institutions to approach their plan and schedules keeping in mind the well-being of the animals and making every effort to not delay necessary changes in the animal care and use program. Recognizing that the scope of changes needed varies considerably across institutions, OLAW cannot give a specific date for final completion by all institutions. This is why we have asked the question about the status of implementation in the 2012 annual report."

In addressing a couple of scenarios presented by questioners, Brown emphasized that an institution would be in compliance with the new *Guide* even if implementation of a plan wasn't completed, as long as the plan itself was.

Brown also clarified that the annual report "and the assurance document are separate stand-alone documents required by the PHS policy."

Include Review, Inspection Dates

One questioner asked, "What are the consequences of failure to use the eighth edition of the *Guide* in 2012?" Brown responded that "this would be considered non-compliance and would be reported to our division of compliance oversight for follow-up. The institution will be required to provide OLAW with information on how it plans to comply."

Examples of non-compliance with the annual report are "missing dates for the semi-annual program review and facility inspection"; "performing the reviews in a time span that is greater than seven months apart"; "a minority view that describes a reportable incident that was not promptly reported by the institution"; "changes that were made to the IACUC [that] result in a not properly constituted committee"; and "program changes that were made involving the protocol review process were not compliant with the PHS policy for either designated member review or full committee review," Brown said.

OLAW plans to have an online submission process for the reports, Brown said. Until that happens, institutions will download the template for the form, print it out, complete it with a signature, and scan it to convert it to a PDF before emailing it as an attachment to OLAWARP@mail.NIH.gov.

Reports should be signed by the IO and IACUC chair (vice chair is also acceptable, Brown said). If the IO is not available, another "authorized" individual

---

Inside NIH

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

◆ **NIH Director Francis Collins and Sally Rockey, NIH's deputy director for extramural research, announced steps the agency will take to increase "diversity in the biomedical research workforce," at the Dec. 7 meeting of the Advisory Committee to the Director.** Plans include new grant programs and the appointment of a "chief diversity officer." Although NIH issued a press release and Rockey blogged about the plans, they provided few details but promised "the full presentations with more detailed information on NIH's implementation plans will be posted on the meeting and working group pages of the ACD website in the coming weeks and are available upon request." *(12/13/12)*

◆ **NIH plans to continue permitting just one resubmission for funding after a grant application has been rejected, Sally Rockey, NIH deputy director for extramural research, said in a post on her blog.** As of January 2009, NIH no longer allows two resubmissions in order to address "concerns that applications were piling up in a 'queue' and subject to a holding pattern that delayed funding until the resubmission (A1 and A2) stages, and as a consequence highly meritorious science proposed in original (A0) applications was made to wait additional months for funding," Rockey explained. Comments posted in response to her announcement indicate the policy remains controversial. *(12/6/12)*

---

may sign the document, but OLAW needs to be notified in writing, by the IO, of such authorization, Brown said.

Institutions will not receive an acknowledgement by email of their submission, but should expect a letter at a later date "accepting the annual report," Brown said.

Sending the report electronically "allows us to better track submission," Brown said. "We are also able to process the record and associate it with the electronic record of your assurance file more efficiently than FAX or hard copy reports," she added, noting that NIH has implemented a nearly 100% electronic system for grant applications.

"Upon receipt, the annual reports are logged into our database as received and then the document is reviewed by personnel and the division of assurances," Brown explained. "If there are program changes, these are reviewed by an assurance officer for appropriateness with the PHS policy and compliance with the provisions of the guide. If OLAW has questions, we will contact the IACUC for clarification or updates. Once reviewed and accepted, the IO and the IACUC will receive a letter of acceptance. A copy of the report is maintained in the assurance file."

Link to webinar: http://grants.nih.gov/grants/olaw/educational_resources.htm#

Link to annual report page: http://grants.nih.gov/grants/olaw/sampledoc/report.htm ✧

De-Identification Guidance Issued
continued from p. 1

"HHS should invest in data privacy research, support openness in sharing test data, encourage re-identification testing, and help establish channels for [government agencies] or a professional data privacy body to operationalize research results so that data sharing decisions and standards can rely on the latest guidelines and best practices," they wrote.

OHRP received more than a thousand comments on the ANPRM and is still reviewing them; it has not issued a decision on whether, or when, a proposed rule will be published *(RRC 8/12, p. 4).*

Data, biospecimens and other health-related information that have been de-identified are not subject to HIPAA.

The privacy rule provides just two approved avenues for de-identification — essentially, removal of 18 common identifiers, referred to as the "safe harbor" method, and the use of techniques to blind the information as sanctioned by an "expert." This is called the "expert determination" method.

If a HIPAA covered entity hasn't properly complied with either method, it runs the risk of exposing the data

to loss, misuse and possible HIPAA violations — not to mention the same costs and bad publicity that accompany news of a breach.

The ANPRM proposed applying HIPAA-modeled standards regardless of whether the research was conducted by a HIPAA covered entity and to encompass "all types of research studies, including social and behavioral research," but also asked "what standards would be more appropriate?"

The guidance was required by the HITECH Act but issued more than two years after the deadline specified in the legislation.

Healthcare attorney Kristen Rosati, a partner at Coppersmith Schermer & Brockelman PLC, in Phoenix, who assists academic medical centers and health systems to establish data-sharing and research consortia, said the guidance "is very useful for people who have not been working in this area for long," and said it contained at least one "gem."

"OCR has confirmed that an effective way to control for re-identification of a de-identified data set is a contract with the recipient that prohibits re-identification," Rosati told *RRC*. "While a contract prohibiting re-identification is not required under the HIPAA privacy rule — it's only required for the release of limited data sets — it is a useful step for a covered entity to be able to conclude that the information released will not be used, either alone or in combination with other available data sets, to identify individuals."

The safe harbor method is satisfied if specified "identifiers of the individual or of relatives, employers, or household members of the individual, are removed," including names, phone numbers, internet protocol (IP) addresses, email addresses, etc., and "any other unique identifying number, characteristic, or code," combined with the CE attesting that it "does not have actual knowledge that the information could be used alone or in combination with other information to identify an individual who is a subject of the information."

Paper: Re-Identification 'Hard'

A paper published in 2011 from a $453,000 HHS contract concluded that re-identification was "much harder" than expected. The contract was let in 2010 by the Office of the National Coordinator for Health Information Technology, and called for an entity with "in-depth" HIPAA knowledge and "experience with conducting comprehensive research on re-identifying a HIPAA deidentified dataset" to take one or two such datasets and "demonstrate the ability or inability to reidentify the data" using various methods.

According to the paper, the contract found two possible re-identifications from 15,000 patients in a data

set that had been de-identified using the safe harbor method.

Sweeney and her fellow commenters were highly critical of the outcome of the project, writing in their letter that government agencies "seem to consider the test as evidence that the HIPAA safe harbor provision offers sufficient protection, even though the data that was the subject of the ONC re-identification test itself is not available publicly or even available for researchers to review or inspect or to test with other re-identification methodologies."

Rosati termed the safe harbor method "not very useful for research because it requires the removal of most dates related to patients and geographic designations." The expert method is a "better alternative," she said.

According to the rule, the expert method has three parts:

"(1) A person with appropriate knowledge of and experience with generally accepted statistical and scientific principles and methods for rendering information not individually identifiable;

"(i) Applying such principles and methods, determines that the risk is very small that the information could be used, alone or in combination with other reasonably available information, by an anticipated recipient to identify an individual who is a subject of the information; and

"(ii) Documents the methods and results of the analysis that justify such determination."

Expert Method Also Faulted

In her experience, "One of the effective ways of de-identifying health information is to aggregate data across data sources in a manner that obfuscates most HIPAA identifiers," Rosati said. "A statistician I work with on this uses 'one-way hash algorithms,' which permits linking the same individual's information across disparate data sets, yet keeps the individual anonymous."

But Sweeney and her colleagues said the expert method has "many shortcomings."

"How small is a 'very small risk'? What qualifications should a person have to certify the results? What exactly are the criteria used to make the determination?" they asked.

The guidance notes that "there is no specific professional degree or certification program for designating who is an expert at rendering health information de-identified," and advised organizations to look for individuals who have "relevant expertise," gained "through various routes of education and experience."

The guidance adds that, "From an enforcement perspective, OCR would review the relevant professional experience and academic or other training of the expert used by the covered entity, as well as actual experience of the expert using health information de-identification methodologies."

Regarding the issue of "risk," the guidance states that "an expert will define an acceptable 'very small' risk based on the ability of an anticipated recipient to identify an individual."

It also says the risk of identification is based on consideration of four "principles":

◆ *Replicability,* which means to "prioritize health information features into levels of risk according to the chance it will consistently occur in relation to the individual";

◆ *Data source availability,* which means to "determine which external data sources contain the patients' identifiers and the replicable features in the health information, as well as who is permitted access to the data source";

◆ *Distinguishability,* which means to "determine the extent to which the subject's data can be distinguished in the health information"; and

◆ *Risk assessment,* which wraps up the previous three.

According to the guidance, "The greater the replicability, availability, and distinguishability of the health information, the greater the risk for identification."

'Millions' of De-Identified Records in Use

The need for methods with which researchers, compliance officials and regulators feel comfortable is intensifying, as sharing of ever more, increasingly personal, data is occurring. Research subjects and patients also must trust their data is safe from unauthorized use and disclosure. The Presidential Commission for the Study of Bioethical Issues recently called for increased protections for data from whole genome analysis *(RRC 11/12, p. 1).*

"As more health systems, hospitals and physicians are migrating to electronic health records, our health care community is building an incredible resource of information that can be used for research, quality improvement activities, public health activities like drug safety surveillance, and other purposes," Rosati said.

At Vanderbilt University, for example, some 2 million medical records have been de-identified and "made available to scientists at the university for research purposes," Brad Malin, an associate professor of biomedical informatics and computer science and director of the Health Information Privacy Laboratory at Vanderbilt, told *RRC.*

On its website, OCR thanks Malin for his assistance with the guidance and credits him with organizing a 2010 workshop in which he and other experts weighed in on de-identification strategies and challenges.

Vanderbilt researchers have "combined this information with over 150,000 de-identified DNA specimens and

have been conducting a wide range of investigations into genotype-phenotype associations," Malin said.

He also pointed out that the NIH-sponsored Electronic Medical Records and Genomics Network (EMERGE) "now consists of approximately 10 academic medical centers in the United States that are reusing electronic medical records to conduct such studies."

Similarly, "de-identified data associated with such studies is being made available to the NIH-managed Database of Genotypes and Phenotypes (dbGaP)," Malin said. "This resource has become a clearinghouse for sharing research data and has made it significantly easier to validate published studies, as well as conduct new research, with relatively large datasets that were unavailable beforehand."

Link to guidance: http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/De-identification/guidance.html

Link to ONC re-identification paper: http://dataprivacylab.org/projects/identifiability/kwokLafky.pdf

Link to comment letter: http://dataprivacylab.org/projects/irb/DataPrivacyLab.pdf ✧

In This Month's E-News

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

◆ **The Office for Human Research Protections has asked the University of Minnesota to provide a corrective action plan to address the failure of consent documents to mention gastrointestinal disorders as a possible side effect of canakinumab, a drug under study for diabetes.** OHRP found unsubstantiated an allegation of noncompliance with HHS human subjects regulations for inclusion of children in the study and an allegation that the university's institutional review board failed to consider a Food and Drug Administration advisory board recommendation regarding the medication, according to a Nov. 28 letter. OHRP asked for the corrective action plan to be submitted by Jan. 9, 2013. *(12/13/12)*

◆ **FDA issued a warning letter to Salem Hospital in Oregon for failures of its IRB to "prepare and maintain adequate documentation of IRB activities," "prepare and maintain adequate documentation of written procedures for the IRB" and follow regulations regarding the use of expedited reviews.** In its Nov. 29 letter, posted Dec. 10, FDA also cited the IRB for making decisions at meetings at which a majority of members were not present and failing to prepare and maintain a list of IRB members identified by name, degree, experience and expected contributions to the IRB. The IRB "acknowledges the validity of each of the violations" listed in the letter, FDA said, and promised to "develop new written procedures to address each violation." FDA called the IRB's response "inadequate." *(12/13/12)*

◆ **The Office of Management and Budget received a final rule from the Centers for Medicare & Medicaid Services on Nov. 27 that addresses creation of a public database that lists pharmaceutical and device manufacturers' payments to physicians and teaching hospitals.** CMS was required to create the database under Recovery Act provisions known as the Sunshine Act *(RRC 12/12, p. 10)*. The final rule, "Transparency Reports and Reporting of Physician Ownership of Investment Interests," is now posted as "review pending" on OMB's website that tracks regulations under development. CMS issued a proposed rule in December 2011 and will miss the deadline imposed by Congress to begin data collection and to issue guidance. OMB reviews can take three months or longer. *(12/6/12)*

◆ **Eric Smart, formerly a professor of pediatrics and physiology at the University of Kentucky, will not participate in certain government-funded programs or serve in any advisory capacity to the Public Health Service for seven years following a finding by the Office of Research Integrity that he engaged in misconduct over a 10-year period.** A Nov. 20 notice on ORI's website and published in the *Federal Register* said Smart's falsifications and/or fabrications of data "were included in 10 published papers, one submitted manuscript, seven grant applications, and three progress reports," and that he also reported "experimental data for knockout mice that did not exist in five grant applications and three progress reports and also falsified and/or fabricated images in 45 figures." ORI required Smart to seek a retraction or correction of the published papers, as recommended by UK. *(11/29/12)*