

RESEARCH COMPLIANCE

News and Analysis for Colleges, Universities and Teaching Hospitals

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summaries of more than 90 laws, regs and other federal requirements applicable to sponsored programs — has now been posted at www.ReportonResearchCompliance.com. If you don't already have a Web site password, please call 800-521-4323 or e-mail customerserv@aispub.com.

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SACHRP Recommends Greater Oversight, Possible Consent for Use of Biospecimens

The Secretary's Advisory Committee on Human Research Protections adopted a series of recommendations last month that would put the brakes on some long-standing practices of researchers and institutions that share biospecimens from repositories.

One recommendation calls for investigators who are not involved in the collection of biospecimens to first consult their institutional review board, or provide an assurance that the consent form accompanying the donation allows for reuse, if the new use differs from the original purpose. This would be required even if the samples are de-identified.

Barbara Bierer, SACHRP chair, told RRC that investigators who acquire a specimen have a "covenant" with the subject that both the "investigator and the institution have a duty to honor." If implemented, the recommendations could result in "huge changes" in research practices for the use of biospecimens, said Bierer, a professor at Harvard Medical School and senior vice president for research at Brigham and Women's Hospital.

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In Rare Move, University Returns NSF Grant Funds After Plagiarism Finding

Finding an investigator guilty of research misconduct in connection with a federal grant is bad enough, but having to repay the grant — with that action reported publicly — isn't the kind of publicity any university would desire. Although rare, sometimes grants must be repaid. And that's exactly the situation Central Michigan University found itself in last month.

In the wake of an investigation that concluded two researchers were guilty of plagiarism in a grant application and subsequent research, in violation of its research integrity policy, CMU's board voted late last month to return \$619,489 in grant funds received from the National Science Foundation. By law, the funds, however, go into the national treasury, not back to the funding agency.

Steven Smith, CMU's director of public relations, declined to comment on whether the university took disciplinary actions against the unidentified researchers, members of the math faculty.

NSF awarded the three-year grant in 2005 to a team of seven CMU math faculty for a project called "CONCEPT: CONnecting Content and Pedagogical Education of Pre-service Teachers."

Allegations of plagiarism arose as early as March 2007 when teaching materials connected with the program were given out to students. They came to a head in July of that year after one of the two researchers later found guilty of misconduct left CMU and wanted to transfer the funds to the new institution. As recommended by federal

guidance on handling misconduct, CMU began an “inquiry” to first determine whether a full investigation was warranted.

Two Investigations Were Done

“The original allegations were brought forth by members of the research team,” Smith said. He noted that the university conducted two separate “preliminary” and two “official” investigations.

The first investigation was of possible plagiarism in the work produced with grant funds, and the finding of plagiarism there gave rise to a suspicion that there could also have been plagiarized material in the grant application itself.

Two outside experts concluded material was plagiarized by one researcher and also held accountable the principal investigator for not catching the misconduct.

Materials were believed to have been lifted from work by the University of Missouri.

“Most of the formal investigation concluded in September 2008,” Smith told RRC, adding that after this time there was a “back and forth with NSF.” The board action to return the grant didn’t occur until recently, however, due in part to what Smith termed “a significant amount of administrative turnover” at CMU.

But, Smith added, “as soon as we confirmed there was plagiarism, we stopped the process,” he said, referring to the ongoing work funded by the grant. CMU couldn’t allow the work to proceed because it was “tainted,” Smith said.

CMU: ‘System Worked’

Asked what measures CMU has taken to prevent a similar occurrence in the future and what lessons it may have learned from this situation, Smith said, “We aren’t done with this matter. We continue to review this and see what other steps we might put in place [to detect] that a faculty member, or anyone for that matter, might be involved in unethical behavior involving grants.”

Smith added that, “We had ethical members who said, ‘Hey, this isn’t right,’ and brought it to our attention. We have an ethical misconduct policy and it did work... thanks to the care and attention of the research team to high standards.”

“To the best of my knowledge, we have never [before] had a situation like this where plagiarism has been involved in research done here at Central Michigan,” Smith told RRC.

The CMU board action to repay the grant took place on Oct. 2, and on Nov. 12, an NSF spokeswoman told RRC that the funds had already been returned — “both the \$619,000 and unspent grant funds, totaling more than \$700,000,” said Maria Zacharias, with NSF’s Office of Legislative and Public Affairs.

This does not square with CMU’s information that the \$619,000 was actually unspent, but Zacharias would not explain further, stating “I’m unable to provide further detail on this issue at this time.”

RRC also asked NSF whether grants had previously been returned by institutions, and if so, under what circumstances. But Zacharias, again declined to provide any information beyond stating “while this has happened before with other grantees, this does not happen often, and the circumstances involved vary.”

Agencies’ Investigative Functions Vary

While all the federal grant-making agencies operate under a common definition of research misconduct, which is generally described as “fabrication, falsification, and plagiarism,” each has a different mechanism for investigating and different procedures for handling misconduct, including whether findings are publicized.

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The Office of Research Integrity investigates misconduct related to grants and funding from the Public Health Service within the Department of Health and Human Services.

PHS agencies include the National Institutes of Health, Food and Drug Administration, Centers for Disease Control and Prevention, Health Resources and Services Administration, and the Agency for Healthcare Research and Quality.

Like NSF, the departments of Defense, Agriculture, Energy, and Education, as well as the Veterans Administration, all have their own staff investigating misconduct among grantees. While the Office of Inspector General handles this function at NSF, it may be carried out by separate research integrity offices at the other agencies, or by officials working within administrative or management departments.

Some agencies, especially those with billions in grants, don't place a priority on recovery of relatively small grants that might be related to the misconduct.

MIT Also Repaid Grants

ORI receives approximately 200 allegations of misconduct each year, of which about half require review to establish jurisdiction and referral to an institution for action, said John Dahlberg, director of the division of investigative oversight.

Sometimes grants are returned when ORI makes a misconduct finding, but ORI itself cannot request repayment, said Dahlberg, as ORI's actions are limited to "certain administrative actions, such as debarment."

It would be up to the funding agency to seek repayment, he said, or an institution could voluntarily return the funds. CMU has said it repaid the NSF funds to increase its chances of receiving grants in the future, but it is not clear whether NSF required repayment.

Dahlberg cited one case of repayment that involved massive fraud over many years. Luk Van Parijs was found guilty of misconduct in 2009 that had occurred while he was at the Harvard Medical School, Brigham and Women's Hospital, California Institute of Technology, and Massachusetts Institute of Technology.

Allegations first arose in 2004, and MIT fired Van Parijs in 2005. Dahlberg said MIT "promptly returned grant funds to NIH and cancelled additional grants that had been awarded but not yet funded," due to Van Parijs' "extensive admissions" of misconduct. Dahlberg was not sure how much money had been returned.

If grant funds are already spent, an institution might have to dip into its own coffers to repay an agency. Obviously, it would be "less painful to return funds sent to the institution, but not yet spent, than it is to return funds spent by a principal investigator," Dahlberg added.

ORI Supports Disclosure

NSF, in contrast to ORI, does not reveal the names of those who commit misconduct. In its semi-annual reports to Congress, it describes misconduct cases it has been involved in without using investigator names or, in some cases, even an institution's name, although it may name the state where it is located.

Its March report, for example, describes a case in which "the director of a university medical research center, who served as a PI on an NSF award, made inappropriate purchases and improperly charged \$282,409 to the NSF award over a 2-year period. The university returned \$282,409 to NSF for these inappropriate expenditures and terminated the PI from his position at the university."

ORI supports publicizing the names of the investigators who are disciplined so that other institutions are aware should they seek employment with them.

ORI findings are published in the *Federal Register*, posted for three years on ORI's Web site, and included in its annual report and the NIH Guide. All findings that include debarment are also listed on the federal List of Excluded Individuals and Entities, as are debarments by other agencies.

"Additionally, ORI and NIH maintain an ALERT listing on ORI's Web site to permit NIH funding components making awards to check recipients' names against ORI's listing of individuals with active administrative actions," Dahlberg said. ✧

Agencies Poring Over ARRA Reports, Say Most Were on Time

The National Institutes of Health received, on time, nearly 100% of the reports it expected from grantees submitting the first of the new quarterly reports required for funds received from the American Recovery and Reinvestment Act.

The National Science Foundation experienced a similarly high rate of on-time reports, according agency officials who spoke at a recent meeting of the Council on Governmental Relations (COGR).

ARRA funds carry with them a series of unprecedented reporting and other requirements (*RRC*, 3/09, p. 1). The run-up to the Oct. 10 deadline for the first report was accompanied by much *sturm and drang*, but it appears most institutions got it right, at least according to the two biggest grant-making agencies.

Recovery.gov has reported that prime and subrecipients filed a total of 130,362 award reports with *FederalReporting.gov*. Of those, 13,080 were contract reports, 116,675 were grant reports, and 607 were reports on loans.

continued

The reports said that 640,329 jobs were created or retained.

ARRA gave agencies a week to review the reported awards and work to acquire missing reports; agencies were required to screen the data to identify material omissions and significant reporting errors.

NIH expected to receive approximately 11,900 ARRA award reports; by the close of the reporting and correction period, it was only 98 reports shy of that number, a compliance rate of more than 99%, said Joe Ellis, director of NIH's Office of Policy for Extramural Research Administration.

For NIH, the primary issues in reporting, according to an initial analysis, were that the award amount reported did not match the actual award, the award date did not match the NIH date awarded, expenditures exceeded the amount awarded, and an unreasonably high number of jobs were reported, Ellis said.

NIH will further scrutinize the text fields as it continues its analysis. Benchmarks for analysis could be changed or enhanced for the next reporting cycle, based on the results of NIH's analysis.

Incorrect Award Numbers Noted

Of the 4,502 ARRA awards that were to have been reported to NSF, 98% also were received on time, said Jean Feldman, head of NSF's policy office.

Incorrect award numbers, invalid funding agency codes, invalid CFDA numbers, registration issues, and incorrect annual totals for jobs created and retained were the most frequent errors NSF found, she said.

Frequent questions from recipients during the reporting period were regarding the Treasury Department accounting symbol, the activity code, and the contracting agency code, as well as the question, "Do I have an NSF ARRA award?" Feldman added.

Feldman also reminded the audience that for ARRA awards, NSF standard policies and procedures are in effect for pre-award costs, post-award notifications and requests, extension of projects, and the period of availability of funds.

However, there are two notable exceptions from NSF standard terms: disallowed are transfers of grants from a principal investigator's previous institution to a new one and there can be no subawards to foreign institutions, she said.

Jobs Data Still Puzzling

To audience members, though, there was little surprise about what was most difficult for them about the reporting requirements — jobs (*RRC, 10/09, p. 1*). Confusion still exists on how to compute the jobs created and retained. As *RRC* has reported, there are major differences in how the computations were made, audience members said.

Using the example of an employee who worked 100% time for the period July through September, it appeared from audience comments that some institutions reported one job created/retained while others computed .25 full-time equivalent created/retained.

A representative from the Office of Management and Budget, who also attended the meeting, said OMB would be issuing additional information on job computation prior to the next reporting deadline, which is Jan. 10. She also said OMB would issue guidance on the "Buy America" requirements under ARRA (Section 1605).

Next Deadline Looms

The Jan. 10 reporting deadline will cover grant activity from October–December 2009. Some grantee institutions have expressed concern at the timing of this deadline, coming on the heels of the holiday season, when staff often take time off and some offices shut down for semester break.

Experts tell *RRC* that institutions should develop strategies to overcome these challenges. For example, they may want to start collecting data with an early deadline to ensure compliance, as those that rely on PIs to estimate the percent of project completion, for example, may find they are off-campus prior to the reporting deadline.

These individuals are also likely to be the source for the job creation numbers.

Finally, because the ARRA awards will be subject to special audit scrutiny, it is important for institutions,

Other Resources From NCURA and AIS

✓ *A Guide to Managing Federal Grants for Colleges and Universities*, co-published by NCURA and NACUBO, in conjunction with AIS, is a four-part information service: a comprehensive content-rich Web site, daily Web postings of agency actions and weekly e-mail summaries, printed reference documents and a monthly newsletter, *Federal Grants News*.

✓ *Sponsored Research Administration: A Guide to Effective Strategies and Recommended Practices* provides research administrators with a "living textbook" on the wide range of research management challenges they face each day. The publication includes quarterly updates and a CD.

Visit www.AISEducation.com

if they haven't already, to document their reporting processes. This should include how the reported expenditure amounts were derived and the method of calculating jobs created and retained, experts say.

Note: This article is based on an article that appeared in the November 2009 Federal Grants News. ✧

NSF Issues Effort Reporting Audits Of U. Wisc.-Madison, Stony Brook

The Research Foundation of the State University of New York (SUNY) at Stony Brook and the University of Wisconsin-Madison had well functioning effort reporting systems, but both had areas of weakness that should be addressed, according to two new audits by the Office of Inspector General of the National Science Foundation.

The audits are part of a series "of the labor effort distribution systems being conducted at NSF's top-funded universities in order to assess the adequacy of internal controls to ensure salaries and wages claimed on NSF grants are properly managed, accounted for and monitored," the auditors said.

Wisconsin: Review of FY 2007 Activity

Wisconsin is "one of the top five universities in the country in terms of research expenditures, and in 2007 reached over \$1 billion in new awards," according to the auditors. Its review looked at fiscal year 2007, during which Wisconsin's federally sponsored projects totaled approximately \$719 million, of which \$125 million, or 17%, were funded by NSF. Of the \$125 million, more than \$31 million were for labor costs directly charged to NSF awards.

"Our review disclosed that Wisconsin generally had a well-established and sound grants management program. However, the audit disclosed internal control weaknesses that Wisconsin needs to correct to ensure proper implementation and oversight of its effort reporting system," the report said.

The auditors found "weaknesses in oversight of the effort reporting process, calculations for NSF summer salary limitations and the effort reporting training program."

They identified an "overcharge" resulting because "Wisconsin did not fully comply with NSF's salary limitations for faculty research. This resulted in two of four principal investigators (PIs) exceeding the limitation and overcharging NSF \$2,941 in salary and benefits," the auditors said.

To address these issues, the auditors made recommendations for "developing and implementing clear written policies for periodic oversight of the effort reporting process, compliance with NSF's salary limitations, and a training program."

The auditors said Wisconsin "generally agreed with the facts and findings and concurred with the recommendations" and will "address future, regular evaluations of its effort reporting processes and practices, enhance its policies and procedures, repay the questioned costs and provide additional opportunities for refresher training."

Training Recommended at Stony Brook

Although considerably smaller than Wisconsin, the OIG auditors nonetheless included the SUNY research foundation, in Stony Brook, in one of its planned reviews of effort distribution systems. The audit covered fiscal year 2008, during which time the institution's charges to federally sponsored projects totaled \$148.6 million, of which \$23.2 million, or about 16%, were charges to NSF. More than \$8.1 million were for labor costs.

On the basis of a review of 30 employees' reports, the auditors determined that the Stony Brook payroll distribution system "substantially supports payroll costs charged to NSF awards," they said.

"The employee effort reports were generally consistent with the fiscal year 2008 salary costs of \$703,260 directly charged to NSF grants. The audit also revealed that the foundation has updated policies, improved procedures, and strengthened internal controls in the areas of labor effort reporting and cost transfers. Notable accomplishments at Stony Brook are the timely certifications of labor effort reports and the identification, track-

NSF to Again Use APPLY Function at Grants.gov

The National Science Foundation released an updated Grants.gov Application Guide on Nov. 16 that states, "Unless otherwise specified in an NSF solicitation, applications to NSF may be submitted via use of Grants.gov or the NSF FastLane System." The guide also has been updated to reflect the availability of Research.gov to track the status of NSF grant applications. An October "advisory" posted on the FastLane Web page stated that the agency would "re-establish" the option for grantees to apply for NSF funding opportunities on Grants.gov "no later than Dec. 1." NSF began accepting applications through FastLane only earlier this year to relieve the burden on the Grants.gov system caused by the American Recovery and Reinvestment Act. **Link:** www.nsf.gov/pubs/policydocs/grantsgovguide1209.pdf?WT.mc_id=USNSF.

ing, and recording of cost-shared effort committed by principal investigators in grant proposals.”

However, there were a number of areas where improvement is necessary, according to the auditors. They contended that the foundation’s “policies and procedures did not incorporate first-hand knowledge as a condition of suitable means of verification to support labor charges to federal awards.”

Greater Integration Recommended

They also said that “policies concerning effort reporting and labor cost transfers were unclear and appear contradictory; the effort reporting system did not include all employee sponsored and other activities on an integrated basis; Stony Brook employees were inadequately trained on their effort reporting responsibilities; and monitoring was insufficient to ensure that all Stony Brook departments complied with established foundation effort reporting policies and procedures.”

Some effort reports were signed by individuals who “did not understand the certification criteria” or lacked the means to verify the accuracy of the reports, according to the audit.

Auditors also took issue with the fact that the foundation’s effort reporting system was not fully integrated to include all academic, administrative, and research effort for both sponsored and all other work activities. “We also identified system weaknesses that allowed for labor cost transfers to be made without required justifications and incorrect salary charges that did not directly benefit NSF grants,” the auditors said

To address these issues, the auditors recommended that the foundation “establish clear and complete policies, fully integrate the effort reporting process, establish a training program for all individuals involved in the effort reporting process, and provide more oversight over the effort reporting program.”

The foundation was in general agreement with the audit findings. It already “has revised or plans to revise certain policies and procedures to address opportunities for improvement in effort reporting and cost transfer practices. The foundation will work with its internal audit office and the external independent auditor to ensure that the scope of work performed for the annual OMB Circular A-133 audit encompasses those areas required for the federally-mandated independent evaluation of the effort reporting system,” the report said.

Common NSF Audit Findings

Since 2006, the Office of Inspector General of the National Science Foundation has conducted 14 in its planned series of 16 audits of effort reporting systems at major universities, with the two most recent reports issued this month (see p. 5).

Some of the most common findings from the audits appear below.

- ◆ Effort reports certified by individuals with insufficient knowledge of the work performed
- ◆ Missing or incomplete documentation that serves as a “suitable means for verification” of effort reports
- ◆ Training available, but not required; training inadequate
- ◆ Improper calculation of summer faculty compensation — 2/9ths rule
- ◆ Failure to conduct adequate periodic independent reviews of the effort reporting system, as required by Circular A-21 (Auditors have concluded that A-133 audits are not sufficient to satisfy the requirement.)
- ◆ Timing of certifications and failure to follow the university’s policies and procedures, for example, on the deadline for submitting verified effort reports

- ◆ Failure to adequately account for unfunded effort and voluntary uncommitted cost sharing
- ◆ Policies and procedures do not reflect grants management regulations and requirements
- ◆ Failure to include all institutional effort in the effort percentage calculation or to calculate the percentages based on a normal work week when, in fact, a longer workweek is the actual time spent
- ◆ Inaccurate statements of effort on federal projects
- ◆ Direct charging a grant for unrelated or unallowable activities
- ◆ Failure to reconcile effort report data with salary charges
- ◆ Failure to adjust for significant changes in effort levels between effort reports
- ◆ Effort committed in grant proposal not charged to the grant
- ◆ Failure to maintain grant-related and salary information in official employee HR files

For copies of all the NSF OIG audit reports, go to www.nsf.gov/oig/pubs.jsp.

But the foundation, based on the fact that it is a separate legal entity from SUNY, “disagrees that, to be compliant with OMB Circular A-21, its procedures must be revised to ensure that all employee effort reports include all academic, administrative, and research activities, including state-funded activities,” the audit said.

Yet, the auditors contended that this doesn’t matter. “We believe our finding is valid and that the legal distinction between the two entities does not negate the foundation’s responsibility for the reporting of all compensated employee work activities on an integrated basis as required by Circular A-21,” the auditors said.

“This is particularly true given that the foundation already has an existing procedure for including state-funded activities on effort reports for faculty and other Stony Brook staff with sponsored research duties,” the report said. “Therefore, it needs to consistently apply these same effort reporting procedures to all employees working on federal sponsored projects.”

Links: www.nsf.gov/oig/10_1_002_uwm.pdf (Wisconsin); www.nsf.gov/oig/10_1_001_suny.pdf (Stony Brook). ✧

OHRP Posts ‘Helpful’ Answers On Exempt Research Designation

The Office for Human Research Protections has posted three new frequently asked questions and answers designed to help institutions determine when research is exempt from regulations.

The questions and answers were in response to a recommendation made by the Secretary’s Advisory Committee on Human Research Protections, which said OHRP should “develop a consolidated, comprehensive guidance document on the implementation of the provisions under HHS regulations at 45 CFR 46.101(b) for exemption of research from the requirements of 45 CFR 46. The guidance should address both general issues impacting the application of the exemption categories and specific guidance for each of the six existing exemption categories.”

In addition, OHRP Director Jerry Menikoff promised in May that OHRP would offer some kind of clarification reiterating that institutional review boards don’t have to be the ones determining exempt research (*RRC*, 6/09, p. 7). At the time, Menikoff said, “First of all, the regulations don’t say you cannot allow researchers to make determinations of exemptions.”

Two research officials told *RRC* the new information is somewhat useful but may not clarify thorny issues such as how much authority principal investigators themselves should have in declaring research exempt.

Question two of the three asks, “Must there be review by someone other than the investigator before a research study is determined to be exempt?” While the answer states, “No, the regulations do not require that someone other than the investigator be involved in making a determination that a research study is exempt,” it goes on to say, “Because of the potential for conflict of interest in this situation, OHRP’s long-standing recommendation is that investigators not be given the authority to make an independent determination that human subjects research is exempt.”

Norm Braaten, research compliance coordinator at South Dakota State University (SDSU), thought it was unlikely that the FAQs would result in any changes at institutions. “Most IRBs already have systems — hopefully efficient ones — to review exempt research,” he said.

“At SDSU, we made no changes to our procedures based on the new guidance,” he said, but added that the FAQs were “helpful in that they acknowledge flexibility in the regulations and allow for variation in how low risk — exempt — research can be reviewed.”

“If an organization has a bottleneck in reviewing low risk research, these could be very helpful in enabling them to look at novel approaches to relieve the burden of review,” he said.

Under the guidance, research work might occur sooner than some institutions had been allowing, Braaten added.

“One idea I found particularly interesting was the ability for a researcher to immediately commence research after submission of some initial paperwork, a concept that may have been borrowed from the recombinant DNA guidelines,” Braaten said.

At SDSU, Exemptions Requested by E-Mail

Review of research proposals to determine status is done by the IRB chair or his or her designee. The individual making the determination must be qualified and “skilled in the interpretation of the regulations,” Braaten added.

“We provide the basis for the exempt determination in our approval letter, so it becomes part of the record. Exempt activities carry no expiration date,” he said, but “changes are required to be forwarded to the IRB and are reviewed to make sure that the activity would continue to be exempt.”

His institution is usually able to make an exemption determination in a few days, due partly to a low volume of applications; he said SDSU receives about 100–120 new protocols or inquiries per year.

“All applications, protocols and inquiries are sent to an e-mail account monitored by the research compliance coordinator, the person currently designated to make

exempt determinations," Braaten said. "If an activity is not exempt, it is moved to the appropriate level of review, and a completed application form would be required, if not completed already. All activity can be done online — we prefer this — but paper submissions are also accepted."

Investigators would indicate by checking a box that they believe a study might be exempt and can select the exemption category. "We can view the form and at a glance know if it should be considered for exemption,"

he added. "The investigators usually get this correct. When an investigator does not complete our form, the e-mail usually consists of the message: 'Can you take a look at my survey? I think it is exempt.' If the survey meets the conditions for exemption in the Common Rule, SDSU will exempt it with no additional information/paperwork required."

He added that if an exemption is not appropriate, "we determine if it fits one of the expedited review cat-

Inside NIH

Dates that appear at the end of NIH news briefs indicate the issue of RRC's weekly e-mails in which a news item first appeared, where links for documents may be included. Go to "Recent E-Mail Issues" at the RRC Web site, www.Reporton-ResearchCompliance.com.

◆ **NIH has issued a final rule revising the definition of principal investigator.** The definition will now include "one or more individuals designated by the grantee in the grant application...who is or are responsible for the scientific and technical direction of the project," a change from the previous limit of a single PI, the agency announced in the Nov. 10 *Federal Register*. The change comes as part of the NIH Roadmap for Medical Research and is also in keeping with the Jan. 4, 2005, directive from the Office of Science and Technology Policy to all federal research agencies "to accommodate the recognition of two or more principal investigators on research projects (grants and contracts)." NIH is revising the definition of PI in section 52.2 and the conditions for multiple or concurrent awards in section 52.6, paragraph (d) of its Grants for Research Projects regulations, codified at 42 CFR part 52. The final rule is effective Dec. 10. (11/12/09)

◆ **The National Cancer Institute is developing an electronic resource, the NCI Clinical Trials Reporting Program (CTRP) Database.** The database will "serve as a single, definitive source of information about all NCI-supported clinical research." NCI announced a data collection request to support the project in the Nov. 9 *Federal Register*. NCI is seeking comments within 60 days on specific data elements proposed to be collected. The notice, however, does not include the actual data elements; to receive more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact John Speakman at 301-451-8786 or john.speakman@nih.gov. (11/12/09)

◆ **Under certain circumstances, institutions may not need to report research animals that experi-**

ence an unexpectedly high level of pain as a "category E" event on their annual report to USDA. But technicians must be trained to promptly and properly respond to a spike in pain, according to new guidance issued jointly by USDA and the Office of Laboratory Animal Welfare. The annual reports are just one page and consist of categories of information from A to F. Category E must detail "the number of animals upon which experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests." The guidance appears in a protocol review "scenario" column in the November issue of the publication *Lab Animal*, entitled "Categorizing Insufficient Pain Alleviation," and is also posted on the OLAW Web site. (10/29/09)

◆ **NIH has announced the transition of applications for additional programs to electronic submission through Grants.gov using the SF 424 (R&R) forms.** For due dates on or after Jan. 25, 2010, the following programs will transition: institutional national research service awards (T32, T34, T35, T36, T90), other institutional training grants (D43, D71, T01, T02, T03, T14, T15, T37, TU2, U2R), and institutional career development programs (K12). All applications in response to announcements for these grant programs must be submitted electronically. The T42 program (used by the Centers for Disease Control and Prevention and the National Institute of Occupational Safety and Health) will not transition to e-submission at this time. (10/29/09)

egories" in the law. Expedited review is conducted by a subcommittee of the IRB, usually three people for new applications or protocols and one person for continuing review, he said.

"We do not have a medical school and much of our activity is in educational and social science research," Braaten explained. In fiscal year 2008, the latest year for which statistics are available, of the protocols submitted, 73% were exempt, 22% expedited, and 5% underwent full IRB review, he said.

Similar System at South Carolina

Thomas Coggins, director of the Office of Research Compliance at the University of South Carolina, agreed with Braaten's assessment of the questions and answers.

"I did not see any substantive change in the guidance from what OHRP has been advocating for years, including the position that researchers should not determine their own exemptions," said Coggins. "Of course, the regulations do not require any specific oversight, but OHRP always has taken the position that there should be some oversight beyond the PI."

He added that "most in the academic research compliance community are already fairly clear and comfortable with the concept" of making exemption determinations. What is needed, in his view, is more guidance on the definition of human subjects research itself.

Research that qualifies as exempt has first been deemed to be human subjects research, and there is still confusion about research that does not have to meet the regulations not because it has been deemed exempt, but because it is not human subjects research. This can include studies done on de-identified tissue samples (see p. 1).

His institution also has an online system for submitting protocols for approval, which allows investigators to select whether they think the work is exempt or should undergo expedited review.

Institutions may wish to tweak their systems based on the guidance. Braaten urged those who make changes to be "thoughtful and deliberate" in their actions, and pointed out that "change is something that takes time, perhaps especially so with IRBs."

"Other problems that may inhibit efficient review are not as easy to resolve," said Braaten. "For example, IRBs and administrators may act conservatively because they got 'burned' by a researcher, even if it was once, a long time ago. Institutions fear litigation. The bottom line is that researchers and IRBs need to identify and classify risks and appropriately protect people."

Link: www.hhs.gov/ohrp/compliance/ohrpcomp.pdf. ✦

SACHRP Looks at Biospecimens

continued from p. 1

SACHRP, which advises the secretary of Health and Human Services and the Office for Human Research Protections, acknowledged that it is treading into a difficult and complex area with these recommendations. But members strongly believe that federal guidance is needed to strengthen oversight of the millions of biospecimens that are routinely used today in research.

Millions of Specimens Available

The issue of consent and use of tissues and other samples from banks falls under the purview of SACHRP's Subpart A Subcommittee, which is charged with reviewing the section of the law that includes basic regulations governing human subjects in research.

According to the subcommittee, "institutions, investigators and institutional review boards are struggling with scenarios that involve tissue banks, DNA repositories, storage of biospecimens for future unspecified use, and related issues."

A study by the Rand research organization in 2000 estimated there were some 300 million specimens available, with 20 million new samples added each year. Much biomedical research relies on use of human specimens, which can result from surgery, various medical procedures — such as *in vitro* fertilization — pathology techniques, and blood donations.

According to the subcommittee, there are "few universal or widely accepted practices" and "much inconsistency on what 'must' or should be done."

At its previous meeting in July, SACHRP adopted some of the subcommittee's recommendations to address these issues.

All told, the Subpart A Subcommittee developed 28 frequently asked questions on biorepositories, in which the oversight recommendations are embedded. SACHRP to date has approved the first 11 FAQs, with the goal of approving the remaining during its next quarterly meeting, which will be sometime in early 2010. After approval, they would be sent to HHS and OHRP.

One previously approved FAQ, for instance, states that tissues from biopsies that are used by investigators for research purposes must have the consent of the patient if the material contains identifiers such that the investigator can readily ascertain the identity of subjects.

'Investigator' Definition an Issue

According to the subcommittee, "OHRP does not consider research involving only coded private information or specimens to involve *human subjects* if the following conditions are both met:

“(1) the private information or specimens were not collected specifically for the currently proposed research project through an interaction or intervention with living individuals; and

“(2) the investigator(s) cannot readily ascertain the identity of the individual(s) to whom the coded private information or specimens pertain because, for example, there are agreements, IRB-approved policies and procedures, or legal requirements in place that prohibit the release of the key to the code to the investigators under any circumstances until the individuals are deceased.”

But the subcommittee pointed out that “there are many circumstances where a secondary use of coded information or specimens would not constitute human subjects research, were it not for the peripheral involvement of the individual who gathered the original data or specimens.”

For example, the “original collector [could be] involved as a coauthor on resulting manuscripts or listed on grants, in recognition of his/her work in obtaining the data or specimens, but with an agreement that prevents release of the coding key to secondary users.” In addition, an original collector could join “with others to form a centralized repository, with no continued personal access to identifiers.”

“Under these circumstances, current OHRP guidance defines the original collector as an ‘investigator’ in the secondary use, even though their role may still effectively be limited to ‘solely providing’ coded information or specimens,” subcommittee representatives said in their presentation to SACHRP. “This interpretation is overly restrictive, poorly understood, and therefore variably applied by IRBs and investigators.”

SACHRP agreed with the subcommittee’s recommendation that “OHRP should revise its interpretation of who is considered an ‘investigator’ in secondary use of coded information or specimens to exclude those individuals who are providing such information or specimens, even if they are involved in analysis of aggregate data or publication of results, *provided the secondary users are unable to readily ascertain the identity of subjects.*”

Under current regulations, the use of de-identified samples generally falls outside the scope of the law, as they are deemed not research involving human subjects.

Links in the News

Links to documents referred to in this issue are posted at www.ReportonResearchCompliance.com under “Links in the News.” Back issues of newsletters also are posted at the Web site.

“Nevertheless, the original investigator and his/her institution have made an agreement with the subjects about use of their specimens, and have an obligation to honor that agreement,” the subcommittee said in materials developed for the meeting.

Specifically, the recommendation is that, “Institutions should establish mechanisms to determine whether secondary uses are compatible with the original informed consent; this could involve consultation with the IRB that approved the original research, or review by some other body designated for these purposes.”

SACHRP adopted the subcommittee’s statement that “coding should not be used as a means to circumvent the original terms of consent. This is ethically problematic, even if the original project is over and the secondary use is no longer considered to be research involving human subjects.”

Other scenarios addressed by the FAQs include whether an academic medical center that has established a centralized tissue bank of identifiable specimens could automatically move “excess clinical specimens...with identifiers...to the bank after their original purpose has been served, even if there was no research consent obtained from the patients.” The answer is no, according to the approved FAQ.

“The creation of this bank is human subjects research activity and requires IRB review and approval, which should include the policies and procedures under which the bank will be managed, the control of specimens, and the types of research to be conducted. Because this is human subjects research, consent would be required, unless the IRB determines that a waiver of consent is appropriate under these circumstances.”

Donations for Additional Uses

Another approved FAQ concerned patients undergoing surgery who agree to donate tissue beyond that needed for clinical purposes to a tissue bank. “The creation of the bank is reviewed and approved by the IRB. The consent form makes it clear that the specimens and associated clinical data will be used for research, but *does not specify or limit that use.* If specimens are provided to the researchers with clinical information that allows the researcher to readily ascertain the identity of the subjects, is a new consent from the patient/subject [or IRB waiver of informed consent] required?”

The answer is yes, “[A] new consent is required unless the IRB determines that the original consent was adequate to allow the subsequent research use, or the IRB determines a waiver is appropriate.” In both scenarios, the subcommittee cited the regulations that specify waiver criteria, which are that “the research involves no more than minimal risk; the waiver would not adversely affect the

rights and welfare of subjects; the research could not practically be carried out without the waiver; and whenever appropriate, the subjects will be provided with pertinent information after participation."

Should HHS and OHRP adopt the FAQs and the recommendations on samples and consent, Bierer said investigators and institutions would then need to be "sensitive to this issue."

She added that, "it is very possible that OHRP will consider this a significant enough change that they would allow for public comments" before issuing final guidance or another statement endorsing the need for greater oversight of tissue and related samples.

Universal Adverse Reporting to Come?

At its meeting, SACHRP also heard from Philip M. Budashewitz, associate director of the National Institutes of Health's Clinical Research Policy Analysis and Coordination (CRPAC) program. Budashewitz said the key initiatives of the program were related to informed consent, clinical trials, privacy, optimizing IRB review, specimens and data, as well as spearheading the Federal Adverse Event Task Force.

According to Bierer, Budashewitz said the task force had been working for six years and was closing in on a project to harmonize the Food and Drug Administration's and NIH's adverse event reporting processes, with the goal of producing "a single form that investigators can fill out and submit to all the agencies."

Bierer reported that Budashewitz said this could be "rolled out in the next couples of months." The task force is composed of representatives from the Department of Defense, Veterans' Administration, and all major HHS agencies, including NIH, OHRP, and FDA.

Slides presented by Budashewitz indicated the task force's goal was to develop a "federal-wide safety reporting portal," that would draw upon a single baseline set of core medical information adopted by all relevant agencies and that would encompass "all forms of clinical research. It would permit safety information to [be reported to] multiple agencies, IRBs, and data safety monitoring boards." Unanticipated problems could be reported to OHRP through the portal, as could pre- and post-market reports due to FDA.

Bierer added that, referring to task force members, she "could not give them enough credit" for their efforts. "We were really very encouraged" by the report, she said.

At its previous meeting in July, SACHRP asked HHS to approve the creation of a SACHRP subcommittee to address the harmonization of various human subject regulations and conflicts with other laws, such as HIPAA. However, HHS has not yet acted on this request,

Bierer said, adding there has been "some question" about the "mission" of the subcommittee.

The NIH presentation convinced Bierer that the proposed SACHRP subcommittee would work well with the task force and not duplicate its efforts. There could be "synergy" between the SACHRP subcommittee and the task force, she said.

"Our proposed subcommittee would take the issues that we know exist in the regulated community and 'tee' them up and think about proposed solutions, see areas of disharmony, things that are burdensome or challenging in terms of interpretation," Bierer said.

Consent, Community Research Discussed

One of the panelists, Ann Partridge, a breast cancer oncologist at the Dana Faber Cancer Institute and an assistant professor in the department of medicine at Harvard Medical School, told SACHRP members that she believes all Phase III clinical trials should include a plan to share results.

Study participants should be asked if they want results before they are sent to them. Researchers should anticipate that some participants may be anxious and misinterpret the findings and require educational and psychosocial support, Partridge said.

Among the issues addressed were the possibility of "subdividing the process" into more than one part. For example, it is not advisable (though it may happen often) to discuss participating in a clinical trial immediately after the person has received a diagnosis, she said.

The process of obtaining consent and the forms needs to be simplified and streamlined, the panelists agreed, and multimedia approaches, such as showing a video, can prove effective and efficient in explaining a trial.

Bierer also described as "wonderful" a panel that addressed SACHRP on community-based research, although there were no recommendations made following the presentations.

SACHRP is just beginning the process of reviewing community-based research to determine whether there are enough issues to empanel a new subcommittee, Bierer said.

At the meeting, SACHRP was joined by Christina Hyde, its new ex-officio member who represents the Office for Civil Rights. OHRP and SACHRP have been working to eliminate the burdens that the HIPAA privacy and security rules place on researchers and institutions and invited OCR to appoint a nonvoting member.

Link: www.hhs.gov/ohrp/sachrp/mtgings/mtg10-09/mtg10-09.html. ✧

In This Month's E-News

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

◆ **H.R. 2868 was amended to “recognize that colleges and universities are not the same as major chemical facilities...and to acknowledge the unique chemical usage and laboratory structure of academic institutions.”** The U.S. House on Nov. 9 approved the bill, the Chemical Facility Antiterrorism Act. Six higher education associations, including the Association of American Universities and the Council on Governmental Relations, wrote to members urging adoption of the amendment, which sets separate standards and security procedures for protecting chemicals used in research versus those used by chemical manufacturing facilities. (11/12/09)

◆ **ARRA included tougher enforcement and increased penalties for violations of the HIPAA privacy and security rules.** Universities may have to comply with these new provisions as either covered entities or business associates of covered entities, as under ARRA BAs must meet the same requirements as CEs. On Oct. 30, HHS published an interim final rule clarifying the four tiers of fines described in ARRA that can reach \$1.5 million per year for violations; the previous maximum was \$25,000. Factors that will play into the size of the penalties are whether the entity knew of the violation; whether it resulted from willful misconduct; whether it was corrected within 30 days; and whether the covered entity/BA reasonably could not have known about the violation. HHS is seeking comments on how to calculate the so-called 30-day “cure” period. The rule takes effect Nov. 30, but the penalties have been in effect since February when ARRA was signed into law. The deadline for comments is Dec. 29. (11/5/09)

◆ **OHRP issued draft guidance documents regarding continuing review by institutional review boards and concerning their approval of research with conditions.** According to the two notices in the Nov. 6 *Federal Register*, OHRP is seeking feedback on the documents by Jan. 5, 2010. In the continuing review guidance, among other revisions, OHRP proposes a change to its long-standing policy regarding what event triggers the time frame for continuing review. The document on research with conditions is the first time OHRP has addressed this topic. OHRP has also issued a revised version of its 2005 document, “OHRP’s

Compliance Oversight Procedures for Evaluating Institutions.” (11/12/09, 10/22/09)

◆ **FDA issued final guidance on investigator and sponsor responsibilities that includes minor changes from the May 2007 draft, FDA said in the Oct. 26 *Federal Register*.** In finalizing the guidance, “Investigator Responsibilities—Protecting the Rights, Safety, and Welfare of Study Subjects,” FDA “carefully considered all substantive comments” concerning the content of the guidance. In preparing the final document, the notice states, “FDA’s major emphasis was on clarifying issues that were identified as confusing and correcting apparent errors.” The agency said the guidance is intended to assist investigators in meeting their responsibilities with respect to protecting human subjects and ensuring the integrity of data in the conduct of clinical investigations. It also “clarifies FDA’s expectations concerning the investigator’s responsibility for supervising a clinical study in which some study tasks are delegated to employees of the investigator or to outside parties.” (10/29/09)

◆ **Creation of the National Institute of Food and Agriculture will lead to “transformative change” and a more vigorous research enterprise at USDA.** With these words, USDA Sec. Tom Vilsack on Oct. 8 officially kicked off the new agency. NIFA consists of five units: Institute of Food Production and Sustainability; Institute of Bioenergy, Climate, and Environment; Institute of Food Safety and Nutrition; Institute of Youth and Community Development; and Center for International Programs. NIFA was created out of the Cooperative State Research, Education, and Extension Service. Roger N. Beachy heads the institute. (10/15/09)

◆ **The Department of Commerce’s Bureau of Industry and Security has posted the fiscal year 2010 schedule of its training seminars.** BIS offers one- and two-day basic courses on the Export Administration Regulations, as well as in-depth courses on special topics and conferences for those experienced in export controls. Also available are online training modules and pre-recorded webinars. (10/15/09)

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