

RESEARCH COMPLIANCE

News and Analysis for Colleges, Universities and Teaching Hospitals

Contents

- 3** *Inside NSF*
- 4** Former UCLA Researcher Faces Jail for Viewing Co-workers' Records
- 5** AAHRPP: Strong Protections Still Needed Even if 'Box' Is 'Unchecked'
- 7** Proposed 'Helpful' Export Control Reforms Depend On Senate Support
- 9** When Taking Care of Animals, Don't Overlook Physical Plant
- 10** *Inside NIH*
- 12** *In This Month's E-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.

If you don't already have a Web site password, please call 800-521-4323 or e-mail customerservice@aispub.com.

Editor

Theresa Defino

Managing Editor

Darla Fera

Executive Editor

Francie Fernald

University Settlement With Arizona Tribe Sparks Discussions About Consents, Reuse

All the worrisome and prickly issues that can arise in human subjects research seemed to coalesce in the case filed seven years ago against Arizona State University by members of the Havasupai tribe of Native Americans.

The tribe alleged there were misunderstandings or misrepresentations about the types of research underway with ASU, that culturally insensitive studies were undertaken that could harm them, and that work was done with tissue samples or other DNA that was outside the consent they had given. Their case also brings up the issue of whether sharing the findings of studies with subjects should be routine, a way of ensuring that the subjects do benefit in some way.

While a trial might have determined the validity of the Havasupai's claims, the case was settled last month, with a large payment from the Arizona university system to the tribe, along with a return of blood samples — but no admission of wrongdoing by the lead researcher who collected the blood. Yet the broader issues also remain far from settled and are the subject of debate and discussion by institutions, investigators, and institutional review boards across the country, as the research community seeks to learn whatever lessons it can from this.

continued on p. 9

Groups Request Changes to DoD Plan For 'Safeguarding' Unclassified Data

Citing high compliance costs and a chilling effect on research, associations representing universities and other organizations have asked the Department of Defense to refine, clarify, and revise its recent proposal to require contractors and subcontractors to employ "basic" or "enhanced" safeguards to unclassified information.

DoD described the safeguards in an advance notice of proposed rulemaking published in the March 3 *Federal Register* and accepted comments until May 3 (*RRC 3/10, p. 1*). In addition, DoD held a day-long meeting April 22 to explain the ANPR and hear testimony from affected organizations.

Apparently DoD has gotten an earful — both at that meeting and in comment letters submitted by academic research institutions and other stakeholders.

Robert Hardy, director of contracts and intellectual property management for the Council on Governmental Relations, which, along with the Association of American Universities, sent DoD a letter critical of the proposed requirements, told *RRC* the next steps are uncertain. Hardy also attended the April 22 meeting.

"I don't know about the timing for the next round of public comments," he said. "One university person who talked to DoD was told that they may issue an interim final rule with a request for comments next, which means they would put the rule into

effect while waiting for additional comments," Hardy said. "I also don't know if they will follow our advice on the ANPR. They did follow our advice (after three previous tries) on the DFARS export control compliance requirements, as mentioned in our comment letter."

Universities Raised Objections

Despite the information being unclassified, two levels of safeguards would be required under the proposal, and even under the basic level, data could not be posted on public websites; under the enhanced level, wide use of encryption would be required. The requirements would be imposed regardless of the dollar value of the DoD contract.

Affected data are defined as "any unclassified information that has not been cleared for public release in accordance with DoD Directive 5230.09, Clearance of DoD Information for Public Release, and that is provided by or on behalf of DoD to the contractor or its subcontractor(s); or collected, developed, received, transmitted, used, or

stored by the contractor or its subcontractor(s) in support of an official DoD activity."

Basic requirements "apply to any unclassified DoD information that has not been cleared for public release in accordance with DoD Directive 5230.9, Clearance of DoD Information for Public Release." Enhanced safeguards, the strictest level of control, would apply to a variety of data that today are marked "for official use only," "sensitive but unclassified," and even information falling under HIPAA.

At the April 22 meeting, representatives of eight organizations made presentations in which they asked for changes to the ANPR. These included Ron Hutchins, chief technology officer for the Georgia Institute of Technology, and Jeffrey Reich, director of operations at the Institute for Cyber Security, part of the University of Texas at San Antonio.

Hutchins noted that "expectations are somewhat vague" in the "basic" restrictions on nonclassified data, with users required to use the "best level of security available," an undefined concept. Similarly, there is no information on how compliance will be measured and assessed, how data will be monitored, and whether new controls will be mandated with new reporting requirements.

Compliance Could Be Costly

Additional costs will be incurred even with the basic category, Hutchins said, because so many researchers would be affected. While there is a "limited number of faculty researchers working with DoD-classified data today, many more faculty, graduate students, and research scientists are working with nonclassified data on DoD contracts," he said.

Costs, described as "potential" but "immediate," include education of faculty working on any DoD data, moving faculty to a controlled network, consolidating management of workstations and laptops, self-assessment for compliance, and "personnel time required to implement these processes for all DoD data, not just classified data," he said.

According to his prepared comments, Reich's main point seemed to be one shared by many of the presenters: Why all this bother for *unclassified* information? "Without question, the rules and procedures presently in place for classified data are appropriate. That being said, however, unclassified data are just that, unclassified," he said. "These unclassified data are the lifeblood for researchers who need to use and to share this type of data in their collaborations, publications, and efforts to protect resulting intellectual property."

He also expressed fear that the very core of academic research could be damaged by such controls — and work

Report on Research Compliance is co-published monthly by National Council of University Research Administrators and Atlantic Information Services, Inc., 1100 17th Street, NW, Suite 300, Washington, D.C. 20036, 202-775-9008, 800-521-4323.

Copyright © 2010 by National Council of University Research Administrators and Atlantic Information Services, Inc. All rights reserved. It is permissible to forward portions of this publication (e.g., 3-4 articles per month) to small groups of employees on the same campus (e.g., 3-4 individuals per article) in order to distribute content to those who can use it most effectively. It is not permissible to photocopy, fax or e-mail an entire print or e-mail issue, or to post even portions of a print or electronic newsletter on a Web site or intranet, without permission. **Report on Research Compliance** is published with the understanding that the publishers are not engaged in rendering legal, accounting or other professional services. If legal advice or other expert assistance is required, the services of a competent professional person should be sought.

Editor, Theresa Defino; Managing Editor, Darla Fera; Executive Editor, Francie Fernald; Co-Publishers, Kathleen Larmett and Richard Biehl; Marketing Director, Donna Lawton; Fulfillment Manager, Gwen Arnold; Production Coordinator, Russell Roberts

Subscriptions to **Report on Research Compliance** include this monthly newsletter, weekly e-mail newsletters and access to www.ReportonResearchCompliance.com, which contains article archives and other practical tools. To order:

- (1) Call 800-521-4323 (major credit cards accepted),
- (2) Order online at www.AISHealth.com, or
- (3) Staple your business card to this form and mail it to:

AIIS, 1100 17th St., NW, Suite 300, Wash., DC 20036.

Please include your e-mail address (required for delivery of e-mail newsletters and access to the password-protected Web site).

Subscription Rates

- | | |
|-------------------|---|
| Payment Enclosed* | <input type="checkbox"/> NCURA member (\$379) |
| | <input type="checkbox"/> Non-member (\$479) |
| Bill Me | <input type="checkbox"/> NCURA member (\$379) |
| | <input type="checkbox"/> Non-member (\$479) |

*Make checks payable to Atlantic Information Services, Inc.
D.C. residents add 6% sales tax.

that could enhance the nation's security might itself be thwarted.

"Effective academic research thrives when collaboration and peer review help to develop and hone the research... Any restrictions placed on the exchange of academic research will greatly slow our progress in cyber security and thereby increase our vulnerability to attack and exploitation," he said. "Academic research often forms the foundation for applied research. Applied research focuses on the development of innovative intellectual property, which often results in patent applications and the direct improvement of our cyber security posture."

The reach of the proposal is just too great, said AAU and COGR in their comment letter.

"We understand and appreciate DoD's need to assure appropriate safeguards for the protection of certain unclassified DoD information that resides on contractor information systems," the groups said in their letter. "We also share DoD's concerns about the threats raised by unauthorized access and disclosure and cyber intrusions. However, we fear that the rule as proposed will adversely affect both DoD and our member institutions in their ability to conduct critical research by making universities more reluctant to partner with DoD in such research."

Research Might Stop

Some universities will simply "refuse to conduct DoD-funded research," because they will reject "deal-breaking" prohibitions on publication and dissemination, the organizations said.

"Even those universities that will conduct export-controlled work and accept CUI [controlled unclassified information] typically will not do so when controls are inappropriately applied to fundamental research," the letter stated. "The effects will be detrimental both to universities and to DoD. Universities will lose an important source of research funding, and DoD will lose access to many leading universities for the performance of research which it has judged as critical to DoD. This is an unfortunate outcome for both."

Section 204.7XX3 "Contract clauses" is where the new requirements, if imposed, would go.

The organizations have already called attention to the deleterious effect of the DFARS 7000 clause. "The clause restricts not only publication of research results, but also the release of any information pertaining to the project without prior government approval," according to AAU and COGR. Currently, the 7000 clause applies "in solicitations and contracts when the contractor will have access to or generate unclassified information that may be sensitive and inappropriate for release to the public."

"In this ANPR, that provision is replaced by a proposed new prescription... that the 7000 clause is to be used in 'solicitations and contracts when the contractor will have access to or generate DoD information.'... Our concern is that this expansive definition will lead to greatly increased use of the 7000 clause by DoD contracting officers in solicitation and contract terms and conditions," the groups wrote.

In reports issued in 2004 and 2008, the groups "recommended that DoD revise the DFARS prescription guidance to prevent the 7000 clause from being used in contracts for university research, either directly or as a flow down from industry contracts. We also recommended that DoD revise its guidance to contracting officers stipulating that no controls should be imposed on publications in contracts for fundamental research either in direct awards or sub-awards," the letter said.

DoD has not acted on these recommendations.

As RRC noted last month, the ANPR seems to conflict with the June 2008 memorandum by DoD Under

Inside NSF

NSF Applications Must Soon Include Data Sharing Plans

Beginning in October, all proposals for funding from the National Science Foundation must include a two-page "supplementary document" describing how research data will be shared, according to an announcement by NSF at the recent meeting of the National Science Board, NSF's governing body. "This is the first step in what will be a more comprehensive approach to data policy," said Cora Marrett, NSF acting deputy director. "It will address the need for data from publicly funded research to be made public."

Additional guidance from NSF, expected before October, will include the agency's expectations for the data management plans. This requirement is a departure from NSF's long-standing policy "requiring grantees to share their data within a reasonable length of time, so long as the cost is modest," NSF said. The change is also in keeping with "the growing interest from U.S. policymakers in making sure that any data obtained with federal funds be accessible to the general public" and the Obama administration's efforts to make government "more transparent and more participatory," the agency said.

Link: www.nsf.gov/news/news_summ.jsp?cntn_id=116928&org=NSF&from=news.

Secretary of Defense John Young, which “indicated that DoD awards for the performance of fundamental research should, with rare exceptions, not be subject to publication restrictions,” the letter said (*RRC 7/08, p. 7*).

Subcontractors Present a Challenge

Another problem is compliance by subcontractors, the groups said.

“As documented in the AAU/COGR reports, the flow down of the clause in subcontracts from prime defense contractors to universities has been a major source of difficulty,” the letter stated. “We have repeatedly urged DoD to eliminate this requirement, and are disappointed that it is not addressed in this ANPR. Universities also are experiencing increased difficulty with inappropriate inclusion of the clause in subcontracts from DoD Small Business Innovation Research awardees. The additional new requirements for safeguarding information will further exacerbate these problems.”

In their comment letter, the groups said many concerns were raised about the definition of various terms at the April 22 meeting. Among these are the terms “best level of security available” and “advanced persistent threat.”

Any regulations must “allow for the evolving, risk-based nature of security controls,” and it is not clear that these proposed requirements meet that goal, they said. In addition, there is the potential for “overwhelming both contractors and DoD with cyber intrusion reporting requirements.”

Another Unfunded Mandate?

The cost of compliance was a common objection in the comments and April 22 presentation, cited by both Hutchins, as previously noted, and the associations. As COGR and AAU noted, “there may be significant cost implications for contractors associated with the new requirements, and there is no indication in this ANPR that DoD intends to provide commensurate additional cost reimbursement to contractors for these purposes.”

The requirements could be improved if certain exceptions are allowed. The fact that “almost all items” in-

involved in DoD research fall under export controls “could have the effect of requiring the more onerous enhanced safeguarding clause for virtually all contracts,” the group say. “Low control” items do not have a specific export classification number on the Commerce Control List and should be clearly excluded, they said.

The 7000 clause should not be inserted in contracts with universities conducting “fundamental research, whether direct or through sub-awards,” according to the groups. Prohibiting the use of the clause would be the “primary way to mitigate burdens for DoD university contractors.”

They added that the clauses, as drafted in the ANPR, do not “provide clear guidance” and will “result in considerable burdens for universities” and have serious negative consequences if the ANPR is imposed as drafted.

Unchanged, “the proposed new policy will lead to indiscriminate application of the requirements by DoD contracting officers,” the groups say. “This will contravene stated DoD policy, lead to increased refusal of universities to perform DoD-funded research, and greatly increase burdens for those that do.”

Beyond COGR and AAU, other organizations have released their comment letters, which are also critical of the proposal.

In an eight-page letter, the Professional Services Council, a trade association representing more than 330 companies, “many of whom work extensively in the Defense Department,” urged the DoD to rethink its approach. “While we recognize that the goal of the rule is to protect DoD information regardless of which contractor comes into possession of the DoD information, the ANPR imposes a significant system and cost burden on a contractor at any level and alternatives should be evaluated to determine whether they can be adopted,” the council said.

Links: www.acq.osd.mil/dpap/ops/news/index.html, see April 22; www.aau.edu/WorkArea/DownloadAsset.aspx?id=10798. ✧

Former UCLA Researcher Faces Jail For Viewing Co-workers’ Records

A former University of California at Los Angeles Health System employee is the first individual to be sentenced to prison for improperly accessing protected health information in violation of HIPAA, even though there is no evidence the data were used for personal gain. His defense that UCLA had failed to adequately train him about HIPAA was not enough to spare him jail time.

Huping Zhou, a cardiothoracic surgeon in China, pleaded guilty just prior to a trial in January to four mis-

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.

If you don’t already have a Web site password, please call 800-521-4323 or e-mail customerserv@aispub.com.

demeanor counts of violating HIPAA. He was sentenced late last month to four months in prison and a \$2,000 fine; he faced a maximum prison term of four years.

“Zhou is the first person in the nation to be convicted and incarcerated for misdemeanor HIPAA offenses for merely accessing confidential records without a valid reason for authorization,” DOJ said in a statement, although a guilty plea is not a conviction.

His lawyer has indicated he will appeal the sentence, calling it “harsh.” In the sentencing memorandum, Zhou asked for probation, noting the stress to his family, the loss of his job, and the possibility that he may not be able to become a physician in the United States.

On Oct. 29, 2003, Zhou, employed as a researcher by UCLA’s School of Medicine, was notified he would be fired for job performance issues, according to DOJ.

That night, he accessed and read his supervisor’s medical records and those of other co-workers. Apparently his curiosity continued, as over the next three weeks, Zhou accessed and read health records belonging to various celebrities, reportedly including Sharon Osborne, Tom Hanks, and Leonardo DiCaprio.

UCLA Training Faulted

He accessed UCLA’s patient records system 323 times over the three-week period, but the U.S. attorney’s office said Zhou never disclosed any of the information or tried to sell it, unlike in previous HIPAA cases that have been prosecuted.

Zhou’s attorneys contended there were problems with the way UCLA was training its employees, and that he did not know he was violating HIPAA.

UCLA officials, who initiated the investigation after learning of the inappropriate access, told investigators that HIPAA training at that time consisted of a training module (i.e., manual), a six-question quiz, and a certificate showing that the employee completed the course, according to court documents.

Employees could take the test without reading the manual first, and they could take it online or in person, the officials said. During the quiz, employees were given three chances to answer a question correctly, after which they would be shown the correct answer. In-person HIPAA training courses were an option.

UCLA System Upgraded Safeguards

After the sentencing, the UCLA Health System issued a statement saying Zhou’s access should have been terminated sooner, and that changes have been made to ensure that now happens without delay.

In addition, UCLA said it had “put in place a number of safeguards to help ensure patient confidentiality” including that it:

- ◆ “Expanded the auditing capabilities of our information systems and more than doubled the number of individuals who we proactively audit to ensure their privacy is maintained.
- ◆ Evaluated and enhanced our clinical information systems to reduce the risk of information security violations.
- ◆ Implemented a mandatory and expanded HIPAA training and certification module required for all physicians, staff and students.”

Past HIPAA guilty pleas or convictions involved individuals who profited or sought to make money using protected health information, such as to obtain credit card accounts or defraud Medicare. In cases involving celebrity patients, information was sold to tabloid news outlets. In 2008, UCLA fired 13 and suspended seven workers for snooping in celebrities’ files.

In Arkansas, a physician and two hospital employees pleaded guilty to improperly accessing the records of a local news anchorwoman who was beaten to death. Because they did not use or sell the information, the individuals were sentenced to fines and probation, not jail time.

The UCLA case shows that the federal government is not letting snoopers off the hook. “The fact that the U.S. attorney’s office brought charges for curiosity peeking — albeit a great deal of curiosity peeking — indicates that the Department of Justice is indeed taking privacy seriously,” said Phoenix attorney Kristen Rosati, with Copersmith Schermer & Brockelman PLC.

Link: www.justice.gov/usao/cac. ✧

The above article was adapted from the May 10 Report on Medicare Compliance, www.AISHealth.com.

AAHRPP: Strong Protections Still Needed Even if ‘Box’ Is ‘Unchecked’

Institutions that receive funding from the U.S. Public Health Service to conduct studies that meet the definition of human subjects research are required to have a federalwide assurance (FWA), an attestation made to the government that they will comply with human research protections known as the Common Rule, found at 45 CFR Part 46.

On their FWAs, organizations may also check a box indicating that they will voluntarily apply those federal standards to non-PHS-funded research. They can choose to apply just Subpart A regulations, which address basic protections, or all the requirements, which include special protections for pregnant women, fetuses and neonates (Subpart B), for prisoners (Subpart C), and children (Subpart D).

continued

With more universities than ever “unchecking” the box, the Association for Accreditation of Human Research Protections Programs recently held a webinar on the topic, with Peter Vasilenko, AAHRPP vice president of accreditation. Vasilenko made it clear that when federal protections are not in place, researchers still must apply “equivalent” standards that in some cases may exceed those mandated by U.S. law.

This applies, of course, to those organizations that intend to seek or maintain AAHRPP accreditation, a number that has now reached 250. But it is not possible to know what percentage of human subjects programs this represents.

Vasilenko shared the slides from the webinar and discussed his presentation with *RRC*. He quoted statistics from the Office for Human Research Protections indicating that about a third of institutions submitting FWAs have unchecked the box entirely, a third apply the federal regulations to all non-PHS-funded research, and a third apply just Subpart A.

In a recently published analysis of determination letters that it issues following investigations, OHRP acknowledged that less research is falling under its watchful eye. The article noted almost in passing that previously “greater than 90%” of institutions checked the box (or boxes), but this has dropped to 74%, based on an “informal review of a sample of institutions” (*RRC 4/10, p. 6*).

One reason to uncheck the box is to shield the research from OHRP oversight. While not implying that an institution has anything to hide, the act might simply mean the institution doesn’t want uninvited government scrutiny, and it doesn’t tie the institution to meeting the federal standards.

Role of Accreditation

OHRP has not commented publicly on whether the unchecking trend is troubling and should be addressed in some manner. Vasilenko said AAHRPP has not had any discussions with OHRP about this issue. But the decline makes accreditation all the more important, he said, as a way of ensuring the research participants are protected, regardless of whether PHS funding is involved in their trial.

However, institutions that are unchecking the box appear to be applying the PHS standards, Vasilenko said. When applying for or renewing accreditation, the institution reports to AAHRPP how it oversees the research that is not subject to the Common Rule.

When institutions are asked if they are “doing anything different” for non-PHS-funded research, “they say they are not,” he said.

Exempting research from the federal requirements, when that discretion exists, can be beneficial, Vasilenko

said. Administrative burdens are reduced, research designs and outcomes can be improved, and subject recruitment can be enhanced, he said.

One aspect of Vasilenko’s presentation seemed to catch the audience off guard: he mentioned that the requirement to follow the Common Rule is triggered when a researcher who is federally funded works on a project that might not be supported by PHS dollars.

This caused a lot of questions, which Vasilenko said he found surprising. Some participants, during and following the webinar, asked AAHRPP whether certain funding sources, by name, might trigger the federal requirement.

Making such a determination is “complex,” Vasilenko said, and institutions should seek advice from their legal counsel and from the contract or grants management officer to be sure they have the right answer.

But sometimes the answer is clear. “If you have a fellow with an NIH training fellowship working on a project, that project is federally funded,” and thus the regulations apply, he said. In contrast, the involvement of a student with a Pell grant would not qualify the research as falling under federal research requirements, he said.

Equivalent Standards Appropriate

Vasilenko spent a fair bit of time describing what is meant by “equivalent” standards. These are “not necessarily the same” but are equal in “function or effect,” which is to protect research subjects. These protections must show “respect for the autonomy and dignity of all persons” and encompass “the principles of respect for persons, beneficence, and justice.”

If the institution chooses to apply equivalent protections, these should result from a process that includes discussions with institutional review board members, researchers, and administrators and be based on the federal regulations as a “guide or starting point,” he said.

The application of equivalent protections may be considered for

- ◆ the consent process, including the elements of disclosure, documentation, and waivers;
- ◆ IRB approvals, allowing for certain types of modifications without IRB action;
- ◆ policies for adults who are unable to give consent and for research conducted by students;
- ◆ designations for categories of research that is exempt from review and that can be eligible for expedited review; and
- ◆ different or varying time frames for re-review of ongoing research.

In his talk, Vasilenko discussed some of the benefits of unchecking the box and of the difficulties that can

pose. But, he told *RRC*, “We don’t care if you check the box or uncheck the box. We are going to hold you to your standards either way.”

“Sometimes we have to do things for compliance that don’t necessarily contribute to the protection [of subjects],” he said. “If we can tailor the protections more toward a specific population, and not because of regulation, it makes more sense.”

For example, outside the United States, potential research subjects often have a negative view of written consent forms, he said. “In the U.S., we have the philosophy that it is giving protection, and in other countries they see it as signing away their rights,” Vasilenko said.

In social science research, AAHRPP would expect to see an institution apply “professional standards” if federal regulations are optional. For example, the Oral History Association has evaluation guidelines that could be followed, and these may be stricter than the federal regulations, he said.

Yet difficulties with this two-process oversight can arise if research that began as non-PHS-funded later receives a grant, or a PHS-funded researcher joins the project. Then the Common Rule would apply.

When Research Becomes ‘Funded’

Institutions “have to have a process to make sure they are aware” of funding sources and can track when such a shift occurs, Vasilenko said. “Investigators may have funded and unfunded research and may become confused over which policies to follow,” he pointed out.

When funding switches to federal, “if they are applying something that is not allowed [under the Common Rule] they would have to review it again” and impose new requirements, as necessary, on the research, he explained.

“That is part of the complexity, and why I think it is better not to have two completely different sets of policies,” Vasilenko said.

Those that uncheck the box also should have “appropriate limitations for equivalent protections,” as well as an education strategy for researchers and IRB members, Vasilenko said. He said institutions are “thoughtfully going through” their policies and “not making big changes” to their oversight of non-PHS-funded projects.

“I don’t think we are ever going to get to the point, and we wouldn’t recommend [having] a whole separate set of standards for federally funded research,” he said. What is more appropriate is “changes where the regulations don’t make sense,” Vasilenko said.

This webinar has been held twice. It was the third topic in AAHRPP’s ongoing Educational Webinar series, which began in October with “Unanticipated Problems:

Navigating OHRP and FDA Guidance and AAHRPP Requirements,” followed by “Attracting Sponsors to Your Research Program” and “Providing Equivalent Protections when Conducting Research Outside the U.S.”

The webinars are not archived but popular ones, such as that on the FDA guidance, have been offered up to three times. A webinar on “Organizational Conflict of Interest” is scheduled for June 17. Fees for a computer hookup are \$90 to \$130.

Link: www.aahrpp.org/www.aspx?PageID=341. ↩

Proposed ‘Helpful’ Export Control Reforms Depend on Senate Support

The Department of Defense has laid out an aggressive “fundamental reform” of the nation’s export control system to make it more competitive with other countries and ease some of the administrative burdens that constrain university researchers. But full realization of the plan requires new laws, and opposition from Senate Republicans could sink it.

Apparently implementation of the three-pronged plan has already been initiated, but it was first mentioned publicly by Robert Gates, secretary of defense, in a speech late last month. DoD and the White House then released documents filling in the details. The move to loosen some controls would appear to be the opposite of one contemplated by DoD that would lock up unclassified information (see p. 1).

President Obama has expressed the need to change the export control system since he was a candidate, and in August 2009, he impaneled a government-wide study group to recommend options. He repeated the pledge to make improvements during the State of the Union address Jan. 27. Since then, Gates and other members of Obama’s cabinet have been briefing members of relevant congressional committees on their efforts.

Cliff Burns, an attorney with the Washington, D.C., firm of Bryan Cave LLC who specializes in export law, told *RRC* he supports the proposed changes, which he said are necessary to bring the United States in line with other nations and eliminate fights between federal agencies.

Current System ‘Protects Too Much’

In developing the reforms, the Obama administration acted on the recommendations of the interagency study group, the White House said.

“The assessment found that the current U.S. export control system does not sufficiently reduce national security risk based on the fact that its structure is overly complicated, contains too many redundan-

cies, and tries to protect too much," it said. "The administration has determined that fundamental reform of the U.S. export control system is needed in each of its four component areas, with transformation to a single control list, single primary enforcement coordination agency, single information technology system and single licensing agency."

Gates revealed the plan in a speech to the Business Executives for National Security, promising that ideas would "turn...into action through a three-phased process that will unfold over the course of the next year."

While there are many reasons the current system is dysfunctional, Gates said, "[o]ne major culprit is an overly broad definition of what should be subject to export classification and control. The real-world effect is to make it more difficult to focus on those items and technologies that truly need to stay in this country," he said. "Frederick the Great's famous maxim that 'he who defends everything defends nothing' certainly applies to export control."

Steps to Reform Outlined

At least the first phase, and perhaps part of the second, can be accomplished without Congress, Gates said. "In the first phase, the executive branch begins the transition towards the single list and single licensing agency by making significant improvements to the current system. These efforts would include establishing criteria for a tiered control list and standing up an integrated enforcement center," he said.

The next phase would continue this work and "complete the transition to a single information technology structure, implement the tiered control list, and make substantial progress towards a single licensing system," Gates said. "These changes, which can be made through executive action, represent substantial progress and momentum towards reform. But they are by themselves insufficient to fully meet the challenge at hand."

The final changes "most notably the single licensing agency and single enforcement coordination agency... will require congressional action," Gates said.

Burns agreed. "Some of the regulatory changes can be done by the administration without congressional action. Mostly this covers the part of the reform plan that would amend the existing regulations. However, the proposed consolidation...one license agency, one list, one enforcement agency and one IT system will require congressional action," Burns said. "And that consolidation won't make it past the deadlocked Senate if the Republicans continue to filibuster everything proposed by the White House."

According to a fact sheet DoD issued after Gates' speech, some of the changes are already in motion. The following actions would occur under Phase I:

- ◆ Control List — refine, understand, and harmonize definitions to end jurisdiction confusion between the two lists; establish new, independent control criteria to be used to screen items for control into a new tiered-control list structure.
- ◆ Licensing — implement regulatory-based improvements to streamline licensing processes and standardize policy and processes to increase efficiencies.
- ◆ Enforcement — synchronize and de-conflict enforcement by creation of an Enforcement Fusion Center.
- ◆ IT — determine enterprisewide needs and begin the process to reduce confusion by creating a single U.S. government point of entry for exporters.

Phase II, the sheet states, "results in a fundamentally new U.S. export control system" compared to the current system. Congress would be notified of plans "to remove munitions list controls or transfer items from the munitions list to the dual-use list."

Phase III completes the transition to the new U.S. export control system, with the following accomplishments:

- ◆ Control List — merge the two lists into a single list, and implement systematic process to keep current.
- ◆ Licensing — implement single licensing agency.
- ◆ Enforcement — consolidate certain enforcement activities into a Primary Enforcement Coordination Agency.
- ◆ IT — implement a single, enterprisewide IT system (both licensing and enforcement).

More Changes Needed

If fully implemented, the plan could help universities, according to Burns, who also writes the well-regarded www.exportlawblog.com. But other changes are also needed, he said.

"Almost every other country has a unified export list that is administered by one agency," Burns said. "That works well and avoids the jurisdictional squabbles that we've seen among the State Department and the Commerce Department over jurisdictional issues."

Having one IT system "might be of some benefit here if it simplifies the procedure for applying for licenses to provide technical data to foreign students," Burns said.

The changes could benefit exporters if lists are simplified, he added. "The current Export Administration Regulations are almost the size of the Internal Revenue Code."

But he added a note of realism, saying he wasn't sure how "much of the reform is going to be useful for universities." To be helpful, more focus would need to be put on deemed exports, or "on the problems in defining

what technology or technical data is controlled under these rules," he said.

Link to fact sheet: www.pmdtdc.state.gov/documents/WhiteHouseFactSheet.pdf. **Link to speech:** www.defense.gov/speeches/speech.aspx?speechid=1453. ✧

When Taking Care of Animals, Don't Overlook Physical Plant

While the care of animals is key to ensuring high quality nonhuman research, the facility that houses them creates a foundation for quality research outcomes and also must be maintained in good order.

That was the theme of a talk by Ron Banks, director of the Office of Animal Welfare Assurance at Duke University, who spoke at the latest educational webinar held by the Office of Laboratory Animal Welfare for members of institutional animal care and use committees.

Banks is also affiliated with the Association for the Assessment and Accreditation of Laboratory Animal Care and has been a member of its Council on Accreditation, which conducts site visits and evaluates and accredits programs for 10 years.

Speaking generally, an effective plant is one that is environmentally stable, flexible, accommodating, research supportive, occupationally safe, and disaster-preventive, he said. For example, facilities must be adapted to the animals they serve. "We're really talking lower ventilation rates for rodents when compared to other species like swine," he said.

As a way of encapsulating his advice, Banks said that "the focus needs to always be at the nose of the animal. That is the micro environment" that should be attended to, versus "what some book says we ought to do."

Based on AAALAC survey and inspection data, the biggest physical plant issues have concerned heating, ventilation, and air conditioning (known as HVAC), representing three-fourths of all cited deficiencies, followed by construction guidelines, functional areas, and facilities for aseptic surgery.

The following were the most frequent HVAC-specific concerns:

- ◆ HVAC not capable of maintaining temperature according to the *Guide for the Care and Use of Laboratory Animals* recommendations
- ◆ Inappropriate relative air pressure differential
- ◆ HVAC performance data not provided or incomplete
- ◆ Inadequate air exchange
- ◆ Inability to maintain humidity according to guide recommendations

◆ No monitoring of HVAC system performance

Banks called it "exceedingly troubling" that there were "institutions that had no clue of HVAC performance, performance data were not provided, or were incomplete." Journals are asking for information on the conditions of the animals used in research papers submitted for publication, he said.

Animal 'Care' Needs Attention

Institutions, he said, "should be confident [that] at any time during any day or hour of the year, the animals in the institutions are being held within a set confine or rigor for HVAC performance. Without doing those assessments, how does one know whether you are living within that predetermined set?" he asked. "The goal of the HVAC and the physical plant is really very simple — to provide a consistent environment," so an assessment to determine this is "a critical component."

Banks also took a variety of questions from the audience, including one about the limits of an IACUC's responsibilities. The questioner asked if the regulations were established to protect animals, why would the IACUC get involved in safety and ergonomic issues? A related question was "whose responsibility is it to verify HVAC systems are working properly — facility managers or physical plant personnel?"

Answering the two questions together, Banks said: "When we talk about an animal care and use program, we need to remember that the title says animal care and also animal use. Sometimes I think animal care committees will tend to focus on the animal use component, and they do a grand job of overseeing experimentation and not quite a good job of overseeing the aspects of animal care. Animal care does include such things as HVAC assessments."

The issue appears to be of great interest, as more than 400 institutions registered to participate in the webinar, held March 11. A transcript will be posted on the OLAW website. An archive and Banks' slides are available now. OLAW is accepting questions about physical plant issues, which it will answer, if they are submitted by June 7. The next webinar will be "Ethics and IACUC Responsibility," scheduled for June 10.

Link: http://grants.nih.gov/grants/olaw/educational_resources.htm. ✧

Consent Discussions Continue

continued from p. 1

Among those pondering these issues is Elizabeth Bankert, assistant provost at Dartmouth College and a member since 2007 of the Secretary's Advisory Committee on Human Research Protections (SACHRP), who summarized the areas of concern.

continued

"I think the research community is in agreement we need to generate wording in consent forms so as to not completely impede all secondary-use research; allow for opting out of future research; ensure subsequent reviews are conducted including the potential impact on community; and educate researchers, IRBs, and research participants," Bankert told RRC.

SACHRP advises the federal government on clinical research oversight, through the development of guidance and regulations, and has been concerned about informed consent and secondary uses for the past several years.

Bankert, who was not commenting for SACHRP or the federal government, added that the settlement "certainly confirms that more discussions are needed."

Tribe Was Concerned With Diabetes

The research at the heart of the dispute began 20 years ago, when members of the Havasupai, which has some 600 members residing at the base of the Grand Canyon in an area not reachable by car (and where none is driven), contacted Arizona State University for help in understanding the high rate of diabetes among members. While 100 gave blood, 41 eventually filed suit, after learn-

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 www.ReportonResearchCompliance.com.

◆ **NIH Director Francis Collins announced that he had approved as eligible for federal funding four stem cell lines previously sanctioned by President Bush.** The four were part of a total of 13 lines recently approved, Collins announced April 28. Overturning restrictions on stem cell research put in place by his predecessor was a key campaign pledge of President Obama. When NIH first implemented its new approval process and began reviewing stem cells for approval last September, it did not grandfather in some 20 or so lines that President Bush had cleared for use (*RRC 12/09, p. 1*). Researchers using the Bush lines that are now approved "can continue without interruption, and we can all be assured that valuable work will not be lost," Collins said. The total approved lines now stands at 64, and another 100 are in the pipeline awaiting a decision. (4/29/10)

◆ **Director Collins testified on April 28 before the House Appropriations Subcommittee in support of the president's fiscal 2011 budget request of \$32.2 billion for NIH, a 3.2% increase over the current level.** Meanwhile, ResearchMeansHope.org is collecting signatures on an online petition "to help demonstrate broad public support for increased federal funding of medical research," according to a statement by the organization, founded by the Association of American Medical Colleges, the Association of American Universities, and the Federation of American Societies for Experimental Biology (*RRC 10/22/09*). "We, the undersigned believe that medical research is leading the way towards important discoveries that improve people's health and save lives... To realize this hope fully, we must increase federal support for medical research funded by the

National Institutes of Health in the next budget year," the petition states. (5/6/10)

◆ **NIH has clarified grantees' responsibilities "when animal activities have been conducted which do not meet the terms and conditions of grant award."** On April 15, NIH issued "Guidance on Confirming Appropriate Charges to NIH Awards during Periods of Noncompliance for Activities Involving Animals." (4/22/10)

◆ **NIH recently published "Instructions for Completion and Technical Evaluation of the Vertebrate Animal Section" of contract proposals.** The instructions, published in the *Guide for Grants and Contracts* on April 19, "clarify the information that must be included in a separate section of the technical proposal, titled the vertebrate animal section of contract proposals for biomedical and behavioral research and development, research training, and biological testing activities that use live vertebrate animals," NIH said. How NIH evaluates this section when making awards and the oversight role of the institutional animal care and use committee as distinct from the review responsibility of NIH's scientific review group are also detailed. (4/22/10)

◆ **The Office of Animal Laboratory Welfare has updated its sample animal welfare assurance for foreign institutions.** Published on April 16, the *NIH Guide* notice "informs Public Health Service grantee institutions regarding revisions to the sample animal welfare assurance for foreign institutions document, formerly known as the Statement of Compliance for Foreign Institutions." (4/22/10)

ing the blood they thought was donated for diabetes research had also been used to study schizophrenia, inbreeding, and migration patterns among their members, which they said was done without their consent.

While the tribe said they did not give consent for anything other than diabetes research, the consent forms they signed said the blood would be used to “study the causes of behavioral/medical disorders,” according to a report in the *New York Times*. A research dissertation based on the blood samples postulated that the tribe had originated in Asia and was not native to the Grand Canyon area as it had believed. In their suit, the members said the research was offensive and deeply hurtful to them.

The Arizona Board of Regents’ settlement included an apology, a payment of \$700,000, and a return of the remaining samples to the plaintiffs. In addition, the settlement calls for “collaborations between ABOR and the Havasupai people in areas such as health, education, economic development, and engineering planning. For example, the Havasupai will collaborate with ASU, the largest public research university in the United States, to seek third party funding to build a new health clinic and a high school. Havasupai Tribal Members will also be eligible for scholarships at ASU, the University of Arizona and Northern Arizona University,” according to the statement from ABOR.

Scope of Consent Scrutinized

The settlement raises issues that are not new, but they are receiving greater attention now as a result of media coverage of the case, said Susan Kornetsky, director of clinical research compliance at Children’s Hospital in Boston.

“People are being very mindful of these issues,” she added, and are “getting permission up front” for future use of samples collected for research.

But such focus may have been lacking in the past, and that is giving rise to problems today. Many institutions, hers included, likely “have freezers of tissues and samples that are very valuable” and their future use may not have been contemplated at the time of collection, Kornetsky said.

When Children’s IRB reviews research in which investigators have proposed studies using such samples, “we have gone back and said ‘is this within the scope of the consent or not?’” Kornetsky said.

She noted that once data are de-identified, as is sometimes the case during secondary research, they are no longer considered human subjects research and thus outside the mandatory purview of the IRB. But, said Kornetsky, “that doesn’t give you the approval to breach

the original consent. This is an important issue, and it really is a conundrum.”

Like Kornetsky, Susan Adams, director of the IRB at Dartmouth, brought news articles about the settlement to the attention of her IRB members. She assigned a *New York Times* article to an IRB member to “review” for discussion at this month’s meeting, Adams said. Sharing such news reports and other items is a regular practice at each meeting and part of the “continuing education offerings” available to IRB members, she said.

In her experience, researchers who proposed to hold on to tissue or other samples indefinitely typically make that an option available to participants, she said. “I would say we have always looked at these consent forms pretty carefully, but this settlement will increase our anxiety,” Adams said.

Problems with the ASU research came down to a situation where the consent forms indicated the samples could be used for research other than on diabetes, “but that was not the understanding of the individuals in the tribe,” Adams said. “That gap worries me, the gap between the consent form and the consent discussion.”

But, she said, there is only so much an IRB or the institution can do. “It is hard for the IRB to ensure that gap is closed. We can’t monitor every consent process,” she said.

GWAS Studies Raise Consent Issues

The issue of permission for secondary uses has also come up at Dartmouth in connection with the national database maintained by the National Center for Biotechnology Information for the National Human Genome Research Institute, both part of the National Institutes of Health, Adams said.

Since January 2008, investigators conducting federally funded genome-wide association studies have been required to submit certain data to the Database of Genotypes and Phenotypes (dbGaP) (*RRC 6/08, p. 1*).

“Under GWAS [submission requirements], they ask us to certify that folks from whom the tissue samples or blood were taken have agreed to the sharing that will occur,” Adams said. “We reviewed 20 years of consent forms and epidemiological research for that study. Fortunately, the investigator had a good idea of where the research was going to go in the future,” and the consent forms reflect this, she said.

Kornetsky and Adams agree that federal guidance on these issues would be helpful.

Link: www.abor.asu.edu/1_the_regents/news_releases/Havasupai-ABOR-Resolve-Lawsuit.html; www.nytimes.com/2010/04/22/us/22dna.html?ref=us. ↪

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.

◆ **The Office for Human Research Protections has posted correspondence with Carolinas Medical Center in Charlotte, N.C., on its website to help clarify its position regarding the use of a central institutional review board in multisite research.**

OHRP said its letter clarifies that (1) "OHRP fully agrees with the Food and Drug Administration's position on the benefits of relying on a single central IRB for multi-center research"; (2) its advance notice of proposed rulemaking on IRB accountability issued on March 5, 2009, "was proposed to address this issue"; and (3) even without any new regulations, "OHRP is taking steps to address institutions' concerns about relying on an IRB external to the institution." OHRP's ANPR explored holding IRBs directly accountable for meeting relevant requirements, rather than institutions (*RRC 3/09, p. 3*). (5/13/10)

◆ **The USDA's Animal and Plant Health Inspection Service will move "more swiftly to take enforcement action" and will make such actions available to the public on its website, APHIS Director Cindy Smith said.**

In June, APHIS will start issuing monthly press releases with case summaries about individuals and businesses charged with violations of the Animal Welfare Act as well as summary data about closed cases and penalties, Smith said in a statement. (5/6/10)

◆ **APHIS and the Centers for Disease Control and Prevention are holding a select agent workshop on June 15 in Sparks, Nev.**

The day-long workshop will include information on entity registration, security risk assessments, biosafety requirements, and security measures. The workshop is free; space is limited. Representatives from the FBI will also be presenting, in addition to APHIS and CDC staff members. In related news, a recent article in the *Proceedings of the National Academy of Sciences* reports that as a result of the USA PATRIOT Act and the 2002 Bioterrorism Preparedness Act, U.S. research on select agents experienced "a loss of efficiency, with an approximate two-to-five-fold increase in the cost of doing select agent research." (5/13/10)

◆ **The Department of Commerce's Bureau of Industry and Security is presenting a series of webinars on the federal export regulations.**

The webinars will run from May 24–28 and address the following topics: Overview of the Export Administration Regulations, What Is an ECCN?, How to Classify My Item, General Prohibitions and End Use/End User Controls, License Exceptions, Support Documents, SNAP-R, Export Clearance and Record-keeping, and Export Management and Compliance. Each webinar includes a question-and-answer session following the presentation. (5/13/10)

◆ **The federal government has adopted a universal Research Performance Progress Report format, according to memo from the Office of Management and Budget and the Office of Science and Technology Policy.**

The draft form was published Nov. 9, 2007; the final format was published in the Jan. 13 *Federal Register*. The form "is intended to replace other interim performance reporting formats currently in use by agencies" but does not change the performance reporting requirements specified in 2 CFR Part 215 (OMB Circular A-110) and the grants management Common Rule implementing OMB Circular A-102. According to the memorandum, each federal agency will post a policy or implementation plan on the NSF or Research Business Models Subcommittee website within nine months after issuance of this policy. Implementation plans will detail whether the agency will use a paper or electronic filing format and "anticipated implementation date." (5/6/10)

◆ **The Massachusetts Institute of Technology and the American Council on Education have joined Stanford University in its petition to have the U.S. Supreme Court review a five-year-old case, *Stanford v. Roche*.**

Stanford sued Roche, a pharmaceutical company, claiming patent infringement related to an HIV quantifying method developed by a researcher who worked at both Stanford and a firm Roche bought. Stanford won its case in federal district court but lost in circuit court and petitioned the Supreme Court in March. Both MIT and ACE joined the suit, which already has a host of other university backers, on April 26. (5/6/10)

**IF YOU DON'T ALREADY SUBSCRIBE TO THE NEWSLETTER,
HERE ARE THREE EASY WAYS TO SIGN UP:**

1. Return to any Web page that linked you to this issue
2. Go to the MarketPlace at www.AISHealth.com and click on “newsletters.”
3. Call Customer Service at 800-521-4323

**IF YOU ARE A SUBSCRIBER AND WANT TO
ROUTINELY FORWARD THIS PDF EDITION OF
THE NEWSLETTER TO OTHERS IN YOUR ORGANIZATION:**

Call Customer Service at **800-521-4323** to discuss AIS's very reasonable rates for your on-site distribution of each issue. (Please don't forward these PDF editions without prior authorization from AIS, since strict copyright restrictions apply.)