

RESEARCH COMPLIANCE

News and Analysis for Colleges, Universities and Teaching Hospitals

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— with 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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After GAO 'Sting,' OHRP's FWA, IRB Registration Processes Under Microscope

Someone at the Office for Human Research Protections probably should have caught the fact that the federalwide assurance application from Phake Med Devices, Inc., had a weird name, gave an address on Wounded Limb Drive, and that its senior staffer was named Dr. Vince N. Feelgood.

An institutional review board registration, also sent to OHRP, was for a firm called E-Z Reviews, Inc., which listed among its staff Donald McSpeed III, April Phuls, Timothy Wittless, and Alan Ruse. Its location? Chetesville, Ariz. Perhaps someone at OHRP should have noticed this, too. But no one did. So Phake Med got an FWA, and E-Z Reviews became a registered IRB. And a third company also got an FWA and even went on to get approval for a clinical trial from Coast IRB, a private, for-profit firm in Colorado Springs.

Meanwhile, no one at Coast IRB spotted the fact that documents submitted with a protocol included a copy of the lead investigator's medical license, dated 1990, indicating it was expired. And Coast reviewers did not know that the protocol itself included a falsified Food and Drug Administration number indicating the device under review was similar to one already approved.

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HIPAA Expansion Under ARRA Means New Mandates, Business Associates Oversight

Universities and academic medical centers that must comply with HIPAA should begin familiarizing themselves with the enhanced privacy and security provisions contained in the American Recovery and Reinvestment Act, which became law in February.

They should also be aware of the prospect for more requirements affecting research, as the law mandated that the Department of Health and Human Services complete several studies, including a review of data de-identification methods, and required it to issue an annual report on the best practices for security compliance.

ARRA's primary objective is to help the economy through government spending, with billions allocated for the National Institutes of Health, the National Science Foundation, and other federal agencies. But it also contains unprecedented regulatory burdens and reporting requirements, and it significantly expands the reach of HIPAA (see *RRC*, February and March 2009, p. 1).

Typically, universities with academic medical centers or that conduct clinical research comply with HIPAA privacy protections. They must also follow the privacy requirements under the Common Rule, and numerous studies have reported conflicts between these two, which ARRA did not clear up.

But a number of important changes did occur. For one, the law gave state attorneys general the authority to prosecute civil cases of HIPAA violations and doubled the

penalties for HIPAA infractions (see box, p. 3). Secondly, ARRA essentially made organizations that function on behalf of a HIPAA covered entity, known as business associates, into nearly full-fledged CEs.

BA's Now Have More Obligations

Until ARRA, a business associate was generally required to have safeguards in place to protect data and to notify the CE if any breaches occur, but it did not have to meet the same requirements as a CE. Under ARRA, however, many CE requirements — old and new — are applicable to BAs, and they have one year from the effective date of the law to comply (by February 2010).

CEs are required to have a contract or agreement with their BAs, known as a BAA for short. When the privacy rule was first adopted in 2003, the Office for Civil Rights issued a model BAA, which many CEs may have used. It is unclear whether OCR will issue a new model agreement that incorporates the new provisions.

Kristen Rosati, a partner at the law firm of Copper-Smith Schermer & Brockelman PLC, said it wasn't clear based on the language in the new law whether covered entities are required to amend their business associate agreements or whether the new requirements are automatically included in existing BAAs as a matter of law, due to the somewhat cryptic language in ARRA.

"The additional requirements of this subtitle that relate to privacy and that are made applicable with respect to covered entities shall also be applicable to such a business associate and shall be incorporated into the business associate agreement between the business associate and the covered entity," the law states. Similar wording refers to BAs and security requirements.

Rosati said she favored the interpretation that these provisions automatically become a part of existing BAAs, because the law makes those requirements applicable to — and enforceable against — business associates. She noted, however, that there is a difference between what is wise and what is required, and she did suggest that "CEs will want to revisit their BAAs" with an eye toward reducing risk from the business associate relationship.

Time to Review BA's?

Rachel Nosowsky, senior counsel in the Ann Arbor office of international law firm Miller Canfield LLP, said that some covered entities "may need to spend time and money recontracting with their BAs depending on how they wrote their original agreements."

A CE might also want to amend a contract to specifically spell out that business associates are now required to meet many of the same privacy and security requirements as CEs, she said.

"Based on the increased penalties, CEs may want to re-evaluate the risk of contracting with certain BAs and change their agreements to impose higher standards and revise indemnification clauses," Nosowsky added.

For example, many existing agreements between CEs and vendors contain liability limitation provisions that may have been acceptable under HIPAA, given less severe penalties, but may not be any longer, with the possibility of much more significant penalties under ARRA.

Some BAs try to impose a provision saying that should any claims result from the agreement, the BA's liability is capped, for instance, at the total value of the contract. With a potential for high penalties, "this could leave the CE extremely exposed, where the total fees paid to the vendor may be relatively limited," she explained.

A CE could determine that, in light of the threat of greater enforcement, some BAs are not worth the risk and agreements with them should be terminated. But Nosowsky cautioned against any hasty action.

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"To me, HIPAA cannot drive your business," she said. She acknowledged, though, that, "You should always be wary of who you add [as a BA]. You should always be careful about doing background checks, getting references. Due diligence should still be done."

Often breaches and privacy violations that CEs experience occur through vendor errors. Whether an outside vendor is needed is a business decision ultimately and involves whether "it makes sense to have that function performed inside or not," Nosowsky said. The increased penalties and threat of enforcement "is an additional consideration about whether to hire a vendor at all, or to hire vendor A over vendor B," she added.

Notification Deadline Is New

One change that should be made as soon as possible deals specifically with the new breach notification requirements. ARRA requires BAs to notify CEs within 60 days of a breach, but it also requires CEs to notify individuals—and the media and HHS if more than 500 people are affected—also within the same 60-day period. Obviously, if the BA takes all of the allotted 60 days, the CE will miss the notification deadline, Rosati pointed out.

"The BAA can shorten that time," she said. "Once the BA learns of a breach, it should be required to report the breach to the covered entity in a short period of time, perhaps within five days, so that the covered entity has sufficient time to determine the impact of the breach and how it will handle notification."

CEs could also insert a requirement in their BAA that if the BA is responsible for a breach requiring notification, the BA is responsible for those costs, which Rosati said can be "exceedingly expensive."

Payment for Data Now an Issue

One area of specific concern to research institutions is new restrictions on the sale of protected health information. Previously, the privacy rule permitted a CE to receive payment for a disclosure of PHI "where that disclosure is permitted by the regulations, such as for the entity's health care operations, for research, and other activities," Rosati said.

Under ARRA, section 13405(d) "prohibits indirect and direct remuneration for a disclosure of PHI without the individual's authorization, and the authorization document must also explain whether PHI can be further exchanged for remuneration by the downstream entity receiving the PHI," she added.

This provision came about because many privacy advocates had complained the CEs were selling PHI to pharmaceutical and other firms that were using the information to market to patients and voiced other concerns about data-mining activities. The law adds exceptions to

this prohibition on payment for public health purposes and for research sale of PHI. However, it caps the price charged for PHI for research to the costs of preparation and transmittal of the data.

"There is a lot of uncertainty with this provision," Rosati said. For example, if a medical center is sharing data and tissue samples in a federally funded, multi-center research study with an academic medical center, the medical center is probably receiving some of the grant funds.

This would be "remuneration" to the medical center, but it may be unclear how to value the costs of preparation and transmittal of the data. If a medical center

Stimulus Act Adds Teeth to HIPAA Enforcement

The existing civil penalties in HIPAA, which have rarely been imposed, consist of a fine of \$100 per violation with a cap of \$25,000 for "identical" violations per calendar year. Covered entities are permitted to mount an "affirmative defense" to show lack of knowledge or reasonable cause, which, if proven, would eliminate the penalty.

Changes to HIPAA under the Recovery Act (see p. 1) make all violations subject to fines and establish a tiered penalty system, with ranges within each tier as follows:

- ◆ If the violator did not know that he or she violated the provision, the fine for identical violations is a minimum of \$100 for each violation up to \$25,000 and a ceiling of \$50,000 per violation, not to exceed \$1.5 million, during a calendar year.
- ◆ If the violation was due to reasonable cause, not willful neglect, the penalty is a minimum of \$1,000 per violation up to \$100,000 within a calendar year, with a maximum of \$50,000 for each violation, not to exceed \$1.5 million.
- ◆ If the violation was due to willful neglect but was corrected, the penalty is at least \$10,000 per violation up to \$250,000 for identical violations and a maximum of \$50,000 per violation up to \$1.5 million within a calendar year.
- ◆ If the violation was due to willful neglect and is not corrected, the penalty is at least \$50,000 per violation up to \$1.5 million within a calendar year.

To read the privacy and security provisions of the Recovery Act, visit AIS's Government Resources at the Compliance Channel at www.AISHealth.com.

physician is a co-author on a resulting publication, does this represent “indirect remuneration” under the statute, Rosati wondered.

“It is completely up in the air about how HHS will interpret this,” she said. HHS is required to issue regulations within 18 months to further refine this requirement, which would then be effective six months after they are issued. ⇨

NAS Guide Promotes Responsible Researcher, Institutional Conduct

Twenty years ago, the National Academy of Sciences issued a guide to foster ethical behavior among scientists. Although much has changed since then, the principles expressed have remained the same. Last month, along with the National Academy of Engineering and the Institute of Medicine, the three organizations issued the third edition of that seminal work.

As before, both researchers and institutions will find value in “On Being a Scientist: a Guide to Responsible Conduct in Research.” According to the preface, “The volume offers researchers — particularly early-career scientists and their mentors — guidance on how to conduct research responsibly, avoid misconduct such as fabrication and plagiarism, and think about how to respond in complex ethical situations.”

The guide is needed even more now than when it was first issued because the competing pressures on universities and researchers have increased, and studies have demonstrated that those working in a scientific pressure-cooker are more likely to commit misconduct and ethical breaches.

Under federal law, scientific or research misconduct is narrowly defined as fabrication, falsification, and plagiarism. Violations that occur during the performance of federally funded research can result in debarment, loss of funding, and damaging adverse publicity for the university.

And no type of research is immune — misconduct is possible whether the investigator is involved in human trials, animal studies, social science work, or molecular-level experiments.

The guide contains “an overview of the professional standards of science and explains why adherence to those standards is essential for continued scientific progress. While directed primarily toward graduate students, postdocs, and junior faculty in an academic setting, this guide is useful for scientists at all stages in their education and careers, including those working for industry and government,” the authors write.

It is a truism that mentoring is one of the best ways for young researchers to learn responsible ways of conducting themselves and their work, and institutions have a duty to support and foster this mentor-mentee relationship. But these opportunities are being lost today, the guide states.

“Science nowadays is so fast-paced and complex that experienced researchers often do not have the time or opportunity to explain why a decision was made or an action taken. Institutional, local, state, and federal guidelines can be overwhelming, confusing, and ambiguous,” it says. “And beginning researchers do not always get the best advice from others or witness exemplary behavior. Anonymous surveys show that many researchers admit to engaging in irresponsible practices or have witnessed others doing so.”

The guide points out that “all research institutions that receive federal funds must have policies and procedures in place to investigate and report research misconduct, and anyone who is aware of a potential act of misconduct must follow these policies and procedures.”

The authors also recommend that universities and investigators go beyond the strict definition of misconduct to also hold the line on “questionable research practices,” which can set the stage for misconduct.

“Scientists and their institutions should act to discourage questionable research practices through a broad range of formal and informal methods in the research environment. They should also accept responsibility for determining which questionable research practices are serious enough to warrant institutional penalties,” the guide says.

However, it also suggests a clear line between the two: “[T]he methods used by individual scientists and research institutions to address questionable research practices should be distinct from those for handling misconduct in science.”

Managing ‘Conflicts in Commitment’

The guide also makes reference to situations that can sometimes get an institution and its staff who have committed time to various projects in trouble, which the authors see as separate and apart from conflicts of interest.

Numerous universities have been investigated and fined by the federal government for violations of effort reporting requirements. These can fall into a category the guide terms “conflicts in commitment.”

“Conflicts of interest should be distinguished from conflicts of commitment,” the guide states. “Researchers, particularly students, have to make difficult decisions about how to divide their time between research and other responsibilities, how to serve their scientific disciplines, how to respect their employer’s interests, mission,

and values, and how to represent science to the broader society. Conflicts between these commitments can be a source of considerable strain in a researcher's life and can cause problems in his or her career. Managing these responsibilities is challenging but different from managing conflicts of interest."

Here institutions should help, the guide states. "As in the case of conflicts of interest, many institutional policies offer some guidance on conflicts of commitment. For example, there are limits in many academic institutions regarding time spent on outside activities by faculty members. Training in laboratory management may offer valuable information on how to manage conflicts of commitment. As with conflicts of interest, identifying the conflict is an important first step in arriving at an acceptable solution."

Be on the Lookout for Possible Bias

The guide also suggests universities and researchers be alert to how researchers' "values and beliefs" could contribute to bias in the conduct of their work.

The growing collaboration between universities and commercial interests also presents dangers to ethical conduct, the guide notes. It urges universities and researchers to go beyond its pages, offering an extensive list of other documents and Web sites for more information.

"Increased ties among academic, industrial, and governmental researchers have strengthened research but have also increased the potential for conflicts. And the rapid advance of technology — including digital communications technologies — has created a wealth of new capabilities and new challenges. In this changing environment of the early 21st century, a short guide like *On Being a Scientist* can provide only an introduction to the responsible conduct of research," the guide states.

And the organizations say more guidance is coming: "The challenges posed particularly by the increasing number of global and multinational ties within the science community will be further addressed in a subsequent publication of the National Research Council."

Link: www8.nationalacademies.org/onpinews/newsitem.aspx?RecordID=12192. ✦

OLAW Discusses Reporting, Reasons for Noncompliance

As any compliance official whose responsibilities include oversight of federally funded animal research knows, serious problems must be reported to the Office of Laboratory Animal Welfare. But it may not always be clear which incidents to report, and having an understanding of the most common reported incidents could make the job easier.

That was the purpose behind the most recent online seminar presented by OLAW last month, "Reporting Noncompliant Events to OLAW." The speaker was Axel Wolff, director of OLAW's division of compliance oversight.

As Wolff explained, according to law, institutions receiving Public Health Service funding are required to report events to OLAW that represent

- ◆ serious or continuing noncompliance,
- ◆ a serious deviation from provisions in the *Guide for the Care and Use of Laboratory Animals*, or
- ◆ any suspension of activity by an institutional animal care and use committee.

When reporting noncompliance to OLAW, institutions are to use these categories, and he gave examples of each.

Serious or continuing noncompliance includes performing research that has not received prior approval by an IACUC; failures by investigators to follow an approved protocol; failure of the IACUC to follow IACUC-approved institutional policies or procedures; or a failure of the institution to correct deficiencies identified during the semiannual evaluation in a timely manner.

Serious deviations from the provisions of the *Guide* would include "any conditions that jeopardize the health or well-being of animals, including accidents, natural disasters, or physical plant failures," he added.

Reports Come From Various Sources

Problems identified in the overall program of veterinary care, occupational health, or staff training, if not corrected as outlined in a plan and schedule, would need to be reported, Wolff said.

In addition, the suspension of an activity by the IACUC that "occurs after review of the matter by a convened IACUC quorum with a majority voting for suspension which results in temporary or permanent interruption of the animal research" must be reported, he added.

After consulting with the IACUC and implementing corrective action, the institutional officer is to report the incident to OLAW, Wolff said.

Wolff noted that instances must be reported regardless of how they come to light, whether "identified internally or by other agencies, site visitors, or consultants including USDA, CDC, FDA, the Association for the Assessment and Accreditation of Laboratory Animal Care International ... or NIH officials."

The law requires that "appropriate institutional policies are to be in place to ensure prompt self-identification, correction, and reporting of noncompliance," he said. "OLAW assesses reports of alleged noncompliance from numerous sources, including those just mentioned as

well as institutional employees, members of the public, or animal activist organizations.”

If the semiannual program review and facility inspection report “identified a serious problem that qualifies for prompt reporting, it must be reported,” he said.

In terms of the requirement for prompt reporting, this means “as soon as possible when the facts are ascertained,” Wolff said, adding that a preliminary report could “be made by phone, fax, e-mail but should not be held up until the matter is solved.” A final report must contain “specific and reasonable plans and schedules for the correction,” he said.

He pointed out that these self-reports are important because “the Public Health Service policy oversight system is based on OLAW-monitored self-regulation and self-reporting.”

When a PHS-supported project is suspended, a report must also be sent to the funding agency. And no funds can be expended for research during the suspension. “Costs for animal maintenance may be allowed by the funding component on a case-by-case basis,” he said. The final report must also confirm that the grant was not charged for unallowed costs.

Incidents, Corrections Described

One of the most reported instances of noncompliance is when investigators carry out research that has not received IACUC approval, which can result from a failure to obtain initial approval, when a protocol has expired, or when the research is based on an “unapproved significant change,” Wolff said.

“When these incidents occur,” Wolff said, “the corrective actions taken consist of stopping the unapproved activity, placing the animals on a holding protocol, and obtaining the IACUC approval.” He added that in these incidents, staff may also be counseled and retrained, and often “enhanced laboratory oversight is put in place.”

“Another common problem involves the IACUC itself,” Wolff said. “Sometimes a committee is not properly constituted, conducts business in the absence of a quorum when one is required, or allows animal activities to continue after the three-year approval has ended. IACUC problems usually stem from inadequate training or monitoring.”

Corrective actions in these instances similarly involve retraining IACUC members, and further official IACUC actions may also be required.

“Official actions undertaken without a quorum or inappropriate membership need to be re-approved with a quorum or properly constituted committee,” he said.

If re-reviews are the issue, the IACUC “needs to conduct adequate approval monitoring in order to ensure

that animal activities are being carried out as described in the protocol,” he said.

Often reports are prompted by inadequate clinical care of research animals, he said. These include “inadequate perioperative monitoring, failure to provide required analgesia, and failure to ensure death after euthanasia procedure, failure to follow the veterinarian’s orders, and failure to separate rodents leading to overcrowded cages,” he said.

In these cases, corrective actions include

- ◆ establishment of standard operating procedures;
- ◆ assigning dedicated personnel;
- ◆ keeping adequate records;
- ◆ ensuring that staff is properly trained;
- ◆ ensuring that the veterinarian has appropriate authority; and
- ◆ establishing standard operating procedures for separating weaned rodents.

He added that institutions need record-keeping systems and must “keep a copy of the assurance, minutes of IACUC meetings, records of IACUC review of protocols, semiannual reports including minority reports, and the determination of accrediting bodies such as AALAC.”

Reports May Improve Programs

Despite the difficulties involved in dealing with incidents that need to be reported, they can have a positive effect on an animal research program, Wolff said. Identifying and reporting noncompliance can have a beneficial impact on an institution. “The primary result is the implementation of corrective and preventive measures which ultimately lead to an improved animal care and use program,” he said.

Failure to act, in contrast, can have serious consequences.

“Should an institution not effectively address noncompliance, OLAW has the authority to restrict or withdraw the assurance, which would prevent receipt of PHS funds for animal work,” Wolff said. “Sometimes special terms and conditions can be placed on awards, costs may be disallowed, a grant can be terminated, and in the most egregious situations, the matter may be turned over to the Department of Justice for criminal prosecution.”

According to Wolff, the best ways to avoid noncompliance are to have

- ◆ clear institutional policies and procedures in place;
- ◆ a strong training program for staff at all levels;
- ◆ regular continuing education;
- ◆ effective channels of communication; and

◆ an internal mechanism for staff to register animal-related concerns with the IACUC.

The institutions, investigators, and IACUC all have roles to play.

“The institution is responsible for the financial and administrative aspects of the grant and the animal care and use program. The investigators are accountable for carrying out the research as approved by the IACUC and for complying with the animal care and use program, and the IACUC with the institutional official provides oversight of the animal care and use program,” Wolff said.

He added that NIH “expects an institutional climate that promotes compliance, relevant internal policies, adequate training, effective checks and balances, and open communication channels within the institution and with NIH.”

Questions, Seminar Suggestions Welcomed

Grantees are encouraged to contact OLAW with any questions. “If you are unsure whether an incident is reportable, feel free to call or e-mail,” Wolff said. “It is always preferable to report items than to cover the matter up, as the consequences are less dire than if reportable events are withheld but discovered later.”

In response to a question posed during the seminar, Wolff said an institution, when filing a report of noncompliance, does not need to list the principal investigator’s name but does need to provide the grant number.

“What happens with the report is, OLAW acknowledges receipt. ... [W]e take a look at the nature of the incident and then determine whether the corrective and preventive measures offered up by the institution do address the problem and have a reasonable expectation of preventing it in the future. If all those factors are met, then we thank the institution, and the report goes on file here,” he said.

One individual submitted a question pertaining to “a catastrophe like a hurricane, tornado, or flood.” The question was how soon should OLAW be informed about the status of a facility, and if there was damage, whether NIH would assist in the recovery.

“We suggest that as soon as the situation is stable and the primary priorities have been taken care of, such as human and animal health, then you’d notify OLAW and whoever else you need to about the matter. If no damage has occurred, it’s not necessary to report, but OLAW and NIH [do] appreciate the courtesy calls to confirm that everyone is safe,” Wolff responded.

He added that, “as far as whether NIH will assist grantees, NIH has done it in the past when natural

disasters occur. I assume that practice will continue,” he said.

At the conclusion of the session, Jeffrey Collins, with OLAW’s division of policy and education and former chair of the IACUC at Yale University School of Medicine, said OLAW welcomes additional questions on this topic. In addition, Collins issued a call for topics for future seminars, saying also that OLAW was considering a session that might be “more of a question and answer period rather than a specific focus on a given topic.”

“We really do hope you will send your comments and suggestions about both this and future seminars,” he said. “We are currently developing topics for presentation in 2010, and we appreciate receiving from you your suggestions.” The e-mail address is olaw@od.nih.gov.

Link: <https://webmeeting.nih.gov/p31061868>. ✦

Bill Puts All Human Research Under The Feds, Harmonizes Agency Regs

Introduced in every congressional session since 2002, proposed legislation that would put all human subjects research under the oversight of the federal government, regardless of the funding source, could gain steam this year following the incendiary findings of a Government Accountability Office “sting” operation.

Rep. Diana DeGette (D-Colo.), vice-chair of the Energy and Commerce Committee, introduced H.R. 1715, the Protection for Participants in Research Act, a day after a hearing before the committee’s investigations subcommittee. At the March 26 hearing, it was revealed that GAO was able to dupe Coast IRB Inc., a private, for-profit firm in Colorado, into approving a risky protocol proffered by a bogus medical device company that GAO created (see p. 1).

As part of its undercover operation, GAO was also able to get a federalwide assurance for this and one other fictitious research firm, as well as register two fake IRBs with the Office for Human Research Protections.

Total ‘Upgrade’ Proposed

In introducing her bill, DeGette said it would “upgrade the entire patient protection system in this country.”

“Research is the key to innovation and discovery, including curing deadly diseases,” she said. “But, as this whole panel agrees, that research must be conducted ethically so that participants understand the risks and make informed decisions about volunteering. That’s why we need to upgrade our entire patient

protection system in this country. I don't want to be here for thirteen hearings, like we have been on food safety. I want to get this done. We've been working on it for a number of years, we know the problem, we know the solutions, and I'm looking forward to working with everybody on this committee to[ward] improving research so that we have a robust system but at the same time protect the participants."

Under the bill, the protections now mandated for subjects enrolled in federally funded research would be extended to all individuals participating in any research. This would mean that all IRBs, including Coast, that review human subjects research would have to meet federal regulations, including provisions related to conflict of interest among investigators and IRB members and requirements for continuing reviews and reporting adverse events.

Standards would also be set for the number and type of members on an IRB (scientific vs. lay). The bill also calls for the Department of Health and Human Services to facilitate "the accreditation of institutions and IRBs by recognizing a private accrediting entity or entities."

In addition, it calls for the Common Rule to be harmonized with regulations imposed by the Food and Drug Administration. Under the bill, OHRP would also have new powers to halt research, when necessary, that was not federally funded. (The FDA can do this now but only in trials of products or devices planned to be submitted for agency approval.)

The bill also codifies and gives OHRP new authority to suspend or debar individuals from serving as principal investigators and from receiving federal funds for human subjects research.

AAMC Is Supportive

Some organizations, including the Association of American Medical Colleges, have long advocated for the elimination of a two-tiered oversight system, a goal that would be achieved by this bill. Dave Moore, AAMC senior director of government relations, said his organization supports the bill and has worked with DeGette over the years to refine the proposed legislation.

"Everybody who is willing to make the huge personal commitment to human research should have the

If You Needed an Outside IRB, Could You Find a Good One?

Say your university's IRB is overworked, and understaffed. There's a deadline looming to get a trial approved and recruitment underway. Or, perhaps there's a complicated protocol that requires expertise that your IRB doesn't have.

What do you do? Do you use an outside IRB? And if so, how would you go about picking a good one?

The Office for Human Research Protections maintains a registry of IRBs, but as a recent Government Accountability Office "sting" involving Coast IRB in Colorado Springs revealed last month, the entries are not checked for accuracy and provide no qualitative data (see p. 1). As the head of OHRP testified before a U.S. House of Representatives subcommittee, inclusion in the registry or the issuance of a federalwide assurance is not a government seal of approval.

Perhaps the only real way to measure the quality of an independent IRB is to see whether it is accredited by the Association for the Accreditation of Human Research Protection Programs, Inc. AAHRPP is the only organization of its type, and it lists organizations on its Web site that have been accredited and whether they received full or "qualified" accreditation.

There are other categories — accreditation revoked, withheld, pending, or probationary — but AAHRPP doesn't list entities that fall into those. So while it would be useful to know if an IRB or clinical research program had failed to pass AAHRPP's muster, that information isn't going to come from AAHRPP.

AAHRPP Provides Limited Info

At its founding, AAHRPP officials decided to make the process as confidential as possible, believing that this would encourage more entities to seek accreditation, which remains voluntary.

RRC asked AAHRPP President Marjorie Speers how a university or other entity should select an independent IRB to work with, if it needed one. Perhaps as expected, she suggests choosing an AAHRPP-accredited IRB.

Yet, this may prove difficult, as more IRBs are *not* accredited than are. There is also misinformation about accreditation. For example, in a recent story about the Coast IRB, the *Scientist*, a reputable publication, said "independent IRBs require no accreditation to function, though most are accredited through an independent body called the Association for the Accreditation of Human Research Protection Programs."

maximum protections" regardless of the source of funding, Moore said.

In 2006, AAMC issued "Principles for Protecting Integrity in the Conduct and Reporting of Clinical Trials," saying it had been "troubled by evidence that significant variation continues to exist within the academic community over the application of appropriate standards for analyzing and reporting the results of sponsored clinical research, especially clinical trials sponsored by industry" (see *RRC*, February 2007, p. 5).

While the paper dealt mostly with data analysis and publication of trial results and did not specifically address subject protections, it did urge that "investigators fully disclose, and journals should publish, the existence of all relevant financial interests, including consultancies of any investigator, in all communications of trial results."

There is no Senate companion yet to DeGette's bill — Sen. Ted Kennedy (D-Mass.) introduced one in the past — and progress could still be derailed this year if the Energy and Commerce Committee becomes too busy. There are many other issues on its plate that may be

deemed of greater priority, such as health reform, regulation of tobacco by the FDA, and a biosimilar bill, which would authorize the FDA to approve generic versions of medications made using live organisms.

But, said Moore, the prospects for congressional action are greater than in the past. "I think the chances of passage are higher [now] because of what happened at the hearing," Moore told *RRC*. "We saw very broad, bipartisan support that oversight by HHS and the FDA needs to be strengthened."

After the hearing, *RRC* contacted DeGette's office to see if she was planning to amend the bill based on any new information presented. Her spokesman said she "is currently working in consultation with a range of stakeholders, including academic and industry organizations, on the best way forward regarding this piece of legislation."

"As with many pieces of legislation, I do not have any specific timeframe for you," Krisofer Eisenla said.

Link: <http://degette.house.gov/?sectionid=17&parentid=4§iontree=4,17&itemid=1082>. ✧

If You Needed an Outside IRB, continued

In fact, most are not. There are more than 6,000 registered IRBs, although some of them are not active. According to AAHRPP, approximately three dozen of those are not part of other institutions, such as universities or medical schools. Of these "independent" IRBs, it lists 12 as accredited. Coast IRB is not listed as accredited, and AAHRPP spokesman David Ward, in keeping with AAHRPP policy, would not say whether it had ever applied for accreditation.

Some independent IRBs may also be part of the Consortium of Independent Review Boards, which does not accredit organizations but does expect adherence to certain subject protections and other requirements.

Accredited Groups Must Take Precautions

Typically, universities whose human subjects research programs are AAHRPP-accredited have an internal IRB, which is also accredited as part of the process. When an external or central IRB is used, these are expected to be accredited. Under appropriate circumstances, an AAHRPP-accredited organization may use an unaccredited IRB without jeopardizing its accreditation status; however, it must have oversight mechanisms in place, Speers told *RRC*.

An accredited organization that "wants to use an IRB at an unaccredited organization for the review of a single study or only a few studies ... may do so as long as the accredited organization has a mechanism to ensure that the unaccredited organization's IRB is reviewing properly," she said.

Speers said such mechanisms include reviewing the unaccredited IRB's standard operating procedures. The university or other accredited organization could also conduct "an administrative review of the protocol, [IRB meeting] minutes, and correspondence between the IRB and the investigator."

Of course, IRB accreditation or lack thereof is not the only consideration. Scott Davis, an administrator in the University of Oklahoma's Office of Sponsored Research, told *RRC* that he has "always thought there was a conflict, or at least an appearance of conflict of interest," that could mar the operations of a stand-alone, for-profit IRB. Such an entity may feel pressure to approve a study or face the prospect of losing business, said Davis, whose research program is AAHRPP-accredited. "I have always kind of wondered how reliable these independent IRBs are," he said.

Links: www.consortiumofirb.org;
www.aahrpp.org.

GAO's Undercover Operation

continued from p. 1

All of this chicanery was an “undercover test” of the nation’s IRB system pulled off by the usually staid Government Accountability Office, at the request of a subcommittee of the House Energy and Commerce Committee. The findings were described at a March 26 hearing before the committee’s Investigations and Oversight Subcommittee.

“We wanted to know whether IRBs are rubber stamping research studies, whether clinical researchers are ‘IRB shopping’ or choosing IRBs based on how quickly and inexpensively they approve studies, and whether governmental oversight of IRBs is adequate,” said Rep. Bart Stupak (D-Mich.) chair of the subcommittee.

The subcommittee called the hearing to examine “whether IRBs and the federal government are adequately protecting human subjects of biomedical research.” What was revealed may lead to new government oversight, with a bill introduced by Rep. Diana DeGette, a

member of the subcommittee. Her bill would put all research under federal review, regardless of funding source (see p. 7). Other changes may also be made concerning OHRP’s IRB registration and FWA processes.

Not a ‘Seal of Approval’

The GAO investigation and congressional hearing opened a window into the world of private IRBs, which are increasingly playing a larger role in oversight of clinical research in America today. While universities typically operate internal IRBs, they may occasionally need an external board, and to date there are few ways to judge their quality (see p. 8).

At the hearing, Jerry Menikoff, newly appointed head of OHRP, wearily explained to outraged subcommittee members that GAO was able to register the fake IRBs and obtain FWAs for nonexistent companies because the system is nearly automated — and automatic.

This did not sit well with the subcommittee. “What troubles me greatly and I think would trouble the people I represent, is that virtually anybody, even with the most

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.ReportonResearchCompliance.com.

◆ **NIH published a notice on April 3 describing the standard terms and conditions for awards issued with Division A ARRA funds.** The “Division A” refers to provisions in the act applicable to NIH funding. The notice also addresses other information related to these funds, including that they will be issued with a special “Document Number” schema and that special procedures must be used when accessing funds. (4/9/09)

◆ **A provision in the 2009 Consolidated Appropriations Act, signed into law on March 11, makes permanent NIH’s Public Access Policy.** The policy requires the deposit in PubMed Central of all manuscripts that result from NIH-funded research, within 12 months of their publication in a peer-reviewed journal. When it was implemented last April, the initial policy was subject to annual renewal. The law now states, “The director of NIH shall require in the current fiscal year and thereafter that all investigators funded by the NIH submit or have submitted for them to the National Library of Medicine’s PubMed Central an electronic version of their final, peer-reviewed manuscripts upon acceptance for publication to be made publicly available no later than 12 months after the official date of

publication: *Provided*, That the NIH shall implement the public access policy in a manner consistent with copyright law.” While libraries and others have praised the policy, publishers have opposed it, and a bill is pending in Congress that would temporarily suspend it. The new law’s mention of “consistent with copyright law” leaves the debate open still, as publishers have claimed the policy violates copyright laws. (3/19/09)

◆ **NIH has prepared its draft “Guidelines for Human Stem Cell Research.”** The guidelines (<http://stemcells.nih.gov/policy/2009draft>) will be published soon in the *Federal Register* for public comments. They pertain to NIH-funded research, would establish policy and procedures under which NIH will fund research in this area, and help ensure that such research is “ethically responsible, scientifically worthy, and conducted in accordance with applicable law.” The guidelines implement E.O. 13505, issued on March 9 (see *RRC E-News*, March 12, 2009), which instructed the HHS Secretary to “review existing NIH and other widely-recognized guidelines on human stem cell research and issue new NIH guidance within 120 days of the date of the executive order.”

silly of applications, can register as an IRB, simply by e-mailing your agency and it gets entered ... [even if] the name you are from is Chetesville, Arizona, for which I assume there is no zip code," said Rep. Greg Walton, R-Ore. He paused, stumbled for words, and then asked Menikoff, "Is this permissible?"

"Congressman," Menikoff replied, "it is true that anybody could enter information into the registration system. The registration system was a response to [a federal report] that several of you commented on, and it basically established a registration system, a method of collecting minimum information so there would be a list of registered IRBs."

"By registering an IRB, the government, the federal government, is in no way endorsing that IRB or in any way saying that that IRB meets any standards," he told the subcommittee. "We were not aware that this was a problem, that people were out there thinking that because an IRB was registered that the federal government was endorsing it. The federal government has many systems by which it has lists of ... again, this is sort of like a contact [list], a phone book."

Stupak was incredulous, saying registered IRBs are "supposed to be set up to protect patient safety. This isn't a phone book."

Menikoff said the system currently is not set up to verify information or to ascertain that IRBs and entities with FWAs have met certain qualifications.

"We do not have our staff going through the names to see whether people have put funny names on the list. ... We are not in [that] business currently. ... That would be a different system, and we welcome your input in terms of whether or not you think that would be a good thing to do. That would be a dramatic change from the system. The system was never designed to basically have us from the outset endorsing and putting some sort of stamp of approval" on IRBs, he said.

The hearing also contained some discussion about whether the fictitious entities could ever have obtained federal funding — if the hoax could have gone that far. While Menikoff said the odds were "extraordinarily low," GAO's representative pointed out at the hearing that his agency did not try to get a federal grant.

IRB, Congress Vow Improvements

Coast's president, Daniel Dueber, was also grilled by the subcommittee about how his firm could have approved such a shoddy protocol — it was rejected by two other independent IRBs — and why it did not discover that the sponsoring company was a sham. For his part, Dueber maintained that Coast was "hood-winked" by the GAO, and that GAO's actions were illegal.

Immediately following the hearing, however, Coast stopped accepting any new business for 30 days so that it could undergo a self-initiated review by an outside firm and implement changes. "We share Congress's objective of ensuring maximum protection for human subjects in clinical trials," Dueber said in a statement. "We are instituting comprehensive reforms to prevent recurrence of the vulnerabilities the subcommittee brought to light. Our number one priority is the protection of human subjects."

However, on April 14, FDA imposed on Coast a ban on new reviews and halted recruitment in previously approved studies the agency regulates, saying Coast had committed five "serious" violations of FDA regulations, including failing to "determine that risks to subjects are minimized."

"These restrictions will remain in effect until such time that you receive written notification from FDA that adequate corrections have been made. These restrictions do not relieve Coast IRB of its responsibility for receiving and responding to reports of unexpected and serious reactions and routine progress reports from ongoing studies," FDA's letter to Coast stated.

It is not clear whether any Coast-reviewed studies are federally funded, which would put them under OHRP's purview. A Coast spokeswoman told RRC she could not provide an answer to this question, while an OHRP representative said the agency didn't know. Menikoff said at the hearing, however, that OHRP would work closely with FDA as it delves into Coast's operations.

Stupak said his committee would have more hearings on the subject of IRBs, and promised other action. "This is our second hearing on IRBs and something that we will have an interest in and there will be legislation. I know Ms. DeGette has legislation. And there will be other legislative proposals after this hearing I am sure," he said.

Link to hearing: http://energycommerce.house.gov/index.php?option=com_content&task=view&id=1552&Itemid=95. **Link to FDA letter:** www.fda.gov/bbs/topics/NEWS/2009/NEW01996.html. ♦

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.

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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.

◆ **OMB on April 3 issued its second guidance on compliance with requirements in the American Recovery and Reinvestment Act.** Unlike the first document issued Feb. 18, the new 175-page guidance deals more with requirements that apply to the federal government generally and agencies specifically. However, it does contain sections on grants and contracts, noting that "agencies must take steps, beyond standard practice, to initiate additional oversight mechanisms in order to mitigate the unique implementation risks" of ARRA. (4/9/09)

◆ **Interim regs published in the March 31 Federal Register spell out reporting and other requirements that contractors receiving ARRA funds must follow.** The requirements cover quarterly reporting on various data elements, including the number of jobs created. Also addressed are the new whistleblower protections and the power that GAO will have to investigate contractors, similar to that exercised by OIG. The interim rules are effective March 31 and apply to all solicitations and contracts awarded on or after the effective date. Contracting officers also must modify existing contracts to include the new clause if ARRA funds are used. Comments submitted by June 1 will be considered in formulating a final rule. (4/2/09)

◆ **OMB published "Standard Data Elements for Reports under Section 1512 of the American Recovery and Reinvestment Act of 2009," for grants, cooperative agreements, and loans.** The notice, published for comment in the April 1 *Federal Register*, lists the elements that would be required for award and award recipient information, project/activity including ARRA amounts received and expended and descriptions of the projects, and subrecipient information. Subrecipient information is limited to first-tier recipients and the amount of information varies depending on whether the funding is over \$25,000. Comments are due by May 1. (4/2/09)

◆ **OHRP has posted guidance on how to comply with the relevant provisions of the Genetic Information Nondiscrimination Act, some of which go into effect in May.** The document provides

background on protections provided by GINA and "discusses some of the implications of GINA for investigators who conduct, and institutional review boards that review, genetic research, particularly with respect to the criteria for IRB approval of research and the requirements for obtaining informed consent." (4/9/09)

◆ **NSABB will meet April 29 to discuss strategies for a personal reliability program for individuals with access to select agents and toxins.** Among other things, the board will review the findings of a special April 3 NSABB meeting "on proposed optimal characteristics of individuals with access to select agents." The meeting will be webcast. (4/9/09)

◆ **The Association of American Medical Colleges has asked the Centers for Medicare & Medicaid Services to revisit its payment and coverage policy for clinical trials.** In a March 12 letter, AAMC deemed the policy "confusing to implement, lacking consistency with other Medicare policies that affect clinical trials, and variable in its application due to differing interpretations by Medicare contractors." AAMC said its members "collectively perform more than 60% of all extramural research sponsored by" NIH. (3/26/09)

◆ **At a congressional hearing last month, GAO described its role in helping to ensure accountability and transparency of ARRA funds.** Gene L. Dodaro, acting comptroller general, testified before the Senate Homeland Security and Government Affairs Committee that "GAO is charged with reviewing the use of funds by selected states and localities." (3/19/09)

◆ **To "facilitate" improvements to Grants.gov, OMB Director Peter Orszag is asking each federal grant-making agency "to cover a proportionate share" of the costs.** An April 8 memo from Orszag sets down a contribution level for each agency. The "pace" of applications submitted to Grants.gov "is expected to grow as key Recovery Act deadlines approach. As it currently stands, the existing infrastructure would not be able to handle that influx of applications," Orszag wrote. (4/9/09)

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